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# A systematic review of the effectiveness of interventions based on a stages-of-change approach to promote individual behaviour change

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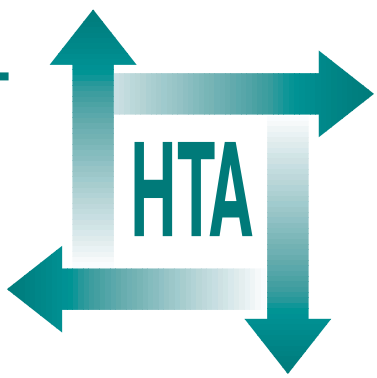
**Health Technology Assessment**
**NHS R&D HTA Programme**





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# NHS R&D HTA Programme

The NHS R&D Health Technology Assessment (HTA) Programme was set up in 1993 to ensure that high-quality research information on the costs, effectiveness and broader impact of health technologies is produced in the most efficient way for those who use, manage and provide care in the NHS.

Initially, six HTA panels (pharmaceuticals, acute sector, primary and community care, diagnostics and imaging, population screening, methodology) helped to set the research priorities for the HTA Programme. However, during the past few years there have been a number of changes in and around NHS R&D, such as the establishment of the National Institute for Clinical Excellence (NICE) and the creation of three new research programmes: Service Delivery and Organisation (SDO); New and Emerging Applications of Technology (NEAT); and the Methodology Programme.

This has meant that the HTA panels can now focus more explicitly on health technologies ('health technologies' are broadly defined to include all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care) rather than settings of care. Therefore the panel structure has been redefined and replaced by three new panels: Pharmaceuticals; Therapeutic Procedures (including devices and operations); and Diagnostic Technologies and Screening.

The HTA Programme continues to commission both primary and secondary research. The HTA Commissioning Board, supported by the National Coordinating Centre for Health Technology Assessment (NCCHTA), will consider and advise the Programme Director on the best research projects to pursue in order to address the research priorities identified by the three HTA panels.

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The views expressed in this publication are those of the authors and not necessarily those of the HTA Programme or the Department of Health. The editors wish to emphasise that funding and publication of this research by the NHS should not be taken as implicit support for any recommendations made by the authors.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.



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# Contents

# List of abbreviations

| | |
|---|---|
| ACSM | American College of Sports Medicine |
| ALA | American Lung Association |
| ANCOVA | analysis of covariance |
| ANOVA | analysis of variance |
| ATOD | alcohol, tobacco and other drugs |
| BI | brief intervention |
| BSE | breast self-examination |
| CBE | clinical breast examination |
| CDCP | Centers for Disease Control and Prevention [US] |
| CI | confidence interval |
| df | degrees of freedom |
| GP | general practitioner |
| HMO | health maintenance organisation |
| MANOVA | multivariate analysis of variance |
| MAS | Medication Adherence Scales |
| MET | metabolic equivalent |
| NRT | nicotine replacement therapy |
| NS | not significant |
| OR | odds ratio |
| PAL | Physically Active for Life |
| PASE | Physical Activity Scale for the Elderly |
| PERM | patient-empowered readiness model |
| RCT | randomised controlled trial |
| SD | standard deviation |
| SE | standard error |
| SoE | stages of exercise |
| STARS | Start Taking Alcohol Risks Serious |
| SUSI | Substance Use Screening Instrument |
| TMC | transtheoretical model of change |
| TTM | transtheoretical model |
| URICA | University of Rhode Island Change Assessment Scale |
| WIC | Special Supplemental Nutrition Programme for Woman, Infants and Children |

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.

# Executive summary


## Background

Over recent years, interest in reducing early mortality and preventing morbidity through lifestyle changes has grown exponentially. Interventions (or methods) used within healthcare settings to modify risky behaviours have increasingly been based on stage theories or staged approaches to behaviour change. The attraction of stage-based models lies in their ability to explain why interventions aimed at large groups or the general public, such as mass media or community interventions, are rarely universally effective. Stage-based models propose that 'tailored' interventions, which take into account the current stage an individual has reached in the change process, will be more effective than 'one size fits all' interventions.

Despite the widespread use of stage-based models, it has been suggested that there is little evidence available about the effectiveness of this approach in changing behaviour. Therefore, this systematic review draws together information about the effectiveness of interventions based on the stages-of-change approach from different settings and different population groups.

## Objective

To systematically assess the effectiveness of interventions using a stage-based approach in bringing about positive changes in health-related behaviour.

## Methods

### Search strategy

A wide range of electronic databases were searched from inception to May 2000. In addition, searches of the Internet were carried out using a range of search engines.

The bibliographies of retrieved references were scanned for further relevant publications. The authors of abstracts appearing in conferences proceedings identified by the literature search were contacted for further information about their research.

### Selection criteria

Randomised controlled trials (RCTs) evaluating interventions, that aimed to influence individual health behaviour, used within a stages-of-change approach were eligible for inclusion. Only studies that reported health-related behaviour change such as smoking cessation, reduced alcohol consumption or dietary intake and stage movement were included. The target population included individuals whose behaviour could be modified, primarily in order to prevent the onset, or progression, of disease. There was no limitation of study by country of origin, language or date.

### Procedure

Assessment of titles and abstracts was performed independently by two reviewers. If either reviewer considered a reference to be relevant, the full paper was retrieved. Full papers were assessed against the review selection criteria by two independent reviewers, and disagreements were resolved through discussion. Data were extracted by one reviewer into structured summary tables and checked by a second reviewer. Health behaviour change was the primary outcome of interest. Secondary outcomes included: assessment of stage movement, health-related outcomes, intermediate outcomes, any adverse effects resulting from the intervention, as well as cost-effectiveness data. Information about the implementation of each intervention and how the relevant professionals were trained was also recorded where given. Any disagreements about data extraction were resolved by discussion. Each included trial was assessed against a comprehensive checklist for methodological quality and quality of the implementation of the intervention. Quality assessment was performed by one reviewer and checked by a second, with disagreements resolved by discussion.

## Results

Thirty-seven RCTs were included in the review. Three studies evaluated interventions aimed at prevention (two for alcohol consumption and one for cigarette smoking). In 13 trials the interventions were aimed at smoking cessation, seven studies evaluated interventions aimed at the promotion of physical activity, and five studies

evaluated interventions aimed at dietary change. Six trials evaluated interventions aimed at multiple lifestyle changes. Two studies evaluated interventions aimed at the promotion of screening mammography, and one study evaluated an intervention aimed at the promotion of treatment adherence. Four of these studies also included an economic evaluation.

### Results of the quality assessment

Methodological quality of the trials was mixed, and ranged from 2 to 11 out of 13 quality items present. The main problems were lack of detail on the methods used to produce true randomisation (methods of randomisation and concealment of allocation); lack of blinding of participants (where appropriate), outcome assessors and care-providers; and failure to use intention-to-treat analysis. The main issue with the quality of the implementation was lack of information on the validity of the instrument used to assess an individual's stage of change.

### Evidence of effectiveness

In one of the 13 trials aimed at **smoking cessation** the results could not be compared to a non-stage-based intervention, because only stage-based interventions were included. In four of the remaining 12 smoking cessation trials, significant differences favouring the intervention group for scores on quit rates were found; in three of these the comparator was a usual-care control group and in one a non-stage-based intervention. One study showed mixed outcomes. In the remaining seven smoking cessation trials no significant differences between groups in behavioural change outcomes were found. One of the seven trials aimed at the promotion of **physical activity** did not report any data on behaviour change. Three trials found no significant differences between groups in behavioural change outcomes. Two trials showed mixed effects, and one trial mainly showed significant effects in favour of the stage-based intervention. Two of the five trials aimed at **dietary change** reported significant effects in favour of the stage-based intervention; in one trial this was in comparison to a non-stage-based intervention and in the other to a usual-care control group. Two trials showed mixed effects, and in one trial no significant differences between groups in behavioural change outcomes were found. Three of the six studies aimed at **multiple lifestyle changes** showed no differences between groups for any outcomes included. Two studies showed mixed effects, and one study showed positive effects for all outcomes included: smoking cessation, fat intake and physical activity. One of the two trials aimed at the promotion of **screening mammography** found no significant differences between groups for nearly all outcomes. The other trial showed a significant difference in favour of the stage-based intervention. The trial aimed at the promotion of **treatment adherence** showed significant results in favour of the stage-based intervention. Two out of three trials aimed at **prevention** showed no significant differences between groups for any measure of behaviour change. The other trial showed mixed outcomes. Studies with low-income participants tended not to report effects favouring the stage-based intervention. Other study characteristics, such as number of respondents, age and sex of respondents, year of publication, setting and verification of outcome measures, seemed to have little relationship with the effectiveness of the stage-based intervention.

## Conclusions

Overall there appears to be little evidence to suggest that stage-based interventions are more effective compared to non-stage-based interventions. Similarly there is little evidence that stage-based interventions are more effective when compared to no intervention or usual-care. Out of 37 trials, 17 showed no significant differences between groups, eight trials showed mixed effects, and ten trials showed effects in favour of the stage-based intervention(s). One trial presented no data on behavioural outcomes, and another included stage-based interventions only. Twenty trials compared a stage-based intervention with a non-stage-based intervention, ten trials reported no significant differences between groups, five reported mixed effects and five reported significant effects in favour of the stage-based intervention.

There does not seem to be any relationship between the methodological quality of the study, the targeted behaviour or quality of the implementation (both in terms of exposure and in terms of full use of the model) and effectiveness of the stage-based intervention.

The methodological quality of studies was mixed, and few studies mentioned validation of the stages-of-change instrument. In addition, there was little consistency in the types of interventions employed once participants were classified into stages and little knowledge about the types of interventions needed once people were classified. It was unclear in a number of trials whether the intervention was properly stage-based.

Given the limited evidence for the effectiveness of interventions tailored to the stages-of-change approach practitioners and policy makers need to recognise that this approach has a status which appears to be unwarranted when it is evaluated in a systematic way.

## Recommendations for research

There is a need for well-designed and appropriately implemented RCTs that are characterised by tailored interventions derived from accurate stage measurement, and which involve frequent reassessment of readiness to change in order to permit evolving, stage-specific interventions.

# Chapter 1
# Background

Some of the mortality and morbidity in industrialised countries stems from diseases that are due, in part, to particular patterns of individual behaviour. Individuals contribute to their own health by adopting health-enhancing behaviours such as exercise, and avoiding behaviours such as smoking which compromise health. For example, it has been shown that physical activity can lower blood pressure[1] and also prevent the occurrence of major cardiovascular events.[2]

In people with established disease, changing current behaviour can also reduce the risk of subsequent morbidity and mortality. For example, in individuals with coronary heart disease, education and counselling aimed at behaviour change can lower blood pressure and reduce lipid levels.[3] Two recent UK surveys of people with established coronary heart disease have highlighted the potential for behaviour change as a form of secondary prevention.[4,5] In one study, for example, 18% of patients were current smokers, 64% were overweight and 52% ate more fat than recommended. Overall, around two-thirds of the sample had at least two lifestyle behaviours that could be changed as a way to enhance health.[5]

Over recent years there has been an increased interest in reducing early mortality and preventing morbidity through lifestyle changes. Although it is acknowledged that alternative means of achieving changes in the socio-environmental determinants of health may be found by focusing on the larger forces that shape the way people live, such as the food industry, tobacco advertising and transport policy,[6] this systematic review focuses on changes in individual health-related behaviour.

The methods currently used to change behaviour include: education and advice, behaviour modification, family therapy, counselling and self-help groups. Underpinning many of these methods are a variety of different theoretical models, including the health belief model,[7] the theory of planned behaviour,[8] learning theory[9] and social learning theory.[10] In addition to such models, there are also stage theories or stage-based approaches to behaviour change, including the transtheoretical model (TTM),[11] the health action process approach[12] and the precaution adoption process model.[13]

## Stage-based approaches to behaviour change

Stage theories propose that behaviour change is not a continuous process but instead that it occurs through a series of qualitatively different stages. They also propose that the barriers people face in trying to change their behaviour will be different at different stages. The implication of this approach for behaviour change is that one type of intervention would not be expected to work for everyone, because the barriers people encounter are different at each stage. Instead, these models propose that interventions will be most effective when they are tailored to an individual's current stage in the progression. The number of stages proposed vary between models, but they all distinguish between three classes of individual:

- those who have not yet decided to change their behaviour
- those who have decided to change and
- those who are already changing.

The TTM is the most widely used model to date, and its theoretical framework has been applied to a range of different behaviours including smoking, sexual practices and screening uptake.[14] The TTM separates individuals into five different stages: **precontemplation**, where there is no intention to change; **contemplation**, where change is intended sometime in the future; **preparation**, where change is intended in the immediate future and steps are taken to help the change; **action**, where modifications to behaviour have been made; and finally, **maintenance**, which is the stage reached when change is established. Progression through the stages is seen as sequential although relapse to an earlier stage can occur.

In addition to identifying these five **stages** of change, the TTM proposes that there are ten **processes** of change.[15] These are activities or events that people participate in to overcome the barriers they encounter and progress towards their desired state. For example,

finding out more about the effects of the behaviour (consciousness raising), seeking support and help from others (helping relationships) or rewarding themselves for making changes (reinforcement management). The theory proposes that the effectiveness of the different processes of change will vary according to the stage the person is in, however, this has not always been supported in empirical studies.[14]

The attraction of stage-based models lies not only in their intuitive and theoretical plausibility but also in their ability to explain why interventions aimed at large groups or the general public, such as mass media or community interventions, may not result in widespread behavioural change. They propose that 'tailored' interventions, which take into account the current stage which the individual has reached in the change process, will be more effective and efficient than 'one size fits all' interventions.

## Use of stage-based approaches

There is increasing use of stage-based interventions in the UK, which may be in part due to the Helping People Change training programme developed by the Health Education Authority in 1994.[16] Many health promotion staff in the UK became accredited trainers, and ran this training programme for literally thousands of practice nurses and health visitors, to enable them to deliver one-to-one health education counselling to help patients stop smoking, eat a healthier diet, and so on. 'The Helping People Change' programme was based on the model originally developed by Prochaska and Di Clemente in 1986, and is known by names such as 'the wheel of change', 'stages of change' and 'the revolving door model'.

The stages-of-change model is part of many smoking cessation training packages offered by specialist smoking advisors to practice nurses, health visitors and midwives and other health professionals throughout the UK.[17] Once trained, registered advisors identify individuals who are 'ready to quit', often measured by some form of scale loosely based on the stages-of-change, and then offer a variety of brief interventions. Although these schemes appear to be successful in helping smokers to quit, with approximately 48% of those who set a quit date being stopped at 1 month, it is unclear whether the use of the stages-of-change model to identify potential quitters plays any part in this success, or whether the pharmacotherapies alone offered to all smokers with group or individual support would be sufficient.

Helping smokers to quit is often reported as being one of the most cost-effective interventions in the NHS. Approximately £60 million has been set aside by the government to support community smoking cessation clinics over a 3-year period, with more being earmarked for services to target pregnant women. Smokers attending these clinics are offered Zyban (buproprion) or nicotine replacement therapy (NRT) in the context of an individual or group support package provided by a specialist or registered smoking advisor.

Also, health promotion activities aimed at behavioural change are readily available through, for instance, high street pharmacies. Some branches of Boots currently offer a free, individually tailored computer program in-store, based on Prochaska and DiClemente's stages and processes of change, to help people to quit smoking.

Although stage-based interventions are intuitively appealing, they raise a number of methodological and practical issues, including how to identify which stage an individual has reached. For example, stages are constructs imposed on a fluid and non-unidirectional process. The problem with this is a tendency to subsequently treat the stages as if they were real, rather than as a shorthand way of describing complex social and psychological change. Nevertheless, the advantage of a stage-matched intervention does depend on the ability to identify stages accurately, and it is important to assess the reliability of the scales used to classify individuals into the various stages-of-change.

## The present review

Despite the widespread use of stage-based models and the TTM in particular, a recent review has suggested that there is little evidence available about the effectiveness of this approach in changing behaviour.[18,19] The review sought to clarify the conceptual base of training and health education activities using the stages-of-change model, and focused on literature that included the interrelationships between professional and disciplinary backgrounds, the supporting theory and model development/practice.[18] The review was not a formal systematic review of effectiveness, although observations were made on the nature of the evidence associated with the stages-of-change model. Therefore, a cross-cutting

review was proposed to draw together information about the effectiveness of interventions based on the stages-of-change approach. This allows the generalisability of findings to be assessed across different healthcare settings and different population groups and recommendations about effective (and ineffective) interventions to be made.

The HTA Programme explicitly requested that the focus of the review be on 'stages of change'.

# Chapter 2
# Methods

A systematic review of the literature was undertaken following the NHS Centre for Reviews and Dissemination guidelines *Undertaking Systematic Reviews of Research on Effectiveness.*[20]

## The research question

The following question was addressed: 'How effective are interventions using a stage-based approach in bringing about positive changes in health-related behaviour?'

Within this broad question the different types of stage-based models used, and their effectiveness were assessed; as well as the effectiveness of stage-based models in specific health areas and populations. In addition, where appropriate, comparisons were made between stage-based interventions and non-stage-based interventions as well as between stage-based interventions and usual-care.

## Inclusion criteria

### Intervention

Any intervention that aimed to influence individual health behaviour which was used within a stages-of-change approach. Stages-of-change theories include: The TTM,[11] the health action process approach[12] and the precaution adoption process model.[13] Although these models differ from each other, they all distinguish among three classes of individual: those who **have not** yet decided to change their behaviour, those who **have** decided to change and those who have **already** changed. Any other stages-of-change models or theory identified in the literature searches were also included. To be included, trials had to report some form of outcome data, for example, behaviour change or stage movement.

### Participants

The target population included individuals whose behaviour can be modified primarily in order to prevent the onset or progression of disease. Behaviours targeted include inadequate exercise, smoking, excessive alcohol consumption, hazardous sexual practices and illicit drug use.

### Outcomes

Health-related behaviour change such as smoking cessation, reduced alcohol consumption or dietary intake is the primary outcome measure. Secondary outcomes include: assessment of stage movement; health-related outcomes such as blood pressure, serum cholesterol levels and body weight; intermediate outcomes such as beliefs, attitudes and self-efficacy; patient satisfaction; any adverse effects resulting from the intervention; as well as data assessing the cost-effectiveness of behaviour change interventions. Necessary outcomes for trial inclusion included behaviour change or stage movement.

Other outcomes of interest were implementation measures (i.e. documentation of the way an intervention operates in practice); these data can be used to interpret outcomes – whether positive or negative – and can help to understand why the intervention did or did not work. Similarly, information about how the relevant professionals were trained was also recorded where given.

### Type of study

Study designs eligible for inclusion were randomised controlled trials (RCTs).

### Settings

All settings were considered relevant, to reflect the cross-cutting nature of the review.

## Search strategy

A wide range of databases and other information resources were searched to locate details of both published and unpublished studies, and other information on the effectiveness of interventions using a stage-based model in bringing about changes in health-related behaviour.

The search strategy was devised by the information service team at the NHS Centre for Reviews and Dissemination, University of York, and was independently checked by the review team and the expert advisory panel to the review. Following comments from the advisory panel, additional terms for stages-of-change models were included in the search strategy.

A comprehensive and systematic literature search was carried out on the following databases (listed alphabetically):

AMED (Allied and Complementary Medicine database)
ASSIA
BIOSIS
British Education Index
British Library Catalogue
British Nursing Index
CAB-Health
CINAHL
Cochrane Library CD-ROM
Conference Papers Index
DARE
DH-Data
Dissertation Abstracts
EconLIT
EMBASE
EPPI-Centre Register of Reviews of Effectiveness
ERIC (Educational Resources Information Center)
HEBS (Health Education Board Scotland journals database)
HealthPromis/Health Education Authority Unicorn Database
HEED
HELMIS
HTA database
Index to Scientific and Technical Proceedings
International Bibliography of the Social Sciences
King's Fund Database
MANTIS (Manual, Alternative and Natural Therapy)
MEDLINE
Mental Health Abstracts
NHS EED (NHS Economic Evaluation Database)
NRR (National Research Register)
PsycLIT
Science Citation Index
SIGLE
Social Science Citation Index
Sociological Abstracts

In addition to the databases listed above, searches of the Internet were also carried out using a range of search engines. All searching was carried out in May 2000, and resources were searched from their date of inception to the most recent date available at that time. There was no limitation of study by country of origin, language or date.

The bibliographies of retrieved references were scanned for further relevant publications. The authors of any conferences proceedings abstracts found by the literature search were contacted for further information about their research.

Full details of the search strategy used, and further information on the resources searched, are provided in appendix 1.

# Chapter 3

# Procedure

All titles and abstracts identified from the searches of electronic databases were assessed independently by two reviewers (RPR and JP). If either reviewer considered a reference to be potentially relevant, a hard copy of the paper was retrieved for further consideration. At this stage, relevant studies were those that either focused on: (1) the evaluation of an intervention; (2) the evaluation of a stage-based model; (3) the validation of a questionnaire to assess the stage of change; (4) the description of a new stage-based model; (5) background information on stage-based models or reviews of behavioural interventions.

The primary focus of this review was on studies that had evaluated an intervention (No. 1 studies). The full papers of these studies are assessed against the selection criteria detailed above (see pre-screen form, appendix 2). Pre-screening was performed independently by two reviewers (RPR and JP). Disagreements were resolved through discussion, and, if necessary, by recourse to a third reviewer (AJS).

Studies focusing on the validation of a questionnaire to assess the stage of change (No. 3 studies) were retrieved and used to assess the validity of instruments used in the No. 1 studies. A full list of studies focusing on the validation of stages-of-change instruments can be found in appendix 3. All of the included evaluation studies were checked for references referring to the validation of the stages-of-change instrument used. References were retrieved and information from these studies was extracted and used to describe the validity of the instrument. Validation of the stages-of-change instrument was not an inclusion criterion.

Background information on stage-based models and reviews of behavioural interventions were used to retrieve more publications of interest.

Studies focusing on the evaluation of a stage-based model (No. 2 studies) and on the description of a new stage-based model (No. 4 studies) are listed in appendix 3.

## Data extraction

Study details were extracted by one reviewer (RPR or CB) into standardised, structured tables using ACCESS software (see appendix 4), and were checked by a second reviewer (RPR, CB, JP, ISW or AJS). Any disagreements were resolved through discussion, and, if necessary, by recourse to a third reviewer. Where there were multiple publications of the same evaluation, all publications were examined to ensure that all the relevant data for that study were recorded. The data extracted included:

- author, date, country and language
- stages-of-change information and any other information relating to the theoretical basis of the intervention
- intervention details (content, frequency, duration, information about person/s delivering the intervention, including the relevant training they were given)
- participants – including details of how participants were classified into stages-of-change, and the validity and reliability of the measures used
- details of the study design
- results (behaviour change, stage movement, physiological changes, intermediate outcomes, documentation of the way an intervention operates in practice and cost-effectiveness).

## Quality assessment

Quality assessment was carried out, using an existing quality assessment tool,[20] by one reviewer (RR) and checked by a second (CB), using the following predefined criteria:

**Methodological quality**

- Method of randomisation and adequate concealment of allocation.
- Blinding of participants, outcome assessors and/or care-providers (where appropriate).
- Baseline comparability of groups.
- Adjustment for groups that were not comparable at the baseline.
- Completeness of follow-up.
- Description of eligibility criteria.

- Point estimates and variability.
- Handling of drop-outs and missing data (intention-to-treat analysis).
- Description of the statistical analysis.
- Sample size calculation.
- Whether the groups were treated identically other than the named interventions.

**Quality of the implementation**

- Stages-of-change assessed at the baseline.
- Stages-of-change instrument validated.
- Intervention tailored to stage of change.
- Process evaluation reported.
- Details of training for care-providers/ educators reported.

Discrepancies were resolved by discussion or, when agreement could not be reached, by consultation with a third reviewer. Quality assessment was not used for inclusion or exclusion of studies. Results of the assessment were tabulated (see appendix 5), and were also discussed in the main text of the review. The effectiveness of the interventions has been discussed in relation to the quality of the studies.

## Extent to which interventions were tailored to an individual's stage of change

Assessments were made concerning the extent to which interventions were tailored to an individual's stage of change. This information was extracted from the paper or from communication with the author. Without sufficient information, some studies were classified as **partially** stage-based, and in some trials it was **unclear** whether the intervention was tailored to a participant's particular stage of change.

Assessment was conducted by two reviewers independently, with disagreements resolved through discussion, and, if necessary, recourse to a third reviewer.

## Methods of analysis/synthesis

A narrative summary of the results is presented, with results grouped according to the health behaviour targeted. The studies were too heterogeneous in terms of design, intervention, participants, settings and outcomes to carry out a formal pooling; therefore, a qualitative synthesis was presented.

## Taxonomy of models/theories

In addition, as requested by the NCCHTA, a taxonomy of other models/theories aimed at behavioural change (non-stage-based) identified in the literature searches has been assembled (see appendix 6).

## Advisory expert panel

A panel of experts was formed to provide guidance on the scope of the review and advise on both contents and methodological issues (see the *Acknowledgements* section). Panel members were chosen for their expertise in the fields of health promotion, public health (practice and/or academic), health psychology and methodology.

Throughout the project the expert panel provided help with definitions of key concepts, devising the protocol, search strategy and the frameworks for the quality assessment and data extraction. The expert panel also commented on the draft report.

# Chapter 4
# Results

## Results of searches

The search strategy (see chapter 2 and appendix 1) generated 2168 references of possible relevance (see also *Figure 1*). Once titles (and where available, abstracts) were assessed, hard copies of 516 papers were retrieved and examined. Two hundred and twelve papers were ordered because they described the evaluation of an intervention (No. 1 studies); 117 papers were ordered because they described the evaluation of a stage-based model (No. 2 studies); 75 papers were ordered because they described the validation of an instrument to assess the stage of change (No. 3 studies); 30 papers were ordered because they described the description of a new stage-based model (No. 4 studies); and 100 papers were ordered because they contained background information on stage-based models or reviews of behavioural interventions (No. 5 studies).

Overall, out of 212 papers screened, 50 RCTs met the review's selection criteria. Six of these were identified after data extraction had stopped.[21–25] After data extraction and quality assessment, six studies were excluded,[26–31] mainly because the interventions appeared not to be stage-based or because the outcomes did not include information on behaviour change or stage movement (see appendix 7). One study, which was initially included in the review, was later excluded on the advice of the expert panel, as it was regarded as not targeting a health-related behaviour.[32] Details of the remaining 37 studies are summarised in appendix 4 (data extraction table).

Originally it was envisaged that we would provide a list of trials whose interventions were based on methods other than stages-of-change, along with a brief report of the findings. However, due to the large number of trials based on stage-based approaches, we did not have time for a detailed description of trials that used methods other than stages-of-change.

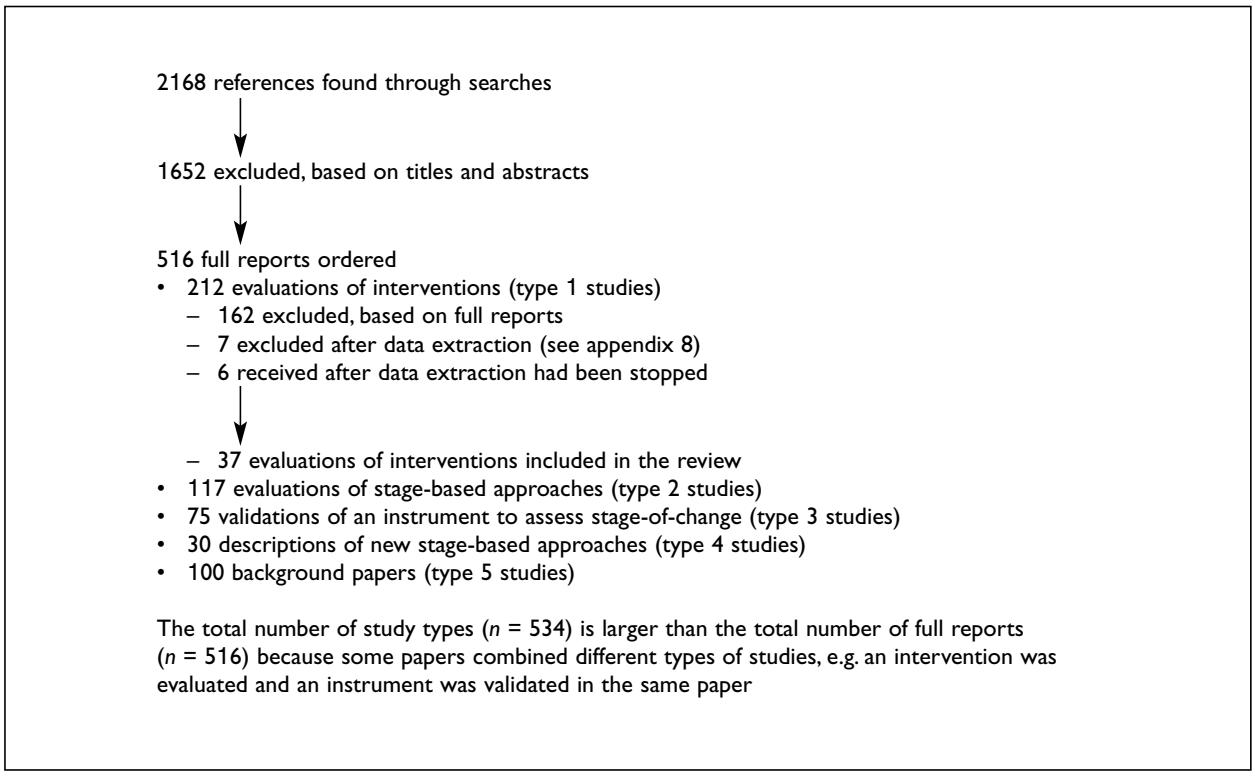


***FIGURE 1*** *Flow diagram of search results*

## Stage-based models used

Most studies used the TTM as the theoretical basis for the intervention. Six studies used the TTM in combination with other models, such as the social learning theory,[33–35] the health belief model,[33,36] motivational interviewing,[34,37] social cognitive theory,[36] goal-setting theory,[36] or the precaution adoption process.[38] Three studies did not use the TTM model: one study used the classic model of Anderson,[39] another study used the precaution adoption process,[40] and the third used motivational interviewing as the theoretical framework for the intervention.[41]

## Behaviours targeted

For the purposes of this review, interventions based on a stage-of-change approach to promote individual behaviour change were grouped in the following categories, with the number of studies in each of these categories:

- interventions aimed at smoking cessation (13 studies[34,42–53])
- interventions aimed at the promotion of physical activity (seven studies[37,54–59])
- interventions aimed at dietary change (five studies[36,38,39,60,61])
- interventions aimed at multiple lifestyle changes (six studies[35,62–66])
- interventions aimed at the promotion of screening mammography (two studies[67,68])
- interventions aimed at the promotion of treatment adherence (one study[41])
- interventions aimed at the prevention of smoking and alcohol use (three studies[33,69,70]).

In this chapter the results have been discussed by category. Within each category the characteristics, methodological quality and (cost-)effectiveness of included studies has been synthesised. A summary of the details by study can be found in appendix 4 (data extraction table), and an overall summary of the results can be found in *Table 7*.

## Results of interventions aimed at smoking cessation

### Number of studies

Thirteen RCTs of interventions aimed at smoking cessation were identified (see also appendices 4 and 5).[34,42–53]

### Number of participants

Two studies included less than 100 respondents at 6-months follow-up.[48,53] Two studies included a little over 100 participants[44] and a little over 200 participants[42] at 12-months follow-up, and one study included 265 participants after 2 years.[47] Four studies included approximately 500 participants at final follow-up (6, 9 or 18 months).[34,46,49,51] One study included 750 participants at 6-months follow-up,[43] and three studies included more than 1000 participants at the final follow-up (6, 14 or 18 months).[45,50,52]

### Characteristics of participants

All studies included smokers only. Two studies recruited participants through advertisements,[43,49] one through the workplace,[52] and five through general practices.[34,45,46,51,53] In one study, participants were clinic patients with newly diagnosed, first primary squamous cell carcinomas of the head and neck, with a life expectancy of more than 1 year.[44]

Seven studies explicitly stated that they only included adults.[42,44–47,50,52] In one of these, participants between 50 and 74 years only were included.[46] One study was among tenth and 11th grade students.[48] One study included only men.[47] One study was among low-to-middle-income multiethnic individuals[42] and one among African Americans, some of whom were from low-income public housing developments.[50] One study included smokers with low readiness to change.[43]

### Characteristics of interventions

#### *Setting of the intervention*

In five studies the intervention was based in primary care practices.[34,45,46,51,53] In one study the intervention was delivered in hospital-based medical and dental clinics.[44] In six studies the intervention was mail delivered;[42,43,47,49,50,52] two of these studies also included telephone contacts.[49,50] In one study the intervention took place at a school.[48]

#### *Number of intervention arms*

Most studies included two intervention arms, a stage-based intervention and a comparison group.[34,42,44–48,50,51] In one study, the stage-based intervention was compared to a non-stage-based intervention and a no-intervention control group.[53] Two studies included four intervention arms; in one study there were two stage-based interventions, a non-stage-based intervention and a no-intervention control group,[43] and in the other, three stage-based interventions and a non-stage-based intervention.[49] Finally, one study included eight stage-based interventions.[52]

### *Stage-based interventions*

In nine trials the interventions were classified as fully stage-based.[34,43,46–52] In four of these trials, stage-based advice was provided by health professionals or educators.[34,46,49,51] In four trials a computerised system was used to generate stage-based feedback,[43,48,49,52] and in five trials stage-based education materials were used.[46,47,49,50,52] Some trials included more than one stage-based intervention or within one intervention a combination of education materials, expert system and counselling was used.

Two trials were classified as partially stage-based.[42,44] One trial was classified as partially stage-based because the main intervention – a seven-session smoking-cessation class – was not stage-based, but brief smoking cessation booster messages delivered after 3 and 6 months were stage-based.[42] The other trial was classified as partially stage-based because the initial advice session was not stage-based but six booster sessions were.[44] For two trials the interventions were mainly aimed at health professionals, with limited data on patient outcomes.[45,53]

### *Comparison groups*

In eight studies the intervention was compared to a non-stage-based intervention. In four such cases, general health education materials were used as a comparator.[42,43,49,50] The fifth study used an action-orientated cessation programme as a comparator. This programme included three sessions using a computer presentation with predetermined feedback.[48] Two other studies used smoking education by untrained health professionals as a comparator.[45,53] In one of these the general practitioners (GPs) implementing the intervention received a poster to remind them.[53] In another trial the stage-based intervention was compared to 'brief advice', consisting of one statement urging participants to stop smoking.[34] In six studies the intervention was compared to a non-intervention or usual-care comparison group.[43,44,46,47,51,53] One study did not include a non-stage-based comparison group.[52]

## Outcome assessment

All 13 studies evaluating the effectiveness of interventions aimed at smoking cessation reported the primary outcome of smoking behaviour. Five studies included data on the secondary outcome of stage movement,[34,43,45,47,48] and two also reported intermediate outcomes (including intention to quit, pros and cons of quitting or self-efficacy).[43,48] Eight studies reported data on the implementation of the intervention (including data on participation rates, exposure to materials or usefulness of the intervention, training attendance and delivery of the intervention),[42,44–48,50,51] and one study reported other outcomes (acceptability of the intervention and adverse effects).[34] None of the studies reported outcomes on health.

## Quality of included studies

### *Methodological quality*

Details of the quality assessment of trials aimed at smoking cessation are presented in appendix 5 (quality assessment table). Although all 13 studies were published as RCTs, only four described the method of allocation[34,42,48,49] and only two stated that allocation of the intervention was concealed.[34,45] Blinding of participants was described in one study,[45] and not applicable in two.[43,47] Blinding of outcome assessors was described in another study.[34] None of the studies reported blinding of care-providers, although this was not applicable in three studies.[43,48,52] Seven studies either reported no differences between groups at the baseline,[34,48,52,53] or reported adjustment for baseline differences.[43,45,50] In six studies, at least 80% of respondents provided follow-up data.[43,46,49–51,53] Intention-to-treat analysis or handling of drop-outs was reported in four studies.[34,43,44,46] Point estimates and variability were reported in five studies.[34,45,48,50,53] All studies reported the inclusion criteria, while all but one[51] gave a clear description of the statistical methods used. Three studies reported a sample size calculation.[34,45,50] For all but three studies it was assumed that the groups were treated in an identical way apart from the named intervention. In one study the authors reported that 'brief advice' (control group) may have included elements of 'motivational consulting' (intervention group).[34] In another study the authors stated that 'contamination of the control condition during the initial assessment' may have been the case;[44] while in another study the authors discussed the effects of differential exposure to intervention as a potential confound.[47]

### *Quality of the intervention and stage-of-change instrument*

All but two studies assessed stage of change at the baseline,[46,51] but only two studies reported validation of the stage-of-change instrument.[45,49] One study reported data collected from more than 400 smokers at two worksites before and during a 10-month intervention.[45] Significant associations were found between stage of change and reported intention to quit, number of previous quit attempts, perceived co-worker encouragement to quit, and socio-economic status. Stage-of-change scores predicted subsequent participation in programmes designed

to educate workers about their smoking habit and its contingent risks. Stage-of-change scores did not predict biochemically validated abstinence of 24 hours or more. To assess the instrument's ability to distinguish between groups known *a priori* to differ in readiness, the stage-of-change instrument was administered to 36 participants in a clinic-based smoking cessation programme. As predicted, clinic patients scored significantly higher than the workers on the instrument.[45,71]

In the other study, evidence for the validity of the stage classification was reported as strong;[72] and that stage classifications for smoking cessation were consistently related to self-efficacy,[73,74] to a decision-making construct[75] and to the processes of change for smoking cessation[15,72] in a consistent and theoretically compatible manner. Regarding the development of the same instrument, it was reported that an initial pool of 125 items representing the five stages was reduced to a final test of 32 items on the basis of principal component analysis, Cronbach's coefficient alpha and item analysis results.[76] One of the five initial stages was eliminated based on the analyses. The resulting four stages (precontemplation, contemplation, action and maintenance) were represented by high loadings on distinct components. Cronbach's coefficient alpha for the four scales ranged from 0.88 to 0.89. A cluster analysis was performed on the standardised scores for each participant on each of the four scales. The resulting 18-cluster solution produced seven major and two minor client profiles that are highly distinct.[76]

Eight studies reported some detail of the quality of the implementation.[42,44–48,50,51] In one study, 75% of respondents attended their practice at least once over the 14-month follow-up period, and approximately 80% of them recalled smoking having been mentioned during the consulation.[45] In a second study, 89% of respondents attended two or three intervention sessions.[48] In a third study, 69% of respondents reported having read most or all of the manuals.[47] In a fourth study, only 24% attended group classes, but 90% reported having read any of the materials.[42] In a fifth study, 92% of respondents read most or some of the guide, while booster telephone calls were completed for 31% of respondents.[50] Ninety-six per cent of respondents received the guide, 88% recalled the doctor's advice and 79% of physicians reported spending between 3 and 10 minutes with each patient in a sixth study.[46] In a seventh study, participants completed exit checklists after initial advice, but the data were not reported.[44] Finally, in one study 90% of health professionals reported having utilised the training; however, patient data were not provided.[51]

Eight studies reported details of the training of care-providers or educators,[34,44–46,49–51,53] although this was not applicable in three studies.[43,48,52]

## Effectiveness of interventions

### *Primary outcome: behaviour change*

Eight studies compared stage-based interventions with non-stage-based interventions.[34,42,43,45,48–50,53] Five of these studies found no significant differences between intervention groups at final follow-up.[42,43,45,48,50] However, in one study a subgroup of respondents in the stage-based intervention who had attended booster sessions showed significantly better results compared to respondents in the non-stage-based intervention for point prevalence quit rates and quit attempts.[50] One study compared three different stage-based interventions with one non-stage-based intervention, and found significantly better results for the stage-based interventions at 6, 12 and 18 months follow-up.[49] Another study found no significant differences between groups for scores on self-reported abstinence in the previous month, three measures for quit attempts, and numbers of cigarettes cut down, but significant differences for scores on self-reported abstinence in the previous 24 hours (odds ratio (OR) = 2.86; 95% confidence interval (CI): 1.21 to 6.76) and the number of respondents who smoked within 5 minutes after awakening (OR = 2.25; 95% CI, 1.29 to 3.93) were found favouring the stage-based intervention.[34] And one study found no significant difference between groups for scores on quit rate, but the change in daily cigarette consumption was significantly better in the stage-based intervention compared to the non-stage-based intervention (OR = 8.06; 95% CI, 1.61 to 45.65).[53]

Six studies compared stage-based interventions with a usual-care control group.[43,44,46,47,51,53] Three studies found no significant differences between intervention groups at final follow-up.[43,44,51] One study found no significant difference between groups for prolonged abstinence at 2-year follow-up, but a significant result was found for the 7-day quit rate ($p < 0.05$).[47] Another study found significant differences between groups for scores on quit rate (OR = 8.80; 95% CI, 1.00 to 198.53), and change in daily cigarette consumption (OR = 12.73; 95% CI, 2.10 to 99.51) favouring the stage-based intervention compared to the usual-care control group.[53] And one study found a significant difference for quit rate favouring the stage-based intervention ($p < 0.05$).[46]

One study evaluated the effectiveness of four types of interactive smoking cessation interventions in comparison to four types of non-interactive smoking cessation interventions.[52] All interventions were stage-based; there was no non-stage-based comparison group. At 18-months follow-up, interactive interventions showed better results for scores on 24-hour point-prevalent abstinence, 7-day point-prevalent abstinence, 30-day sustained abstinence, and 6-month prolonged abstinence.

### *Secondary outcome: stage movement*

Four out of eight studies comparing stage-based interventions with non-stage-based interventions did not report stage movement as an outcome.[42,49,50,53] Two of the remaining four studies found no significant differences between groups for scores on stage movement.[45,48] One study found a significant effect of one stage-based intervention (multiple tailored letters) compared to the non-stage-based intervention for 'immotives' but not for 'precontemplators'. The other stage-based intervention (single tailored letter) showed no differences in stage movement compared to the non-stage-based intervention for 'immotives' and 'precontemplators'.[43] The other study found a linear trend after 6 months for stage movement favouring the stage-based intervention compared to the non-stage-based intervention.[34]

Four out of six studies comparing stage-based interventions with a usual-care control group did not report stage movement as an outcome.[44,46,51,53] One study found a significant effect of both stage-based interventions compared to the usual-care control group for 'immotives' but not for 'precontemplators'.[43] The other study found a significant effect favouring the stage-based intervention compared to the usual-care control group for contemplators ($p < 0.05$) but not for 'precontemplators' at 1-year follow-up.[47] At 2-years follow-up, no significant differences between groups were found.

### *Health, intermediate outcomes, adverse effects and other outcomes*

None of the 13 studies aimed at smoking cessation assessed health status as an outcome. Eleven studies did not report any between-group results for scores on intermediate outcomes.[34,42,44–47,49–53] One study found no significant differences between groups on decisional balance scores (the pros and cons of quitting).[48] And another study found no significant differences between one stage-based intervention (single tailored letter) compared to a non-stage-based intervention and a usual-care control group for scores on intention to quit, the pros and cons of quitting, and self-efficacy.[43] However, the other stage-based intervention (multiple tailored letters) did show significant differences compared to the non-stage-based intervention in favour of the stage-based intervention for scores on intention to quit ($p < 0.05$), pros of quitting ($p < 0.05$), and self-efficacy ($p < 0.001$). And similarly, significant differences were found in favour of the stage-based intervention (multiple tailored letters) in comparison with the usual-care control group for scores on intention to quit ($p < 0.001$), pros of quitting ($p < 0.01$), and self-efficacy ($p < 0.001$). The cons of quitting were assessed as well, but no significant differences between groups were found.[43]

In one study qualitative interviews with participants revealed that patient-centred interventions like motivational consulting were acceptable, and that repeated brief advice to stop smoking could damage doctor–patient relationships and adversely affect help-seeking behaviour.[34]

### *Implementation outcomes*

Implementation outcomes were reported in eight studies aimed at smoking cessation.[42,44–48,50,51]

Four studies reported participant data only,[42,47,48,50] three studies reported data from participants and health professionals,[44–46] and one study reported data from health professionals only.[51]

In one study, 62.5% of participants in the stage-based intervention attended all three intervention sessions while 74.5% of participants in the non-stage-based intervention attended all three sessions.[48] In another study, 31.2% of participants reported at 2 years follow-up having read none or only some of the manuals mailed to them, while 38.3% reported having read all the manuals.[47] Almost 50% rated the manuals as either not useful or only a little useful in their quit attempts, and 14.4% rated the manuals as quite helpful or very helpful. In another study, 89.9% (196/218) of respondents reported having read any of the materials, and 92.3% of these reported that they had read the stop-smoking components.[42] Only 26 participants in this study attended some of the sessions, 18 attended at least 50% of the seven sessions and four participants attended the booster sessions. Another study reported that approximately 60% of respondents had read most of the self-help guide, approximately 36% of respondents had watched most of the video, and booster calls were completed for 31% of respondents in the intervention group.[50]

Of the three studies reporting data from participants and health professionals, one study reported that 89.2% of GPs, 93.7% of practice nurses and all health visitors attended the intervention workshops.[45] Over the 14-month follow-up period, 75.0% of intervention smokers and 76.9% of smokers in the control group attended their practice at least once. Smokers in the intervention group were more likely than smokers in the control group to recall smoking having been mentioned in a consultation during the 14-month follow-up period. In another study, 95.8% of respondents in the intervention group reported having received a self-help guide at the 2–4-week follow-up, 88.4% reported that the doctor recommended them to stop smoking, and 35.1% received a letter about quitting plans from the doctor since the visit.[46] In the same study, 79% of physicians reported spending between 3 and 10 minutes per patient implementing the counselling intervention, and 43% thought patients were receptive to advice to quit. Providers rated the protocol as practical and helpful and 93% expressed increased confidence in counselling older patients to stop smoking. The third study, reporting data from patients and health professionals, reported that 110 doctors attended the training session, and that there was some evidence of contamination (i.e. advice meant only for the intervention participants was delivered to control participants). Specifically, setting a target quit date and discussing withdrawal symptoms were reported by control participants (7.25% and 48.5%, respectively).[44]

One study reported data from health professionals only.[51] Ninety-five per cent rated the training as a 'very good' or 'good' learning experience and a worthwhile use of their time. Ninety-eight per cent thought that they would be able to use what they had learned in their work. At 12-months follow-up, 89.9% had utilised the training; over 90% agreed that the 'cycle of change' model was a good way of understanding the stop smoking message; almost three-quarters felt that the training had made a difference to the way they counselled 'customers' who were trying to stop smoking and that it had helped them to help these customers; and around 80% felt confident in their ability to assess the stage of change their customer was at by asking them a few questions and to tailor the advice they gave to customers to their current stage of change. Sixteen months after the training a subsample of 20 health professionals was selected from those available to assess their perceptions of the value and utility of the training. The majority of pharmacists (9/10) and assistants (7/10) were extremely positive about the training.[51]

### *Cost-effectiveness of interventions*

Two studies included economic evaluations.[34,51] In the first trial the costs of motivational consulting were calculated as the costs of training (time plus travel) plus the costs of longer consultations.[34] The marginal costs per quitter were assessed and costs were compared for other outcomes. The marginal cost per quitter was estimated at £450.65 (which may fall to an extreme of £265.00 with increased use). The marginal cost per reduction in addiction was estimated at £279.63 (minimum: £164.44). And the marginal cost per quit attempt was estimated at £311.99 (minimum: £183.47).[34]

In the second trial, advice to stop smoking given by pharmacy personnel trained in the stage-of-change model was compared with advice to stop smoking given by personnel who have not had this training.[51] For the purposes of cost-effectiveness analysis the outcome measures used were the number of quitters (continuous cessation) at 9 months and an estimate, based on previous studies, of the life-years gained by smoking cessation. Incremental cost-effectiveness ratios were calculated, that is, the cost of producing one additional unit of effectiveness (e.g. a quitter or a life-year) by using intensive rather than standard pharmaceutical support. A wider societal perspective was adopted. The most obvious cost to the NHS arose from the organisation of the training sessions and trainee's out-of-pocket expenses, including staff costs and travel (NRT was a cost of the intervention to the client and cost of materials and documentation was borne by the research project but would not ultimately be a cost to the NHS).

The total costs of the intervention were estimated at £14,915.76, while the total costs for the control group were estimated at £14,121.13. The incremental cost-effectiveness ratios for the intervention were estimated at £300.00 per quitter and £83.00 per life-year.[51]

## Summary

Thirteen studies aimed at smoking cessation were included.[34,42–53] An overview of the main characteristics of each study is given in *Table 1.* Five of the eight trials comparing stage-based interventions with non-stage-based interventions found no significant differences between groups in behavioural change outcomes,[42,43,45,48,50] whilst two found mixed effects,[34,53] and in one all stage-based interventions outperformed the non-stage-based intervention.[49]

***TABLE 1*** *Characteristics of studies with interventions aimed at smoking cessation*

| Study details | Interventions* | Results† |
|---|---|---|
| **Butler (1999)**[34], UK, primary care setting. *n* = 536. Smokers consulting a GP in South Wales. Mean age 41 years; 70% female | A 6-month study to compare the clinical and cost-effectiveness of motivational consulting with brief advice to quit smoking<br><br>**I**: Motivational consulting is based on inviting patients to numerically rate their motivation and confidence to quit smoking (phase 1). Clinicians respond to these scores using specific questions and strategies (phase 2). The aim is to build motivation or confidence by encouraging the patient to identify arguments for change (motivation) or practical, attainable steps for quitting (confidence). Finally, patients are invited to set meaningful targets for themselves (phase 3)<br><br>**C**: Brief advice consisted of the following statement: "Smoking is an extremely serious matter. Apart from lung cancer, smoking can damage your health in many other ways. If you give up now, a lot of the harm can be undone. It is my professional duty to tell you that you must give up smoking in the interest of your future health" | **Health behaviour**: No significant differences between groups for scores on self-reported abstinence in the previous month, three measures for quit attempts, and numbers of cigarettes cut down. Significant differences for scores on self-reported abstinence in the previous 24 hours and the number of respondents who smoked within 5 minutes after awakening were found favouring the stage-based intervention<br><br>**Stage movement**: A linear trend was found after 6 months for stage movement favouring the stage-based intervention |
| **Lennox (1998)**[45], UK, primary care setting. *n* = 1693. Adult smokers on the participating practices' lists. Mean age and % female: not stated | A 14-month study to assess the effects of training (1-day stages-of-change workshop for health professionals) on patient smoking outcomes<br><br>**I**: Smoking education by trained health professionals<br><br>**C**: Smoking education by untrained controls | **Health behaviour**: No significant differences between intervention groups at final follow-up<br><br>**Stage movement**: No significant differences between groups |
| **Resnicow (1997)**[50], USA, community setting. *n* = 1244. Low-socioeconomic adult African Americans. Mean age 45 years, 60% female | A 7-month study to test a culturally sensitive, low-intensity smoking cessation intervention<br><br>**I**: 'Kick It' guide, a two-part 'Kick It' video (part 1, for precontemplators and contemplators to initiate a quit attempt; part 2, for action and maintenance, providing instruction on how to quit, how to stay quit, and how to start over for those who did not initially succeed), a booster call (to encourage the use of intervention materials and provide brief motivational counselling), quit contract, and an invitation to enter two separate prize-draw contests – entry criteria for both was 30-day abstinence<br><br>**C**: Previously developed printed health education materials related to substance use, HIV/AIDS, diet, heart disease, and cancer (but no materials that exclusively addressed tobacco use or tobacco-related cancers) and a 10-minute cholesterol education video developed for African–Americans | **Health behaviour**: No significant differences between intervention groups at final follow-up. However, a subgroup of respondents in the stage-based intervention who had attended booster sessions, showed significantly better results compared to respondents in the non-stage-based intervention for point prevalence quit rates and quit attempts<br><br>**Stage movement**: Not reported |

*continued*

***TABLE 1* contd** *Characteristics of studies with interventions aimed at smoking cessation*

| Study details | Interventions* | Results† |
|---|---|---|
| **Dijkstra (1999)**[43], The Netherlands, community setting. *n* = 843. Cigarette smokers with low readiness to change, recruited by newspaper advertisements. Mean age 41.7 years, 62.8% female | A 7-month study to investigate the efficacy of two different tailored smoking cessation self-help interventions and one standardised smoking cessation self-help guide compared to a no-information control group and with each other<br><br>**I1**: Tailored intervention. Computerised system used to generate three consecutive tailored letters.<br><br>**I2**: Tailored intervention. Computerised system used to generate a single tailored letter<br><br>**I3**: Self-help guide. 46-page colour self-help manual developed for use in a community smoking cessation project<br><br>**C**: No information | **Health behaviour**: No significant differences between intervention groups at final follow-up<br><br>**Stage-based versus no information**: No significant differences between intervention groups at final follow-up<br><br>**Stage movement**: A significant effect of one stage-based intervention (I1) compared to the non-stage-based intervention (I3) for 'immotives' but not for 'precontemplators'. The other stage-based intervention (I2) showed no differences in stage movement compared to the non-stage-based intervention (I3) for 'immotives' and 'precontemplators'<br><br>**Stage-based versus no information**: A significant effect of both stage-based interventions (I1and I2) compared to the usual care control group (C) for 'immotives' but not for 'precontemplators' |
| **Pallonen (1998)**[48], USA, school setting. *n* = 135, tenth and 11th grade students, currently smoking. Mean age 16.5 years, 40.1% female | A 6-month study to evaluate the ability of the computer-based interventions to engage and to retain the interest of adolescents in a school setting<br><br>**I**: TMC-based expert system cessation programme. Each assessment and feedback section at each intervention session were provided in small, logically meaningful segments of the four TMC constructs: (1) stage of change, (2) decisional balance, (3) processes of change, and (4) self-efficacy, or temptations to smoke. Feedback is provided as text on a computer screen<br><br>**C**: Action-orientated cessation programme; Original ALA (1988) clinic program was shortened and modified into three sessions and altered for a personal computer screen presentation. The feedback from the program was predetermined and based on the assumption that the smoker was prepared to quit smoking | **Health behaviour**: no significant differences between intervention groups at final follow-up<br><br>**Stage movement**: no significant differences between intervention groups |
| **Wang (1994)**[53], Taiwan, primary care setting. *n* = 82. Clinic patients who smoked at least one cigarette a day. Age: 37.6%, < 40 years; 39.8%, 40–59 years; 22.6%, > 60 years; 4.3% female | A 6-month study to assess the feasibility and effectiveness of a stages-of-change model in cigarette smoking cessation counselling<br><br>**I1**: Physicians were given two lectures on the stages-of-change model for cigarette smoking and received specific practice guidelines for clinical counselling on cigarette smoking cessation<br><br>**I2**: Physicians did not receive stages-of-change training but did receive a poster to be placed in the examination room to remind the doctor to conduct smoking cessation intervention in their clinic practice<br><br>**C**: No intervention, i.e. physicians received no lecture, nor reminder and continued to practice in their usual style | **Health behaviour**: No significant difference between groups for scores on quit rate, but the change in daily cigarette consumption was significantly better in the stage-based intervention compared to the non-stage-based intervention<br><br>**Health behaviour** (stage-based versus no intervention): significant differences between groups for scores on quit rate, and change in daily cigarette consumption favouring the stage-based intervention (I1) compared to no intervention (C)<br><br>**Stage movement**: Not reported |

*continued*

***TABLE 1* contd** *Characteristics of studies with interventions aimed at smoking cessation*

| Study details | Interventions* | Results† |
|---|---|---|
| **DiClemente (1991)**[49], USA, community setting. *n* = 1758. Volunteers responding to newspaper, radio and other media advertisements. Mean age 40 years, 62% female | A 6-month study to test the TTM of change that posits a series of stages through which smokers move as they successfully chance the smoking habit<br><br>**I1**: Based on their pretest scores, participants were sent the manual matched to their individual stage of change and manuals for all subsequent stages (five manuals: (1) precontemplation; (2) contemplation; (3) action; (4) maintenance; (5) relapse)<br><br>**I2**: Transtheoretical manuals and individualised written feedback (a series of three computer-generated reports) based on pretest, post-test and 6-month questionnaires<br><br>**I3**: Transtheoretical manuals and individualised written feedback plus a series of four personalised counsellor calls (following a protocol for social support in stressful decisions) at pretest, post-test, 3 months and 6 months. The telephone counselling protocols were stage matched and basically followed the outline of the expert system reports<br><br>**C**: American Cancer Society/ALA materials and manuals | **Health behaviour**: Significantly better results for the stage-based interventions (I1, I2 and I3) at 6-, 12- and 18-months follow-up<br><br>**Stage movement**: Not reported |
| **Morgan (1996)**[46], USA, primary care setting. *n* = 573. Smokers visiting a primary care practice. Mean age 60.1 years, 56% female | A 6-month study to test the effectiveness of an office-based smoking cessation programme tailored to midlife and older smokers<br><br>**I**: Physicians received on-site training to implement a modified National Cancer Institute smoking cessation intervention. The programme comprises four steps: ask about smoking at every opportunity; advise all smokers to stop; assist the patient to stop smoking; arrange for follow-up support<br><br>Patients were give a copy of a smoking cessation guide tailored to older smokers ('Clear Horizons') and asked: "If we give you some help, are you willing to try to quit?" Smokers in different stages received stage-specific counselling. Smokers received a brief follow-up counselling call within 2–4 weeks of the intervention visit to reinforce their efforts, explore barriers and discuss their quit plans<br><br>**C**: Delayed intervention practices were instructed to provide usual care to their older smokers over the accrual and follow-up period | **Health behaviour** (stage-based versus usual care): A significant difference for quit rate favouring the stage-based intervention<br><br>**Stage movement** (stage-based versus usual care): Not reported |

*continued*

***TABLE 1* contd** *Characteristics of studies with interventions aimed at smoking cessation*

| Study details | Interventions* | Results† |
|---|---|---|
| **Velicer (1999)**[52], USA, workplace setting. *n* = 2882. Smoking adults in four offices of a managed care system. Mean age 38.4 years, 56% female | An 18-month study to compare interactive and non-interactive smoking cessation interventions<br><br>**I1–I4**: Interactive. Participants completed smoking cessation questionnaires and received individualised and detailed (computerised) feedback reports containing information about their progress and referring them to sections in their stage-matched self-help manuals<br><br>**I5–I8**: Non-interactive. Self-help manuals were based on research on how self-changers progress through each stage of change and how they recycle through the stages if they relapse. The manuals instruct users about their particular stage of change and the processes they can use to progress to the next stage. On the basis of their pretest scores, participants were sent the manual matched to their individual stage of change and the manuals for all subsequent stages. In the multiple-contact conditions, a different manual was mailed on each occasion<br><br>Both I1–I4 and I5–I8 treatments were delivered in one of four doses: one, two, three or six mailings, at 3-month intervals<br><br>**C**: I1–I8 were compraed with each other | **Health behaviour** (interactive stage-based versus non-interactive stage-based): At 18-months follow-up, interactive interventions showed better results for scores on 24-hour point-prevalent abstinence, 7-day point-prevalent abstinence, 30-day sustained abstinence and 6-month prolonged abstinence<br><br>**Stage movement** (interactive stage-based versus non-interactive stage-based): Not reported |
| **Berman (1995)**[42], USA, community setting. *n* = 348. Low-to-middle-income multi-ethnic smoking adults within an inner-city school district. Mean age 36.7 years, 50.9% female | A 12-month study to test the effectiveness of a preventative health programme featuring smoking cessation tailored to an under-served, multi-ethnic (Latino and African American) adult population of smokers<br><br>**I**: Received health education materials targeting cardio-vascular risk factors, and invited to participate in a seven-session (1.5 hours per session) smoking cessation group class conducted after the 6-month follow-up. Brief, tailored smoking cessation booster messages were delivered at the end of 3- and 6-month interviews, based on point-prevalence smoking status and history. Also received a tailored support letter based on smoking status, referring to specific sections of the smoking cessation materials<br><br>**C**: Received health education materials targeting cardiovascular risk factors | **Health behaviour**: No significant differences between intervention groups at final follow-up<br><br>**Stage movement**: Not reported |
| **Gritz (1993)**[44], USA, outpatient clinic setting. *n* = 186. Patients with newly diagnosed, first primary squamous cell carcinomas of the oral cavity, pharynx, and larynx. Mean age 57.8 years, 30.7% female | A 12-month study to compare a state-of-the-art provider delivered smoking cessation intervention with a usual-care advice control condition<br><br>Head and neck surgeons and maxillofacial prosthodontists deliver smoking cessation advice according to standardised protocols to surgical patients 2–3 days before hospital discharge and, to radiation-only patients, prior to treatment initiation<br><br>**I**: The protocol then called for providers to give 6-monthly booster advice sessions to experimental participants as part of regular medical or dental post-treatment care. The six booster sessions consisted of debriefing respondents regarding their smoking cessation efforts prior to the visit and then tailoring advice to the respondent's current smoking status (abstainer, relapser, continuing smoker) according to the provider advice guidelines<br><br>**C**: Received standardised 'usual-care' advice from doctors regarding smoking and its contingent risks, as well as the benefits of cessation for head and neck cancer patients | **Health behaviour** (stage-based versus usual care): no significant differences between intervention groups at final follow-up<br><br>**Stage movement** (stage-based versus usual care): Not reported |

*continued*

***TABLE 1* contd** *Characteristics of studies with interventions aimed at smoking cessation*

| Study details | Interventions* | Results† |
|---|---|---|
| **Sinclair (1999)**[51], UK, primary care setting. *n* = 474. Smokers, who either asked for advice on smoking cessation or bought an over-the-counter anti-smoking product for their own use. Mean age and % female: not stated | A 12-month study to assess the cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking<br><br>**I**: Staff from pharmacies attended one of seven health promotion workshops held to explain the stage-of-change model. Pharmacists tailored their advice to match the client's stage of change<br><br>**C**: Standard advice and support with respect to smoking cessation and NRTs | **Health behaviour** (stage-based versus usual care): no significant differences between intervention groups at final follow-up<br><br>**Stage movement** (stage-based versus usual care): Not reported |
| **Pallonen (1994)**[47], Finland, community setting. *n* = 265. Finnish men, smoking at least ten cigarettes a day, from rural and urban settings. Ages: 42, 48, 54 and 60 years; 100% male | A 2-year study to examine longitudinally how well manuals based on the TTM were accepted by smokers and to determine their efficacy in accelerating the smoking cessation process<br><br>**I**: Five 10–20-page self-help manuals designed for each stage of change. One of these manuals corresponding to the current stage of change observed at the baseline and at each follow-up assessment was mailed to a participant bi-annually after an assessment. If the smoking stage did not change from one 6-month assessment to the next, no manual was mailed at that time<br><br>**C**: Usual care. Annual mail surveys constituted the only communication with the intervention centre | **Health behaviour** (stage-based versus usual care): One study found no significant difference between groups for prolonged abstinence at 2-year follow-up, but a significant result was found for 7-day quit rate, favouring the stage-based intervention<br><br>**Stage movement** (stage-based versus usual care): A significant effect favouring the stage-based intervention for contemplators but not for 'precontemplators' at 1-year follow-up. At 2-year follow-up, no significant differences between groups were found |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

Six studies compared stage-based interventions with a usual-care control group.[43,44,46,47,51,53] Three studies found no significant differences between intervention groups at final follow-up[43,44,51] The remaining three studies found significant differences favouring the intervention group for scores on quit rates.[46,47,53]

Overall, whilst there is some evidence favouring the use of stage-based interventions for smoking cessation compared to no intervention, there is little evidence that stage-based interventions are more effective than non-stage-based interventions.

# Results of interventions aimed at the promotion of physical activity

## Number of studies

Seven RCTs of interventions aimed at promoting physical activity were identified.[37,54–59]

## Number of participants

Two studies included less than 100 participants at final follow-up.[56,58] One study included 163 respondents at 8 weeks follow-up.[59] The remaining studies included over 300 respondents at the final follow-up, with up to 527 in one study at 6 weeks follow-up.[54]

## Characteristics of participants

All studies included adults only. Two trials imposed explicit age restrictions of more than 50 years,[55] and more than 60 years.[56] Three trials recruited participants through general practices,[37,55,57] three through place of employment,[54,58,59] and one through place of residence.[56] In two trials, inclusion criteria included clinical status, such as ambulatory patients[55] and patients with at least one modifiable cardiovascular disease risk factor.[57]

## Characteristics of interventions

### *Setting of the intervention*

In two studies the intervention was based in primary care practices.[55,57] In one study the intervention was delivered by a health visitor in the general practice or local leisure centre.[37] In another study the intervention was delivered at the respondent's elderly housing units.[56] In three studies the intervention was mail delivered.[54,58,59]

### *Number of intervention arms*

Two trials included two intervention arms, comparing a stage-based intervention with a usual-care control group.[55,56] Three trials had three interventions, comparing a stage-based intervention with a non-stage-based intervention and a usual-care control group in one study,[54] and two stage-based interventions with a usual-care control group in the other two studies.[57,58] One trial had four intervention arms, comparing a stage-based intervention with two non-stage-based interventions and a usual-care control group.[59] And one trial had five intervention arms, comparing four stage-based interventions with a usual-care control group.[37]

### *Stage-based interventions*

All seven trials aimed at promoting physical activity included at least one stage-based intervention. In four trials these were classified as fully stage-based,[54,55,58,59] In one trial the intervention was delivered through counselling by the participants' physician.[55] In the other three trials written materials were send through inter-office mail,[54] campus mail[59] or regular mail.[58]

In three trials the stage-based interventions were classified as unclear.[37,56,57] One trial was classified as unclear because there was no account of how people were allocated to particular stages or how interventions were tailored to each stage.[37] A second trial was classified as unclear since it was not clear to what extent individuals received feedback tailored to their particular stage of change.[56] In the third trial the intervention was tailored according to the patient's risk factor profile, since it was not known what was meant by 'risk factor profile'; thus, the intervention was classified as unclear.[57] Clarification of this term was requested from the authors but no reply was received.

### *Comparison groups*

In three trials the stage-based intervention was compared to a no-information or usual-care comparison group,[54,55,59] and in four trials the intervention was compared to an information only intervention.[37,56–58] In two trials the comparison group received a non-stage-based intervention.[54,59] In one trial, this was a generic intervention, consisting of non-stage-based materials;[54] and in the other trial the comparison group received either materials based on each individual's private needs and concerns or group seminars.[59]

## Outcome assessment

With the exception of one trial,[56] all studies reported data on the primary outcome of physical activity. Four trials reported data on the secondary outcome of stage movement,[54,55,58,59] and two trials reported intermediate outcomes.[57,59] Four trials reported data on the implementation of the intervention.[37,54–56] None of the trials reported results for health, adverse effects or other outcomes.

## Quality of included trials

### *Methodological quality*

Details of the quality assessment of trials aimed at promoting physical activity are presented in appendix 5 (quality assessment table). All seven trials were published RCTs, though only one described the method of randomisation, [37] and only one stated that intervention allocation was concealed.[37] Blinding of participants was not described in any of the trials, although this was not applicable in two.[54,59] In only one trial was the blinding of outcome assessors described.[37] None of the studies reported blinding of care-providers, although this was not applicable in two studies.[54,58]

Six studies either reported no differences between groups at the baseline,[37,55,58,59] or reported adjustment for baseline differences.[56,57] One study failed to report baseline comparability or adjustment for baseline differences.[54] At least 80% of respondents provided follow-up data in four trials.[37,55,56,59] Intention-to-treat analysis or handling of drop-outs was reported in two studies.[37,58] All trials reported point estimates and variability, and gave a clear description of the statistical methods used. All but one[54] reported participant inclusion criteria. One trial reported a sample size calculation.[37] Two trials reported that the groups may not have been treated identically other than the named intervention.[55,56] In one study the authors reported that physicians may have provided physical activity counselling (intervention) to control patients.[55] In the other study it was noted that control participants had access to additional physical activity facilities.[56]

### *Quality of the intervention and stage-of-change instrument*

All but two studies assessed stage of change at the baseline,[37,57] and five studies reported validation of the stage-of-change instrument.[54–56,58,59] In three trials,[54–56] the exercise stages-of-change instrument was used.[77–84] The kappa index of reliability over a 2-week period was 0.78. Concurrent validity was demonstrated by its significant association with the 7-Day Recall Physical Activity Questionnaire. In the other two trials,[58,59] Cardinal's five-item ordered categorical scale was used to assess respondents' stage of change.[85–87]

The construct validity, predictive validity and test–re-test reliability of the scale were reported as satisfactory.

The quality of the implementation was reported in four studies.[37,54–56] In one study, 82% of participants attended at least one interview.[37] In another study, 93% of respondents reported that they had received the message, and the same percentage had read the information.[54] In a third study, 93% of participants reported receiving physical activity counselling from their physician.[55] However, only 67% recalled receiving the written exercise prescription. Ninety-seven per cent of participants reported receiving a manual, and 94% of those stated they had read it. In a fourth study, a criterion of 60% attendance was perceived to be the minimum exposure necessary to categorise an individual as a participant in the intervention programme; 17 out of 27 participants met this 60% criterion.[56]

Three studies reported details of the training of care-providers or educators,[37,55,57] although this was not applicable in two.[54,58]

## Effectiveness of intervention

### *Primary outcome: behaviour change*

Two studies compared stage-based interventions with non-stage-based interventions.[54,59] At 6 weeks, one trial reported significant differences ($p < 0.05$) in mean changes of physical activity between the stage-based intervention (+4.94), the non-stage-based intervention (+0.66) and the no-intervention control group (–3.12).[54] However, pairwise comparisons between groups were not reported, therefore it is not clear whether the difference between the stage-based intervention and the non-stage-based intervention is significant. The other trial reported no significant differences between groups for scores on physical activity.[59]

All trials compared a stage-based intervention with either a control group receiving information only,[37,56–58] or a no-intervention control group.[54,55,59] Of the four trials comparing a stage-based intervention with a control group receiving information only, one trial showed significant differences between all four stage-based interventions and the control group at 12-weeks follow-up.[37] At 1-year follow-up the difference was no longer significant. A second trial found no significant differences for scores on energy expenditure between groups over 12 months.[57] A third trial found a significant increase in weekly leisure-time exercise at 31 days follow-up for one stage-based intervention (promoting small increases in routine physical activity) compared with the control group.[58] There was no significant difference between the other stage-based intervention (promoting physical activity according to guidelines from the American College of Sports Medicine) and the control group. The fourth trial did not report any data on behaviour change.[56]

Of the three trials comparing a stage-based intervention with a no-intervention control group, one trial found a significant differences ($p < 0.05$) in mean changes of physical activity between the stage-based intervention (+4.94), the non-stage-based intervention (+0.66) and the no-intervention control group (–3.12).[54] Although pairwise comparisons between groups were not reported, it is likely that the difference between the stage-based intervention and the no-intervention control group was significant. The other two trials found no significant differences between groups for scores on physical activity.[55,59]

### *Secondary outcome: stage movement*

Five out of seven trials reported data on stage movement,[54–56,58,59] In one trial, differences in stage movement were not reported.[59] However, it was reported that the mean stage of exercise in one non-stage-based intervention significantly increased over time, while it did not significantly increase in the stage-based intervention. Another study reported no significant differences between groups at 1- and 7-months follow-up.[58] Another trial reported that, of those in the precontemplation and contemplation stages at the baseline, significantly more respondents in the stage-based intervention moved into preparation or action stages at 6 weeks follow-up compared to controls ($p < 0.01$).[55] However, at 8 months follow-up there were no significant differences. In another trial, respondents in the stage-based intervention were significantly more likely to progress at least one stage compared to respondents in the non-stage-based intervention and the control group.[54] In the fifth trial, the mean stage of change for the intervention group was significantly higher at post-intervention than for the information-only control group, using pre-intervention stage of change as a covariate.[56]

### *Health, intermediate outcomes, adverse effects and other outcomes*

None of the trials reported results for health, adverse effects or other outcomes.

One study assessed respondents' intention to change, and found a significant difference between groups after 4 months, with 23% of respondents

progressing in the stage-based intervention, 17% in the non-stage-based intervention, and 27% in the information-only control group.[57] After 12 months, no significant results between groups were found. In another study, self-motivation was assessed; no significant between group differences were found over time.[59]

#### *Implementation outcomes*

Four trials reported data on the implementation of the intervention.[37,54–56] In one trial it was reported that among participants in the intervention groups 82% attended at least one interview.[37] Among participants offered six interviews, the median number of interviews attended was three. Another trial reported that 92.5% of participants in the stage-based intervention had received the message, compared with 82.8% in the non-stage-based intervention ($p < 0.006$).[54] In the stage-based intervention, 92.5% had read the information, compared with 79.3% in the non-stage-based intervention ($p < 0.0001$). A third trial reported that copies of exercise prescriptions were obtained for 99% of patients in the intervention.[55] Exercise prescriptions obtained from practices after follow-up visits indicated that 139 patients (77%) received follow-up physical activity counselling, which suggested that there were difficulties in arranging and providing follow-up counselling for some participants. Ninety-three per cent of patients in the intervention group who provided data at 6 weeks reported receiving physical activity counselling from their physician during the initial visit. However, only 67% recalled receiving the written exercise prescription at the initial visit. Two control patients reported receiving an exercise prescription. In the fourth trial it was reported that participant attendance ranged from 1 to 41 (2–80%) of the 51 intervention sessions, with 37% of respondents ($n = 17$) attending at least 60% of sessions.[56]

#### *Cost-effectiveness of interventions*

None of the studies evaluating interventions aimed at promoting physical activity included an economic evaluation.

### Summary

Seven studies aimed at promoting physical activity were included.[37,54–59] An overview of the main characteristics of each study can be seen in *Table 2*. One of the two trials comparing a stage-based intervention with a non-stage-based intervention found no difference in effectiveness between groups.[59] In the other trial it was unclear whether there was any difference in effectiveness on scores of behaviour change.[54] All trials compared a stage-based intervention with a usual-care or information-only control group, though one trial did not report data on behaviour change.[56] Three trials found no significant effects between the stage-based intervention(s) and the control group.[55,57,59] Of the three trials that showed some significant effects in favour of the stage-based intervention,[37,54,58] these were observed in the short-term only and no trials reported significant effects that outlasted 12 weeks, although all three contained over 500 participants.

Overall, there is little evidence for the effectiveness of stage-based interventions to promote physical activity, even when the comparison is with a no-intervention control group.

## Results of interventions aimed at dietary change

### Number of studies

In five trials the interventions were aimed at promoting dietary change.[36,38,39,60,61]

### Number of participants

All studies included more than 500 respondents at the final follow-up. Two studies included more than 1500 respondents at the final follow-up, with 1758[39] and 2358[60] respondents respectively.

### Characteristics of participants

One study did not provide any details on the participants.[61] Two studies explicitly stated that participants had to be 18 years or older.[36,60] One study included male respondents only; women were excluded because they constituted less than 5% of the total cohort.[39] One study included female respondents only.[60] In two studies, participants were employees from selected worksites. In one of these two studies the worksites were not specified,[39] in the other participants were health maintenance organisation (HMO) clients who worked for one of ten employer groups covered by the HMO who agreed to have their employees participate in this study.[36] One study recruited participants through advertisements.[38] In one study participants had to be enrolled in the Special Supplemental Nutrition Programme for Woman, Infants and Children (the WIC programme) or have children enrolled.[60] The WIC programme is federally funded, involves approximately 7.1 million low-income participants, and operates in all 50 USA states. In one study, participants following a special diet that would prevent them from eating more fruit and vegetables were excluded.[36]

***TABLE 2*** *Characteristics of studies with interventions aimed at physical activity*

| Study details | Interventions* | Results† |
|---|---|---|
| **Harland (1999)**[37], UK, primary care setting. *n* = 523. Adults from one urban general practice. Age: 24% 40–44 years, 23% 45–49 years, 19% 50–54 years, 15% 55–59 years, 19% 60–64 years; 58% female | A 1-year study (12-week intervention) to evaluate the effectiveness of combinations of three methods to promote physical activity<br>Information pack on the benefits of physical activity, other lifestyle factors, recommended activity levels for men and women of different ages, and 19 leaflets on leisure facilities and activities available locally. Brief advice was given, comparing the individual's results with recommended levels and highlighting details in the information pack<br>**I1**: Brief interviewing: one motivational interview (40 minutes, at practice/local leisure centre)<br>**I2**: Brief interviewing with financial incentive<br>**I3**: Motivational interviewing: six motivational interviews over 12 weeks<br>**I4**: Motivational interviewing with financial incentive<br>**C**: No further intervention | **Health behaviour** (stage-based versus information only): Significant differences between all four stage-based interventions and the control group at 12-weeks follow-up. At 1-year follow-up the difference was no longer significant<br>**Stage movement** (stage-based versus information only): Not reported |
| **Cardinal (1996)**[58], USA, workplace setting. *n* = 580. Female clerical staff employed full time at a major urban research university. Mean age 37 years, 100% female | A 7-month study to investigate the efficacy of mail-delivered, self-instructional exercise packets designed to motivate, encourage and support women's movement through the stages-of-exercise behaviour<br>**I1**: Lifestyle exercise packet. Promoting small increases in routine physical activity. Including information on participants' health status, predicted body fat percentage, predicted VO(2max) and stage of exercise; accompanied by cognitive and behavioural activities tailored to each specific stage using the change processes. Also containing an 'exercise success' story based on the modelling and self-efficacy constructs of social cognitive theory<br>**I2**: Structured exercise packet. This packet promoted the structured exercise guidelines established by the ACSM, encouraging participants to follow a standard exercise prescription with specific recommendations for frequency, intensity and duration<br>**C**: Control packet. No exercise recommendation or stage of exercise feedback. However, participants were as in I1 and I2, informed of their health status, predicted body fat percentage, and predicted VO(2max) | **Health behaviour** (stage-based versus information only): A significant increase in weekly leisure-time exercise at 31-days follow-up for one stage-based intervention (I1) compared with C; no significant difference between the other stage-based intervention (I2) and C<br>**Stage movement** (stage-based versus information only): No significant differences between groups at 1- and 7-months follow-up |
| **Cash (1997)**[59], USA, workplace setting. *n* = 900. Full-time university employees. Mean age 44 years, 57.6% female | An 8-week study to compare the effects of different exercise strategies (i.e. "Just move" programme, lifestyle exercise programme, group seminars, and no-exercise intervention) and stage of exercise on reported physical activity, self-motivation and stage of exercise<br>**I1**: "Just move" programme, written literature. The programme provides ideas on ways to motivate and support participants in their exercise efforts and maintenance of healthy lifestyles. Participation is specific to each individual's current exercise level and offers different levels of intervention materials to all participants over an 8-week period. The programme offers a wide range of flexibility and is based on each individual's private needs and concerns<br>**I2**: Lifestyle exercise programme, stage-matched written literature. Covers the following attributes: stage-of-exercise feedback, activity to encourage stage-of-exercise improvement, exercise success stories and lifestyle exercise guidelines<br>**I3**: Group seminars. Conducted by primary investigators once a week (1 hour). In the first meeting participants received a copy of the "Tips for Staying on the Exercise Track" information sheet from the "Just move" programme booklet. Following sessions: follow up on the previous week's action step(s), note the participants' exercise progress, provide encouragement and assistance, help the participants overcome any barriers, and remind the participants about the following week's meeting<br>**C**: No exercise intervention | **Health behaviour** (stage-based versus non-stage-based and no intervention): No significant differences between groups for scores on physical activity<br>**Stage movement**: (stage-based versus non-stage-based and no intervention): Differences in stage movement were not reported. However, it was reported that the mean stage of exercise in one non-stage-based intervention significantly increased over time, while it did not significantly increase in the stage-based intervention |

*continued*

***TABLE 2* contd** *Characteristics of studies with interventions aimed at physical activity*

| Study details | Interventions* | Results† |
|---|---|---|
| **Goldstein (1999)**[55], USA, primary care setting. *n* = 355. Ambulatory patients who were scheduled for routine visits (non-acute care) with the participating physician. Mean age 66 years; 65% female | To evaluate the efficacy of a brief medical office-based intervention to increase the physical activity level of sedentary middle-aged and older adults compared to usual care and to assess the degree to which changes in physical activity levels are maintained over 8 months of follow-up<br><br>At the initial appointment the study was explained and the patient was interviewed to obtain information on the stage of motivational readiness for physical activity, physical activity preferences and barriers to becoming physically active<br><br>**I**: Information collected was placed on the patient's chart and used to guide counselling to be appropriate to the patient's stage of readiness. The physician was asked to counsel the patient for about 5 minutes and give a written exercise prescription and a manual with instructions to read the section in the manual appropriate to the patient's stage of motivational readiness for physical activity. Participants were also encouraged to read subsequent sections of the manual when they felt ready to move on<br><br>Prior to follow-up, appointment research staff provided exercise prescriptions for the patient's chart. At follow-up the physician was expected to provide activity counselling and complete a new exercise prescription for the patient, give the patient an attractive poster with tips on adoption and maintenance of physical activity<br><br>The manual consisted of five colour-coded sections, one for each stage of physical activity adoption. The content was based on behavioural and social–cognitive concepts (e.g. social support, cues and prompts) and stage-specific processes (e.g. pre-contemplators/contemplators were given information on health benefits, while preparers were given information on planning regular physical activities)<br><br>After follow-up, patients received five monthly mailings including another copy of the manual, and four newsletters<br><br>**C**: Physician meeting for usual care | **Health behaviour** (stage-based versus no intervention): No significant differences between groups for scores on physical activity<br><br>**Stage movement** (stage-based versus no intervention): Of those in the precontemplation and contemplation stages at the baseline, significantly more respondents in the stage-based intervention moved into the preparation or action stages at 6-weeks follow-up compared to controls. However, at 8 months follow-up there were no significant differences |
| **Braatz (1999)**[56], USA, community setting. *n* = 46. Elderly from low-income elderly housing units. Mean age 77 years, 93% female | To evaluate whether low-income elderly individuals exposed to a 15-week intervention designed in accordance with the TTM (a) sustain, advance, or regress in their stage of change toward a more active lifestyle, and (b) change more than a group of controls who do not receive the treatment condition; and whether effects remain 2 months after the intervention<br><br>**I**: The intervention consisted of a 3-week promotional and recruitment period followed by a 15-week educational and physical activity programme entitled: 'Unlock the Door to Better Health, Physical Activity Is the Key'. The 15-week programme included a health fair, educational programmes, a chair exercise programme, and a contract physical activity programme. All intervention events were held at the housing sites, in the community room, library, or game room<br><br>**C**: Participants in the comparison group were provided with the same promotional protocol, though they did not receive the subsequent treatment | **Health behaviour** (stage-based versus information only): No data on behaviour change reported<br><br>**Stage movement** (stage-based versus information only): The mean stage of change for I was significantly higher than for C at post-intervention, using pre-intervention stage of change as a covariate |

*continued*

***TABLE 2* contd** *Characteristics of studies with interventions aimed at physical activity*

| Study details | Interventions* | Results† |
|---|---|---|
| **Graham-Clarke (1994)**[57], Australia, primary care setting. *n* = 758. Patients with at least one modifiable cardiovascular disease risk factor (overweight, high blood pressure, elevated cholesterol or smoking). Mean age 52 years, 49% female | An 18-month study to evaluate the impact of a multiple risk factor intervention programme for the reduction of cardiovascular disease risk factors in general practice patients, using Prochaska and DiClemente's TTM<br><br>**I1**: Lifestyle counselling using videos. GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk. Following assessment and feedback, GPs were asked to offer the patient the Fresh Start programme, and to tailor the programme according to the patient's risk factor profile<br><br>**I2**: Lifestyle counselling using videos and self-instructional materials. GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk. Following assessment and feedback, GPs were asked to offer the patient the Fresh Start programme, and to tailor the programme according to the patient's risk factor profile. Additionally, GPs were provided with three self-help booklets for patients, targeting risk factor behaviours and supplementing the videos<br><br>**C**: Routine care: GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk, followed by the GP's routine care | **Health behaviour** (stage-based versus information only): No significant differences for scores on energy expenditure between groups over 12 months<br><br>**Stage movement** (stage-based versus information only): Not reported |
| **Peterson (1999)**[54], USA, workplace setting. *n* = 784. Employees of a large telecommunications company. Age: 79.3% were < 45 years; 60.4% female | A 6-week study to evaluate the effect of a stage-based exercise intervention in a randomised trial of adults working in a corporate setting<br><br>**I1**: Generic intervention. Approximately 2 weeks after the baseline questionnaire deadline, employees received non-tailored materials based on information from the "Report of the Surgeon General" on physical activity. The message focused on the known benefits of exercise and the amount of exercise required for health benefit<br><br>**I2**: Stage-based intervention. Baseline questionnaires were examined to determine stage of change. Approximately 2 weeks after the baseline questionnaire deadline, employees received two-page written messages tailored to their individual stage of change. Separate messages were developed to be used between each of the three stages (to assist contemplators in becoming preparers; to assist preparers in becoming action takers; and to assist action takers in becoming maintainers). The messages contained stage-based information, motivational information, exercises designed to initiate change processes (goal-setting exercises, relapse prevention exercises, etc.), and graphics. Message content was developed for each stage of change using the specific cognitive and behavioural processes utilised in each stage as described by Prochaska<br><br>**C**: Did not receive any materials, only questionnaires | **Health behaviour**: At 6 weeks, significant differences in mean changes of physical activity between the stage-based intervention (+4.94), the non-stage-based intervention (+0.66) and the no-intervention control group (–3.12). However, pairwise comparisons between groups were not reported, therefore it is not clear whether the difference between the stage-based intervention and the non-stage-based intervention is significant<br><br>**Health behaviour** (stage-based versus no-intervention): Although pairwise comparisons between groups were not reported, it is likely that the difference between the stage-based intervention and the no-intervention control group was significant<br><br>**Stage movement** (stage-based versus non-stage-based and no intervention): Respondents in the stage-based intervention were significantly more likely to progress at least one stage compared to respondents in the non-stage-based intervention and the control group |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

## Characteristics of interventions

### *Setting of the intervention*

All studies included a mail delivered intervention. In two studies, additional nutrition sessions were given at the worksite,[39] or at the WIC programme site.[60]

### *Number of intervention arms*

Most studies included two intervention arms, a stage-based intervention and a comparison group.[39,60,61] In one study, two stage-based interventions were compared to a non-stage-based intervention.[38] In another study, two stage-based interventions were compared to a non-stage-based intervention and a no-intervention control group.[36]

### *Stage-based interventions*

All five trials aimed at dietary change included at least one stage-based intervention. One trial was classified as fully stage-based, and the two stage-based interventions included a computer-tailored newsletter and a computer-tailored newsletter with stage-based goal-setting information to tailor the intervention.[36]

Two trials were classified as partially stage-based.[39,60] The first trial was classified as partially stage-based as the first year of the intervention was not stage-based.[39] In the second year, personalised feedback (based on stage of dietary change and food frequency questionnaire responses) were mailed to intervention participants who completed the year 1 dietary assessment. In the second study the intervention consisted of three components: nutrition sessions by peer educators, printed materials and direct mail.[60] Only the direct mail was tailored to respondents' stage of change. Therefore, the main part of the intervention was not stage-based.

Two trials were classified as 'unclear'.[38,61] In the first trial it was stated that respondents in the experimental group received computer-generated feedback letters tailored to their dietary intake, intentions, attitudes, self-efficacy expectations, and self-rated behaviour.[38] However, stage of change was not explicitly mentioned, and it was not clear how stage of change was assessed. More information was requested from the authors, but no reply was received. In the other trial it was stated that the intervention group received a mailed leaflet tailored to their answers to a questionnaire completed approximately 6 months before baseline;[61] and that the theoretical basis for the tailoring of the intervention was Prochaska and DiClemente's stage-of-change model.[88] However, this information was based on an abstract only. Authors were asked for more information, but no reply was received. Since it was unclear which role respondents' stage of change played in the tailoring of the intervention, the study was classified as 'unclear'.[61]

### *Comparison groups*

In three studies the intervention was compared to a non-stage-based intervention. In two such cases, generic newsletters were used as the comparator.[36,38] The third study used the normal WIC programme as the comparator; generally this involves less than 10 minutes of nutrition education at the bimonthly voucher pick-up.[60] In three studies the intervention was compared to a non-intervention or usual-care comparison group.[36,39,61]

## Outcome assessment

All five studies evaluating the effectiveness of interventions aimed at dietary change reported the primary outcome of dietary intake. Three studies included data on the secondary outcome of stage movement,[36,39,60] and four reported intermediate outcomes (such as predisposing and enabling factors, self-efficacy or outcome expectations).[36,39,60,61] Four studies reported data on the implementation of the intervention (such as: participation rates and exposure to materials),[36,38,39,60] two studies reported other outcomes (knowledge, social support and responsibility).[60,61] None of the studies reported outcomes on health or adverse effects.

## Quality of included studies

### *Methodological quality*

Details of the quality assessment of trials aimed at dietary change are presented in appendix 5 (quality assessment table). All five trials were published RCTs, though only two described the method of randomisation,[36,60] and none stated that intervention allocation was concealed. Blinding of participants, outcome assessors and care-providers was not described in any of the trials. However, blinding of participants was not applicable in three studies,[36,39,61] and blinding of care-providers not applicable in one study.[36] Four studies either reported no differences between groups at the baseline,[36,38,61] or reported adjustment for baseline differences.[60] In one study, baseline differences between groups were present, without adjustment for baseline differences.[39] At least 80% of respondents provided follow-up data in three trials;[36,38,61] and intention-to-treat analysis or handling of drop-outs was also reported in three studies.[36,38,60] Two trials reported point estimates and variability.[36,38] Four trials gave a clear description of the statistical methods used;[36,38,39,60] while two reported participant inclusion criteria.[36,60] Four trials reported a

sample size calculation.[36,38,39,60] None of the trials reported that the groups may not have been treated identically other than the named intervention.

### *Quality of the intervention and stage-of-change instrument*

All but one study assessed the stage of change at the baseline,[39] and one study reported validation of the stage-of-change instrument.[60] In this trial it was reported that Cronbach alpha values for the stage-of-change scale and four other scales ranged from 0.80 to 0.92, indicating high levels of internal response consistency.[60]

The quality of the implementation was reported in four studies.[36,38,39,60] In one study, about 10% of retired employees and about 25% of active employees attended classes.[39] In another study, 99% of respondents had read the letters, and 71% had discussed it with others.[38] In a third study, attendance at the nutrition sessions varied considerably by site; overall, 19% attended all three sessions, 14% attended two sessions, 20% attended one session, and 46% attended no sessions.[60] In the fourth study, 64% of those receiving newsletters remembered receiving at least three of four newsletters, and 71% of these read most or all of each issue.[36]

One study reported details of the training of care-providers or educators,[60] although this was not applicable in another study.[36]

## Effectiveness of interventions

### *Primary outcome: behaviour change*

Three studies compared stage-based interventions with non-stage-based interventions.[36,38,60] One study, using intention-to-treat analyses, showed no significant differences at 4 months follow-up between both stage-based interventions and the non-stage-based intervention for scores on daily fruit and vegetable intake, variety of fruit and vegetables eaten each week and specific eating behaviours.[36] Another study found significantly lower mean fat scores in both stage-based interventions compared to the non-stage-based intervention.[38] There were higher mean vegetable scores in one stage-based intervention (tailored letters with iterative feedback) compared to the non-stage-based intervention, but not in the other stage-based intervention (tailored letters). There were no significant differences between groups in the number of servings of fruit per day.[38] The third study showed a significant change in the frequency of consuming fruit and vegetables at 8 months follow-up ($p < 0.002$).[60]

Three studies compared stage-based interventions with a usual-care control group.[36,39,61] One study found no significant differences between the stage-based intervention and the control group.[39] Another study, using intention-to-treat analyses, found significantly higher post-test fruit and vegetable intake scores for both stage-based interventions compared to the control group, as well as significantly higher scores for the total variety consumed per week.[36] However, there were no differences among groups regarding post-test eating behaviours. The third study found a significant difference between groups over time in consumption of both fruit and vegetables with the stage-based intervention increasing fruit and vegetable intake more than controls ($p < 0.001$).[61]

### *Secondary outcome: stage movement*

One of the three studies comparing stage-based interventions with non-stage-based interventions did not report stage movement as an outcome.[38] One study found no significant differences between groups for scores on stage movement.[36] And the third study found that there had been significantly more movement to higher stages among participants in the stage-based intervention, compared with the non-stage-based intervention, who were in the precontemplation, contemplation and preparation stages at the baseline.[60]

One of the three studies comparing stage-based interventions with a usual-care control group did not report stage movement as an outcome.[61] One study found, using the control group as the reference, that for those in the precontemplation, contemplation and preparation stages, both stage-based interventions as well as the non-stage-based intervention were significantly more likely to experience forward stage movement compared to the usual-care control group.[36] For those in the action and maintenance stages, no significant differences were found between groups. The third study found that participants in the stage-based intervention were, in general, significantly more likely than controls to move into later stages of dietary change.[39]

### *Health, intermediate outcomes, adverse effects and other outcomes*

None of the five studies aimed at dietary change assessed health status or adverse effects as an outcome. Four studies reported results for intermediate outcomes.[36,39,60,61] One study reported outcomes for predisposing factors (individuals' beliefs and attitudes about a behaviour, motivation to engage in the behaviour, and knowledge about specific actions that constitute the behaviour) and enabling factors (pro-

mote or impede practice of a behaviour, including barriers, norms and social support).[39] Intervention effects on the predisposing scale score were statistically significant ($p < 0.001$) for both year 1 and year 2. The intervention effect on enabling scale scores reached significance at the year 2 follow-up only. In another study, attitudes, self-efficacy and perceived barriers were assessed.[60] Significantly greater positive changes in attitudes and self-efficacy occurred among participants in the stage-based intervention compared to participants in the non-stage-based intervention. There were no significant differences between groups for scores on perceived barriers. In another study, participants in the stage-based intervention had more positive attitudes at follow-up compared to participants in the usual-care control group.[61] And in the fourth study, no significant differences over time between groups were found for scores on self-efficacy to eat more fruit and vegetables.[36] Respondents in one stage-based intervention (tailored newsletter) showed a significant increase in self-efficacy toward eating at least five servings of fruit and vegetables each day compared to respondents in the usual-care control group, but in comparison to the non-stage-based intervention there was no significant difference in scores. Respondents in the other stage-based intervention (tailored newsletter with stage-based goal-setting information) showed no significant differences in scores on self-efficacy compared with both the usual-care control group and the non-stage-based intervention.

Two studies reported other outcomes.[60,61] One study showed significant differences between the stage-based intervention and the non-stage-based intervention for scores on knowledge ($p < 0.001$), but no differences between groups at 8 months follow-up for scores on social support and responsibility.[60] The other study showed a significant increase in nutritional knowledge among respondents in the stage-based intervention compared to respondents in the usual-care control group.[61]

#### *Implementation outcomes*

Implementation outcomes were reported in four studies aimed at dietary change.[36,38,39,60] Two studies reported participation rates,[39,60] and two studies reported exposure to the materials.[36,38] With respect to participation rates, it was reported in one study that about 10% of retired employees and about 25% of active employees attended classes.[39] In another study, overall, 19% attended all three sessions, 14% attended two sessions, 20% attended one session and 46% attended no sessions.[60] With respect to exposure to the materials it was reported in one study that respondents in both stage-based interventions were more likely to have read the letter ($p < 0.01$) and to have discussed it with ($p < 0.01$) compared to respondents in the non-stage-based intervention.[38] Respondents in both stage-based interventions rated the nutrition information letters as more interesting, more personally relevant, felt the content was new to them and thought it more credible ($p < 0.01$ for all) compared to respondents in the non-stage-based intervention. In another study, 64% of all receiving newsletters remembered receiving at least three of four newsletters, and for all who remembered receiving at least three newsletters, 71% read most or all of each issue.[36]

#### *Cost-effectiveness of interventions*

None of the studies evaluating interventions aimed at dietary change included an economic evaluation.

### Summary

Five trials aimed at promoting dietary change were included.[36,38,39,60,61] An overview of the main characteristics of each study can be seen in *Table 3*. Of the three studies comparing stage-based interventions with non-stage-based interventions, one study found no significant differences between groups,[36] one found that the stage-based intervention outperformed the non-stage-based intervention,[60] and the third found mixed effects.[38] Of the three studies comparing stage-based interventions with a usual-care control group, one study found no significant differences between groups,[39] one found significant results in favour of the stage-based intervention for some outcomes,[36] and the third reported that the stage-based intervention outperformed the control group on all outcome measures.[61]

Overall, there is limited evidence about the effectiveness of stage-based interventions in promoting dietary change.

## Results of interventions aimed at multiple lifestyle changes

### Number of trials

Six RCTs of interventions aimed at promoting multiple lifestyle changes were identified.[35,62–66]

### Number of participants

Two studies included less than 100 participants at the final follow-up.[65,66] One study included 146 respondents at 18 weeks follow-up.[35] The remaining studies included over 500 respondents at the final follow-up, with up to approximately 16,500 respondents in one study at 2.5 years follow-up.[64]

***TABLE 3*** *Characteristics of studies with interventions aimed at dietary change*

| Study details | Interventions* | Results† |
|---|---|---|
| **Baker (1993)**[61], UK, home setting. *n* = 658. No population details. Mean age and % female not stated | A 6-week study to investigate the effectiveness of a personalised tailored leaflet in modifying behaviour, knowledge and attitudes relating to fruit and vegetable intake<br><br>**I**: Received a mailed leaflet tailored to their answers to a questionnaire completed approximately 6 months before the baseline<br><br>**C**: No treatment | **Health behaviour** (stage-based versus no treatment): Significant difference between groups over time in consumption of both fruit and vegetables with the stage-based intervention increasing fruit and vegetable intake more than controls ($p < 0.001$)<br><br>**Stage movement**: Not reported |
| **Brug (1998)**[38], The Netherlands, community setting. *n* = 800. Recruited through newspaper advertisements. Mean age 44 years, 82% female | An 8-week intervention studying the impact of tailored nutrition information and additional effects of feedback on fat, fruit and vegetable intake<br><br>**I1**: Computer-generated feedback letters tailored to dietary intake, intentions, attitudes, self-efficacy expectations and self-rated behaviour<br><br>**I2**: Same as I1, plus half of the experimental group received additional iterative feedback tailored to changes in behaviour and intentions<br><br>**C**: A single general nutrition information letter | **Health behaviour**: Significantly lower mean fat scores in both stage-based interventions. Higher mean vegetable scores in one stage-based intervention (I2) compared to the non-stage-based intervention, but not in the other stage-based intervention (I1). No significant differences between groups in the number of servings of fruit per day<br><br>**Stage movement**: Not reported |
| **Havas (1998)**[60], USA, community setting. *n* = 3122. Women served by the WIC programme. Age: 40%, 18–24 years; 27%, 25–29 years; 33%, 30+ years; 100% female | A 2-year study (6-month intervention) to increase fruit and vegetable consumption among women<br><br>**I**: Three components: (1) nutrition sessions conducted by peer educators, focusing on building skills and providing social support; (2) printed materials and visual reminders; (3) direct mail. Peer educators delivered two types of education: (1) brief messages regarding increasing fruit and vegetable consumption at enrolment; (2) a series of three group discussion sessions (45 minutes/small groups/over 6 months)<br><br>**C**: Normal WIC programme, generally less than 10 minutes of nutrition education at the bimonthly voucher pick-up | **Health behaviour**: A significant change in the frequency of consuming fruit and vegetables at 8-months follow-up ($p < 0.002$)<br><br>**Stage movement**: Significantly more movement to higher stages among participants in the stage-based intervention, compared with the non-stage-based intervention, who were in the precontemplation, contemplation and preparation stages at the baseline |
| **Kristal (2000)**[39], USA, workplace setting. *n* = 1758. Worksite employees. Mean age 58.5 years, 100% male | A 2-year study examining how a dietary intervention programme affected mediating factors for dietary change<br><br>**I**: Year 1: five nutrition classes during work hours at intervention worksites, and self-help nutrition materials mailed to employees at home. Year 2: personalised feedback (based on stage of dietary change and food frequency questionnaire responses) mailed to intervention participants who completed the year 1 dietary assessment; and posters and brochures promoting low-fat, high-fibre eating were placed in worksite cafeterias. In both years, employees received a quarterly newsletter with information about screening and nutrition<br><br>**C**: No details reported | **Health behaviour** (stage-based versus no treatment): No significant differences between the stage-based intervention and the control group<br><br>**Stage movement** (stage based versus no treatment): Participants in the stage-based intervention were, in general, significantly more likely than controls to move into later stages of dietary change |

*continued*

***TABLE 3* contd** *Characteristics of studies with interventions aimed at dietary change*

| Study details | Interventions* | Results† |
|---|---|---|
| **Lutz (1997)**[36], USA, community setting. *n* = 710. HMO clients who work for one of ten employer groups. Mean age 39.3 years, 64.4% female | A 4-month intervention that aimed to evaluate the effectiveness of nutrition newsletters at three levels of tailoring to increase fruit and vegetable intake<br><br>**I1**: Non-tailored or generic newsletter<br><br>**I2**: A computer-tailored newsletter<br><br>**I3**: A computer-tailored newsletter with tailored goal-setting information<br><br>**C**: No newsletter | **Health behaviour**: No significant differences at 4-months follow-up for scores on daily fruit and vegetable intake, variety of fruit and vegetables eaten each week and specific eating behaviours<br><br>**Health behaviour** (stage-based versus no treatment): Significantly higher post-test fruit and vegetable intake scores for both stage-based interventions compared to the control group, as well as significantly higher scores for the total variety consumed per week. However, there were no differences among groups regarding post-test eating behaviours<br><br>**Stage movement**: No significant differences between groups<br><br>**Stage movement** (stage-based versus no treatment): Using the control group as the reference, for those in the pre-contemplation, contemplation and preparation stages, both stage-based interventions as well as the non-stage-based intervention were significantly more likely to experience forward stage movement compared to the usual-care control group. For those in the action and maintenance stages, no significant differences were found between groups |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

## Characteristics of participants

All studies included male and female adults, though one trial also included a subset of adolescents aged 12–18 years.[65] Four trials recruited participants through healthcare settings,[35,63,65,66] and two through place of employment.[62,64] In three trials inclusion criteria included clinical status: patients treated for hypertension,[35] patients with coronary heart disease[66] and patients with at least one modifiable risk factor.[63]

## Characteristics of interventions

### *Setting of the intervention*

In four studies the intervention was delivered in a medical setting.[35,63,65,66] In the two other studies the intervention was delivered at the worksite.[62,64]

### *Number of intervention arms*

Four of the six trials included two intervention arms.[62,63,65,66] In two trials that was a stage-based intervention compared with a usual-care control group,[62,65] and in the other two trials that was a stage-based intervention compared with a non-stage-based intervention.[63,66]

Two trials included three interventions.[35,64] In one trial, two stage-based interventions were compared to a usual-care control group,[35] and in the other trial a stage-based intervention was compared to a non-stage-based intervention and an information-only control group.[64]

### *Stage-based interventions*

Three trials were classified as fully stage-based.[63,65,66] In one of these studies, participants were recruited

through three clinics, and only one clinic (clinic A) used a stage-based intervention.[65] In this report, results from clinic A only will be reported.

The remaining three trials were classified as unclear.[35,62,64] In two of these trials the stage-based interventions were part of worksite programmes: from the publications it was unclear what really happened in these interventions.[62,64] The third trial was classified as unclear because the intervention was delivered by a nurse counsellor, and it was unclear how stage of change was used to tailor the intervention.[35] An additional problem in studies aimed at multiple lifestyle changes is that the interventions need to be tailored to levels of readiness to change for different behaviours at the same time.

#### *Comparison groups*

Four trials compared a stage-based intervention to a no-intervention or usual-care control group.[35,62,64,65] One of these trials included an additional comparison group who received a minimal, non-stage-based, information-only intervention.[64]

Two trials compared a stage-based intervention to a non-stage-based intervention.[63,66] In one trial patients were counselled by practice nurses using their own usual methods,[63] and in the other trial patients received the traditional programme, which consisted of supervised exercise sessions and a series of didactic lectures.[66]

## Outcome assessment

All trials reported multiple data on the primary outcome of behaviour change. All but one reported data on smoking prevalence,[35] five on diet,[35,62–64,66] two on exercise,[63,66] two on substance use (alcohol and drugs),[35,65] and one on medical compliance.[66] Two trials reported data on the secondary outcome of stage movement,[62,66] and one trial reported intermediate outcomes.[62] Four trials reported data on the implementation of the intervention,[62–64,66] and four trials reported health outcomes.[35,62,63,66]

## Quality of included trials

#### *Methodological quality*

Details of the quality assessment of trials aimed at multiple lifestyle changes are presented in appendix 5 (quality assessment table). All seven trials were published RCTs, though three failed to described the method of randomisation,[35,62,64] and only one stated that intervention allocation was concealed.[66] Blinding of participants and outcome assessors was not described in any of the trials, and in none of the trials were care-providers blinded. However, blinding of participants was not applicable in two studies.[62,64] Three trials reported no differences between groups at the baseline.[62,63,66] The three trials not reporting baseline comparability did not report adjustments for baseline differences.[35,64,65] Only two trials provided follow-up data for at least 80% of respondents.[35,66] Intention-to-treat analysis or handling of drop-outs was reported in one trial,[66] and five trials reported point estimates and variability.[35,62–64,66] All trials gave a clear description of the statistical methods used, and all reported participant inclusion criteria. Three trials reported a sample size calculation.[62–64] One trial reported that the groups may not have been treated identically other than the named intervention due to patient interaction.[66]

#### *Quality of the intervention and stage-of-change instrument*

All but one trial reported that stage of change was assessed at the baseline.[62] Four trials did not report validation of the stage-of-change instrument,[35,62,64,65] and two did report validation of the stage of change instrument.[63,66] In one of these two trials it is reported that the kappa index of reliability over a 2-week period was 0.78.[63] Concurrent validity for the stages-of-change measure has been demonstrated by its significant association with the 7-Day Recall Physical Activity Questionnaire. It was also concluded that pros (positive perceptions of exercise), cons (avoidance of exercise) and a decisional balance measure (pros minus cons) were significantly associated with the stage of exercise adoption.[63] In the other study it was reported that total scores on self-efficacy items reliably differentiated employees at different stages, and the proportion of variance accounted for was 0.28.[66] Test–re-test reliability (kappa index) for the stages-of-change instrument over a 2-week period was 0.78.[66]

The quality of the implementation was reported in four studies.[62–64,66] In one study it was reported that programme implementation was recorded by staff; however, no data were reported.[62] In another study, 90% attended at least one counselling session, 73% attended two, and 56% attended three.[63] In a third study, it was reported that 82% of nutrition objectives were achieved and 74% of smoking objectives.[64] In the last study, 72% of participants attended exercise sessions, the attendance rate for exercise classes was 79%, and 69% completed the 12-week rehabilitation programme.[66]

Two studies reported details of the training of care-providers or educators.[62,63]

## Effectiveness of intervention

### *Primary outcome: behaviour change*

Five trials reported data on smoking cessation.[62–66] All but one found no significant differences between groups on smoking outcomes. One trial found significant reductions in the number of cigarettes smoked per day and increases in quit rates among participants in the stage-based interventions compared to the non-stage-based intervention at 4- and 12-months follow-up.[63]

Five trials reported data on dietary behaviour.[35,62–64,66] Two trials found no significant differences between groups.[62,66] One trial found significant reductions in sodium intake in one stage-based intervention (low intensity) compared to the control group, but no differences in sodium intake between the other stage-based intervention (high intensity) and the control group.[35] Another study found greater reductions in dietary fat in the stage-based intervention compared to the non-stage-based intervention.[63] And the third study found significant differences for scores on the percentage of energy from fat and servings of fruit and vegetables favouring the stage-based intervention, but no difference between groups for scores on dietary fibre intake.[64]

Two studies reported data on physical activity.[63,66] One study found no differences between groups on physical activity scores.[66] The other study found a significant increase in the number of exercise sessions in the stage-based intervention compared to the non-stage-based intervention.[63]

Two studies reported data on substance use.[35,65] One trial found significant reductions in alcohol consumption in one stage-based intervention (low intensity) compared to the control group, but no differences in alcohol consumption between the other stage-based intervention (high intensity) and the control group.[35] The other study found no significant differences between groups at 3-months follow-up.[65]

One trial reported data on medical compliance: no differences between groups were found for scores on adherence to prescribed medication at 12-weeks follow-up.[66]

### *Secondary outcome: stage movement*

Two trials reported data on stage movement.[62,66] One trial assessed stage of change for tobacco- and dietary-related behaviour change, and reported no significant differences between groups over time.[62] The other trial assessed stage of readiness to change for managing stress, exercise, avoid dietary fat, adhere to prescribed medications and quit smoking.[66] Data were reported in graphs, but the significance of differences between groups was not reported.

### *Health, intermediate outcomes, adverse effects and other outcomes*

Four trials reported health outcomes,[35,62,63,66] one trial reported intermediate outcomes (perceived support),[62] and one trial reported adverse effects.[66] One trial reported that behaviour changes were not translated into differences in biological risk factors.[63] The only difference was in systolic blood pressure, where the decrease at 4 months was greater in the intervention group than in the control group; this reduction was sustained at 12 months. Another trial reported that, at 12 weeks, participants in the intervention group had significantly lower scores on measures of perceived stress ($p = 0.005$) and the Arizona Heart Test ($p = 0.008$) compared to controls.[66] No significant differences were reported for measures of blood pressure, body mass index or waist–hip ratio. This trial also reported one death, one transluminal coronary intervention, three emergency room visits and one hospitalisation in the intervention group, and three emergency room visits and one hospitalisation in the control group.[66]

In a third trial, significant falls in systolic and diastolic blood pressure were found, as well as a significant reduction in weight, for participants in one stage-based intervention (high intensity) but not in the other (low intensity).[35] A fourth trial reported no significant differences between groups for changes in cholesterol levels.[62] In addition, it was found that participants in the intervention group reported significantly higher levels of perceived support from supervisors for tobacco- and diet-related behaviour change at post-intervention compared to controls, but not from co-workers.[62]

### *Implementation outcomes*

Four trials reported data on intermediate outcomes.[62–64,66] One trial reported that the employee steering committees implemented the intervention menu approach as recommended, and there were substantially more improvements in the number and types of health promotion activities offered in the intervention group compared with the control group.[62] Another trial reported that 90% of the patients in the intervention group attended at least one counselling session, 73% attended two and 56% attended three.[63] In the third trial it was reported that

82% of nutrition objectives and 74% of smoking objectives were achieved.[64] And that significant differences in activities directed toward behaviour change and awareness of intervention activities were found between groups favouring the stage-based intervention. The fourth trial reported that in the intervention group 72% attended exercise sessions, 79% attended education classes, and 69% completed the 12-week rehabilitation programme.[66] For the control group these percentages were 63, 61 and 59%, respectively. None of these differences between groups were significant.

#### *Cost-effectiveness of interventions*

In one study it was stated that the actual cost of the intervention were assessed and would be used to compute cost-effectiveness, defined as the cost per unit of behaviour and organisational change.[64] However, these data were not reported.

None of the other studies evaluating interventions aimed at promoting multiple lifestyle changes included an economic evaluation.[35,62,63,65,66]

### Summary

Six studies aimed at promoting multiple lifestyle changes were included.[35,62–66] An overview of the main characteristics of each study can be seen in *Table 4*. Three studies showed no differences between groups for any outcomes measured.[62,65,66] One study showed significant effects for a stage-based intervention of low intensity but not for the high-intensity stage-based intervention.[35] Another study showed significant effects for only some behavioural outcomes,[64] and the last showed positive effects for all outcomes included.[63]

Overall, only one study showed effects in favour of the stage-based intervention, two studies were inconclusive, and three studies showed no differences between groups. Thus, there is little evidence that stage-based interventions are more effective in promoting multiple behaviour changes.

## Results of interventions aimed at the promotion of screening mammography and the promotion of treatment adherence

### Number of studies

In two trials the interventions were aimed at the promotion of screening mammography,[67,68] and in one trial the intervention was aimed at the promotion of treatment adherence.[41]

### Number of participants

Both trials aimed at the promotion of screening mammography included over 1000 participants, with 2212 respondents in one,[67] and 1397 in the other.[68] The study aimed at the promotion of treatment adherence included 121 respondents.[41]

### Characteristics of participants

In one study, female residents from low-income and minority neighbourhoods were included.[67] Participants were aged 50 years and older, and not previously diagnosed with breast cancer and had no current symptoms of breast cancer. In the other study aimed at the promotion of screening mammography, women aged between 40 and 74 years who had a medical visit for any reason in the departments of family practice, internal medicine or obstetrics/gynaecology during the 8 months prior to the date of selection were included.[68] Women with a personal history of breast cancer, being evaluated or followed for possible breast cancer, or pregnant or nursing were excluded.

Participants in the study aimed at the promotion of treatment adherence were psychiatric hospital patients who were there on a voluntary status after admission due to potential danger to themselves or others or due to grave disability. Patients who were acutely psychotic, manic and/or hostile were initially excluded, until there was significant reduction of their symptoms.[41]

### Characteristics of interventions

#### *Setting of the intervention*

In one study aimed at the promotion of screening mammography the intervention was mail delivered,[68] and in the other the intervention was delivered through telephone calls.[67] The intervention in the study aimed at the promotion of treatment adherence was hospital based.[41]

#### *Number of intervention arms*

Both studies aimed at the promotion of screening mammography included three intervention arms. In one study, two stage-based interventions were compared to a no-intervention control group.[67] In the other study, a stage-based intervention was compared to a non-stage-based intervention and a usual-care control group.[68] The study aimed at the promotion of treatment adherence included two intervention arms: a stage-based intervention was compared to non-stage-based usual-care.[41]

***TABLE 4*** *Characteristics of studies with interventions aimed at multiple lifestyle change*

| Study details | Interventions* | Results† |
|---|---|---|
| **Scales (1998)**[66], USA, outpatient clinic setting, *n* = 61. Patients with diagnosed coronary artery disease, referred by a cardiologist or primary care physician. Mean age 59.6 years, 29% female | A 12-week study to assess the effectiveness of a lifestyle behaviour change programme<br><br>**I**: Motivational interviewing and skills-based counselling (integrated within the framework of the TTM of behaviour change) in addition to the traditional programme. Included all the components of C, plus a multiple behaviour, stage-matched approach to lifestyle change. This involved a 1-hour motivational interview and three 30-minute skills-based counselling sessions. Further appropriate strategies were applied to support the patient in their efforts to change the specified behaviours (goal setting, behavioural contracting, setting up a reward management system, training in self-monitoring skills, and brief follow-up assessment with the provision of swift feedback on progress)<br><br>**C**: Traditional programme. Supervised exercise sessions (1 hour, three times per week) and a series of eight 45-minute didactic lectures with group discussion on topics related to heart disease. With an option to participate in additional behavioural interventions designed to change lifestyle, to include personal feedback from a dietician at the start of the programme, cooking demonstrations, and classes in smoking cessation, weight control and stress management | **Health behaviour**: No significant differences between groups on smoking outcomes; no significant differences between groups on dietary behaviour; no differences between groups on physical activity scores; and no differences between groups were found for scores on adherence to prescribed medication at 12-weeks follow-up<br><br>**Stage movement**: Stage of readiness to change for managing stress, exercise, avoid dietary fat, adhere to prescribed medications, and quit smoking were assessed. Data were reported in graphs, but the significance of differences between groups was not reported |
| **Steptoe (1999)**[63], UK, community setting, *n* = 883. Patients from a medical school selected for the presence of one or more modifiable risk factors: regular cigarette smoking, high serum cholesterol concentration (6.5–9.0 mmol/l), and high body mass index (25–35) combined with low physical activity. Mean age 47 years, 54% female | To measure the effect of behaviourally oriented counselling in general practice on healthy behaviour and biological risk factors in patients at increased risk of coronary heart disease<br><br>**I**: After recruitment and baseline assessment patients were counselled by practice nurses in smoking cessation, dietary fat reduction, and increasing physical exercise as appropriate using behaviourally oriented methods<br><br>The goal in the smoking intervention was complete abstinence, and counselling was supported by NRT when appropriate. Patients with an increased serum cholesterol concentration were counselled to reduce dietary fat intake and to increase fruit and vegetable consumption within the context of a balanced diet, without specifying targets of the proportion of energy derived from fats. Patients with combined increased body mass index and lack of regular physical activity were counselled to increase their activity levels to 12 sessions of moderate or vigorous activity per month<br><br>Patients in the intervention arm of the study were invited for three counselling sessions if they had two risk factors and for two counselling sessions if they had only one risk factor. The order in which risk factors were targeted was determined after negotiation between the nurse and patient. Counselling sessions were scheduled to last no more than 20 minutes, and between sessions the nurse contacted the patient by telephone one or two times to consolidate the counselling and to encourage behaviour change<br><br>**C**: After recruitment and baseline assessment patients were counselled by practice nurses in smoking cessation, dietary fat reduction, and increasing physical exercise as appropriate using their own usual methods, involving information provision and exhortation | **Health behaviour**: Significant reductions in the number of cigarettes smoked per day and increases in quit rates among participants in the stage-based interventions at 4- and 12-months follow-up; greater reductions in dietary fat favouring the stage-based intervention; and a significant increase in the number of exercise sessions favouring the stage-based intervention<br><br>**Stage movement**: Not reported |

*continued*

***TABLE 4* contd** *Characteristics of studies with interventions aimed at multiple lifestyle change*

| Study details | Interventions* | Results† |
|---|---|---|
| **Glasgow (1995)**[62], USA, workplace setting, *n* = 1222. Employees at eligible worksites. Mean age not stated, 34% female | A 2-year study to evaluate the short-term effects of a low-intensity worksite heart disease risk reduction programme using a matched-pair design with the worksite as the unit of analysis<br><br>**I**: Early intervention: A 'kick-off' event was planned by each work site to familiarise employees with the programme. Intervention activities were developed by means of a 4 x 2 matrix that listed examples under each of four activity classes (motivational/incentive, educational/skills training, policy/environmental and maintenance) for both tobacco and nutrition. Each worksite was encouraged to conduct at least two activities from each of the eight cells of the matrix during the 2-year intervention period: motivational and incentive activities/educational and skills training/policy and environmental change/maintenance<br><br>**C**: Delayed intervention: No details reported | **Health behaviour** (stage-based versus no intervention): No significant differences between groups on smoking outcomes; no significant differences between groups on dietary behaviour<br><br>**Stage movement** (stage based versus no intervention): Stage of change for tobacco- and dietary-related behaviour change were assessed; no significant differences between groups over time were found |
| **Gritz (1998)**[64], USA, workplace setting, *n* = 15,582. Workers from selected worksites. Mean age not stated, 31% female | A 5-year study to assess whether a sustained 2-year comprehensive cancer control worksite health promotion intervention (the Working Well Trial) addressing dietary change and smoking cessation, delivered by a participatory strategy that targeted individuals and the worksite environment, would be more effective than a minimal intervention in achieving both individual behavioural and environmental changes<br><br>**I**: Comprehensive health promotion programme including strategies to encourage smoking cessation. Interventions were targeted to individuals (posters, interactive events, self-assessment) and to the organisation/environment (prohibit or restrict smoking at work). The essence of the operating principles (serving as an intervention plan) can be shown as a two-dimensional matrix. The matrix consists of two intervention target levels, individual (A) and organisational/environmental (B); and three distinct intervention components, 1, promotion/awareness building, 2, action/skills training, and 3, maintenance/relapse prevention. Several working groups were formed to develop specific intervention strategies based on the theoretical model<br><br>**C1**: Any health promotion activities that occurred at the worksites were documented. Received summary results of baseline survey<br><br>**C2**: Same as C1 plus three of the four study centres offered an optional minimal intervention that consisted of the distribution of widely available print materials such as posters and brochures | **Health behaviour** (stage-based versus no intervention): no significant differences between groups on smoking outcomes; significant differences for scores on the percentage of energy from fat and servings of fruit and vegetables favouring the stage-based intervention, but no difference between groups for scores on dietary fibre intake<br><br>**Stage movement** (stage based versus no intervention): Not reported |
| **Woollard (1995)**[35], Australia, primary care setting. *n* = 146. Treated hypertensive patients in 13 general practices. Mean age 58 years, 47% female | An 18-week study to assess whether a lifestyle modification programme implemented by nurse counsellors in a general practice setting would improve blood pressure control in treated hypertensive patients<br><br>GPs continued routine treatment of all patients throughout the programme<br><br>**I1 and I2**: Contacted every 4th week by the nurse counsellor throughout the 18-week period. The patients were counselled using a stage-of-change behavioural model and motivational interviewing to: reduce alcohol consumption, dietary fat and salt intake and weight; cease smoking; and increase leisure time physical activity. Patients were provided with an educational manual that discussed each risk factor from a perspective of both programme goals and incorporation of behaviour modification strategies. Programme objectives: (1) weight reduction; (2) in drinkers a reduction in alcohol intake; (3) salt restriction; ( 4) less daily energy dietary fat; (5) increase in physical activity; (6) smoking cessation<br><br>**I1**: Low intervention group. One practice appointment (a single face-to-face appointment where they were given their initial results) and five telephone counselling appointments (lasting 15 minutes)<br><br>**I2**: High intervention group. Six appointments in the general practice (lasting 45 minutes)<br><br>**C**: Usual GP care | **Health behaviour** (stage-based versus usual care): Significant reductions in sodium intake in one stage-based intervention (I1) compared to C, but no differences in sodium intake between the other stage-based intervention (I2) and C. Significant reductions in alcohol consumption in one stage-based intervention (I1) compared to C, but no differences in alcohol consumption between the other stage-based intervention (I2) and C<br><br>**Stage movement** (stage-based versus usual care): Not reported |

*continued*

***TABLE 4* contd** *Characteristics of studies with interventions aimed at multiple lifestyle change*

| Study details | Interventions* | Results† |
|---|---|---|
| **Oliansky (1997)**[65], USA, community-based clinic setting, *n* (per clinic) = 41/33/13. Patients 'at risk' for substance abuse, from three community-based urban clinics in the Detroit area (patients were all seeking primary care). Mean age (per clinic) 35/16/25 years, 51/52/100% female | A 3-month study to determine the effectiveness over time of the Substance Abuse Brief Screening and Intervention Project, which was designed to identify people as 'at risk' for substance abuse and then provide brief educational or motivational interventions to encourage behaviour change in ambulatory care settings. The goal was to reduce or stabilise the consumption of alcohol, drugs and/or tobacco use through behavioural changes as a result of the interventions<br><br>**I**: BIs. Each clinic (A, B and C) devised their own BI to be used. **Only BI in clinic A is stage-based.** The BIs for adolescents (clinic B) and for the female adult population (clinic C) were primarily educational in nature, providing information regarding the harmful effects of substances that the patient reported using. Reduction of use was encouraged through the use of a contract which outlined a specific goal formulated by the patient. Clinic A developed the patient-empowered readiness model (PERM), a BI protocol which combines solution-focused therapy principles with Prochaska's transtheoretical stages of change. This approach matches a patient's stage of change with a specific sequence of questions designed to empower the patient to take responsibility for their alcohol, tobacco and/or drug use<br><br>Clinic A: 10-minute solution-focused interview, conducted by a resident or psychologist, establishing written goals related to each patient's substance use; verbal reinforcement from physician. Follow-up: I and C contacted by phone at 1 and 3 months for substance use screening instrument (SUSI) reassessment<br><br>Clinic B: Brief education intervention provided by a registered nurse consisting of pamphlets, motivational interview, contract of personal goals, and/or video; verbal reinforcement from the physician<br><br>Clinic C: Educational intervention provided by a bilingual programme assistant with healthcare experience; consisting of information about the damaging effects of ATOD, identification of barriers to decreasing ATOD, development of personal plan to overcome barriers and decrease ATOD, verbal reinforcement from the physician<br><br>**C**: No intervention. Baseline SUSI assessment and demographics. Follow-up: I and C contacted by phone at 1 and 3 months for SUSI reassessment | **Health behaviour** (stage-based versus no intervention): No significant differences between groups on smoking outcomes; and no significant differences between groups at 3-months follow-up for scores on substance use<br><br>**Stage movement** (stage-based versus no intervention): Not reported |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

### *Stage-based interventions*

All three trials were classified as fully stage-based. In one trial aimed at the promotion of screening mammography the two stage-based interventions consisted of a telephone outcall promoting screening mammography using an interactive barriers counselling protocol based on the stages-of-change model.[67] In one intervention arm the telephone outcall was preceded by a mailed 'invitation' to participate in this programme. In the other trial aimed at the promotion of screening mammography, participants received four different mailed intervention packets (pre-contemplation/relapse/risk of relapse, contemplation, action and maintenance), as well as an expert system computer-generated letter, tailored to be an individualized response to information provided during the interview.[68] After the first follow-up survey, participants received a second packet, containing a personalised letter and stage-matched materials.

In the trial aimed at the promotion of treatment adherence, participants in the stage-based intervention received standard treatment plus a 15-minute session of feedback stage-of-change scores at the beginning of their hospitalisation and a 1-hour motivational interview 1 or 2 days before discharge.[41]

### *Comparison groups*

In one trial a non-stage-based intervention group was used, and participants received mailed intervention packets containing standard materials.[68] In both trials aimed at the promotion of screening mammography, a no-intervention control group was used. In one study, participants received only

four surveys;[68] in the other, respondents received a control telephone interview, containing questions related to health practices and use of health information resources, but no education.[67]

In the trial aimed at the promotion of treatment adherence, participants in the control group received standard treatment, consisting of an intake assessment by a multidisciplinary team, resulting in an individualised treatment plan, which identified psychiatric, psychological, medical and social needs.[41] During the hospitalisation, the patient worked with his or her team to accomplish the treatment plan objectives via pharmacological and psychosocial methods. Before discharge, all patients were provided with an outpatient psychiatric clinic appointment, and the importance of attending this appointment was emphasised routinely. Although patients in the control group were administered the stage-of-change assessment University of Rhode Island Change Assessment Scale (URICA), they were not given any feedback on the results.

#### *Outcome assessment*

Both studies evaluating the effectiveness of interventions aimed at the promotion of mammography screening reported the primary outcome of screening uptake.

One study included data on the secondary outcome of stage movement, data on intermediate outcomes (such as intention and decisional balance) and data on the implementation of the intervention (such as reactions to and acceptance of the telephone calls).[67] Neither of the studies reported data on health outcomes, adverse effects or other outcomes.

In the study aimed at the promotion of treatment adherence, 'appointment adherence' was the only outcome reported.[41]

## Quality of included studies

### *Methodological quality*

Details of the quality assessment of trials aimed at the promotion of mammography screening are presented in appendix 5 (quality assessment table). All three trials were published RCTs, though only two described the method of randomisation,[41,68] and only one stated that intervention allocation was concealed.[68] Blinding of participants was not described in two trials,[41,67] and not applicable in the other.[68] Blinding of outcome assessors was described in one of the trials.[68] Blinding of care-providers was not described in either of the trials.

One study did not report baseline comparability,[68] and another reported that there were differences between groups at the baseline but these were adjusted for in the analyses.[67] Less than 80% of respondents provided follow-up data in both trials aimed at the promotion of mammography screening,[67,68] and intention-to-treat analysis or handling of drop-outs was not reported in any of the three trials. None of the studies reported point estimates or variability. All three trials gave a clear description of the statistical methods used, participants' inclusion criteria, and comparability of treatments except for the intended intervention. None of the trials reported a sample size calculation.

#### *Quality of the intervention and stage-of-change instrument*

Two studies assessed stage of change at the baseline,[41,67] and one study reported on the validation of the stage-of-change instrument.[41] In this trial URICA was used, which defines four theoretical stages-of-change: precontemplation, contemplation, action and maintenance.[41] The four scales have 32 items, with eight items measuring each scale. The assessments were completed based on the problem (i.e. psychiatric illness or substance abuse) that the patient considered to be of primary importance. Results among an original sample of 155 respondents demonstrated that the four components (scales) accounted for 58% of the total variance. The four scales with their respective coefficient alphas were as follows: precontemplation, 0.88; contemplation, 0.88; action, 0.89; maintenance, 0.88. Cluster analysis revealed nine distinct client profiles, which accounted for 90% of the sample. In a second study among 327 adult psychiatric outpatients, the principal component, internal consistency, and cluster profile analyses demonstrated a replication of the original findings.[41,76,89] Both studies aimed at the promotion of mammography screening failed to report on the validation of the stage-of-change instrument.[67,68] The quality of the implementation was reported in one study, in which all women were reached by the telephone outcall.[67] Another other study did not explicitly report on implementation, but it was clear that all respondents had received the motivational interview.[41] All three studies reported details of the training of care-providers or educators.

## Effectiveness of interventions

### *Primary outcome: behaviour change*

One study compared a stage-based intervention with a non-stage-based intervention.[68] Multivariate

analysis showed that the difference in percentage screened between the stage-based intervention (63.6%) and the non-stage-based intervention (58.5%) was significant (OR = 0.74; 95% CI, 0.56 to 0.99).

All three studies compared a stage-based intervention with a usual-care control group. In one study, single-variable logistic regression showed a significant difference in the percentage screened between the stage-based intervention (63.6%) and the control group (54.9%) (OR = 1.43; 95% CI, 1.10 to 1.86).[68] The other study aimed at the promotion of mammography screening, found no significant differences between the two stage-based interventions and the control group for scores on receipt of mammography during six-month follow-up, doing a breast self-examination during 6 months follow-up, and having had a clinical breast examination in the past 12 months.[67] In this trial, mammography adherence at 2-years follow-up was assessed as well, stratified by baseline behaviour. Among those who never had a mammography at the baseline and those who had a mammography more than 2 years ago at the baseline, no significant differences were found between groups. Among those who had a mammography less than 2 years ago at the baseline, pairwise comparisons showed a significant difference between one stage-based intervention (telephone call preceded by a mailed 'invitation') and the control group ($p < 0.01$), but not between the other stage-based intervention (telephone call) and the control group.

In the study aimed at the promotion of treatment adherence significantly more respondents in the intervention group attended the first outpatient session compared to respondents in the control group ($p < 0.01$).[41]

#### *Secondary outcome: stage movement*

One study, comparing two stage-based interventions with a control group, reported stage movement as an outcome.[67] Stratified analyses (for baseline differences) showed no significant differences, although subanalyses of precontemplators at the baseline showed that participants in both stage-based interventions were more likely to be contemplators at follow-up compared to participants in the control group.

#### *Health, intermediate outcomes, adverse effects and other outcomes*

Health, adverse effects and other outcomes were not reported in any of the trials. One trial did report intermediate outcomes.[67] There was a significant shift towards greater intentions to have a mammogram in both intervention groups compared to the control group ($p = 0.002$). Decisional balance (cognitive pros and cons to mammography) scores were higher in both intervention groups (32.1 and 32.3) compared to the control group (30.9) ($p = 0.003$).

#### *Implementation outcomes*

One study reported implementation outcomes.[67] Examination of the effort required to reach women through an outcall mechanism suggests that the strategy is both labour intensive and potentially expensive. While the outcall counselling protocol itself required about 14 minutes to deliver, an additional 26 minutes were required to identify each eligible and consenting woman. Further, six households needed to be called for each enrolled woman. Overall, 86% of the calls were rated as 'very effective' in promoting mammography; an additional 14% of the calls received a 'somewhat effective' rating. Quality measurements obtained from debriefing interviews with call recipients ($n = 129$) indicated that 90–95% of recipients were treated courteously, had no trouble understanding the information presented, felt that the call was not too personal, and that the caller seemed to know what she was talking about. Additionally, 90–95% of call recipients felt that the caller listened carefully to their concerns and really cared if they got a mammogram.[67]

#### *Cost-effectiveness of interventions*

One study included an economic evaluation.[67] The cost analysis was based on a separate non-randomised trial in which a multiple outcall strategy promoting screening mammography was compared with strategies involving a single outcall alone, an advance card plus single outcall, and no intervention.[90] However, the effectiveness data for the three comparison groups came from the randomised trial included in this review.[67] Although the multiple outcall intervention was more costly to deliver (US $14.84 per participant compared with about US $7.00 for the single outcall interventions), it cost considerably less per participant converted from non-adherent to adherent. When 40% of the population is non-adherent at the baseline, the costs of delivering the programme to 1000 participants would be US $5768, $6868 and $10,088 for the single outcall, advance card plus single outcall, and multiple outcall interventions, respectively. The cost per participant who changed were US $288, $390 and $154, respectively. Using different sensitivity

analyses, the multiple outcall intervention was consistently the most cost-effective intervention of the three.[90]

### Summary

Two trials aimed at the promotion of screening mammography were included,[67,68] and one aimed at promoting treatment adherence were included.[41] An overview of the main characteristics of each study can be seen in *Table 5*. One study compared a stage-based intervention with a non-stage-based intervention, and a significant difference in favour of the stage-based intervention was reported.[68] All trials compared a stage-based intervention with a usual-care control group, two of which found a significant difference favouring the stage-based intervention,[41,68] whilst the other did not.[67]

Overall, there is no clear evidence regarding the effectiveness of stage-based interventions in promoting mammography screening. Although a stage-based approach seems to be effective in promoting treatment adherence, given the paucity of data these results should be treated with caution.

## Results of interventions aimed at prevention

### Number of studies

Three trials were aimed at prevention.[33,69,70] One trial was aimed at smoking prevention,[69] and two at the prevention of alcohol use.[33,70]

### Number of participants

One study included less than 100 participants at the final follow-up.[33] Another study included 481 respondents at follow-up.[70] The third study included over 6782 respondents at the final follow-up.[69]

### Characteristics of participants

In all studies, participants were young people recruited through their schools in the UK and the USA.[33,70] The mean age of participants in the US trials was 12.08 (standard deviation [SD] = 0.98)[70] and 12.2 (SD = 1.16),[33] whilst in the UK trial, year 9 pupils were recruited (13–14 years).

### Characteristics of interventions

#### *Setting of the intervention*

In all three studies the interventions took place within schools.

#### *Number of intervention arms*

All trials included two intervention arms.

#### *Stage-based interventions*

One trial was classified as fully stage-based.[69] The other two[33,70] were classified as unclear because although it was stated that all intervention components were matched to the specific stage status and risk/protective factors of individual youths, it was not stated how stage of change was assessed, nor was it stated how stage of change was used in tailoring the intervention.[33,70]

#### *Comparison groups*

The intervention was compared in one trial to a no-intervention control group,[33] and to non-stage-based, minimal interventions in the other two trials.[69,70] In one of these trials the comparison group received usual education about tobacco, as is part of the English national curriculum.[69] In the other trial the comparison group received a 15-page alcohol education booklet and were asked to read the material.[70]

### Outcome assessment

All three trials evaluating the effectiveness of interventions aimed at prevention reported data concerning the primary behavioural outcome: smoking prevalence[69] and alcohol use.[33,70] One study reported the secondary outcome of stage movement,[69] and two reported intermediate outcomes, such as intentions to start drinking and negative consequences experienced during drinking.[33,70] One study reported data on the implementation of the intervention.[69] No other outcomes were reported in the three trials.

### Quality of included trials

#### *Methodological quality*

Details of the quality assessment of trials aimed at prevention are presented in appendix 5 (quality assessment table). All three trials described the method of randomisation, though none stated that intervention allocation was concealed. In none of the trials was the blinding of participants or of outcome assessors stated, and care-providers were not blinded; although blinding of participants was not applicable in one study.[33] Baseline comparability was reported in all trials, and in two trials at least 80% of participants provided follow-up data.[33,69] Two trials reported the inclusion criteria.[69,70] Intention-to-treat analysis or handling of drop-outs was reported in all trials, though only two reported point estimates and variability.[69,70] All trials provided a clear description of the statistical methods used. One trial reported a sample size calculation.[69] For all trials it was assumed that the groups were treated in an identical way apart from the named intervention.

***TABLE 5*** *Characteristics of studies with interventions aimed at the uptake of mammography screening and treatment adherence*

| Study details | Interventions* | Results† |
|---|---|---|
| **Crane (1998)**[67], USA, community setting. *n* = 2212. Female residents from low-income and minority neighbourhoods, not previously diagnosed with breast cancer and no current symptoms of breast cancer. Age: 27%, 50–59 years; 33%, 60–69 years; 29%, 70–79 years; 11%, 80+ years; 100% female | A 2-year study to evaluate the impact of a telephone outcall intervention (based on the TTM) on screening mammography behaviour among lower-income, older women<br><br>**I1**: A telephone outcall promoting screening mammography using an interactive barriers counselling protocol based on the state-of-change model<br><br>**I2**: A telephone outcall preceded by a mailed 'invitation' to participate in this programme<br><br>Both interventions 1l and 12 included several components each tailored to the stage of change of the women. The components were: 1, basic information about mammography (for precontemplators); 2,elicitation of each women's specific barriers or concerns about mammography and counselling directed at those barriers; 3, positive reinforcement to prevent relapse for those in action or maintenance; 4, information about transportation and cost; 5, encouragement to talk to their doctors about getting a mammogram, as well as to get a clinical breast examination and to practise BSE. Prior to ending the call, intentions to get a mammogram were reassessed<br><br>**C**: A control telephone interview, containing questions related to health practices and use of health information resources | **Health behaviour** (stage-based versus usual care): No significant differences between the two stage-based interventions and the control group for scores on receipt of mammography and doing a BSE during 6 months follow-up, and having had a CBE in the past 12 months. At 2-years follow-up, among those who never had a mammography at baseline and those who had a mammography more than 2 years ago at the baseline, no significant differences were found between groups. Among those who had a mammography less than 2 years ago at the baseline, pairwise comparisons showed a significant difference between one stage-based intervention (I2) and C, but not between the other stage-based intervention (I1) and C<br><br>**Stage movement** (stage-based versus usual care): Stratified analyses (for baseline differences) showed no significant differences, although subanalyses of pre-contemplators at the baseline showed that participants in both stage-based interventions were more likely to be contemplators at follow-up compared to participants in the control group |
| **Rakowski (1998)**[68], USA, community setting. *n* = 1397. Women between 40–74 who had a medical visit for any reason. Age between 40 and 74 years; 100% female | A 20-month study to compare the effectiveness of a stage-matched, tailored intervention of mailed educational materials with standard materials (the same for all women) and no materials, in increasing mammography<br><br>**I1**: Standard materials. Received mailed intervention packets (two-sided folder with pockets for materials) after both the baseline interview and the first follow-up (3–5 months). All women received the same materials: (1) mammography question and answer sheet; (2) 'breast health guide' emphasising mammography, BSE and CBE as a three-part plan; (3) tip sheet page, emphasising importance of regular medical check-ups. Same materials at first follow-up, plus BSE shower card<br><br>**I2**: Stage-matched materials. Received mailed intervention packets (two-sided folder with pockets for materials) after both baseline interview and first follow-up. Four different packets: (1) precontemplation/relapse/risk of relapse; (2) contemplation; (3) action; (4) maintenance. Also received an expert-system computer-generated letter, tailored to be an individualised response to information provided during the interview. Other elements: (1) question and answer sheet; (2) information sheet; (3) tip sheet; (4) BSE shower card (3 and 4 same for all stages, and same in standard package). Second package, after first follow-up survey, contained personalised letter and stage-matched materials<br><br>**C**: No education materials. Only four surveys | **Health behaviour**: Multivariate analysis showed that the difference in the percentage screened between the stage-based intervention (I2: 63.6%) and the non-stage-based intervention (I1: 58.5%) was significant<br><br>**Health behaviour** (stage-based versus usual care): Single-variable logistic regression showed a significant difference in the percentage screened between the stage-based intervention (I2) and C<br><br>**Stage movement**: Not reported |

*continued*

***TABLE 5* contd** *Characteristics of studies with interventions aimed at the uptake of mammography screening and treatment adherence*

| Study details | Interventions* | Results† |
|---|---|---|
| **Swanson (1999)**[41], USA, Hospital setting. *n* = 121. Psychiatric inpatients at two inner-city private, not-for-profit hospitals. Mean age 34 years; 37% female | To evaluate the effect of motivational interviewing 2 days before discharge, on outpatient treatment adherence (first aftercare appointment) among psychiatric and dually diagnosed inpatients<br><br>**I**: Standard treatment plus motivational interviewing. Standard treatment plus a 15-minute session of feedback on their URICA scores at the beginning of each hospitalisation and 1-hour motivational interview 1 or 2 days before discharge. Specifically, URICA feedback included: 1, a brief description of the instrument; 2, the results in terms of profiles identified in previous research and composite scores; 3, an interpretation of these results based on the stages-of-changes model (the research therapists were provided with a script so that they could explain the profile or composite score that best described the patient); 4, a discussion of the patient's views of the results and how they may influence his or her commitment to adhere to treatment recommendations<br><br>**C**: Standard treatment. Received an intake assessment by a multi-disciplinary team, resulting in an individualised treatment plan, which identified psychiatric, psychological, medical and social needs. During the hospitalisation the patient worked with his or her team to accomplish the treatment plan objectives via pharmacological and psychosocial methods. Before discharge, all patients were provided with an outpatient psychiatric clinic appointment, and the importance of attending this appointment was emphasised routinely. Although patients in standard treatment were administered the URICA, they were not given any feedback on the results | **Health behaviour** (stage-based versus usual care): Significantly more respondents in the intervention group attended the first outpatient session compared to respondents in the control group<br><br>**Stage movement**: Not reported |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

### *Quality of the intervention and stage-of-change instrument*

One trial reported data concerning the quality of the implementation.[69] Most students received the intervention as intended. Rates of completion were high, with over 77% receiving all three computerised interventions, though baseline smokers were less likely to attend.[69] Two trials provided details of the training of care-providers or educators.[33,69] Two trials reported that the stage of change was assessed at the baseline,[33,69] but only one trial reported validation of the stage-of-change instrument.[69] In this study the validity of the stage-of-change instrument was examined in separate test–re-test ($n = 118$) and parallel form ($n = 3930$) assessments (the kappa values for stage of change were 0.46 and 0.52, respectively, indicating only moderate reliability).[91,92]

## Effectiveness of interventions

### *Primary outcome: behaviour change*

In one study there were no statistically significant changes in smoking outcomes between the groups, or in the subgroups defined by initial smoking status at either the 1- or 2-year follow-up.[69] In one of the alcohol prevention trials there were no significant differences between the groups on measures of alcohol frequency, alcohol quantity or heavy alcohol use.[70] Similarly, in the other trial no significant differences between groups on measures of alcohol frequency and quantity were found.[33] However, a significant difference was found for pre- and post-intervention measures of heavy alcohol use ($p = 0.02$).[33]

### *Secondary outcome: stage movement*

Only one trial reported data on stage movement.[69] Adjusted analyses showed no differences between groups in percentages of positive movement in stage of change.

### *Health, intermediate outcomes, adverse effects and other outcomes*

Two trials reported intermediate outcomes.[33,70] In one trial, intentions towards alcohol use were measured and no significant difference between the groups were found.[70] Similarly, in the other trial no significant differences between the groups were found on pre- and post-intervention measures of cognitive, social and behavioural risk factors associated with alcohol consumption.[33] No health outcomes, adverse effects or other outcomes were reported in the three trials.

### *Implementation outcomes*

One study reported data on the implementation of the intervention, including data on partici-

pation rates, exposure to materials and usefulness of the intervention, as well as data from providers on the delivery of the intervention.[69] Over 77% of students received all three computerised interventions, though baseline smokers were less likely to attend. Most students were found not to hurry through the computer session, though smokers were less likely to spend the time necessary to receive the individualised messages. Students reported finding the computer program easy to use and interesting, though slightly fewer found it useful or valuable, and these percentages were lower for smokers. Teachers who returned their questionnaire showed that they were happy with the lesson delivery and felt that the students had understood the lesson well.

#### *Cost-effectiveness of interventions*

None of the studies evaluating interventions aimed at prevention included an economic evaluation.

### Summary

Three studies aimed at prevention were included.[33,69,70] One study was aimed at smoking prevention,[69] and two were aimed at alcohol prevention.[33,70] An overview of the main characteristics of each study can be seen in *Table 6*. One study found a significant effect in favour of the stage-based intervention for scores on heavy alcohol use,[33] while the remaining two studies found no significant effects.[69,70]

Overall, there is little evidence for the effectiveness of stage-based approaches used to prevent the uptake of smoking or alcohol use.

## Stage assessment

In a critical review on the use of the stages-of-change model in health promotion by the Health Education Board for Scotland it was concluded that "ultimately any predictive value of the stages-of-change model depends on accurate stage recognition and the validity of the 'staging tool'." [18]

Twelve out of the 37 RCTs evaluating stage-based interventions reported some details on the validation of the instrument used to assess stage of change.[41,69,45,49,54–56,58–60,63,66] In two of these 12 studies the authors reported their own validation of the instrument.[69,60] In one of these cases the information reported was very limited, although the data did suggest a high level of internal response consistency.[60] In the other study the validation was more extensive; however, only moderate reliability was found.[69,91,92]

In the other ten trials, four stage-of-change instruments were used:

- five-item ordered categorical scale,[58] or Cardinal's Stage of Exercise Scale[59]
- the exercise stages-of-change instrument developed by Marcus and colleagues[54–56,63,66]
- Biener's contemplation ladder[45]
- The URICA.[41,49]

Additional information regarding the validity of the instruments used in the ten studies reporting the use of existing measures was taken from the 75 papers classified as No. 3 studies (studies focusing on the validation of a questionnaire to assess the stage of change; see appendix 3 for a full list of references).

For the instrument developed by Cardinal, the construct validity, predictive validity and test–re-test reliability of the scale were reported as satisfactory.[85–87,93] Both studies used the instrument to assess readiness to change exercise behaviour which was in accordance with the validated instrument.[58,59]

The instrument developed by Marcus and co-workers has been described in many papers, although they all appear to present the same information.[77–84] These studies reported satisfactory test–re-test validity, and concurrent validity, and the instrument was able to reliably differentiate respondents on relevant factors. The instrument is mainly used to assess readiness to change exercise behaviour, but Rossi and co-workers state that "the stages construct has been found reliable across a wide range of other problem behaviours".[77,81,83,94] Three of the 38 included trials in this review used the instrument to assess readiness to change exercise behaviour[54–56] In two trials the instrument was used to assess readiness to change multiple lifestyle behaviours, including stress management, exercises, diet and smoking.[63,66]

Biener's contemplation ladder was validated in a sample of more than 400 people.[71] Evidence of construct validity was presented: the instrument had some predictive value and was able to distinguish between groups known *a priori* to differ in readiness. The instrument was validated to assess readiness to change smoking behaviour, and was used in a similar way.[45]

In one study it was reported that 'stage classifications for smoking cessation, using the URICA, are consistently related to self-efficacy,[73,74]

***TABLE 6*** *Characteristics of studies with interventions aimed at prevention of smoking and alcohol use*

| Study details | Interventions* | Results† |
|---|---|---|
| **Werch (1996)**[33], USA, school setting. *n* = 138. Sixth to eight Grade students attending an inner-city public school. Mean age 12 years, 59% female | A 7-week study to examine the effects of brief nurse consultations in preventing alcohol use among inner-city youth<br><br>**I**: STARS programme. Students were provided with a two-phase prevention intervention individually administered by registered nurses at the target school site including a brief initial health consultation, and six focused weekly follow-up consultations. Intervention materials were tailored to the stage of alcohol acquisition of the participant by addressing hypothesised risk factors extracted from the three underlying behavioural theories within the multicomponent motivational stages model. Follow-up consultations were designed to provide more intensive and focused coverage of prevention content by targeting two risk factor constructs per session<br><br>**C**: No intervention | **Health behaviour** (stage-based versus no intervention): No significant differences between groups on measures of alcohol frequency and quantity were found; however, a significant difference was found on measures of heavy alcohol use, favouring the intervention group<br><br>**Stage movement**: Not reported |
| **Werch (1999)**[70], USA, school setting. *n* = 481. Sixth grade students from one neighbourhood and one bussed middle school in the economically disadvantaged inner city area. Mean age 12 years, 50% female | A 1-year study to test the effectiveness of stage-based strategies for preventing alcohol use among youth using primary healthcare providers<br><br>**I**: STARS for families programme, including: (1) a media related materials prevention strategy involving a physician-endorsed parent/guardian letter providing key facts for parents to read and discuss with their children about avoiding alcohol; (2) an interpersonal prevention strategy involving a brief one-to-one health consultation provided by a nurse about why and how the child should avoid alcohol; (3) an environmental prevention strategy involving nine physician-endorsed weekly family-based prevention lessons including facts and activities that parents and children work on together to complete. All intervention components are matched to the specific stage status and risk/protective factors of individual youths<br><br>**C**: Minimal intervention control. Received a 15-page alcohol education booklet and were asked to read the material on their own | **Health behaviour**: No significant differences between the groups on measures of alcohol frequency, alcohol quantity, or heavy alcohol use<br><br>**Stage movement**: Not reported |
| **Aveyard (1999)**[69], UK, school setting. *n* = 8352. Students in year 9 (age 13–14 years) at 52 schools. Mean age 15 years, 50% female | A 2-year study to examine whether a year-long programme based on the TTM of behaviour change, incorporating three sessions using an expert system computer program and three class lessons could reduce the prevalence of teenage smoking<br><br>**I**: The intervention group received six sessions of two types: one computer session and one class lesson for each of the three terms of year 9. The computer program was based on that developed by Prochaska and colleagues, containing questionnaires measuring the key concepts of the TTM. After each questionnaire, students received feedback both through the headphones and on-screen of how their temptations, for example, compared to stage-based data collected by Pallonen and co-workers (normative feedback) and, in second and third sessions, what change had occurred since last time (ipsative feedback). The questionnaires were interspersed with video clips of young people talking about their thoughts about smoking that were relevant to the stage of change of the student concerned. The other TTM intervention was a 1-hour lesson delivered by ordinary class teachers. The three lessons developed the young people's understanding of the stages of change and how the pros and cons of smoking would vary in different stages, and the lessons helped young people to use these concepts<br><br>**C**: Students in the control group were exposed to no intervention other than the normal health education on tobacco, which is part of the English national curriculum | **Health behaviour**: No statistically significant changes in smoking outcomes between the groups, or in the subgroups defined by initial smoking status at either the 1- or 2-year follow-up<br><br>**Stage movement**: Adjusted analyses showed no differences between groups in percentages of positive movement in stage of change |

* *C, comparison group; I, intervention group*
† *Comparisons are between stage-based interventions and non-stage-based interventions unless otherwise stated*

to a decision-making construct,[75] and to the processes of change for smoking cessation,[15,72] in a consistent and theoretically compatible manner.' As a result of principal component analysis, Cronbach's coefficient alpha and item analysis results, the five initial stages were reduced to four stages (precontemplation, contemplation, action and maintenance), which were represented by high loadings on distinct components.[76] The principal component, internal consistency and cluster profile analyses were also found satisfactory in two populations of patients with psychiatric illness.[76,89]

Overall, the level of validation of the instruments was limited with some evidence of internal reliability and some evidence of construct validity.

## Summary of results

Overall, 37 trials evaluating a staged approach to behaviour change were included. In 17 studies no effects were reported on behavioural outcomes (*Table 7*).[39,43–45,48,50,51,55,57,59,62,65–67,69] In eight trials the results were inconclusive,[33–38,58,64] and in ten trials the effects favoured the stage-based intervention.[41,46,47,49,53,54,60,61,63,68] In one trial the results could not be compared to a non-stage-based intervention,[52] and in another no behavioural outcomes were reported (however, stage movement was reported, making it eligible for inclusion).[56]

Intervention effects were classified as inconclusive (mixed effects) for two reasons. First, some trials measured multiple outcomes, some of which were positively influenced by the intervention, whilst others were not. Second, some trials examined the effectiveness of more than one stage-based intervention, and the direction of the effects of these interventions was different. In each case, whether multiple outcomes or multiple interventions, there was no clear evidence regarding the effectiveness of stage-based interventions, and, hence, they were classified as inconclusive.

Twenty trials compared a stage-based intervention with a non-stage-based intervention: ten trials reported no significant differences between groups, five reported mixed effects and five reported significant effects in favour of the stage-based intervention. Twenty-three trials compared a stage-based intervention with a no-intervention control group: ten trials reported no significant differences between groups, six reported mixed effects and six reported significant effects in favour of the stage-based intervention, and in one study no data on behavioural outcomes were reported. Taken together, there is little evidence that stage-based interventions are more effective in changing behaviour compared with non-stage-based interventions and even compared with usual-care.

Ten out of the 17 studies which reported no significant results on behavioural outcomes were classified as fully stage-based, three were unclear, three were partially stage-based and one was aimed at health professionals. Methodological quality ranged from three to nine items present out of 13. Three of the eight inconclusive studies were classified as fully stage-based, and five were unclear. Methodological quality ranged from five to 11 items present out of 13. Seven of the ten studies with favourable results for stage-based interventions were classified as fully stage-based, one was unclear, one was partially stage-based and one was aimed mainly at health professionals. Methodological quality ranged from two items present out of 12 to seven out of 13.

Studies with inconclusive results were, on average, of the highest methodological quality, while studies with favourable results for stage-based interventions were, on average, of the lowest methodological quality. However, neither methodological quality nor classification of the intervention (whether interventions were classified as fully or partially stage-based or unclear) can explain the presence or lack of effect, since studies with and without favourable results for stage-based interventions ranged widely in quality scores and included different levels of stage-based interventions.

Overall, there is little evidence for the effectiveness of stage-based approaches used to prevent the uptake of smoking or alcohol use. Whilst there is some evidence favouring the use of stage-based interventions for smoking cessation, there is little evidence that stage-based interventions are more effective than non-stage-based interventions. Similarly, there is little evidence for the effectiveness of stage-based interventions to promote physical activity, even when the comparison is with a no-intervention control group. There is limited evidence about the effectiveness of stage-based interventions in promoting dietary change, multiple behaviour changes, and promoting mammography screening. Although a stage-based approach seems to be effective in promoting treatment adherence, given the paucity of data these results should be treated with caution.

***TABLE 7*** *Summary results table*

| Study details | Methodological quality* | Stage-based versus non-stage-based | | | Stage-based versus no intervention | | |
|---|---|---|---|---|---|---|---|
| | | ++ | +/– | – | ++ | +/– | – |
| ***All interventions*** | | **5** | **5** | **10** | **7** | **6** | **10** |
| ***Prevention*** | | 0 | 0 | 2 | 0 | 1 | 0 |
| S025 Aveyard,[42] 1999 | 9/13 | | | ✔ | | | |
| S062 Werch,[70] 1999 | 7/13 | | | ✔ | | | |
| S272 Werch,[33] 1996 | 6/12 | | | | | ✔ | |
| ***Smoking cessation*** | | 1 | 2 | 5 | 3 | 0 | 3 |
| S402 Butler,[34] 1999 | 9/13 | | ✔ | | | | |
| S227 Lennox,[45] 1998 | 8/13 | | | ✔ | | | |
| S353 Resnicow,[50] 1997 | 7/13 | | | ✔ | | | |
| S021 Dijkstra,[43] 1999 | 6/11 | | | ✔ | | | ✔ |
| S172 Pallonen,[48] 1998 | 6/12 | | | ✔ | | | |
| S330 Wang,[53] 1994 | 6/13 | | ✔ | | ✔ | | |
| S255 DiClemente,[49] 1991 | 5/13 | ✔ | | | | | |
| S452 Morgan,[46] 1996 | 5/13 | | | | ✔ | | |
| S368 Velicer,[52] 1999 | 4/12 | No non-stage-based intervention as comparator included | | | | | |
| S290 Berman,[42] 1995 | 4/13 | | | ✔ | | | |
| S458 Gritz,[44] 1993 | 3/13 | | | | | | ✔ |
| S510 Sinclair,[51] 1999 | 3/13 | | | | | | ✔ |
| S234 Pallonen,[47] 1994 | 2/12 | | | | ✔ | | |
| ***Physical activity*** | | 0 | 1 | 1 | 1 | 2 | 3 |
| S001 Harland,[37] 1999 | 11/13 | | | | | ✔ | |
| S305 Cardinal,[58] 1996 | 6/12 | | | | | ✔ | |
| S480 Cash,[59] 1997 | 6/12 | | | ✔ | | | ✔ |
| S073 Goldstein,[55] 1999 | 5/13 | | | | | | ✔ |
| S089 Braatz,[56] 1999 | 5/13 | | | | No behavioural data reported | | |
| S165 Graham-Clarke,[57] 1994 | 5/13 | | | | | | ✔ |
| S061 Peterson,[54] 1999 | 3/11 | | ✔ | | ✔ | | |
| ***Dietary change*** | | 1 | 1 | 1 | 1 | 1 | 1 |
| S479 Lutz,[36] 1996 | 9/12 | | | ✔ | | ✔ | |
| S288 Brug,[38] 1998 | 7/13 | | ✔ | | | | |
| S378 Havas,[60] 1998 | 7/13 | ✔ | | | | | |
| S084 Kristal,[39] 2000 | 3/12 | | | | | | ✔ |
| S446 Baker,[61] 1999 | 3/12 | | | | ✔ | | |
| ***Multiple lifestyle change*** | | 1 | 1 | 1 | 0 | 2 | 2 |
| S478 Scales,[66] 1998 | 8/13 | | | ✔ | | | |
| S350 Steptoe,[63] 1999 | 7/13 | ✔ | | | | | |
| S219 Glasgow,[62] 1995 | 6/12 | | | | | | ✔ |
| S380 Gritz,[64] 1998 | 5/12 | | ✔ | | | ✔ | |
| S338 Woollard,[35] 1995 | 5/13 | | | | | ✔ | |
| S418 Oliansky,[65] 1997 | 4/13 | | | | | | ✔ |
| ***Mammography screening*** | | 1 | 0 | 0 | 1 | 0 | 1 |
| S027 Rakowski,[68] 1998 | 6/12 | ✔ | | | ✔ | | |
| S022 Crane,[67] 1998 | 4/13 | | | | | | ✔ |
| ***Treatment adherence*** | | 1 | 0 | 0 | 0 | 0 | 0 |
| S453 Swanson,[41] 1999 | 6/13 | ✔ | | | | | |

* *The maximum score for the 13 methodological quality items is 11 or 12 if 'blinding of care providers' and/or 'blinding of participants' is not applicable*

++, *mainly significant outcomes in favour of the stage-based intervention(s)*

+/–, *mixed outcomes. Either one stage-based intervention showed significant effects and another stage-based intervention did not, or some behavioural outcomes showed significant effects in favour of the stage-based intervention and others did not, or analyses presented were not conclusive*

–, *no significant differences between groups*

Overall, there is little evidence that stage-based interventions are more effective in promoting behaviour changes compared with non-stage-based interventions or compared with no intervention.

## Issues related to effectiveness

The wide range of interventions, participants, outcomes, settings, and so on, used within the 37 studies makes comparisons difficult within the review. Studies differed not only in target behaviour (smoking, exercise, diet) but also in the number of participants included (from 46 to 15,582 respondents), the year of publication (from 1991 to 2000), setting (e.g. school, workplace, outpatient clinic), age of respondents (from a mean age of 12 years to 77 years), type of respondents (patients, volunteers) and types of outcomes used (self-report with or without verification or objective). Each of these factors are likely to impact upon effectiveness. We have carried out separate narrative syntheses for each of the above-mentioned factors, which are presented below (see also *Table 8*).

### Number of participants included

One would expect the larger studies to find more reliable results with smaller CIs and be more likely to report significant results. And it does appear that only one out of six studies (17%) with fewer than 500 participants and reporting outcomes for behaviour change showed significant effects favouring the stage-based intervention compared to a non-stage-based intervention, and only two out of eight (25%) when compared with a no-intervention control group. However, among the larger studies (more than 500 participants) still only four out of 14 (29%) reporting outcomes for behaviour change showed significant effects favouring the stage-based intervention compared to a non-stage-based intervention, and only four out of 14 (29%) when compared with a no-intervention control group.

### Year of publication

The most recent studies seem to be less favourable than studies published before 1995, although studies between 1995 and 1998 seem to be least favourable for stage-based interventions. This is in contrast to what might be expected, that with increasing experience with the stage-based approach results would be more favourable.

### Setting

Studies set in a school or at the workplace appear to have the least effective results, whilst studies set in the community appear to achieve the most effective findings. Among the studies set in the community four out of ten studies (40%) reporting outcomes for behaviour change showed significant effects favouring the stage-based intervention compared to a non-stage-based intervention and only two out of five (40%) when compared with a no-intervention control group. For studies set in a medical environment these percentages are 25 and 22%, respectively.

### Age of participants

Studies including participants with a mean age between 30 and 60 years seem to be most effective. However, only three out of 11 studies (27%) reporting outcomes for behaviour change showed significant effects favouring the stage-based intervention compared to a non-stage-based intervention, and only two out of 11 (18%) when compared with a no-intervention control group.

### Sex of participants

There is little difference in effectiveness of stage-based interventions between studies including mostly (> 60%) male and female respondents.

### Type of participants

Interventions with patients (e.g. cancer patients, people with coronary artery disease or people with modifiable cardiovascular disease risk factors) seem to show favourable results for stage-based interventions in comparison with non-stage-based interventions, with two out of three studies favouring stage-based interventions. However, when compared with a no-intervention control group, none of the five studies showed favourable results for stage-based interventions. Interventions with volunteers showed similar results. None of the five studies among participants from low-income or economically disadvantaged areas showed favourable results for stage-based interventions.

### Self-report versus objective outcomes

Studies with objective measures or verification of self-report measures seem to yield better results than studies with self-report measures only. At least 50% of studies with objective measures or verification of self-report measures showed favourable outcomes for stage-based interventions. Only two out of 15 studies (13%) reporting outcomes for behaviour change showed significant effects favouring the stage-based intervention compared to a non-stage-based intervention, and only five out of 18 (28%) when compared with a no-intervention control group.

In summary, contrary to expectations, larger studies (more than 500 respondents) do not

***TABLE 8*** *Summary table of issues related to effectiveness*

| Study details | *n* | Stage-based versus non-stage-based | | | Stage-based versus no intervention | | |
|---|---|---|---|---|---|---|---|
| | | ++ | +/– | – | ++ | +/– | – |
| ***Number of participants*** | | | | | | | |
| < 100 | 4 | 0 | 1 | 1 | 1 | 0 | 1 |
| 100–500 | 10 | 1 | 0 | 3 | 1 | 2 | 3 |
| 500–1000 | 12 | 1 | 3 | 3 | 3 | 3 | 3 |
| > 1000 | 11 | 3 | 1 | 3 | 1 | 1 | 3 |
| ***Year of publication*** | | | | | | | |
| Before 1995 | 5 | 1 | 1 | 0 | 2 | 0 | 2 |
| 1995–1998 | 18 | 2 | 2 | 7 | 2 | 5 | 4 |
| 1999 or later | 14 | 2 | 2 | 3 | 2 | 1 | 4 |
| ***Setting*** | | | | | | | |
| Community | 13 | 4 | 1 | 5 | 2 | 1 | 2 |
| Clinic | 12 | 1 | 2 | 1 | 2 | 2 | 5 |
| Workplace | 7 | 0 | 2 | 1 | 1 | 2 | 3 |
| School | 4 | 0 | 0 | 3 | 0 | 1 | 0 |
| Home | 1 | 1 | 0 | 0 | 0 | 0 | 0 |
| ***Age*** | | | | | | | |
| Mean < 30 years | 6 | 1 | 0 | 3 | 0 | 1 | 1 |
| Mean 30–60 years | 19 | 3 | 3 | 5 | 2 | 4 | 5 |
| Mean > 60 years | 5 | 0 | 0 | 1 | 1 | 0 | 2 |
| ***Respondents*** | | | | | | | |
| Patients | 8 | 2 | 0 | 1 | 0 | 1 | 4 |
| Low-income | 5 | 0 | 0 | 3 | 0 | 0 | 1 |
| Volunteers | 3 | 1 | 1 | 1 | 0 | 0 | 1 |
| ***Sex*** | | | | | | | |
| > 60% female | 12 | 3 | 3 | 3 | 2 | 2 | 3 |
| > 60% male | 9 | 1 | 2 | 2 | 2 | 1 | 3 |
| ***Self-report measures*** | | | | | | | |
| Only self-report | 29 | 2 | 5 | 8 | 5 | 4 | 9 |
| Objective measure | 5 | 2 | 0 | 1 | 1 | 1 | 1 |
| Self-report with verification | 3 | 1 | 0 | 1 | 0 | 1 | 0 |

*++, mainly significant outcomes in favour of the stage-based intervention(s)*
*+/–, mixed outcomes. Either one stage-based intervention showed significant effects and another stage-based intervention did not, or some behavioural outcomes showed significant effects in favour of the stage-based intervention and others did not, or analyses presented were not conclusive*
*–, no significant differences between groups*

appear to be more conclusive than smaller studies (less than 500 respondents), and the most recent studies seem to be less favourable than studies before 1995, although studies between 1995 and 1998 seem to be least favourable for stage-based interventions. Regarding the setting, studies set in a school or at the workplace seem to be least effective, while studies set in the community are the most effective. None of the studies among participants from low-income or economically disadvantaged areas showed favourable results for stage-based interventions.

Regarding age, studies in which the reported mean age of participants was between 30 and 60 years seem to be most effective, although only 27% of studies showed significant effects in favour of stage-based interventions. There is little difference in effectiveness of stage-based interventions between studies including mostly (> 60%) male and female respondents. Studies with objective measures or verification of self-report measures seem to yield better results than studies with self-report measures only.

# Chapter 5
# Discussion

The increasing use in practice of stage-based interventions throughout the UK suggests an acceptance of the value of the approach in changing health-related behaviour. Interventions using a stage-based approach appear to have been wholeheartedly adopted in an uncritical way by healthcare professionals and health promotion staff alike.[95] This is not surprising, as it is easily understood and intuitively appealing with its assumed cyclical progression. Despite widespread acceptance of the approach, the findings from this systematic review suggest that more caution is necessary. In the seven areas assessed (prevention, smoking cessation, physical activity, dietary change, multiple lifestyle changes, mammography screening and treatment adherence) there was limited evidence for the effectiveness of stage-based interventions. This holds true, when compared with other types of interventions and also with usual-care.

## Use of the model

The lack of evidence for effectiveness could be due in part to problems with use (or implementation) of the stage-based interventions that have been evaluated.

From a theoretical perspective, the effectiveness of any stage-based intervention is dependent upon accurate classification of a participant's particular stage of change. Whilst only a few previously validated instruments were used in the included studies, in many cases these instruments were adapted by the researchers for use with a particular target behaviour and/or participant population, with some items being changed, dropped or added.

The difficulties associated with the staging algorithm have been previously reported.[96,97] The usual way to categorise participants into the different stages is by their self-reported behaviour and intentions. Participants are asked whether they intend to change their behaviour within the next 6 months (contemplation), whether they plan to do this within the next 30 days (preparation), whether they have changed their behaviour recently (action), and whether they have sustained healthy behavioural change for a significant amount of time, often operationalised as over 6 months (maintenance).[98,99] However, instead of using the term 'intention' consistently, different versions of the staging questions used in different studies ask, for example, whether the smoker is 'intending to quit', 'seriously considering quitting', 'seriously thinking of quitting' or 'planning to quit' (e.g. compare the approach of DiClemente and co-worker[49] with that of Prochaska and Goldstein[100]). Such apparently small changes can have a large effect. For example, of 400 respondents in a study of radon testing, 23.7% said they had 'planned to test' but only 13.7% said they had 'decided' to test.[32] According to Sutton,[96] only one study to date has directly compared different staging algorithms for smokers. Using data from a large sample of smokers from the California Tobacco Survey, Farkas and co-workers[101] compared the DiClemente algorithm[49] with an earlier algorithm which classified smokers into precontemplation contemplation, and relapse stages. The two algorithms produced markedly different stage distributions. For example, the earlier algorithm classified almost half of the sample as being in the most advanced stage (relapse) whereas the revised scheme placed only 16% in the most advanced stage (preparation). The two algorithms would lead to very different conclusions concerning the proportions of smokers for whom action-orientated programmes are appropriate.[96]

In one study the traditional staging classification method (which is based on intention and self-reported behaviour) was compared with an alternative classification method (which combines estimated actual behaviour, intention and self-rated behaviour) for fruit, vegetable and fat intake.[97] Differences between both classification methods were found to be large. Many respondents who were in maintenance, based on the traditional classification method, were classified in the pre-contemplation stage if the alternative classification method was used. The authors conclude that nutrition education that uses the stages-of-change as a basis for developing educational messages should not provide these participants with information aimed at sustaining their present behaviour but with information that creates awareness of personal dietary behaviour.[97]

None of the studies included in this review addressed the problem of small changes in the staging algorithm and the associated consequences. Sutton[96] mentioned a specific problem associated with the use of multidimensional questionnaires such as the URICA.[96] Respondents can, and do, score highly on more than one 'stage', which is inconsistent with the assumption that the stages are discrete.[102] To the extent that an instrument fails to distinguish between the different stages into which individual participants fall, a tailored intervention becomes somewhat meaningless. This issue was not addressed specifically in any of the included studies. In addition to issues about the validity of the instruments used, the large number of different instruments assessing stages-of-change made interpretation of the results difficult.

Difficulties in using the model or utilising validated and reliable instruments for stage classification have been documented in two earlier critical reviews.[18,96] In one it was reported that practitioners often make changes to the wording of instruments, adapting them to suit the behaviour or intervention, which actually lessens the validity of the instrument, and may even lead to conceptual overlap with a model such as the theory of planned behaviour.[96] The review concluded that the lack of standardisation of measures make it difficult to accumulate the findings of studies into a coherent body of knowledge.[96] The other review documented the importance of accurate stage recognition and validity of the staging tool and concluded that there has been little critical examination of its instrumentation.[18]

The wide range of interventions, participants, outcomes, settings and so on used within the 37 studies made comparisons difficult within this review. Studies differed not only in target behaviour (smoking, exercise, diet), but also in the number of participants, setting, age and type of participants, types of outcome and year of publication. Since each of these factors may have important implications with regard to effectiveness, each was examined. The type of participant suggested a relationship with effectiveness. Specifically, studies with low-income participants tended not to show any favourable effect for the stage-based intervention.

Another issue of importance was that most of the included studies provided a limited description of the intervention. With minimal information about the precise design of the intervention it was difficult to determine if, how and to what extent stages of change were used in tailoring the intervention. In particular, it was unclear in several studies whether the intervention was tailored to a participant's particular stage of change. Within this review this issue is reflected in the classification of studies either as fully stage-based, partially stage-based, or unclear. A full and precise description of the intervention design would have been beneficial.

The possibility that studies with positive outcomes utilised more fully the processes of change within their design was examined. However, no evidence was found to support this assumption. Of the five interventions that were effective when compared to non-stage-based interventions only one stated explicitly that all constructs of the model (not just the stage construct) were utilised in the delivery of the intervention.[49] At least one construct (e.g. self-efficacy, decisional balance, or temptations) was used either directly or indirectly in the interventions of the remaining four studies. However, all the studies included in this review, irrespective of results or type of comparison, incorporated into the intervention at least one key construct of the model, and four included all key constructs.[69,47,48,54] One of these trials compared a stage-based intervention with another stage-based intervention.[47] In the remaining three trials, when the stage-based intervention was compared to a non-stage-based intervention, results were either inconclusive[54] or did not support the stage-based intervention.[69,48] Thus, in terms of the use of key constructs of the model, interventions with positive effects did not differ from interventions whose effects were either inconclusive or showed no significant differences between groups.

The possibility that studies which reached all of the intended participants in the intervention group yielded more positive outcomes was explored. It was found that six out of 15 studies that reported high exposure to the intervention found no significant differences between groups,[69,48,51,55,66,67] three studies reported inconclusive results,[36–38] and six reported results in favour of the stage-based intervention.[41,46,47,54,63] Therefore, exposure to the intervention did not seem to be related to effectiveness of the intervention.

Finally, the length of follow-up has important implications with regard to evaluating effectiveness. The duration of follow-up, for example, was an important factor in evaluating the effectiveness of interventions aimed at increasing physical activity. Specifically, positive effects were observed in studies that reported outcomes up to a

12 week follow-up, and in other studies with longer term follow-up it was reported that positive effects disappeared beyond this point.

In summary, some of the difficulties associated with evaluating stage-based approaches to behaviour change derive from a lack of consistency in the research literature. This lack of consistency is highlighted in the diverse range of intervention types, differences in the sufficiency with which interventions are described, and in the use of adapted or modified instruments assessing the stage of change. The lack of evidence for the effectiveness of stage-based interventions should not undermine the possible effectiveness and use of other theory-based interventions.

An earlier review recommended that practitioners might want to consider integrating key concepts of social cognitive theory, recognising the wider determinants of health choices, and placing the individual in the context of their life circumstances and environment, and thus addressing personal barriers to change.[103] By so doing, this would address the issue raised in *Saving Lives: Our Healthier Nation* about the importance of the environment in encouraging individuals to make healthy decisions.[104]

## Implications

Evidence for the effectiveness of the stages-of-change approach to changing health-related behaviour is limited. Therefore, practitioners and policy-makers need to recognise that this model has a status which appears unwarranted when it is evaluated in a systematic way.

The findings also suggest that the model has been applied in a less than rigorous way. An intervention derived from a stage theory of behaviour change needs to incorporate a number of key elements. It is necessary first to identify accurately an individual's stage of change, or readiness to change, so that an intervention based on stage-specific processes of change can be applied. The stage of change needs to be reassessed frequently, and the intervention should reflect changes in the individual's readiness to change. These elements of the intervention are repeated until the individual achieves and maintains behaviour change. In this way, stage-based or tailored interventions evolve and adapt in response to the individual's movement through the different stages of change. Although there is a substantial research literature available, most of it fails to address sufficiently the issue of effectiveness. Future research should, therefore, be of a kind that enables questions concerning effectiveness to be answered. Specifically, there is a need for well-designed and appropriately implemented RCTs that are characterised by tailored interventions derived from accurate stage measurement, and which involve frequent reassessment of readiness to change in order to permit evolving, stage-specific interventions. Such an intervention would necessarily need to be conducted over a longer period of time than is typically reported in the research literature.

# Chapter 6

# Conclusions

- There is little evidence to suggest that stage-based interventions are more effective than non-stage-based interventions.
- There is little evidence to suggest that stage-based interventions are more effective than no intervention or usual-care.
- There does not seem to be any relationship between the methodological quality of the study, the targeted behaviour or quality of the implementation and effectiveness of the stage-based intervention.
- Studies including participants of low socio-economic status were least likely to report effects favouring the stage-based approach. Other study characteristics, such as the number of participants, age and sex of participants, setting, verification of outcome measures, and year of publication, appeared to have little relationship to the effectiveness of the intervention.
- The methodological quality of included studies was mixed.
- Few studies mentioned validation of the stages-of-change instrument.
- There was little consistency in the types of interventions employed once participants were classified into stages and little knowledge about the types of interventions needed once people were classified.
- Often the description of the intervention was so limited that it was unclear whether the intervention was properly stage-based.
- A wide range of stage-based interventions were used in the included studies.
- Methodologically sound and theoretically consistent intervention studies are required to adequately assess the efficacy of stage-based approaches to behaviour change.

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The views expressed in this report are those of the authors, who are responsible for any errors.

## Expert panel

The expert panel included:

- Professor Steve Baldwin*, School of Social Sciences, University of Teesside.
- Dr Robin Bunton, School of Social Sciences, University of Teesside.
- Dr Jeff French, Director of Planning, Health Development Agency.
- Ms Angela Harden, EPPI-Centre, Social Science Research Unit, University of London.
- Ms Phillipa Press, Practitioner, North Yorkshire Health Promotion Service.
- Dr Stephen Sutton, Health Behaviour Unit, University College London.
- Dr Mary Sissons Joshi, Psychology Department, Oxford Brookes University.
- Dr Gillian Tober, Leeds Addiction Unit.
- Mr Chris Tudor-Smith, Health Promotion Division, National Assembly for Wales.
- Professor Jonathan Watson, Director of Research and Evaluation, Health Education Board for Scotland.

* Unfortunately, Professor Steve Baldwin died during the course of this review. His suggestions to the protocol were highly appreciated.

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# Appendix 1

## Search strategy

### Resources searched

The sources and date ranges searched for this review (listed by format and host) are given below.

#### CD-ROMs (ARC – SilverPlatter)

- AMED (Allied and Complementary Medicine database) (1985 to September 1999).
- British Nursing Index (1994 to December 1999).
- CINAHL (1982 to March 2000).
- DH-Data (1983 to May 2000).
- EconLIT (1969 to May 2000).
- EMBASE (1980 to April 2000).
- HELMIS (1984 to 1998 (now closed)).
- King's Fund Database (1979 to May 2000).
- MEDLINE (1966 to May 2000).
- PsycLIT (1887 to December 1999).
- Sociological Abstracts (1963 to March 2000).

#### Other CD-ROMs

- ASSIA (1987 to May 2000).
- The Cochrane Library CD-ROM (2000, issue 2).
- HEED (May 2000).
- NRR (National Research Register) (2000, issue 2).

#### Online databases (Dialog host)

- CAB-Health (1973 to May 2000).
- Conference Papers Index (1973 to May 2000).
- Dissertation Abstracts (1861 to May 2000).
- MANTIS (Manual, Alternative and Natural Therapy) (1880 to May 2000).
- Mental Health Abstracts (1967 to May 2000).

#### Online databases (STN host)

- SIGLE (1976 to May 2000).

#### Online databases/catalogues (Internet based)

- BIOSIS (via EDINA host) (1985 to May 2000).
- British Education Index (via BIDS host) (1966 to May 2000).
- British Library catalogue (1980 to May 2000).
- DARE (all to May 2000).
- EPPI-Centre Register of Reviews of Effectiveness (all to May 2000).
- ERIC (Educational Resources Information Center) (via BIDS host) (1901 to May 2000).
- HealthPromis/Health Education Authority Unicorn Database (all to May 2000).
- HEBS (Health Education Board Scotland) journals database (all to May 2000).
- HTA database (all to May 2000).
- Index to Scientific and Technical Proceedings (via BIDS host) (1982 to May 2000).
- International Bibliography of the Social Sciences (via BIDS host) (1951 to May 2000).
- NHS EED (NHS Economic Evaluation Database) (all to May 2000).
- Science Citation Index (via BIDS host) (1981 to May 2000).
- Social Science Citation Index (via BIDS host) (1981 to May 2000).

### Search strategy

The search strategy used for retrieving references on the effectiveness of interventions using a stage-based model in bringing about changes in health-related behaviour is given below.

#### ARC SilverPlatter search strategy

This was used to search the following resources: AMED, British Nursing Index, CINAHL, DH-Data, EconLIT, EMBASE, HELMIS, King's Fund database, MEDLINE, PsycLIT and Sociological Abstracts.

#1 stage* of change
#2 transtheoretical model* or trans-theoretical model*
#3 transtheoretical approach* or trans-theoretical approach*
#4 transtheoretical process* or trans-theoretical process*
#5 precaution adoption process*
#6 precaution adoption model*
#7 precaution adoption approach*
#8 rubicon model*
#9 rubicon process*
#10 rubicon approach*
#11 health action process*
#12 health action model*
#13 health action approach*
#14 processes of change questionnaire*
#15 processes of change near5 model*
#16 readiness to change
#17 motivational interviewing

#18 #1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17

Lines #16 and #17 were added to the strategy following comments from the advisory panel. Searches were then conducted again on all databases, removing any duplicate references found by the initial set of searches.

No relevant subject indexing or controlled vocabulary terms were available for this subject area in any of the databases included in this review. The free-text search detailed above was therefore adapted as appropriate for the other databases searched, taking into account variations in syntax and search facilities for individual databases. Full details of all search strategies are available on request from the authors.

## Additional Internet searches

In addition to specific databases, searches were also carried out on the Internet using the biomedical search engine OMNI <http://www.omni.ac.uk>, the meta-search engine The BigHub.com <http://www.thebighub.com/> and the general Internet search engines AltaVista <http://www.altavista.com/> and Google <http://www.google.com/>. The search strategy outlined above was simplified as far as possible in order to allow for the basic search facilities offered by these search engines.

References retrieved were de-duplicated, managed and stored using the Endnote (version 4.0) bibliographic software.

# Appendix 2

## Pre-screen form

ID: <...> Ref ID: … Author: … Year: … Language: …

Study: <<RCT/Controlled before-after study>>

Participants: <<Existing disease/Life style risk/Physiological risk>>

Model: <<Yes/No>>

Model: <<Health Action Process/ Precaution Adoption Process/ Trans-Theoretical Model>>

Behaviour change: <<Yes/No>>

Primary outcome: …

Setting: <<Community/Hospital/Out-patient clinic/Primary care/School/Workplace>>

Comment: …

Decision: <<Include/Exclude>>

# Appendix 3

# Studies focusing on the evaluation of a stage-based model, on the description of a new stage-based model, and on the validation of a questionnaire to assess the stage of change

## Studies focusing on the evaluation of a stage-based model


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Wyse J, Mercer T, Ashford B, Buxton K. Evidence for the validity and utility of the Stages of Exercise Behaviour Change scale in young adults. *Health Educ Res* 1995;**10**:365–77.

Zhu W, Ainsworth BE. Validation of a classification algorithm of stage of change in an urban. *Med Sci Sports Exerc* 1999;**31**:S95.

# Appendix 4

## Included studies and data extraction table

In this appendix the data extraction table for included studies will be described.

The data extraction table includes information from all relevant papers we found on the trials. In the report, the trials will be referred to by the main publication. To clarify which trials are included and which publications were used for each trial, we have made a list of trials and reference numbers as used in the data extraction table:

### S001 Harland, 1999

**Included paper:**
Harland J, White M, Drinkwater C, Chinn D, Farr L, Howel D. The Newcastle exercise project: a randomised controlled trial of methods to promote physical activity in primary care. *BMJ* 1999;**319**:828–32. [S001]

**Additional papers with information on the same trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–402. [S248]

Marcus BH, Simkin LR. The stages of exercise behavior. *J Sports Med Phys Fitness* 1993;**33**:83–8. [S258]

Miller WR, Rollnick S. Motivational interviewing: Preparing people to change addictive behavior. New York: The Guilford Press; 1991. [S618]

Prochaska J, Marcus B. The transtheoretical model: applications to exercise. In: Dishman R, editor. Advances in exercise adherence. Champaign, IL: Human Kinetics; 1994. p. 161–80. [S660]

Buxton K, Wyse J, Mercer T. How applicable is the stages of change model to exercise behaviour? A review. *Health Educ J* 1996;**55**:239–57. [S661]

### S021 Dijkstra, 1999

**Included paper:**
Dijkstra A, DeVries H, Roijackers J. Targeting smokers with low readiness to change with tailored and nontailored self-help materials. *Prev Med* 1999;**28**:203–11. [S021]

**Additional papers with information on the same trial:**
Dijkstra A, De Vries H, Roijackers J, van Breukelen G. Tailored interventions to communicate stage-matched information to smokers in different motivational stages. *J Consult Clin Psychol* 1998;**66**:549–57. [S609]

Dijkstra A, De Vries H, Roijackers J. Computerized tailored feedback to change cognitive determinants of smoking: a Dutch field experiment. *Health Educ Res* 1998;**13**:197–206. [S610]

Dijkstra A, De Vries H, Roijackers J, van Breukelen G. Tailoring information to enhance quitting in smokers with low motivation to quit: three basic efficacy questions. *Health Psychol* 1998;**17**:513–19. [S611]

Mudde AN, De Vries H, Willemsen M, Van Assema P. In: Richmond R, editor. Interventions for smokers: an international perspective. New York: Williams and Wilkins; 1994. p. 293–322. [S612]

Strecher VJ, Rimer BK, Monaco KD. Development of a new self-help guide – Freedom From Smoking for You and Your Family. *Health Educ Q* 1989;**16**:101–12. [S613]

### S022 Crane, 1998

**Included paper:**
Crane LA, Leakey TA, Rimer BK, Wolfe P, Woodworth MA, Warnecke RB. Effectiveness of a telephone outcall intervention to promote screening mammography among low-income women. *Prev Med* 1998;**27**:S39–49. [S022]

**Additional papers ordered with information on the same trial:**
Crane LA, Leakey TA, Woodworth MA, Rimer BK, Warnecke RB, Heller D, *et al.* Cancer information service initiated outcalls to promote screening mammography among low income and minority women: design and feasibility testing. *Prev Med* 1998;**27**:S29–38. [S498]

Crane LA, Leakey TA, Ehrsam G, Rimer BK, Warnecke RB. Effectiveness and cost-effectiveness of multiple outcalls to promote mammography among low-income women. *Cancer Epidemiol Biomarkers Prev* 2000;**9**:923–31. [S509]

Rakowski W, Rimer BK, Bryant SA. Integrating behavior and intention regarding mammography by respondents in the 1990 National Health Interview Survey of Health Promotion and Disease Prevention. *Public Health Rep* 1993;**16**:433–41. [S601]

Rakowski W, Andersen MR, Stoddard AM, Urban N, Rimer BK, Lane DS, *et al.* Confirmatory analysis of opinions regarding the pros and cons of mammography. *Health Psychol* 1997;**16**:433–41. [S602]

Rakowski W, Dube CE, Marcus BH, Prochaska JO, Velicer WF, Abrams DB. Assessing elements of women's decisions about mammography. *Health Psychol* 1992;**11**:111–18. [S603]

Rakowski W, Fulton JP, Feldman JP. Women's decision making about mammography: a replication of the relationship between stages of adoption and decisional balance. Health Psychol 1993;12:209–14. [S604]

## S025 Aveyard, 1999

**Included paper:**
Aveyard P, Cheng KK, Almond J, Sherratt E, Lancashire R, Lawrence T, *et al.* Cluster randomised controlled trial of expert system based on the trans-theoretical ("stages of change") model for smoking prevention and cessation in schools. *BMJ* 1999;**319**:948–53. [S025]

**Additional papers received from authors with information on the same trial:**
Aveyard P, Sherratt E, Almond J, Cheng KK. Can the stages of change for adolescent smoking acquisition be measured reliably? 2001 *Prev Med* In press 2002. [PC2]

Aveyard P, Sherratt E, Almond J, Lawrence T, Lancashire R, Griffin C, *et al.* The change-in-stage and updated smoking status results from a cluster-randomised trial of smoking prevention and cessation using the transtheoretical model in British adolescents. *Prev Med* 2001;**33**:313–24. [PC1]

## S027 Rakowski, 1998

**Included paper:**
Rakowski W, Ehrich B, Goldstein MG, Rimer BK, Pearlman DN, Clark MA, *et al.* Increasing mammography among women aged 40–74 by use of a stage-matched, tailored intervention. *Prev Med* 1998;**27**: 748–56. [S027]

**Excluded paper describing the same trial:**
Rakowski W, Ehrich B, Dube CE, Pearlman DN. Screening mammography and constructs from the trans-theoretical model: associations using two definitions of the stages-of-adoption. *Ann Behav Med* 1996;**18**:91–100. [S202]

**Background/review paper with information on the trial:**
Rakowski W, Dube CA, Goldstein MG. Considerations for extending the transtheoretical model of behavior change to screening mammography. *Health Educ Res* 1996;**11**:77–96. [S004]

Velicer W, Prochaska J, Bellis J, DiClemente CC, Rossi JS, Fava L, *et al.* An expert system intervention for smoking cessation. *Addict Behav* 1993;**18**:269–90. [S420]

## S061 Peterson, 1999

**Included paper:**
Peterson TR, Aldana SG. Improving exercise behavior: an application of the stages-of-change model in a worksite setting. *Am J Health Promot* 1999;**13**:229–32. [S061]

**Excluded papers describing the same trial:**
Marcus BH, Rossi JS, Selby VC, Niaura RS, Abrams DB. The stages and processes of exercise adoption and maintenance in a worksite sample. *Health Psychol* 1992;**11**:386–95. [S115]

Marcus BH, Banspach SW, Lefebvre RC, Rossi JS, Carleton RA, Abrams DB. Using the stages-of-change model to increase the adoption of physical activity among community participants. *Am J Health Promot* 1992;**6**:424–9. [S138]

Marcus BH., Selby VC, Niaura, RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992;**63**:60–6. [S145]

Marcus BH, Simkin LR.. The stages of exercise behavior. *J Sports Med Phys Fitness* 1993;**33**:83–8. [S258]

Marcus BH., Rakowski W, Rossi JS. Assessing motivational readiness and decision making for exercise. *Health Psychol* 1992;**11**:257–61. [S496]

Marcus BH, Owen N. Motivational readiness, self-efficacy and decision-making for exercise. *J Appl Soc Psychol* 1992;**22**:3–16. [S656]

## S062 Werch, 1999

**Included paper:**
Werch C, Pappas D, Carlson J, DiClemente C. Six-month outcomes of an alcohol prevention program for inner-city youth. *Am J Health Promot* 1999;**13**:237–9. [S062]

**Excluded paper describing the same trial:**
Werch CE. Expanding the stages-of-change: a program matched to the stages of alcohol acquisition. *Am J Health Prom* 1997;**12**:34–7. [S055]

**Additional paper with information on the same trial:**
Dielman TE. School-based research on the prevention of adolescent alcohol use and misuse: methodological issues and advances. In: Boyd G, Howard J, Zucker R, editors. Alcohol problems among adolescents: current directions in prevention research. Hillsdale, NJ: Lawrence Erlbaum; 1995. p. 125–46. [S647]

## S073 Goldstein, 1999

**Included paper:**
Goldstein MG, Pinto BM, Marcus BH, Lynn H, Jette AM, Rakowski W, *et al.* Physician-based physical activity counseling for middle-aged and older adults: a randomized trial. *Ann Behav Med* 1999;**21**:40–7. [S073]

**Additional papers ordered with information on the same trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

Pinto BM, Goldstein MG, DePue JD, Milan FB. Acceptability and feasibility of physician-based activity counseling: the PAL project. *Am J Prev Med* 1998;**15**:95–102. [S485]

Pinto BM, Goldstein MG, Marcus BH. Activity counseling by primary care physicians. *Prev Med* 1998;**27**:506–13. [S488]

Marcus BH, Pinto BM, Clark MM, Depue JD, Goldstein MG, Silverman LS. Physician-delivered physical activity and nutrition and interventions. *Med Exerc Nutr Health* 1995;**4**:325–34. [S500]

Grueninger UJ, Duffy FD, Goldstein MG. Patient education in the medical encounter: How to facilitate learning, behavior change, and coping. In: Lipkin M, Putnam S, Lazare A, editors. The medical interview. New York: Springer-Verlag; 1995. [S657]

Bandura A. Self-efficacy: towards a unifying theory of behaviour change. *Psychol Rev* 1977;**84**:191–215. [S658]

Green L. Health education models. In: Matarazzo J, Weiss S, Herd J, Miller N, Weiss S, editors. Behavioral health: a handbook for health enhancement. New York: Wiley; 1984. p. 181–98. [S659]

**Papers with information on the stage-of-change instrument used in the trial:**
Marcus BH, Rossi JS, Selby VC, Niaura RS, Abrams DB. The stages and processes of exercise adoption and maintenance in a worksite sample. *Health Psychol* 1992;**11**:386–95. [S115]

Marcus BH, Banspach SW, Lefebvre RC, Rossi JS, Carleton RA, Abrams DB. Using the stages-of-change model to increase the adoption of physical activity among community participants. *Am J Health Promot* 1992;**6**:424–9. [S138]

Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992;**63**:60–6. [S145]

Marcus BH, Simkin LR. The stages of exercise behavior. *J Sports Med Phys Fitness* 1993;**33**:83–8. [S258]

Marcus BH., Rakowski W, Rossi JS. Assessing motivational readiness and decision making for exercise. *Health Psychol* 1992;**11**:257–61. [S496]

Marcus BH, Owen N. Motivational readiness, self-efficacy and decision-making for exercise. *J Appl Soc Psychol* 1992;**22**:3–16. [S656]

## S084 Kristal, 2000

**Included paper:**
Kristal AR, Glanz K, Tilley BC, Li SH. Mediating factors in dietary change: understanding the impact of a worksite nutrition intervention. *Health Educ Behav* 2000;**27**:112–25. [S084]

**Excluded paper describing the same trial:**
Glanz K, Kristal AR, Tilley BC, Hirst K. Psychosocial correlates of healthful diets among male auto workers. *Cancer Epidemiol Biomarkers Prev* 1998;**7**:119–26. [S142]

**Additional papers ordered with information on the same trial:**
Tilley B, Vernon S, Glanz K, Myers R, Sanders K, Lu M, *et al.* Worksite cancer screening and nutrition intervention for high risk auto workers: design and baseline findings of the Next Step trial. *Prev Med* 1997;**26**:227–35. [S498]

Tilley B, Glanz K, Kristal A, Hirst K, Li S, Vernon SW, *et al.* Nutrition intervention for high risk auto workers: results of the Next Step trial. *Prev Med* 1999;**28**:284–92. [S503]

Tilley B, Vernon S, Myers R, Glanz K, Lu M, Hirst K, *et al.* The Next Step trial: impact of a worksite colorectal cancer screening promotion program. *Prev Med* 1999;**28**:276–83. [S504]

Anderson RA. A behavioral model of families' use of health services. Chicago: University of Chicago Press; 1968. [S616]

Beresford SAA, Farmer EMA, Feingold MA, Graves KL, Sumner SK, Baker RM. Evaluation of a self-help dietary intervention in a primary care setting. *Am J Public Health* 1992;**82**:79–84. [S617]

**Paper with information on the stage-of-change instrument used in the trial:**
Glanz K, Patterson RE, Kristal AR, DiClemente CC, Heimendinger J, Linnan L, *et al.* Stages-of-change in adopting healthy diets: fat, fiber, and correlates of nutrient intake. *Health Educ Q* 1994;**21**:499–519. [S030]

**Background/review paper with information on the trial:**
Kristal AR, Glanz K, Curry SJ, Patterson RE. How can stages-of-change be best used in dietary interventions? *J Am Diet Assoc* 1999;**99**:679–84. [S317]

## S089 Braatz, 1999

**Included paper:**
Braatz JS, Ames B, Holmes-Rovner M, King S, McPhail J, Vogel P. The effect of a physical activity intervention based on the transtheoretical model of changing physical-activity-related behavior on low-income elderly volunteers. *J Aging Phys Activity* 1999;**7**:308–9. [S089]

**Additional paper received from author with information on the same trial:**
Braatz JS. The effect of a physical activity intervention based on the transtheoretical model in changing physical-activity-related behavior on low-income elderly volunteers [PhD]. Lansing: Michigan State University; 1997.

**Papers with information on the stage-of-change instrument used in the trial:**
Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992;**63**:60–6. [S145]

Marcus BH, Simkin LR. The stages of exercise behavior. *J Sports Med Phys Fitness* 1993;**33**:83–8. [S258]

## S165 Graham-Clark, 1994

**Included paper:**
Graham-Clarke P, Oldenburg B. The effectiveness of a general-practice-based physical activity intervention on patient physical activity status. *Behav Change* 1994;**11**:132–44. [S165]

**Background/review paper with information on the trial:**
Oldenburg B, Graham-Clarke P, Shaw J, Walker S. Modification of health behaviour and lifestyle mediated by physicians. In: Orth-Gomer K, Schneiderman N, editors. Behavioral medicine approaches to cardiovascular disease prevention. Mahwah: Lawrence Erlbaum; 1996. p. 203–26. [S326]

## S172 Pallonen, 1998

**Included paper:**
Pallonen UE, Velicer WF, Prochaska JO, Rossi JS, Bellis JM, Tsoh JY, *et al.* Computer-based smoking cessation interventions in adolescents: description, feasibility, and six-month follow-up findings. *Subst Use Misuse* 1998;**33**:935–65. [S172]

**Excluded paper describing the same trial:**
Pallonen UE, Prochaska JO, Velicer WF, Prokhorov AV, Smith NF. Stages of acquisition and cessation for adolescent smoking: an empirical integration. *Addict Behav* 1998;**23**:303–24. [S238]

**Paper with information on the stage-of-change instrument used in the trial:**
Prochaska JO, DiClemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol* 1993;**12**:399–405. [S135]

**Background/review papers with information on the trial:**
Pallonen UE. Transtheoretical measures for adolescent and adult smokers: similarities and differences. *Prev Med* 1998;**27**:A29–38. [S043]

Velicer WF, Prochaska JO, Bellis JM, DiClemente CC, Rossi JS, Fava JL, *et al.* An expert system intervention for smoking cessation. *Addict Behav* 1993;**18**:269–90. [S420]

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Prochaska JO, DiClemente CC. The transtheoretical approach: crossing traditional boundaries of change. Homewood, IL: Dow Jones-Irwin; 1983. [S629]

Velicer WF, Rossi JS, Ruggiero L, Prochaska JO. Minimal intervention appropriate for an entire population of smokers. In: Richmond R, editor. Interventions for smokers: an international perspective. Baltimore, MD: Williams and Wilkins; 1994. p. 69–92). [S630]

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## S219 Glasgow, 1995

**Included paper:**
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**Additional papers with information on the same trial:**
Abrams DB, Emmons KM, Linnan L, Biener L. Smoking cessation at the workplace: conceptual and practical considerations. In: Richmond R, editor. Interventions for smokers: an international perspective. New York: Williams and Wilkins; 1994. [S614]

Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. *Am Psychol* 1992;**47**:1102–14. [S615]

## S227 Lennox, 1998

**Included paper:**
Lennox AS, Bain N, Taylor RJ, McKie L, Donnan PT. Stages-of-change training for opportunistic smoking intervention by the primary healthcare team. Part I: randomised controlled trial of the effect of training on patient smoking outcomes and health professional behaviour as recalled by patients. *Health Educ J* 1998;**57**:140–9. [S227]

**Paper with information on the stage-of-change instrument used in the trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

Biener L, Abrams D. The contemplation ladder: validation of measure of readiness to consider smoking cessation. *Health Psychol* 1991;**10**:360–5. [S515]

**Additional papers with information on the same trial:**
Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York: Guilford Press; 1991. [S618]

## S234 Pallonen, 1994

**Included paper:**
Pallonen UE, Leskinen L, Prochaska JO, Willey CJ, Kaariainen R, Salonen JT. A 2-year self-help smoking cessation manual intervention among middle-aged Finnish men: an application of the transtheoretical model. *Prev Med* 1994;**23**:507–14. [S234]

**Excluded paper describing the same trial:**
Pallonen UE, Fava JL, Salonen JT, Prochaska JO. Readiness for smoking change among middle-aged Finnish men. *Addict Behav* 1992;**17**:415–23. [S388]

**Paper with information on the stage-of-change instrument used in the trial:**
Prochaska JO, Di Clemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol* 1993;**12**:399–405. [S135]

**Additional papers with information on the same trial:**
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Koch GG, Landis JR, Freeman JL, Freeman DH, Lehnen RG. A general methodology for the analysis of experiments with repeated measurement off categorical data. *Biometrics* 1977;**33**:133–58. [S627]

Cancer Prevention Research Center Research Team. Precontemplation: understanding yourself as a smoker; Contemplation: thinking about breaking the smoking habit; Action: taking action to break the smoking habit; Relapse: learning from relapse; Maintenance: STAYING free from smoking. Kingston, RI: University of Rhode Island; 1987. [S628]

## S255 Prochaska, 1993

**Included paper:**
Prochaska JO, Di Clemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol* 1993;**12**:399–405. [S135]

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Velicer WF, Prochaska JO. An expert system intervention for smoking cessation. *Patient Educ Couns* 1999;**36**:119–29. [S310]

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**Papers with information on the stage-of-change instrument used in the trial:**
DiClemente CC, Prochaska JO, Gibertini M. Self-efficacy and the stages of self-change of smoking. *Cognit Ther Res* 1985;**9**:181–200. [S041]

McConnaughy EA, Prochaska JO, Velicer WF. Stages-of-change in psychotherapy: measurement and sample profiles. *Psychother Theory Res Pract* 1983;**20**:368–75. [S099]

Prochaska JO, Velicer WF, DiClemente CC, Fava J. Measuring processes of change: applications to the cessation of smoking. *J Consult Clin Psychol* 1988;**56**:520–8. [S254]

**Background/review paper with information on the trial:**
Velicer WF, Prochaska JO, Bellis JM, DiClemente CC, Rossi JS, Fava JL, *et al.* An expert system intervention for smoking cessation. *Addict Behav* 1993;**18**:269–90. [S420]

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Janis I. The role of social support in adherence to stressful decisions. *Am Psychol* 1983;**38**:143–60. [S605]

Cohen S, Kamarck T, Mermelstein R. A global measure of perceived stress. *J Health Social Behav* 1983;**24**:385–96. [S606]

Cohen S, Williamson GM. Perceived stress in a probability sample of the United States. In: Spacapan S, Oskamp S, editors. The social psychology of health. Newbury Park, CA: Sage; 1988. p. 31–67 [S607]

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## S272 Werch, 1996

**Included paper:**
Werch CE, Carlson JM, Pappas DM, DiClemente CC. Brief nurse consultations for preventing alcohol use among urban school youth. *J Sch Health* 1996;**66**:335–8. [S272]

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Werch CE, DiClemente C. A multi-component stage model for matching drug prevention strategies and messages to youth stage of use. *Health Educ Res Theory Pract* 1994;**9**:37–46. [S646]

## S288 Brug, 1998

**Included paper:**
Brug J, Glanz K, Van Assema P, Kok G, Van Breukelen G. The impact of computer-tailored feedback and iterative feedback on fat, fruit, and vegetable intake. *Health Educ Behav* 1998;**25**:517–31. [S288]

**Excluded paper describing the same trial:**
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**Paper with information on the stage-of-change instrument used in the trial:**
Glanz K, Patterson RE, Kristal AR, DiClemente CC, Heimendinger J, Linnan L, *et al.* Stages-of-change in adopting healthy diets: fat, fiber, and correlates of nutrient intake. *Health Educ Q* 1994;**21**:499–519. [S030]

**Additional paper with information on the same trial:**
Sporny LA, Contento IR. Stages of change in dietary fat reduction: social psychological correlates. *J Nutr Educ* 1995;**27**:191–9. [S600]

## S290 Berman, 1995

**Included paper:**
Berman BA, Gritz ER, Braxton-Owens H, Nisenbaum R. Targeting adult smokers through a multi-ethnic public school system. *J Cancer Educ* 1995;**10**:91–101. [S290]

## S305 Cardinal, 1995

**Included papers:**
Cardinal BJ, Sachs ML. Prospective analysis of stage-of-exercise movement following mail-delivered, self-instructional exercise packets. *Am J Health Prom* 1995;**9**:430–2. [S101]

Cardinal BJ, Sachs ML. Effects of mail-mediated, stage-matched exercise behavior change strategies on female adults' leisure-time exercise behavior. *J Sports Med Phys Fitness* 1996;**36**:100–7. [S305]

Cardinal BJ, Sachs MC. Increasing physical activity using the stages-of-change model and mail delivered exercise programs. *Res Q Exerc Sport* 1994;**65**:A45. [S439]

**Excluded papers describing the same trial:**
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Cardinal BJ. Construct validity of stages-of-change for exercise behavior. *Am J Health Promot* 1997;**12**:68–74. [S059]

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Cardinal BJ. The stages of exercise scale and stages of exercise behavior in female adults. *J Sports Med Phys Fitness* 1995;**35**:87–92. [S244]

Cardinal BJ. Behavioral and biometric comparisons of the preparation, action, and maintenance stages of exercise. *Wellness Perspect* 1995;**11**:36–44. [S442]

## S330 Wang, 1994

**Included paper:**
Wang WD. Feasibility and effectiveness of a stages-of-change model in cigarette smoking cessation counseling. *J Formos Med Assoc* 1994;**93**:752–7. [S330]

**Additional paper with information on the same trial:**
Prochaska JO, Goldstein MG. Process of smoking cessation. Implications for clinicians. *Clin Chest Med* 1991;**12**:727–35. [S645]

## S338 Woollard, 1995

**Included paper:**
Woollard J, Beilin L, Lord T, Puddey I, Macadam D, Rouse I. A controlled trial of nurse counselling on lifestyle change for hypertensives treated in general practice: preliminary results. *Clin Exp Pharmacol Physiol* 1995;**22**:466–8. [S338]

**Additional papers with information on the same trial:**
Prochaska JO, DiCelemente CC. Treating addictive behaviours: process of change. In: Miller W, Heather N, editors. Towards a comprehensive model of change. New York: Plenum Press; 1986. p. 3–27 [S648]

Puddey IB, Beilin LJ, Vandongen R. Regular alcohol use raises blood pressure in treated hypertensive subjects: a randomised controlled trial. *Lancet* 1987;**i**:647–50. [S649]

Saunders B, Wilkinson C. Motivation and addiction behavior: a psychological perspective. *Drug Alcohol Rev* 1990;**9**:133–42. [S650]

## S350 Steptoe, 1999

**Included paper:**
Steptoe A, Doherty S, Rink E, Kerry S. Behavioural counselling in general practice for the promotion of healthy behaviour among adults at increased risk of coronary heart disease: randomised trial. *BMJ* 1999;**319**:943–7. [S350]

**Excluded papers describing the same trial:**
Doherty SC, Steptoe A, Rink E, Kendrick T, Hilton S. Readiness to change health behaviours among patients at high risk of cardiovascular disease. *J Cardiovasc Risk* 1998;**5**:147–53. [S199]

Hilton S, Doherty S, Kendrick T, Kerry S, Rink E. Promotion of healthy behaviour among adults at increased risk of coronary heart disease in general practice: methodology and baseline data from the Change of Heart study. *Health Educ J* 1999;**58**:3–16. [S228]

Curry SJ, Kristal AR, Bowen DJ. An application of the stage model of behavior change to dietary fat reduction. *Health Educ Res* 1992;**7**:97–105. [S445]

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Marcus BH, Rakowski W, Rossi JS. Assessing motivational readiness and decision making for exercise. *Health Psychol* 1992;**11**:257–61. [S496]

**Additional papers with information on the same trial:**
Health Education Authority. Helping people change; health promotion in primary health care. London: HEA, 1994. [S637]

Hunt P, Hillsdon M. Eating and exercise behaviour: a handbook for professionals. Oxford: Blackwell Science, 1996. [S638]

## S353 Resnicow, 1997

**Included papers:**
Resnicow K, Vaughan R, Futterman R, Weston R. The Harlem health connection study group. A self-help smoking cessation program for inner-city African Americans: results from the Harlem health connection project. *Health Educ Q* 1997;**24**:201–17. [S447]

Resnicow K, Royce J, Vaughan R, Orlandi MA, Smith M. Analysis of a multicomponent smoking cessation project: what worked and why. *Prev Med* 1997;**26**:373–81. [S353]

**Background/review papers with information on the trial:**
Prochaska JO, DiClemente CC. Stages-of-change in the modification of problem behaviors. *Prog Behav Modif* 1992;**28**:183–218. [S94]

Prochaska JO, Di Clemente CC, Velicer WF, Rossi JS. Standardized, individualized, interactive, and personalized self-help programs for smoking cessation. *Health Psychol* 1993;**12**:399–405. [S135]

Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

Prochaska JO, Velicer WF, DiClemente CC, Fava J. Measuring processes of change: applications to the cessation of smoking. *J Consult Clin Psychol* 1988;**56**:520–8. [S254]

**Additional paper with information on the same trial:**
Velicer WF, Fava JL, Prochaska JO, Abrams DB, Emmons KM, Pierce JP. Distribution of smokers by stage in three representative samples. *Prev Med* 1995;**24**:401–11. [S632]

## S368 Velicer, 1999

**Included paper:**
Velicer WF, Prochaska JO, Fava JL, Laforge RG, Rossi JS. Interactive versus noninteractive interventions and dose–response relationships for stage-matched smoking cessation programs in a managed care setting. *Health Psychol* 1999;**18**:21–8. [S368]

**Excluded paper describing the same trial:**
Velicer WF, Prochaska JO. An expert system intervention for smoking cessation. *Patient Educ Couns* 1999; **36**:119–29. [S310]

**Background/review paper with information on the trial:**
Velicer WF, Prochaska JO, Bellis JM, DiClememte CC, Rossi JS, Fava JL, *et al.* An expert system intervention for smoking cessation. *Addict Behav* 1993;**18**:269–90. [S420]

**Additional papers with information on the same trial:**
Prochaska JO, Velicer WF, Rossi JS, Goldstein MG, Marcus BH, Rakowski W, *et al.* Stages of change and decisional balance for 12 problem behaviors. *Health Psychol* 1994;**13**:39–46. [S008]

Velicer WF, Rossi JS, Ruggiero L, Prochaska JO. Minimal intervention appropriate for an entire population of smokers. In: Richmond R, editor. Interventions for smokers: an international perspective. Baltimore, MD: Williams and Wilkins; 1994. p. 69–92. [S630]

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Prochaska JO, Velicer WF, Fava JL, Ruggiero L, Laforge RG, Rossi JS, *et al.* Counselor and stimulus control enhancements of a stage-matched expert system intervention for smokers in a managed care setting. *Prev Med* 2001;**32**:23–32. [S641]

Prochaska JO, Velicer WF, DiClemente CC, Fava J Measuring processes of change: applications to the cessation of smoking. *J Consult Clin Psychol* 1988;**56**:520–8. [S254]

Velicer WF, DiClemente CC, Prochaska JO, Brandenburg N. Decisional balance measure for assessing and predicting smoking status. *J Pers Soc Psychol* 1985;**48**:1279–89. [S642]

Velicer WF, DiClemente CC, Rossi JS, Prochaska JO. Relapse situations and self-efficacy: an integrative model. *Addict Behav* 1990;**15**:271–83. [S643]

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## S378 Havas, 2000

**Included papers:**
Havas S, Anliker J, Damron D, Feldman R, Langenberg P. Uses of process evaluation in the Maryland WIC 5-a-Day Promotion Program. *Health Educ Behav* 2000;**27**:254–63. [S083]

Havas S, Anliker J, Damron D, Langenberg P, Ballesteros M, Feldman R. Final results of the Maryland WIC 5-a-day Promotion Program. *Am J Public Health* 1998;**88**:1161–7. [S378]

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**Excluded papers describing the same trial:**
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Anliker J, Damron D, Ballesteros M, Langenberg P, Havas S, Metger W, *et al.* Gem No. 297. Using the stages-of-change model in a 5 a day guidebook for WIC. *J Nutr Educ* 1999;**31**. [S270]

## S380 Gritz, 1998

**Included papers:**
Herzog TA, Abrams DB, Emmons KM, Linnan LA, Shadel WG. Do processes of change predict smoking stage movements? A prospective analysis of the transtheoretical model. *Health Psychol* 1999;**18**:369–75. [S370]

Abrams DB, Boutwell WB, Grizzle J, Heimendinger J, Sorensen G, Varnes J. Cancer control at the workplace: the working well trial. *Prev Med* 1994;**23**:15–27. [S371]

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**Papers with information on the stage-of-change instrument used in the trial:**
Glanz K, Patterson RE, Kristal AR, Feng ZD, Linnan L, Heimendinger J, *et al.* Impact of work site health promotion on stages of dietary change: the Working Well trial. *Health Educ Behav* 1998;**25**:448–63. [S085]

Glanz K, Patterson RE, Kristal AR, DiClemente CC, Heimendinger J, Linnan L, *et al.* Stages-of-change in adopting healthy diets: fat, fiber, and correlates of nutrient intake. *Health Educ Q* 1994;**21**:499–519. [S030]

Prochaska JO, Diclemente CC, Norcross JC. In search of how people change: applications to addictive behaviors. In: Marlatt GA, Van den Bos GR, editors. Addictive behaviors: readings on etiology, prevention, and treatment. Washington, DC: American Psychological Association; 1997. p. 671–96. [S312]

## S402 Butler, 1999

**Included paper:**
Butler CC, Rollnick S, Cohen D, Bachmann M, Russell I, Stott N. Motivational consulting versus brief advice for smokers in general practice: a randomized trial. *Br J Gen Pract* 1999;**49**:611–16. [S402]

**Excluded paper describing the same trial:**
Rollnick S, Butler CC, Stott N. Helping smokers make decisions: the enhancement of brief intervention for general medical practice. *Patient Educ Couns* 1997;**31**:191–203. [S159]

**Papers with information on the stage-of-change instrument used in the trial:**
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Goldberg DN, Hoffman AM, Farinha MF, Marder DC, Tinson Mitchem L, Burton D, *et al.* Physician delivery of smoking-cessation advice based on the stages-of-change model. *Am J Prev Med* 1994;**10**:267–74. [S140]

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**Included paper:**
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Ewing J. Detecting alcoholism: the CAGE questionnaire. *JAMA* 1984;**252**:1905–7. [S624]

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## S446 Baker, 1999

**Included paper:**
Baker A, Wardle J. Low intensity: high impact! Can low intensity interventions change behaviour? 13th Conference of the European Health Psychology Society 'Psychology and the Renaissance of Health' Florence, 1999. [S446]

## S452 Morgan, 1996

**Included paper:**
Morgan GD, Noll EL, Orleans CT, Rimer BK, Amfoh K, Bonney G. Reaching midlife and older smokers: tailored interventions for routine medical care. *Prev Med* 1996;**25**:346–54. [S452]

## S453 Swanson, 1999

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Swanson AJ, Pantalon MV, Cohen KR. Motivational interviewing and treatment adherence among psychiatric and dually diagnosed patients. *J Nerv Ment Dis* 1999;**187**:630–5. [S453]

**Papers with information on the stage-of-change instrument used in the trial:**
McConnaughy EA, Prochaska JO, Velicer WF. Stages-of-change in psychotherapy: measurement and sample profiles. *Psychotherapy: Theory, Research and Practice* 1983;**20**:368–75. [S099]

McConnaughy EA, DiClemente CC, Prochaska JO, Velicer WF. Stages-of-change in psychotherapy: a follow-up report. *Psychotherapy* 1989;**26**:494–503. [S149]

Prochaska JO, Diclemente CC, Norcross JC. In search of how people change: applications to addictive behaviors. In: Marlatt GA, Van den Bos GR, editors. Addictive behaviors: readings on etiology, prevention, and treatment. Washington, DC: American Psychological Association; 1997. p. 671–96. [S312]

**Additional paper with information on the same trial:**
Miller WR, Rollnick S. Motivational interviewing: preparing people to change addictive behavior. New York: Guilford Press; 1991. [S639]

## S458 Gritz, 1993

**Included paper:**
Gritz ER, Carr CR, Rapkin D, Abemayor E, Chang LJ, Wong WK, *et al.* Predictors of long-term smoking cessation in head and neck cancer patients. *Cancer Epidemiol Biomarkers Prev* 1993;**2**:261–70. [S458]

**Additional paper ordered with information on the same trial:**
Gritz E, Carr C, Rapkin D, Chang C, Beumer J, Wartd P. A smoking cessation intervention for head and neck cancer patients: trial design, patient accrual and characteristics. *Cancer Epidemiol Biomarkers Prev* 1991;**1**:67–73. [S513]

**Paper with information on the stage-of-change instrument used in the trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

## S478 Scales, 1998

**Included paper:**
Scales R. Motivational interviewing and skills-based counseling in cardiac rehabilitation: the cardiovascular health initiative and lifestyle education (Chile) study [PhD]. Albuquerque: The University of New Mexico; 1998. [S478]

**Papers with information on the stage-of-change instrument used in the trial:**
Prochaska JO, Velicer WF, Rossi JS, Goldstein MG, Marcus BH, Rakowski W, *et al.* Stages-of-change and decisional balance for 12 problem behaviors. *Health Psychol* 1994;**13**:39–46. [S008]

Marcus BH, Selby VC, Niaura RS, Rossi JS. Self-efficacy and the stages of exercise behavior change. *Res Q Exerc Sport* 1992;**63**:60–6. [S145]

Curry SJ, Kristal AR, Bowen DJ. An application of the stage model of behavior change to dietary fat reduction. *Health Educ Res* 1992;**7**:97–105. [S445]

Rossi JS, Rossi SR, Velicer WF, Prochaska JO. Motivational readiness to control weight. In: Allison DB, editor. Handbook of assessment methods for eating behaviors and weight related problems: measures, theory and research. Thousand Oaks: Sage; 1995. p. 387–430. [S516]

Greene GW, Rossi SR, Reed GR, Willey C, Prochaska JO. Stages of change for reducing dietary fat to 30% of energy or less. *J Am Diet Assoc* 1994;**94**:1105–12. [S633]

O'Connel D, Velicer WF. A decisional balance measure and the stages of change model for weight loss. *Int J Addict* 1988;**23**:729–50. [S634]

Norcross JC, Prochaska JO, DiClemente CC. Stages and Processes of change: two replications with weight control. 100th Annual meeting of the American Psychological Association; 1992; Washington, DC. [S635]

Rossi SR, Rossi JS, Prochaska JO. Processes of change for weight control: a follow-up study. 99th Annual meeting of the American Psychological Association; 1991; San Francisco. [S636]

**Background/review paper with information on the trial:**
Prochaska JO, Diclemente CC, Norcross JC. In search of how people change: applications to addictive behaviors. In: Marlatt GA, Van den Bos GR, editors. Addictive behaviors: readings on etiology, prevention, and treatment. Washington, DC: American Psychological Association; 1997. p. 671–96. [S312]

## S479 Lutz, 1996

**Included paper:**
Lutz SF. The impact of computer-tailored messages and goal setting on daily fruit and vegetable intake [PhD]. Chapel Hill: University of North Carolina at Chapel Hill; 1996. [S479]

**Additional papers with information on the same trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

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## S480 Cash, 1997

**Included paper:**
Cash TL. Effects of different exercise promotion strategies and stage of exercise on reported physical activity, self-motivation, and stages of exercise in worksite employees [Ed D]: Temple University; 1997. [S480]

**Paper with information on the stage-of-change instrument used in the trial:**
Cardinal BJ. The stages of exercise scale and stages of exercise behavior in female adults. *J Sports Med Phys Fitness* 1995;**35**:87–92. [S244]

**Additional papers with information on the same trial:**
Prochaska JO, DiClemente CC. Stages and processes of self-change of smoking: toward an integrative model of change. *J Consult Clin Psychol* 1983;**51**:390–5. [S248]

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Dishman K, Ickes W. Self-motivation inventory. Athens: University of Gergia; 1981. [S655]

## S510 Sinclair, 1999

**Included paper:**
Sinclair HK, Silcock J, Bond CM, Lennox AS, Winfield AJ. The cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking. *Int J Pharm Pract* 1999;**7**:107–12. [S510]

**Excluded papers describing the same trial:**
Sinclair HK, Bond CM. Knowledge of and attitudes to smoking cessation: the effect of stage of change training for community pharmacy staff. *Health Bulletin* 1998;**56**:526–39. [S214]

Sinclair H, Bond C, Scott-Lennox A, Silcock J, Winfield A. An evaluation of a training workshop for pharmacists based on the stages-of-change model of smoking cessation. *Health Educ J* 1997;**56**:296–312. [S225]

# Data extraction table

***Study reference No., author (year), country of origin, aim, design details***

**S025, Aveyard (1999)**[69*]

**Country**
UK

**Aim**
"To examine whether a year long programme based on the transtheoretical model of behaviour change, incorporating three sessions using an expert system computer programme and three class lessons, could reduce the prevalence of teenage smoking"

**Model**
TTM

**Theoretical basis**
"The transtheoretical model proposes that people change behaviour by moving through a sequence of stages "stages of change." The model describes both how people become smokers and how they stop. Ten psychological processes move people through the stages; some processes are important for movement from one particular stage and not others. The other elements of the transtheoretical model comprise decisional balance (the balance of the pros and cons of smoking), self efficacy (the degree of confidence in oneself to accomplish the change to non-smoking or to remain a non-smoker), and temptations (to smoke). This influential model is incorporated in many health promotion programmes"

"The most exciting aspect of the theory is that it leads directly to interventions. Validated questionnaires measure the key elements of the transtheoretical model. An individual can be characterised as being in one particular stage of change. Feedback, together with helpful strategies for increasing confidence, resisting temptation, and thinking about their smoking in the correct way, should help that individual progress to the next stage of change. This process of diagnosis, feedback, and a stock of helpful strategies for how to move stage have been incorporated into a computer program – an expert system"

**Study type**
Clustered RCT

**Design**
"Cluster randomised trial comparing the intervention to a control group exposed only to health education as part of the English national curriculum." Here a large school-based intervention study is reported incorporating the expert system for smoking prevention and cessation in adolescents based on the TTM. Authors calculated that a sample of 8500 was necessary to achieve 90% power to detect a 4% difference in the prevalence of smoking with a 5% type 1 error (intra-class correlation coefficient for smoking prevalence: 0.008)

"Once schools had been randomised (see below) they were visited with baseline questionnaires. The research team administered questionnaires to whole classes as part of personal health and social education lessons. Individuals were able to opt out, though none chose to do so"

"Once schools had agreed to participate schools were randomly allocated, not individuals, to receive the intervention or be controls. Arms were balanced by ordering schools into five groups based on numbers of students in year 9. Each school was allocated a number between 1 and n (the maximum number in the group). A computer program generated n/2 random numbers between 1 and n, and these schools were allocated to intervention"

**Setting**
School

**Length of intervention**
Six sessions between autumn 1997 and summer 1998. Follow-up assessment 1 year after the start of the intervention (about 5 months after the last intervention)

**Personal communication (PC)**
Follow-up assessment after 2 years

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
8352 students in year 9 (age 13–14 years) at 52 schools in the West Midlands region

**Inclusion criteria**
Not stated

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking

[*] *Sections of text reproduced with permission from the BMJ Publishing Group (*BMJ *1999;**319**:948–53)*

*continued*

# Data extraction table *contd*

***contd***
**S025, Aveyard (1999)**[69]

***Intervention details***

**Intervention group**
"The intervention group received six sessions of two types: one computer session and one class lesson for each of the three terms of year 9 (autumn 1997 to summer 1998). For the computer session, the research team set up a classroom with about 30 computers and removed these at the end of the day. Whole classes came in turns and each student used a computer with headphones. The computer program was based on that developed by Prochaska and colleagues, containing questionnaires measuring the key concepts of the transtheoretical model. After each questionnaire students received feedback both through the headphones and on screen of how their temptations, for example, compared to stage-based data collected by Pallonen *et al.* (normative feedback) and in second and third sessions, what change had occurred since last time (ipsative feedback). The questionnaires were interspersed with video clips of young people talking about their thoughts about smoking that were relevant to the stage of change of the student concerned. The other transtheoretical model intervention was a one hour lesson delivered by ordinary class teachers"

"The three lessons developed the young people's understanding of the stages of change and how the pros and cons of smoking would vary in different stages, and the lessons got young people to use these concepts"

Precontemplation: Concerning the whole class lessons, lesson 1 consisted of describing the stages, and using this knowledge to stage someone pupils knew. Lesson 2 concerned the pros and cons of smoking (decisional balance) and an exercise on false beliefs about smoking. Lesson 3 consisted of exercises staging three fictitious letter writers and using this to describe their decisional balance

**Comparison group**
"The aim for students in the control group was that they would be exposed to no intervention other than the normal health education on tobacco, which is part of the English national curriculum. However, as a reward for participation, teachers in control group schools were given three lesson plans and handouts on smoking. These lessons consisted of quizzes on facts about tobacco and one lesson on different ways of persuading someone to stop smoking. The content of the lessons was all taken from generally available teaching support material"

**Classification into stages**
The lesson plans and materials were provided to all control group schools, but teachers in these schools received no training in smoking issues or delivery of the lessons and it was up to the individual schools whether or not they used the materials

The computer program was based on that developed by Prochaska and colleagues, containing questionnaires measuring the key concepts of the TTM

PC1: Stage was defined using the algorithm described by Pallonen *et al.* (S238), although it used a different definition of smoking status. Smoking status was defined as never, tried smoking, ex-smoker, current smoker and unknown smoking status

PC2: The stages of smoking acquisition and cessation in adolescence, defined by Pallonen *et al.* (S238):
Acquisition precontemplation: Not thinking about smoking in next 6 months
Acquisition contemplation: Thinking about smoking in next 6 months
Acquisition preparation: Thinking about smoking in next 30 days
Acquisition recent action: Smoked cigarettes regularly less than 6 months
Cessation precontemplation: Not thinking about quitting in next 6 months
Cessation contemplation: Thinking about quitting in next 6 months
Cessation preparation: Tried to quit in last 6 months and thinking about quitting in next 30 days
Cessation action: Had quit smoking within the last 6 months
Cessation maintenance: Had quit smoking more than 6 months ago

Algorithm for the acquisition and cessation stages for adolescent smoking defined by Pallonen *et al.* (S238):

1. Which of these best describes your cigarette smoking now?
I have never smoked (→ Go to Q2)
I have tried smoking a few times (→ Go to Q2)
I used to smoke regularly, but I have given up (→ Go to Q3)
I am a smoker (→ Go to Q3)

2. Do you think you may try smoking cigarettes in the next 6 months?
No → Acquisition precontemplation
Yes (→ Go to Q4)

3. Have you completely stopped smoking cigarettes?
Yes, more than 6 months ago (→ Cessation maintenance)
Yes, 6 months ago or less (→ Cessation action)
No (→ Go to Q5)

4. Do you think you may try smoking cigarettes in the next 30 days?
No (→ Acquisition contemplation)
Yes (→ Acquisition preparation)

5. How long have you been smoking cigarettes regularly?
6 months or fewer (→ Acquisition recent action)
More than 6 months (→ Go to Q6)

6. Are you seriously considering quitting in the next 6 months?
No (→ Cessation precontemplation)
Yes (→ Go to Q7)

7. Are you seriously considering quitting in the next 30 days?
No (→ Cessation contemplation)
Yes (→ Go to Q8)

8. When was the last time you seriously tried to give up smoking cigarettes?
Less than 6 months ago (→ Cessation preparation)
More than 6 months ago (→ Cessation contemplation)

*continued*

# Data extraction table *contd*

***contd***
**S025, Aveyard (1999)**[69]

***Intervention details* contd**

**Validity of measure**
Not stated

PC1: In separate test–re-test and parallel form assessments, the kappa (95% CI) for stage of change were 0.46 (0.28–0.63), and 0.52 (0.50–0.54) respectively, indicating only moderate reliability for stage

PC2: The aim of this study was to examine the reliability of the algorithm

Method: As part of a RCT, 3930 adolescents completed a paper version of the algorithm questions and a differently worded computerised version on the same day: a parallel form reliability assessment. In a separate assessment, another group of 118 adolescents completed two identical paper versions of the same questionnaire 2 weeks apart: a test–re-test reliability assessment. Kappa values for agreement for stage and the individual questions were calculated. Logistic regression was used to examine whether demographic characteristics, smoking status, and stage predicted agreement for stage

Results: Kappa (95% CI) for stage was 0.52 (0.50–0.54) in the first assessment, and 0.46 (0.28–0.63) in the second assessment, indicating moderate reliability. Some individual questions from the algorithm were moderately reliable, but some were poorly reliable. Acquisition precontemplation was significantly more reliably coded than all other stages. Demographic characteristics did not predict reliability

Conclusion: The algorithm reliably allocates individuals into acquisition precontemplation, but for all other stages its reliability is fair

**Training of educators**
"The teachers attended a two day training course organised by Public Management Associates, who had developed licensed training and lesson plans in consultation with Prochaska and colleagues"

***Baseline characteristics***

**Gender**
I: 51.6% female
C: 47.9% female

**Age**
Mean age (SD) at follow-up:
I: 14 years, 240 (120) days
C: 14 years, 230 (118) days

**Stage of change**
Stage of smoking:
I: 60.1% acquisition/precontemplation, 4.7% acquisition/contemplation, 2.9% acquisition/preparation, 2.5% acquisition/recent action, 3.8% cessation/precontemplation, 2.4% cessation/contemplation, 3.7% cessation/preparation, 3.1% cessation/action, 2.2% cessation/maintenance, 14.8% unknown
C: 62.9% acquisition/precontemplation, 3.9% acquisition/contemplation, 1.9% acquisition/preparation, 2.0% acquisition/recent action, 3.8% cessation/precontemplation, 2.3% cessation/contemplation, 3.5% cessation/preparation, 2.9% cessation/action, 3.4% cessation/maintenance, 13.3% unknown

**Target behaviour**
Smoking habits:
I: 7.6% ex-smoker; 13.3% smoker; 26.5% tried smoking; 51.8% never smoked; 0.9% unknown
C: 8.5% ex-smoker; 12.8% smoker; 23.2% tried smoking; 54.8% never smoked; 0.7% unknown

***Results***

**Statistical techniques**
"All analysis was done using MLwiN (multi-level modelling for windows) to account for cluster randomisation. School was entered as a random effect and all other variables as fixed effects in the logistic regression models. Odds ratios and 95% confidence intervals were calculated. All percentages quoted in the results represent the modelled percentage for the average school from the population of all schools from which the sample of schools was obtained (that is, the random effect is zero)"

"For the outcome of smoking status, the data were analysed in three main ways. Firstly, everyone was included who started in the cohort, whether or not they were followed up (intention to treat analysis). The analysis was repeated making four different assumptions about those lost to follow up [lost to follow-up counted as smokers/counted as non-smokers/assumed to have same smoking habit as at the baseline (unknown baseline counted as smokers)/assumed to have same smoking habit as at the baseline (unknown baseline counted as non-smokers)]. Secondly, only those for whom the smoking status was known at follow up were included. Thirdly, only those students whose smoking status was known and who did not contradict themselves on any question pertaining to smoking status in the questionnaire were included"

"Three models were produced for the outcome: "unadjusted" for any variable, "adjusted for baseline smoking status" as defined in table 1 (see 'baseline target behaviour), and "fully adjusted" adjusted for all variables in table 1 except stage" (sex, ethnic group, family smoking habits, smoking habits of student at the baseline, deprivation, age at follow-up and length of follow-up)

PC1: Logistic regression was used to adjust for baseline smoking status and other potential confounders (age, sex, ethnic group, Townsend score quintiles (based on a census-derived score for the deprivation of the area of the participant's residence), mother, father, sibling and best friend's smoking habits). To account for the cluster randomisation, for all these analyses, a random effects logistic regression was used, with school as a random effect and all other variables as fixed effects dummy terms

The prespecified primary outcome measure was regular smoking. The unadjusted OR and 95% CI were calculated for regular weekly smoking at 2-years follow-up for the TTM group relative to the control group, and from this the modelled percentage smoking in those groups was derived. Again, the authors subsequently adjusted for baseline smoking status and the other potential confounders, calculating the adjusted OR (95% CI) for TTM and control groups

*continued*

# Data extraction table *contd*

***contd***
**S025, Aveyard (1999)**[69]

***Results* contd**

**Behaviour change**
Prevalence of teenage smoking 12 months after the start of the intervention: regular smoking (one or more cigarettes per week)

There were no statistically significant changes in smoking overall between the groups, or in the subgroups defined by initial smoking status (Table 3 of S025). The OR for the intention-to-treat analysis assuming that those lost to follow-up did not change smoking status from the baseline was 1.08 (0.89 to 1.33). There was little confounding by the variables in Table 1 of S025 as shown by the small changes in OR after adjustment

Percentage difference in smokers (I – C) (95% CI)/OR (95% CI):
All participants in comparison, those lost to follow-up counted as smokers: 0.89 (–2.89 to 5.02)/OR = 1.05 (0.86 to 1.28)
All participants in comparison, those lost to follow-up counted as non-smokers: 1.16 (–1.60 to 4.34)/OR = 1.09 (0.88 to 1.35)
All participants in comparison, those lost to follow-up assumed to have the same smoking habit as at the baseline (unknown baseline counted as smokers): 1.24 (–1.74 to 4.62)/OR = 1.08 (0.89 to 1.33)
All participants in comparison, those lost to follow-up assumed to have same smoking habit as at the baseline (unknown baseline counted as non-smokers): 1.21 (–1.76 to 4.57)/OR = 1.08 (0.88 to 1.32)
Only those participants followed up and whose smoking status was known included: 1.28 (–1.87 to 4.89)/OR = 1.09 (0.87 to 1.36)
Only those participants followed up and whose smoking status was known and whose answers were completely consistent included: 1.58 (–1.58 to 5.20)/OR = 1.11 (0.89 to 1.38)

PC1: Results at 2 years. The prespecified primary outcome measure was regular smoking, defined as regularly smoking at least one cigarette per week. Smoking status was provisionally defined by reference to responses to two questions. The first question was 'Have you ever smoked cigarettes?' The responses categorised number of cigarettes smoked in seven categories that ranged from 'Never tried' through to 'One or more cigarettes per week'. The second question was derived from an algorithm published by Pallonen *et al.* (S238) that is used to allocate stage of change. The question stem is 'Which of these statements best describes your cigarette smoking now?' The responses (abbreviated) are 'Never smoked', 'Tried smoking a few times', 'I am a smoker' and 'Used to smoke regularly but I have given it up'. Similarly, participants were categorised as either regular daily smokers or not, meaning that consumption was on average at least one cigarette per day

This was done by reference mainly to two questions on average daily consumption in the last 30 days, and the number of cigarettes consumed in the last 7 days. Where both responses were available, the daily amount was a weighted average of the two, with the 30-day average counting as double the 7-day average. Where only one was available, this was assumed to be the average daily consumption. Where neither were available, the amount consumed in the past 24 hours was taken as the daily average. Using this new definition of regular smoking, the unadjusted and fully adjusted OR (95% CI) was assessed for smoking at 1- and 2-years follow-up as described above. The authors state that these results should be viewed with some caution: this variable was not specified in the protocol as an outcome measure, but *post hoc*, after viewing the results

Percentage of smokers (regular weekly smokers) at 2-years follow-up:
I, 23.5%; C, 22.4%. Difference (95% CI): 1.1% (–1.8 to 4.2%). OR (95% CI): 1.06 (0.90 to 1.26). Fully adjusted OR (95% CI): 1.06 (0.86 to 1.31)

Percentage of smokers (regular daily smokers) at 1-/2-years follow-up:
I, 15.4%/20.2%; C, 16.1%/21.1%. Difference (95% CI): 0.8% (–2.1 to 4.1%)/0.9% (–1.9 to 4.1%). OR (95% CI): 1.06 (0.84 to 1.33)/1.06 (0.88 to 1.27). Fully adjusted OR (95% CI): 1.12 (0.89 to 1.40)/1.07 (0.86 to 1.33)

**Stage movement**
Not stated

Authors' report: One possibility is that participants have moved along the stage of change but their behaviour is not yet influenced. A 2-year follow-up has been scheduled to see if this occurs, but the analysis on change in stage between the arms (data not presented) showed no benefit of the intervention for this outcome either

PC1: Stage of change could not be allocated to 1108 (13.4%) participants with known smoking status at the baseline, 745 (10.0%) participants with known smoking status at the 1-year follow-up, and 511 (7.5%) participants with known smoking status at the 2-year follow-up

PC1: A positive change in stage between the baseline and 1-year or 2-years follow-up was defined as a movement to a stage where acquisition was less likely or cessation more likely. The proportions who had made positive movements in the TTM and control group were examined, and the difference (95% CI) in those proportions

Percentage positive movement in stage of change after 1 year:
I, 8.4%; C, 7.1%. Difference (95% CI): 1.2% (0.4 to 2.2%). OR (95% CI): 1.19 (1.05 to 1.34)

Fully adjusted OR: 1.13 (0.91 to 1.41). Percentage positive movement in stage of change after 2 years:
I, 5.6%; C, 6.6%. Difference (95% CI): 1.1% (–0.5 to 3.2%). OR (95% CI): 1.21 (0.90 to 1.62). Fully adjusted OR: 1.25 (0.95 to 1.64)

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S025, Aveyard (1999)**[69]

***Results* contd**

**Implementation measures**
"Pupils started the computer programme with their identification number and password, so on second and third sessions feedback could be given on their progress. Authors therefore used an accurate attendance register and calculated percentage attendance for each occasion of use. Pupils could skip through the programme by pressing the continue button, which would mean that although they attended physically, they missed the individualised messages. The computer programme, however, measured the time taken to complete the interventions. To assess how long was necessary to get the messages, authors asked four "smokers" in their department and four "non-smokers" to use the intervention rapidly but attentively. The mean time necessary was calculated (7 minutes for a non-smoker and 11 minutes for a smoker) and hence the percentage of smokers and non-smokers who took long enough to have received the full intervention. At the end of the computer programme, a five item Likert scale questionnaire recorded students' reactions to the programme each time they used it. The percentage of smoking and non-smoking participants who endorsed either of the two positive responses by occasion of use was calculated"

"The process of lesson delivery in the intervention arm was evaluated by asking teachers to return a self completion questionnaire after delivering each lesson. Thirty eight teachers from the 26 intervention schools were trained, but it was left to them to decide which teacher taught which of the several classes in year 9 in which term. The questionnaires used a Likert format to get information about teachers' delivery, the content of the lesson plan, and how well each of the activities were received by the pupils; a score of 1–5 was assumed and mean scores were calculated"

1st = first lesson, 2nd = second lesson, 3rd = third lesson:
No. (%) of schools returning questionnaires: 1st, 12 (46%); 2nd, 16 (62%); 3rd, 8 (31%)
No. of questionnaires returned: 1st, 19; 2nd, 46; 3rd, 26
Adequate time (No. (%) 'yes'): 1st, 19 (100%); 2nd, 42 (91%); 3rd, 21 (81%)
Cover all material (No. (%) 'yes'): 1st, 19 (100%); 2nd, 41 (89%); 3rd, 22 (85%)
Lesson delivery (mean score; 1 = very poor to 5 = very good): 1st, 4.0; 2nd, 3.8; 3rd, 3.7
Lesson understanding (mean score; 1 = very poor to 5 = very good): 1st, 4.1; 2nd, 3.9; 3rd, 3.7
Reception of lesson by pupils (mean score; 1 = very poor to 5 = very good): 1st, 4.1; 2nd, 3.8; 3rd, 3.7

Most students received the intervention as intended. Rates of completion were high, with over 77% receiving all three computerised interventions, though baseline smokers were less likely to attend. Most students did not speed through the computer session, though smokers were less likely to spend long enough to receive the individualised messages. Students found the computer program easy to use and interesting, though slightly fewer found it useful or valuable, and these percentages were lower for smokers. Smokers' and non-smokers' ratings of interest and usefulness declined the more they used the intervention

Participation in intervention: First use: 99.8% smokers/99.7% non-smokers. Second use: 91.8% smokers/96.7% non-smokers. Third use: 68.7% smokers/78.8% non-smokers

"All teachers reported that all intervention lessons were delivered, but there is no record of which individuals received the class based intervention. However, the process of receiving the intervention required the same input from students as that for the computer intervention that is, being present on the day that particular lesson was scheduled and so the participation rates were probably similar, according to the authors. Teachers were reluctant to return their questionnaires, despite prompting. Most teachers would have taught the same lesson to several year 9 classes. Although they should have completed a questionnaire for every class they taught, many teachers returned a single questionnaire summarising all of that term's lessons. Those who returned their questionnaire showed that they were happy with the lesson delivery and felt that the students had understood the lesson well (see data above). There is no data on whether the controls actually received the lessons on smoking that were distributed to teachers at control schools"

***Withdrawals/economic evaluation***

**Number per group**
89 schools were approached and 53 (60%) agreed to participate (I, 27 schools, 4660 students; C, 26 schools, 4641 students)

One intervention school dropped out after randomisation (227 students, 4.9%)

Participation in the cohort depended on filling in the baseline questionnaire, and over 90% of potential participants were recruited (I, 4125 (93.1%); C, 4227 (91.1%))

Completed computerised intervention: first term, 3930 (95.3%); second term, 3735 (90.5%); third term, 3603 (87.3%)

Completed follow-up questionnaire: I, 3684 (89.3%); C, 3760 (89.0%)

Of the 8352 students, 7444 (89.1%) were followed up and smoking status could be allocated to 7413 (99.6% of those followed up); 7147 (96.0% of those followed up) gave consistent answers

PC1: Completed 2-year follow-up questionnaire: I, 86.0%; C, 83.1%

At year 2 follow-up: two control schools refused permission to administer the questionnaire because of concern about the time taken. These schools had 136 and 153 pupils enrolled in the trial. Not counting these in the percentage, 6819 (84.6%) original participants were present at the 2-year follow-up. Smoking status was allocated to 6782 participants (99.5% of those followed up)

Many (45.8%) absent from 1-year follow-up were present at 2-years follow-up, suggesting that the main reason for loss of follow-up was non-attendance at the particular lesson when the questionnaire was administered

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S025, Aveyard (1999)**[69]

***Additional comments***

**Authors' conclusion**
"The smoking prevention and cessation intervention based on the transtheoretical model, as delivered in this trial, is ineffective in schoolchildren aged 13–14"

The study showed that smokers were less likely to be present and more likely not to take long enough on the expert system, and that they felt that the expert system was less valuable. This study shows that the intervention based on the TTM had no effect on the prevalence of regular smoking. Examination of the subgroups by initial smoking status revealed no effect

**Other comments**
The authors were criticised by Prochaska (Letter, *BMJ* 2000;**447**): "Aveyard *et al*. applied the adult dose for smoking to an adolescent population. They should have use 6 to 8 expert system interventions over 2 academic years"

Reply by author: "expert system only tested in adults, there is no evidence on how many sessions adolescents might need"

PC (P. Aveyard *et al*., 2001): The authors sent a paper with results after 2 years which was accepted for publication, and a draft version of a publication on measurement of stage of change

PC1 (P. Aveyard *et al*., 2001): The change in stage and updated smoking status results from a cluster randomised trial of smoking prevention and cessation using the TTM in British adolescents. (Article accepted for publication)

PC2 (P. Aveyard *et al*., 2001): Can the stages of change for smoking acquisition and cessation be measured reliably in adolescents? (Article submitted for publication)

**Authors' conclusion**
The intervention was ineffective

## Data extraction table *contd*

| *Study reference No., author (year), country of origin, aim, design details* |
|---|
| **S446, Baker (1999)**[61]<br><br>**Country**<br>UK<br><br>**Aim**<br>To investigate the effectiveness of a personalised tailored leaflet in modifying behaviour, knowledge and attitudes relating to fruit and vegetable (F + V) intake<br><br>**Model**<br>TTM<br><br>**Theoretical basis**<br>The theoretical basis for the tailoring of the intervention was Prochaska and DiClemente's stage-of-change model (1992)<br><br>**Study type**<br>RCT<br><br>**Design**<br>An RCT with a questionnaire 6 months before the baseline for stage assessment, baseline (intake, attitudes, stage of behavioural change and nutritional knowledge) and 6-weeks follow-up assessment (changes in knowledge, attitudes and behaviour)<br><br>**Setting**<br>Home<br><br>**Length of intervention**<br>6 weeks |
| *Inclusion/exclusion criteria* |
| **Participants**<br>Lifestyle risk<br><br>**Population**<br>No details given<br><br>**Inclusion criteria**<br>Not stated<br><br>**Exclusion criteria**<br>Not stated<br><br>**Behaviours targeted**<br>F + V intake |
| *Intervention details* |
| **Intervention group**<br>Received a mailed leaflet tailored to their answers to a questionnaire completed approximately 6 months before the baseline<br><br>**Comparison group**<br>No treatment<br><br>**Classification into stages**<br>Not stated<br><br>**Validity of measure**<br>Not stated<br><br>**Training of educators**<br>Not applicable |
| *continued* |

## Data extraction table *contd*

***contd***
**S446, Baker (1999)**[61]

***Baseline characteristics***

**Gender**
Not stated

**Age**
Not stated

**Stage of change**
Not stated

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
Not stated. Authors report an *F* test (see behaviour change), which looks as if ANOVA analyses were performed

**Behaviour change**: intake of F + V. There was a significant difference between groups over time in consumption of both F + V with I increasing F + V intake more than C ($F(1 \text{ to } 634) = 36.71$, $p < 0.001$)

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**: attitudes. I had more positive attitudes at follow-up compared to C

**Adverse effects**
Not stated

**Other outcomes**: nutritional knowledge. I increased in their nutritional knowledge compared to C

Positive changes in knowledge and attitudes were associated with increases in F + V in I only

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
658 (89%) participants responded at follow-up (no numbers per group presented)

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

These data are based on an abstract only

Request for more information from authors: no reply

**Authors' conclusions**
The results indicate that a low-intensity tailored intervention can have a significant impact on dietary choice, nutritional knowledge and dietary attitudes. The results also show the value of assessing psychological outcomes such as knowledge and attitudes to help shed light on the process of behavioural change

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S290, Berman (1995)**[42]

**Country**
USA

**Aim**
To test the effectiveness of a preventative health programme featuring smoking cessation tailored to an under-served, multi-ethnic (Latino and African–American) adult population of smokers

**Model**
TTM

**Theoretical basis**
Not stated specifically

Brief, tailored smoking cessation booster messages were delivered to intervention respondents at the end of the 3- and 6-month interviews, based on point-prevalence smoking status and history (i.e. quit and relapse experience during programme participation). The intervention respondents also received a tailored support letter based on smoking status, referring to specific sections of the smoking-cessation materials

**Study type**
RCT

**Design**
A quasi-experimental design was used. Randomisation of two sets of schools was done by coin toss. 33 sites used in the adult education programme were assigned based on proximity to or location within the intervention or control 12th grade schools. Parents of K-12 children were invited to intervention or control screenings based on the schools their children attended. And adult students were invited based on their own classroom sites. Walk-in participants were entered into either condition according to the screenings they attended. Participants were interviewed at enrolment and at 3-, 6- and 12-month follow-up to assess changes in smoking related knowledge, attitudes and practices

**Setting**
Community

**Length of intervention**
12 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
446 low-to-middle income multi-ethnic adults within an inner-city school district (I, *n* = 267; C, *n* = 179)

Data regarding smoking behaviours during the follow-up period are for the participants who were current smokers at enrolment, *n* = 348

**Inclusion criteria**
The authors state, "the decision was made not to turn away any community member who wished to participate, regardless of smoking status"

Overall, 78% (*n* = 348) of participants were current smokers, 18.8% (*n* = 84) were former smokers, 2.9% (*n* = 13) were never smokers, and smoking status was not available for one participant

**Exclusion criteria**
None stated

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
Received health education materials targeting cardiovascular risk factors, *n* = 267

Received the ALA *Freedom from Smoking for You and Your Family* (English) or the *Guia Para Dejar de Fumar* (Spanish). Also invited to participate in a seven-session (1.5 hours per session) smoking cessation group class conducted after the 6-month follow-up. English and Spanish classes were conducted utilising the ALA's 'Freedom from Smoking' (or 'Guia Para Dejar de Fumar') programme, modified by ALA/Puerto Rico

Brief, tailored smoking cessation booster messages were delivered at the end of 3- and 6-month interviews, based on point-prevalence smoking status and history. Also received a tailored support letter based on smoking status, referring to specific sections of the smoking cessation materials. Finally, support and additional information from programme personnel was made available

**Comparison group**
Received health education materials targeting cardiovascular risk factors, *n* = 179

*continued*

# Data extraction table *contd*

***contd***
**S290, Berman (1995)**[42]

***Intervention details* contd**

**Classification into stages**
A modified version of the Prochaska and DiClemente stages-of-change instrument was used to assess readiness to stop smoking at the baseline and at each follow-up time point for the participants who had been smoking at the baseline

Six questions and two indicators were utilised to establish stage of change, modified slightly from Prochaska and DiClemente (1983) as follows:
1. Do you currently smoke one or more cigarettes a day?
2. Are you currently trying to stop smoking?
3. Are you seriously considering stopping in the next 6 months?
4. Are you seriously considering stopping in the next month?
5. Have you stopped smoking for at least 24 hours (baseline – in the past year; follow-up – since enrolling in the study (since we last spoke))?

Follow-up only (6–8):
6. Since the last time we spoke, how many days in total were you not smoking?
7. Indicator of continuous abstinence in the last 3 months
8. Indicator of continuous abstinence in the last 6 months

**Validity of measure**
Not stated

**Training of educators**
Not stated

***Baseline characteristics***

**Gender**
50.9% female

**Age**
Mean age (SD): 36.7 (9.7) years

**Stage of change**
Precontemplators (15.2%, *n* = 53), contemplators (39.4%, *n* = 137), preparation (45.4%, *n* = 158)

**Target behaviour**
Smoking cessation: not stated

***Results***

**Statistical techniques**
$\chi^2$ tests were used to examine differences between I and C. Since there was no intervention effect upon smoking cessation, logistic regression models were fitted in order to determine other predictors of point prevalence abstinence at 3, 6 and 12 months

**Behaviour change**
Self-reported abstinence was conceptualised in 4 ways:
Ever quit at 12 months (quit for at least 24 hours at any time during the 12-months follow-up period): I, 89.9%; C, 93.0% (*n* = 218, NS)
Point prevalence abstinence at each follow-up period (3/6/12 months) (did not smoke any cigarettes in 7 days prior to follow-up): I, 25.3%/15.5%/16.9%; C, 18.0%/21.6%/16.3% (*n* = 217/237/218; NS)
Multiple point prevalence regardless of interim status (3 and 6 months/3, 6, and 12 months) (did not smoke any cigarettes in 7 days prior to all designated follow-ups): I, 11.1%/7.9%; C, 12.5%/8.7% (*n* = 169/132; NS)
Continuous abstinence across time points involving no intervening smoking between follow-up points (3 and 6 months/6 and 12 months/3, 6 and 12 months) (not smoking for 7 days prior to first designated follow-up and remained abstinent thereafter): I, 7.4%/5.1%/6.4%; C, 10.2%/4.8%/7.3% (*n* = 169/184/132; NS)

Smoking cessation: None of the I–C comparisons showed a significant difference, indicating no between-group differences regarding smoking status at the baseline or cessation throughout the follow-up period. Overall, 91.8% of participants reported ever having quit smoking for at least 24 hours during the 12 months of study. Among those participants for whom data were available across all time points (*n* = 132), continuous abstinence rate at 12 months was 6.8% (*n* = 9). Utilising the more conservative estimate (assuming those for whom data were missing had never quit), the ever-quit and continuous abstinence rates at 12 months declined to 57.5% (*n* = 200) and 2.6%, respectively. Self-reported point prevalence abstinence rates were 21.2%, 18.9%, and 16.5% for those participants contacted at 3, 6 and 12 months. These rates declined to 13.2% (*n* = 46), 12.9% (*n* = 45) and 10.3% (*n* = 36) utilising the more conservative assumptions

**Stage movement**
Only descriptive data presented. Overall, 72% of precontemplators, and 66% of contemplators evidenced stage progression over the follow-up, but only 19% of those in the preparation stage moved forward

**Health**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S290, Berman (1995)**[42]

***Results* contd**

**Intermediate outcomes**
Significant predictors of smoking status: Participants who were more addicted to cigarette smoking at the baseline were less likely to be abstinent at any of the follow-up points. Contemplators and contemplators ready for action (prepeparation) were more likely to be abstinent at 3 and 6 months. Men were less likely than women to be abstinent at 6 months, the only time point at which a gender difference emerged

**Adverse effects**
None stated

**Other outcomes**
None stated

**Implementation measures**
Participation in smoking cessation group classes (Spanish/English/total):
Expressed interest (baseline): 75/32/107
Received letter/agreed to participate (6 months follow-up): 25/24/49
Attended: 9/17/26
Attended at least 50% of (7) sessions: 5/13/18
Stopped smoking by end of programme: 2/3/5
Interested in booster session: 0/8/8
Attended booster session: 0/4/4

At the 12-months follow-up, over 89.9% (196/218) of respondents reported having read any of the materials, and 92.3% (181/196) of these reported that they had read the stop-smoking components (38.1% (69/181) very thoroughly)

***Withdrawals/economic evaluation***

**Number per group**
446 enrolled: I, 267; C , 179. Data regarding smoking behaviours during the follow-up period are for the participants who were current smokers at enrolment, $n$ = 348

Of those smoking at enrolment, 217, 237 and 218 participants were recontacted at 3-, 6- and 12-month follow-up

118 completed re-screening at 12 months: I, 68; C, 50

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
None stated

**Cost outcomes**
None stated

***Additional comments***

**Authors' conclusions**
No differences were found between intervention and control participants with regard to smoking cessation. There are significant difficulties in attempting to deliver preventive healthcare services through inner-city public school districts. Innovative strategies must be identified to address the pressing unmet healthcare needs in many US communities

**Authors' reported limitations**
The programme components were not tailored to the individual's stage of change at enrolment – the same intervention was utilised for all participants within each condition

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S089, Braatz (1999)**[56]

**Country**
USA

**Aim**
To answer the following research questions:
1. Do low-income elderly individuals exposed to a 15-week intervention designed in accordance with the TTM (a) sustain, advance or regress in their stage of change toward a more active lifestyle, and (b) change more than a group of controls who do not receive the treatment condition?
2. Do low-income elderly individuals exposed to a 15-week physical activity intervention based on the TTM sustain, advance, or regress in their stage-of-change level 2 months after the intervention?
3. Do low-income elderly adults who identify their stage of change as action or maintenance use more behavioural processes of change than those who identify their stage of change as precontemplation, contemplation, or preparation?

**Model**
TTM

**Theoretical basis**
The TTM provides a testable framework for systematically developing, testing, and refining behaviour change programmes in the area of physical activity

The TTM has two components: stages of change (readiness to change a behaviour) and processes of change (strategies to change a behaviour). A successful intervention would advance a person's stage of change toward a more active level

**Study type**
RCT

**Design**
The research designs used in this study were a non-equivalent control group with a delayed treatment and a pretest–post-test

Nine low-income elderly housing units constituted the population of sites for the study. Each housing unit, in the pool of qualifying units, was assigned a number. Originally, the investigator randomly selected two housing units (numbers 1 and 2) from the pool and sent an information letter about the study to the housing site manager. One week later, the investigator telephoned the manager to answer questions and schedule an informational meeting. At this meeting, the investigator explained the study, answered questions, and obtained approval to conduct the study. The two consenting sites were then randomly assigned to control and experimental sites. An insufficient number of subjects volunteered at the experimental site (see following section on recruitment). Accordingly, the third randomly identified housing site was selected from the pool. That site was contacted, and the same protocol was followed as in the original two housing units. Upon consenting to participate, the third housing site became experimental site 2. The three randomly selected housing units represented 518 units, approximately one-third of the total units

Volunteers were recruited from the three low-income elderly housing sites (two experimental and one control). The control site received the 15 week intervention after the experimental sites. Data were collected at three times related to the intervention protocol: pre-intervention (week 2) and postintervention I (week 14) and postintervention II (week 28). Postintervention II is after the control group have received their intervention

**Setting**
Community

**Length of intervention**
15 weeks with follow-up 2 months postintervention

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Elderly from low-income elderly housing units within the Tri-County Office on Aging in Michigan ($n$ = 46)

**Inclusion criteria**
Site selection criteria were (a) a minimum of 100 living units, (b) head of household at least 62 years of age, and (c) a room large enough to accommodate 30 chair/wheelchair exercise participants

Participant criteria were: (a) age (at least 60 years of age), (b) completing the first evaluation form before the health fair, and (c) returning all three evaluation forms (preintervention, postintervention I, and postintervention II)

**Exclusion criteria**
Those who joined late and those who signed consent forms but did not complete postintervention I and postintervention II evaluation forms

**Behaviours targeted**
Inadequate exercise

*continued*

# Data extraction table *contd*

***contd***
**S089, Braatz (1999)**[56]

***Intervention details***

**Intervention group**
The intervention consisted of a 3-week promotional and recruitment period followed by a 15-week educational and physical activity program entitled 'Unlock the Door to Better Health, Physical Activity Is the Key'. The 15-week program included a health fair, educational programmes, a chair exercise program, and a contract physical activity program. All intervention events were held at the housing sites, in the community room, library, or game room. The investigator led all intervention events except two chair exercise sessions per site (six total). A trained graduate student substituted at those sessions. The same graduate student measured height and weight at the health fair and helped two subjects who had visual impairments to perform the chair exercises correctly ($n$ = 27)

**Comparison group**
Participants at all sites were provided with the same promotional protocol, though participants in the comparison group did not receive the subsequent treatment ($n$ = 19)

**Classification into stages**
Adapted stage-of-change instrument designed by Marcus *et al.* (S145)

The adaptation used five levels of change and an updated definition of regular physical activity or exercise

The definition used in this study was an accumulation of 30 minutes of moderate-intensity physical activity on at least 4 days of the week. The original definition used by Marcus *et al.* (S145) was three or more times per week for 20 minutes or more at each time (ACSM, 1990). The original definition represented a fitness benefit rather than a health benefit. The health benefit standard was selected because it was consistent with the current ACSM guidelines and was more appropriate for older adults

**Validity of measure**
A pilot study was used to establish test–re-test reliability for the stages-of-change instrument. Eight female subjects completed the stage-of-change section of the evaluation form on two occasions, (4 days apart), to assess the test reliability. Test–re-test reliability was 0.67 for the stages of change. Between trials, the investigator learned that the pilot subjects had discussed how to respond to the test instruments. These discussions may have negatively affected the reliability of the instruments. Due to the interaction of subjects, small sample size, and an inability to replicate the pilot with a larger group, justification to use the instruments was based on prior research

The reliability of the exercise stages-of-change instrument was tested in S145. Reliability was determined by test–re-test, using a worksite population over 2 weeks. A kappa index of 0.78 was reported

Concurrent validity for the stages of change was assessed with the 7-Day Recall Activity Questionnaire (S258)

S145: The first study (instrument development) was based on a four-item version. Conclusion: scores on efficacy items significantly differentiated employees at most stages. No additional validity information regarding this four-item scale. The scale was refined, adding one item: preparation. This five-item scale showed that total scores on the self-efficacy items reliably differentiated employees at different stages. The proportion of variance accounted for was 0.28. Test–re-test reliability (kappa index) for the stages-of-change instrument over a 2-week period was 0.78 ($n$ = 20)

S258: Used a slightly different scale. Conclusion: scores on physical activity behaviour items significantly differentiated employees among the stages. No additional information on validity

**Training of educators**
Not stated

***Baseline characteristics***

**Gender**
93% female

**Age**
Mean (SD): 77 (7.25) years

**Stage of change**
In the experimental group, 14 of the 27 subjects were at maintenance, the highest stage of change. This left only 48% (13 out of 27) of the experimental group with any potential to advance their stage of change. In the control group, 5 of 19 subjects were at maintenance, leaving 74% (14 out of 19) with the potential to advance their stage of change

**Target behaviour**
Physical activity: not reported

*continued*

# Data extraction table *contd*

***contd***
**S089, Braatz (1999)**[56]

***Results***

**Statistical techniques**
Research question 1 addressed the effect of the 15-week intervention treatment on altering participants' stage of change. An ANCOVA was used to determine differences in the non-equivalent control group design. A *t*-test of dependent samples was used to determine the pretest–post-test differences within experimental groups. These tests were selected to be consistent with previous research (Marcus *et al.* (S145))

Research question 2 addressed the maintenance, advancement, or regression of the stage of change at least 2 months after termination of the physical activity programme. A Wilcoxon matched-pairs signed rank test was used to determine significance of the difference in subjects' stages of change at these points in time

Research question 3 addressed participants' use of behavioural processes of change during early and late stages of change. A *t*-test for independent samples was used to compare the composite score for behavioural processes of change of early stages of change (precontemplation, contemplation and preparation) with the composite score for behavioural processes of change used during late stages of change (action and maintenance)

**Behaviour change**
Physical activity. In this study, a written 7-Day Physical Activity Recall instrument was used as in the Marcus and Simkin study (S258). The recall instrument was used to identify the amount of time a subject spent in physical activity

No data reported

**Stage movement**
Stage of change

Q1. Intervention effect: The postintervention stage of change was compared between the experimental and control groups, with the preintervention stage of change used as a covariate. A significant difference was found between the first experimental group and control group, the mean stage of change for the experimental group was significantly higher than for the control group

Mean (SD) stage of change-scores:
I ($n$ = 17): pretest, 4.47 (0.80); post-test, 4.53 (0.72)
C ($n$ = 19): pretest, 3.42 (1.12); post-test, 4.11 (1.10). $F(2, 35) = 12.58$, $p = 0.001$

Q2. Postintervention effect: 20 out of 22 subjects (91%) sustained or advanced their stage of change 2 months postintervention. Of the seven experimental subjects who advanced their stage of change during the intervention, five sustained (71%) and two advanced (29%) their stage of change 2 months postintervention. Of the 14 experimental subjects who sustained their stage of change during the intervention, 11 sustained (78%), two advanced (14%), and one regressed (7%) their stage of change 2 months postintervention. The one subject who regressed went from maintenance to action. During one-half of the 2-month postintervention period, she had reduced her physical activity level below the maintenance standard of accumulating 30 minutes of physical activity at least four times a week for 6 continuous months

**Health**
Not stated

**Intermediate outcomes**
Q3: Processes of change × stage of change: The results of the *t* test ($t(39) = 1.40$, $p = 0.17$) indicated no significant difference between the use of behavioural processes of change by the action and maintenance group (late) as compared to the precontemplation, contemplation, and preparation group (early)

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Attendance was recorded at all meetings associated with the programme (group sessions, the health fair, educational programmes, contract lectures, and sessions of the physical activity programme)

Excluding the contract option, there were 51 intervention sessions. Participant attendance ranged from 1 to 41 sessions (2% to 80% attendance, respectively). Attendance at the chair exercise sessions varied from 0 to 33 (92%) out of a total of 36 sessions

Participation in the intervention programme: health fair, 85%; education lecture 1, 26%; education lecture 2, 59%; contract log, 19%; contract lectures (mean), 5.0 (SD = 3.7, range = 0–11); chair exercise (mean), 13.59 (SD = 10.71, range = 0–33)

To determine the intervention effect, a criterion of 60% attendance in either the educational programmes (9 out of 15) or the chair exercise sessions (22 out of 36) was established. This criterion was perceived to be the minimum exposure necessary to categorise an individual as a participant in the intervention programme. Seventeen subjects met the 60% criterion to analyse the intervention effect

*continued*

## Data extraction table *contd*

***contd***
**S089, Braatz (1999)**[56]

***Withdrawals/economic evaluation***

**Number per group**
103 consenting volunteers (I, 61; C, 42), 50 failed to meet the inclusion criteria (e.g. too young). 46 participants were included in the data analysis (I = 27, C = 19)

**Reasons**
50 failed to meet the inclusion criteria: five late entry (I, 2; C, 3); eight too young (I, 7; C, 1); 2 chronic disease (C, 2); one moved (C, 1); 12 illness (I, 7; C, 5); 12 other (I, 8; C, 4); ten no response (I, 6; C, 4)

The remaining 53 volunteers were used as subjects for the study. Two of these subjects did not turn in the postintervention I evaluation form but continued to participate in the study. Of the 51 remaining respondents, five were lost due to incomplete data, leaving 46 respondents for data analysis

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusions**
1. Low-income elderly volunteers significantly advanced their stage of change toward a more active lifestyle after a 15-week physical activity intervention programme
2. Low-income elderly volunteers sustained or advanced their stage of change 2 months postintervention
3. Behavioural processes of change were used more (but not significantly so) by low-income older adult volunteers in the action and maintenance stages of change than by low-income older adults in the precontemplation, contemplation and preparation stages of change

**Authors' stated limitations**
The sites chosen for the study offered different opportunities for elderly people to engage in physical exercise, e.g. gardening facilities

Page 92: Although subjects at all sites were provided the same promotional protocol before receiving the treatment, the effect of the promotional activities on subjects at the control site may have affected these subjects' increase in activity level before the intervention. Knowledge that a physical activity intervention was coming to the control site in fall could have increased the control subjects' awareness of their physical activity habits

Also, the recruiting of subjects in late May, when the weather was conducive to more outdoor activity, could have affected the control subjects' physical activity patterns before the treatment. These two factors could account for some of the advancement in the stage of change that occurred before the control group received the complete physical activity intervention in the non-equivalent control group design

Page 93: Several factors could have influenced the results. Two of these possible influences were season of the year and available facilities. First, the three (experimental 1, experimental 2, control), 15-week interventions spanned a 6-month period. Second, the control site offered garden plots to residents. Several of the residents at the control site started gardens after the pre-intervention evaluation data collection and maintained the garden through the postintervention I evaluation data collection. The garden plots provided an additional opportunity for these residents to be physically active, before they received the intervention, and may have confounded the intervention effect. Garden plots were not available at either of the experimental housing sites

There was a significant difference in baseline stage of change between the intervention and control groups (intervention higher), though initial stage of change was used as a covariate in the analysis. The sample size was small

**Comment**
Not clear to what extent individuals received feedback tailored to their particular stage of change

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S288, Brug (1998)**[38]

**Country**
The Netherlands

**Aim**
To study the impact of individualised computer generated nutrition information and additional effects of iterative feedback on changes in intake of fats, fruits and vegetables

**Model**
TTM + Precaution Adoption Process (tailoring)

**Theoretical basis**
Based on existing studies (TTM and Weinstein's Precaution Adoption Process), it was concluded that nutrition education should focus on making people aware of their dietary intake levels before making suggestions for change

Respondents in the experimental group received computer-generated feedback letters tailored to their dietary intake, intentions, attitudes, self-efficacy expectations, and self-rated behaviour

**Study type**
RCT

**Design**
Participants were recruited through advertisements in 35 local newspapers in various Dutch regions and two national newspapers. Registration was stopped after 800 participants had enrolled based on power analysis that was based on a 5% difference in fat score between study groups at post-test and a 20% expected drop-out between registration and second post-test. Participants were randomly assigned to one of three study groups and were sent a 69-item screening questionnaire. Baseline data were collected on dietary intake, self-rated intake and psychosocial factors. I1 and I2 were sent a computer tailored nutrition education letter based on their responses to the screening questionnaire. C received a letter with general nutrition information. A further questionnaire was sent out at 4 weeks after the first feedback (first post-test). I1 received an iterative feedback letter (second post-test) based on their answers to the first post-test questionnaire and the differences between first post-test and baseline measurements. All participants were surveyed a third time 4 weeks after I1 had received the second post-test letter. Other participants in I2 and C did not receive additional contact between first and second post-test

**Setting**
Community

**Length of intervention**
8 weeks

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Participants were recruited through advertisements in 35 local newspapers in various Dutch regions and 2 national newspapers

**Inclusion criteria**
Not stated

**Exclusion criteria**
Not stated

**Behaviours targeted**
Fat, fruit and vegetable consumption

***Intervention details***

**Intervention group**
I1: Received computer-generated feedback letters tailored to their dietary intake, intentions, attitudes, self-efficacy expectations, and self-rated behaviour
I2: Same as I1 and, after the first feedback letter, half of the experimental group received additional iterative feedback tailored to changes in behaviour and intentions

**Comparison group**
Received a single general nutrition information letter (leaflets from the Dutch Nutrition Education Bureau) in a format similar to the tailored letters

*continued*

# Data extraction table *contd*

***contd***
**S288, Brug (1998)**[38]

***Intervention details* contd**

**Classification into stages**
No explicit stages-of-change assessment described

Participants were asked about their attitudes related to reducing fat intake and increasing fruit and vegetable intake with single items on seven-point scales ('very bad' to 'very good'), and about self-efficacy expectations toward these dietary changes on seven-point scales ('very difficult' to 'very easy'). Intentions and past and present efforts to change fat, fruit and vegetable consumption were assessed on seven-point scales ('definitely not' to 'definitely so') (see intermediate outcomes)

The interventions were tailored to respondents' dietary intake, intentions, attitudes, self-efficacy expectations, and self-rated behaviour

The message source file consisted of 223 different feedback messages. Different dietary feedback messages were written for various categories of dietary behaviour for fat, fruits and vegetables. The messages were also tailored to the way participants rated their own consumption

S53: Stages of change were assessed by a four-item algorithm based on measures in previous similar studies (e.g. Glanz *et al.* (S30), Sporny *et al.* (S600)). Stages of change for fruit consumption are described, S53 also reports data on stages of change for vegetable consumption

Action for fruit consumption: when they were presently trying to eat more fruit

Maintenance: when they reported currently eating adequate amounts of fruit and had not increased their fruit consumption in the past 6 months

Preparation: when they intended to increase their consumption within 1 month

Contemplation: when they intended to increase their consumption within 6 months but not in the next month

Precontemplation: when they did not report eating adequate amounts of fruit and did not intend to increase their fruit intake

**Validity of measure**
Not stated

S30: No data on validity of stage-of-change measure

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
82% female

**Age**
Mean age: 44 years (SD = 14)

**Stage of change**
S53: Stages of change for vegetable consumption: 48% maintenance; 33% preparation; 6% precontemplation; 8% contemplation; 5% action. No percentages for intervention groups presented

Stages of change for fruit consumption: 40% maintenance; 36% preparation; 9% precontemplation; 8% contemplation; 5% action. No percentages for intervention groups presented

**Target behaviour**
Mean fat score: 27.2 (SD = 5.2)

Mean number of daily servings of vegetables: 1.0 (SD = 0.4)

Mean number of daily servings of fruit: 2.2 (SD = 1.7)

***Results***

**Statistical techniques**
It was hypothesised that (1) computer-tailored feedback (I1 + I2) would be more effective in stimulating participants to reduce their consumption of fat and increase their consumption of fruits and vegetables than general feedback (C), and that (2) computer-tailored iterative feedback (I2) would significantly enhance the longer term dietary changes

ANOVAs were used to test for baseline differences between the three study groups to detect possible confounding variables. To test whether there were differences in baseline scores between respondents who participated in the entire experiment and drop-outs before the final post-test and to test whether study group was a significant determinant of drop-out, logistic regression analysis was conducted with drop-out (yes/no) as the dependent variable and gender, age, consumption scores, and study group as independent variables

$\chi^2$ tests were used to study differences in the participants' reactions to the nutrition information letters between the three study groups. One-way ANOVAs were used to study differences in the participants' opinions of the nutrition information letters. Descriptive statistics were used to describe the reactions of participants to the iterative feedback letters

Repeated measures ANOVAs were conducted to study differences in mean consumption of fat, fruits and vegetables at the two post-tests, with study group as a between-participants factor, the two post-tests as within-participants factor, and consumption scores at the baseline as covariate. When a significant time-by-group interaction effect was found, ANCOVA was used to study differences in mean consumption scores between the three groups at each post-test separately, again with consumption scores at the baseline as covariate. When a significant group effect was found, pairwise comparisons were conducted to study which specific groups differed significantly in mean consumption scores

All analyses were conducted using 646 respondents (91.8%) who completed all assessments

*continued*

# Data extraction table *contd*

***contd***
**S288, Brug (1998)**[38]

***Results* contd**

**Behaviour change**
Intake levels of fat, fruits and vegetables (dietary intake, self-rated intake). Food-frequency questionnaire (32 items), which assesses fat scores and number of servings of fruits and vegetables. The fat score (range 12–60) is the result of a short food frequency questionnaire in which the frequency of use and portion size of the 12 main fat sources in the Dutch diet are assessed

Mean (SD) fat, fruit and vegetable intake at the baseline (T1), first post-test (T2), and second post-test (T3):

**Fat** (fat points per day):
I1: T1, 28.0 (5.3); T2, 26.4 (5.3); T3, 26.2 (5.2)
I2: T1, 28.3 (5.4); T2, 27.0 (4.9); T3, 25.6 (4.6)
C: T1, 28.2 (5.2); T2, 28.3 (5.4); T3, 27.5 (5.6)

Group effect: $F(2) = 17.1$, $p < 0.001$. Pairwise comparison: I1 and I2 did significantly better than C ($p < 0.001$). No significant differences between I1 and I2

Group-time interaction: $F(2) = 5.5$, $p < 0.01$. At first post-test a significant group effect: $F(2) = 13.0$, $p < 0.001$. Pairwise comparison: I1 and I2 significantly lower mean fat scores than C ($p < 0.001$), but no significant difference between I1 and I2. At second post-test a significant group effect: $F(2) = 15.4$, $p < 0.001$. Pairwise comparison: I1 and I2 significantly lower mean fat scores than C ($p < 0.001$), and I2 significantly lower mean fat scores than I1 ($p = 0.02$)

**Fruit** (servings per day):
I1: T1, 2.18 (1.72); T2, 2.25 (1.51); T3, 2.18 (1.47)
I2: T1: 2.13 (1.70); T2, 2.42 (1.66); T3, 2.45 (1.69)
C: T1: 2.09 (1.75); T2, 2.09 (1.56); T3, 2.02 (1.59)

Group-effect: $F(2) = 5.5$, $p < 0.01$. Pairwise comparison: I2 did significantly better than I1 ($p < 0.03$) and C ($p < 0.002$). No significant differences between I1 and C

Group-time interaction: NS

**Vegetables** (servings per day):
I1: T1, 1.06 (0.41); T2, 1.13 (0.41); T3, 1.15 (0.41)
I2: T1, 1.06 (0.38); T2, 1.14 (0.38); T3, 1.20 (0.36)
C: T1, 1.02 (0.36); T2, 1.05 (0.37); T3, 1.08 (0.41)

Group-effect: $F(2) = 5.2$, $p < 0.01$. Pairwise comparison: I1 and I2 did significantly better than C ($p < 0.001$). No significant differences between I1 and I2

Group-time interaction: $F(2) = 2.13$, $p < 0.12$. At first post-test a significant group effect: $F(2) = 3.1$, $p = 0.05$. Pairwise comparison: I1 ($p = 0.04$) and I2 ($p = 0.02$) significantly higher mean vegetable scores than C, but no significant difference between I1 and I2. At second post-test a significant group effect: $F(2) = 5.8$, $p < 0.01$. Pairwise comparison: I2 significantly higher mean vegetable scores than C ($p = 0.001$), but no significant difference between I1 and I2 ($p = 0.07$), and no significant difference between I1 and C

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Psychosocial factors: A number of psychosocial variables were assessed (27 items). Respondents were asked to rate their own intake levels of (fat, fruits and vegetables) and to compare their intake levels to those of others in their age-gender group

Participants were asked about their attitudes related to reducing fat intake and increasing fruit and vegetable intake with single items on seven-point scales ('very bad' to 'very good'), and about self-efficacy expectations toward these dietary changes on seven-point-scales ('very difficult' to 'very easy'). Intentions and past and present efforts to change fat, fruit and vegetable consumption were assessed on seven-point scales ('definitely not' to 'definitely so')

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
I1 and I2 were more likely to have read the letter (I1 + I2, 99%; C, 93%, $p < 0.01$) and to have discussed it with others (I1 + I2, 71%; C, 45%, $p < 0.01$). They more often reported changing their diet (I1 + I2, 56%; C, 19%, $p < 0.01$), their opinion about diet (I1 + I2, 62%; C, 26%, $p < 0.01$) or intending to change their diet as a result of the nutrition information leaflet they received (I1 + I2, 69%; C, 46%, $p < 0.01$)

Respondents opinions of nutrition information letters at first post-test (range: –3 = very negative, 3 = very positive) (SD):
How interesting: I1 + I2, 1.73 (1.58); C, 0.79 (1.86). $p < 0.01$
How personally relevant: I1 + I2, 1.15 (1.84); C, –0.17 (1.85). $p < 0.01$
How much was new: I1 + I2, –0.44 (1.81); C, –1.60 (1.45). $p < 0.01$
How credible: I1 + I2, 1.49 (1.80); C, 1.98 (1.54). $p < 0.01$
How difficult or easy to understand: I1 + I2, 2.51 (0.91); C, 2.60 (0.80). NS

I1: 99% read the feedback letter; 65% discussed the letter with others; 71% found the letter interesting; 68% found it personally relevant; 73% reported having changed their diet as a result of the nutrition information



*continued*

## Data extraction table *contd*

***contd***
**S288, Brug (1998)**[38]

***Withdrawals/economic evaluation***

**Number per group**
Registration was stopped after 800 participants had enrolled, baseline questionnaire was completed and returned by 762 respondents. The first post-test questionnaire was returned by 704 respondents (92.4%). The final post-test questionnaire was returned by 646 respondents (91.8%): I1, 215; I2, 211; C, 220

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Computer-tailored feedback (I1 and I2) had a significantly greater impact on fat reduction and fruit and vegetable intake than did general information. Iterative computer-tailored feedback (I2) had an additional impact on fat intake. The results confirm that computer-generated individualised feedback can be effective in inducing recommended dietary changes and that iterative feedback can increase the longer term Impact of computer-tailored nutrition education on fat reduction

**Comment**
Not clear whether intervention is stage-based (see 'Theoretical basis'), as not explicitly mentioned. And not clear how stage of change is assessed: might be 'intentions and past and present efforts to change fat, fruit and vegetable consumption' (assessed on seven-point scale). Second feedback letter was tailored to changes that respondents made in intake and intention after receiving their first tailored letter

The authors state: "The results indicate that computer-tailored nutrition education that addresses awareness, attitudes, and self-efficacy can guide respondents through different stages of change". However stage-of-change was not assessed

**Authors reported limitations**
Participants in I1 and C were not provided with an alternative intervention activity or a control for the amount of contact or attention. Therefore effects could be caused by extra attention. Selecting respondents through advertisements in local newspapers may have consequences for the generalisability of results

S53 does describe an algorithm for stage-of-change for fruit consumption, but does only present baseline data, the interventions are not mentioned

Asked authors for more information: no reply

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S402, Butler (1999)**[34]

**Country**
UK

**Aim**
To compare the clinical and cost-effectiveness of motivational consulting with brief advice to quit smoking

**Model**
TTM, self-efficacy, motivational interviewing

**Theoretical basis**
The stages-of-change model groups people according to their 'readiness to change'. The main clinical implication is that interventions, which are sensitive and responsive to people's attitude to change, should produce better outcomes than standard approaches for all

Self-efficacy theory holds that, for change to occur, people must believe that change is worthwhile (outcome expectations) and that they can succeed (efficacy expectations). Enhancing these expectations should therefore promote change

Motivational interviewing is a specialist technique for difficult behaviour change discussions. It relies on patients making decisions for themselves as opposed to clinicians telling them what to do. Patient-centred consultations produce better outcomes

Motivational consulting was developed from these theoretical and clinical antecedents, but is a brief method for use by generalists and does not rely on skilled use of reflective listening

**Study type**
Pragmatic randomised trial

**Design**
Randomised: sealed numbered envelopes in a study pack to be opened in order; blocks of six, order varied. Recruitment of patients, stage assessment, randomisation and intervention all in the same consultation. Questionnaire within 2 weeks of intervention, follow-up after 6 months (telephone calls for non-response)

Sample target size was 600 patients (300 in each arm). Based on meta-analyses results that 5% more smokers quit after brief advice, and that 15% quit after more intensive interventions. A 10% advantage of the new method over brief advice for point prevalence quitting was considered clinically significant. Allowing for up to 33% loss to follow-up, 600 patients would provide 80% power to detect a 10% difference in smoking cessation outcomes at a two-tailed significance level of 5%

General practice registrars were recruited to implement the trial

**Setting**
Primary care

**Length of intervention**
6 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
All smokers (excluding those with terminal illness) consulting one of 24 GPs in South Wales were eligible, regardless if their interest in giving up smoking. 536 randomised

**Inclusion criteria**
Smokers consulting a GP in South Wales

**Exclusion criteria**
Smokers with terminal illness were excluded

**Behaviours targeted**
Smoking

*continued*

# Data extraction table *contd*

***contd***
**S402, Butler (1999)**[34]

***Intervention details***

**Intervention group**
Motivational consulting is based on inviting patients to numerically rate their motivation and confidence to quit smoking (phase 1). Clinicians respond to these scores using specific questions and strategies (phase 2). The aim is to build motivation or confidence by encouraging the patient to identify arguments for change (motivation) or practical, attainable steps for quitting (confidence). Finally, patients are invited to set meaningful targets for themselves (phase 3) (S159)

**Comparison group**
Brief advice consisted of the following statement: "Smoking is an extremely serious matter. Apart from lung cancer, smoking can damage your health in many other ways. If you give up now, a lot of the harm can be undone. It is my professional duty to tell you that you must give up smoking in the interest of your future health"

**Classification into stages**
Questions devised by Prochaska *et al.* (S312): pre-contemplators (not thinking of quitting in the next 6 months)/contemplators (thinking of quitting in the next 6 months)/preparation (thinking of quitting in the next month)/action (in the process of quitting)

However, as in other pragmatic studies, the second criterion for the 'preparation stage' (previous attempt to quit lasting at least 24 hours in the preceding year) was omitted (S140) since this would include those preparing to quit for the first time (S428)

**Validity of measure**
Not stated

**Training of educators**
GPs were trained in motivational consulting for 2 hours (S159)

S159: Training consisted of an overview of the development of the patient centred clinical method, discussion of advantages and limitations of advice-giving using unscripted role-play and discussion, followed by explanation and demonstration of the alternative method. Trainees were given the opportunity to role play the quick assessment of motivation and confidence, as well as the subsequent phases of eliciting solutions from the patient and negotiating individualised goals and follow-up

***Baseline characteristics***

**Gender**
I: 70.4% female
C: 70.7% female

**Age**
Mean age (SD):
I: 41.44 (13.13) years
C: 41.35 (13.30) years

**Stage of change**
Stage of change assessed by clinician before randomisation (1 = precontemplation, 2 = contemplation, 3 = preparation, 4 = action):
I: 1, 49.4%; 2, 28.6%; 3, 10.4%; 4, 11.5%
C: 1, 53.2%; 2, 23.8%; 3, 9.4%; 4, 13.6%

**Target behaviour**
Mean number of cigarettes smoked daily preconsultation (SD): I, 19.07 (9.52); C, 16.61 (6.93). Ever tried to stop: I, 85.7%; C, 88.8%. Quit for 1 week or longer in past: I, 65.3%; C, 63.3%

***Results***

**Statistical techniques**
Analyses were on intention-to-treat basis. Participants lost to follow-up were regarded as smokers when assessing quitting and as 'missing' for all other outcomes. Comparisons between trial arms were made using Pearson's $\chi^2$ test, $\chi^2$ test for linear trend, Fisher's exact test and ORs with 95% CIs for categorical variables, and the unpaired *t*-test for continuous variables. To account for possible effects due to variation between clinicians adjusted 95% CIs for ORs and *p*-values were obtained by logistic regression using Stata. Numbers needed to treat with 95% CI were calculated as described by Cook and Sackett. To assess whether the effects of the intervention were modified by participants' prior stage of change as assessed by their GP, ORs were calculated separately for the less ready subgroup of precontemplative participants and the more ready subgroup of contemplative, preparative or active participants. This potential effect modification was tested statistically by entering an interaction term into logistic regression models

**Behaviour change**
Primary: point prevalence at 6 months of self-reported abstention in the previous month; and self reported abstention from smoking in the previous 24 hours

Secondary: making an attempt to quit, two or more attempts, an attempt lasting a week or longer, delaying smoking longer than 5 minutes after waking, reducing smoking

*continued*

# Data extraction table *contd*

***contd***
**S402, Butler (1999)**[34]

***Results* contd**

**Behaviour change *contd***
Smoking outcomes at 6-months follow-up:
Self-reported abstention in previous month (No. and percentage): I, 8 (3.0%); C, 4 (1.5%). OR = 2.00 (95% CI, 0.63 to 6.29)
Self-reported abstention in previous 24 hours (No. and percentage): I, 22 (8.1%); C, 8 (3.0%). OR = 2.86 (95% CI, 1.21 to 6.76)
Made a quit attempt, yes (No. and percentage): I, 95 (47.0%); C, 84 (40.2%). OR = 1.32 (95% CI, 0.89 to 1.97)
Two or more quit attempts (No. and percentage): I, 48 (24.0%); C, 50 (24.1%). OR = 0.99 (95% CI, 0.60 to 1.63)
Quit attempt lasting 1 week or longer (No. and percentage): I, 38 (18.8%); C, 24 (11.4%). OR = 1.80 (95% CI, 0.95 to 3.38)
Smokes within 5 minutes after waking (No. and percentage): I, 15 (7.9%); C, 33 (16.2%). OR = 2.25 (95% CI, 1.29 to 3.93)
Cut down, yes (No. and percentage): I, 72 (39.8%); C, 73 (37.2%). OR = 1.11 (95% CI, 0.68 to 1.81)

The likelihood of a successful outcome from I versus C appeared to be greater among those initially assessed by the clinician as less ready to quit (precontemplators) compared with those more ready (contemplators, preparation and action). Two significant differences in effect of I among less ready: self-report no smoking in previous 24 hours (OR = 5.41 (95% CI, 1.72 to 17.01)); quit attempt (OR = 1.84 (95% CI, 1.19 to 2.86)). No significant differences in effect of I among more-ready subgroup

**Stage movement**
Stage of change at 6-months follow-up:
I: 1,40.8%; 2,39.3%; 3,13.3%; 4,6.6%
C: 1,48.3%; 2,37.3%; 3,11.4%; 4,3.0%. $\chi^2$ linear trend = 3.83, $p$ = 0.05

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Qualitative interviews with patients revealed that patient-centred interventions like motivational consulting are acceptable, and that repeated brief advice to stop smoking can damage doctor–patient relationships and adversely effect help-seeking behaviour (no data reported)

**Implementation measures**
Not stated

Indirect evidence that physicians implemented the study according to protocol includes the fact that the stage of change was not recorded on data sheets for only two patients. Open questions about the spirit and practical aspects of the intervention during telephone interviews revealed satisfactory knowledge (no data reported)

***Withdrawals/economic evaluation***

**Number per group**
Randomised: I, 270; C, 266
2 weeks (baseline assessment): I, 237 (199 self-complete; 38 telephone; 33 (12.2%) lost); C, 243 (204 self-complete; 39 telephone; 23 (8.6%) lost)
6 months: I, 206 (145 self-complete; 61 telephone; 64 (23.7%) lost); C, 212 (155 self-complete; 57 telephone; 54 (20.3%) lost)

**Reasons**
Not reported

**Economic evaluation**
Yes

**Economic methods**
Cost of motivational consulting included training (time plus travel) plus the cost of longer consultations. Physician time was valued using the method of Netten and Dennett and travel was valued using Automobile Association costs. The duration and number of return visits to discuss quitting, and associated patient travel costs, were recorded. Marginal costs per quitter were assessed, and costs were compared for other outcomes

**Cost outcomes**
The marginal cost per quitter was £450.65 (may fall to an extreme of £265.00 with increased use; extra consultation time only, without training included). The marginal cost per reduction in addiction was £279.63 (£164.44 without training). The marginal cost per quit attempt was £311.99 (may fall to an extreme of £183.47 without training)

*continued*

## Data extraction table *contd*

***contd***
**S402, Butler (1999)**[34]

***Additional comments***

**Authors' comments**
Ideally smoking history would have been determined before the consultation, not to influence recall. Smoking history is significantly different between treatment arms at the baseline; authors explain this by seriously questioning the validity of self-report smoking behaviour. Biochemical validation of quitting was attempted, but uptake was low, and results did not alter conclusions

**Authors' reported limitations**
Brief advice (C) may have included elements of motivational consulting (I)

**Authors' conclusion**
I produces better outcomes than C, especially among those 'not ready to change'. This supports the stages-of-change model. Overall, however, few patients quit. More intensive training might produce better outcomes. If quitting is considered the only goal, I in its present form is not cost-effective in relation to other smoking cessation methods

**Comment**
No analyses reported for differences between baseline and follow-up outcomes. Patients were randomised, therefore contamination of the intervention within practices might have occurred (see authors' limitation)

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S305, Cardinal (1996)**[58]

**Country**
USA

**Aim**
To investigate the efficacy of mail-delivered, self-instructional exercise packets designed to motivate, encourage, and support women's movement through the SoE behaviour

**Model**
TTM

**Theoretical basis**
Interventions were based on the TTM and included an 'exercise success' story based on the modelling and self-efficacy constructs of social cognitive theory

S101: The stage-of-exercise feedback (I1 and I2) was accompanied by cognitive and behavioural activities tailored to each specific stage using the change processes identified by Marcus *et al.* (S115) (e.g. those in precontemplation received a decision balance activity, those in contemplation received a behavioural assessment activity, those in preparation received a goal-setting activity, and those in action and maintenance received relapse prevention activities)

**Study type**
RCT

**Design**
Participants were stratified by their baseline stage of exercise and then randomly assigned to receive one of three mail-delivered, self-instructional, personalised, written exercise packets. 31 days after receiving packets, participants' physical activity levels were assessed, and 7 months after baseline a follow-up survey was conducted (S101)

**Setting**
Workplace

**Length of intervention**
31 days (S305); 7 months after baseline follow-up (S101)

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Female clerical staff employed full time at a major urban research university ($n$ = 580)

**Inclusion criteria**
Female clerical staff employed full time at a major urban research university. Age ≥ 50 years

**Exclusion criteria**
Answering 1 or more of the Physical Activity Readiness Questionnaire items affirmatively

**Behaviours targeted**
Physical activity

***Intervention details***

**Intervention group**
I1: Lifestyle exercise packet. Promoting small increases in routine physical activity with an accumulative total of 30 minutes of low-to-moderate intensity physical activity being encouraged on most days of the week. Including information on participants' health status, predicted body fat percentage, predicted VO(2max) and stage of exercise; accompanied by cognitive and behavioural activities tailored to each specific stage using the change processes identified in a previous study (S115). Also containing an 'exercise success' story based on the modelling and self-efficacy constructs of social cognitive theory

S101: Encouraged participants to integrate more activity into their daily activities, for example take stairs rather than elevator

I2: Structured exercise packet. Same as I1. However, this packet promoted the structured exercise guidelines established by the ACSM. That is, participants were encouraged to gradually progress into a 3- to 5-day per week, 20 to 60 minutes per session, 60% to 90% maximum heart rate type of exercise programme

S101: Encouraged participants to follow a standard exercise prescription with specific recommendations for frequency, intensity and duration

**Comparison group**
Control packet. No exercise recommendation or stage of exercise feedback. However, they were as in I1 and I2, informed of their health status, predicted body fat percentage, and predicted VO(2max)

*continued*

# Data extraction table *contd*

***contd***
**S305, Cardinal (1996)**[58]

***Intervention details* contd**

**Classification into stages**
Stage of exercise was assessed using Cardinal's five-item ordered categorical scale (S442, S244). The scale is theoretically based on the TTM and conceptually resembles a ladder. Each rung of the ladder corresponds to one of the five posited stages.
Precontemplation item: "I presently do not exercise and do not plan to start exercising in the next 6 months"
Contemplation item: "I presently do not exercise, but I have been thinking about starting to exercise in the next 6 months"
Preparation item: "I presently get some exercise, but not regularly"
Action item: "I presently exercise on a regular basis, but I have only begun doing so within the past 6 months"
Maintenance: "I presently exercise on a regular basis and have been doing so for longer than 6 months"

Regular exercise is operationalised in the scale's directions as equal to 3 days or more per week for 20 minutes or more each day

**Validity of measure**
The construct validity, predictive validity, and test–re-test reliability of the scale are satisfactory and have been reported elsewhere (S442, S244, S59)

S59: Hypothesis – it was predicted that a linear pattern of improvement on each variable (body mass index, cardiorespiratory fitness, exercise behaviour (two methods), relapse, barriers and self-efficacy) would be observed across the SoE. The proportion of variance explained on each variate across stages ranged from 0.05 to 0.53, and mean scores generally followed a linear pattern of improvement across the stages in a manner consistent with theory

S244: The ability of the SoE scale to differentiate between participants classified into each of the theoretically posited stages was studied in a sample of 178 female adults (same as S305). Results showed that the scale was able to significantly and meaningfully differentiate between participants classified by stage in terms of exercise energy expenditure, physical activity energy expenditure and VO(2peak)

S442: The ability of the SoE scale to differentiate between participants' classified by stage of exercise on several behavioural and biometric physical activity indices (leisure time exercise behaviour, frequency of sweating, body fat percentage, physical activity rating, difficulty with relapse, and VO(2peak)) was studied in a sample of 80 undergraduate students at a major urban research university. Results showed that the scale was able to significantly ($p < 0.001$) and meaningfully (the proportion of variance accounted ranged from 0.15 to 0.38) differentiate between participants classified by stage on five out of six variates (all except percentage of body fat)

**Training of educators**
Not applicable (self-instructional, mail-delivered intervention packets)

***Baseline characteristics***

**Gender**
100% female

**Age**
Mean age (SD):
I1: 36.6 (7.8) years
I2: 36.8 (6.9) years
C: 37.0 (6.9) years

**Stage of change**
I1: 2.7% precontemplation/21.6% contemplation/37.8% preparation/10.8% action/27.0% maintenance. i2: 2.6% precontemplation/21.1% contemplation/36.8% preparation/13.2% action/26.3% maintenance
C: 2.6% precontemplation/21.1% contemplation/36.8% preparation/13.2% action/26.3% maintenance

**Target behaviour**
Weekly mean leisure-time exercise METs (SD): I1, 18.6 (23.6); I2, 15.1 (14.8); C, 15.1 (11.2)

***Results***

**Statistical techniques**
MANOVA with treatment group serving as the independent variable and age, physical activity behaviour predicted body fat percentage and predicted VO(2max) serving as the dependent variables was performed to test the assumption that there were no baseline stage of exercise differences between the three groups. Next, due to small cell sizes, the five original stage of exercise classifications were recoded into three, based on the premise of successive increase in exercise. Thus a 3 (stage of exercise) × 3 (exercise group) × 2 (time) analysis of variance with repeated measures on the last factor repeated ANOVA (REANOVA) was used to analyse participants' weekly leisure-time exercise behaviour. For *post hoc* comparisons, Tukey tests were performed, along with Cohen's measure of effect size (*d*: 0.20, small; 0.50, moderate; 0.80, large). The proportion of variance explained by each *F* value was determined using $\chi^2$. For all analysis, alpha was set at the $p < 0.05$ level

S101 (7 months results): Friedman's non-parametric analysis of variance was used to determine participants' stage-of-exercise change status across time

Fleiss' test of proportions was used to determine the relationship between: (a) treatment group and participant drop-out rate; (b) treatment group and stage-of-exercise improvement; (c) participants' initial stage of exercise and stage-of-exercise improvement at 7 months, and (d) the proportion of participants who, in comparison to their baseline stage of exercise, improved, maintained, or regressed at 7 months. McNemar's test of symmetry was used to examine within-participant stage-of-exercise change patterns from baseline to 7 months. Each of these statistical tests results in a $\chi^2$ value. The magnitude was determined by use of the contingency coefficient (*c*)

*continued*

# Data extraction table *contd*

***contd***
**S305, Cardinal (1996)**[58]

***Results* contd**

**Behaviour change**
Physical activity was assessed using a weekly leisure-time exercise questionnaire. The instrument accounts for three types of exercise indicator: frequency, intensity and duration). Participants report the number of times they engage in more than 15 minutes of strenuous (running, skiing), moderate (fast walking, tennis) and mild (yoga, easy walking) physical activity during the course of 1 week. Weekly leisure-time METs were calculated by multiplying each exercise session by its assigned MET value (strenuous, 9; moderate, 5; mild, 3)

Mean (SD) weekly leisure-time exercise METs by exercise group and time (post-test = 31 days):
I1: pretest, 18.6 (23.6); post-test, 30.7 (18.5), $n$ = 36
I2: pretest, 15.1 (14.8); post-test, 22.0 (17.4), $n$ = 36
C: pretest, 15.1 (11.2); post-test, 17.6 (13.7), $n$ = 36

There was a significant weekly leisure-time exercise behaviour main effect found for exercise group ($F(2, 99) = 3.38$, $p < 0.05$, $n2 = 0.06$). A *post hoc* Tukey's test showed no difference between I2 and C at postintervention ($p > 0.05$, $d = 0.28$), no significant difference between I1 and I2 ($p > 0.05$, $d = 0.49$) and a significant and large difference between I1 and C ($p < 0.01$, $d = 0.80$)

Within-group effect sizes: I1, 0.57; I2, 0.42; C, 0.20

No significant weekly leisure-time exercise behaviour interactions were observed for any combination of factors (stage of exercise, exercise group, and time)

**Stage movement**
S101 (results at 1 months and 7 months for 81/113 participants):

Mean ranked SoE for each treatment at each time period:
I1: T0, 1.75; T1: 2.10; T2: 2.15 ($\chi^2 = 2.85$, $p = 0.24$, $n = 30$)
I2: T0, 1.85; T1: 2.02; T2: 2.13 ($\chi^2 = 0.90$, $p = 0.64$, $n = 24$)
C: T0, 1.76; T1: 1.94; T2: 2.30 ($\chi^2 = 4.02$, $p = 0.13$, $n = 27$)

There was an overall linear pattern of mean ranked SoE improvement across the three time periods ($\chi^2 = 6.22$, df = 2, $p < 0.05$, $c = 0.28$). However, there were no significant differences within or between groups across the three time periods

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Total weekly leisure-time exercise METs by stage (mean, SD):
Precontemplation/contemplation: pretest, 4.9 (9.7), post-test: 14.4 (8.4), $n$ = 26
Preparation/action: pretest, 16.1 (17.9), post-test, 19.3 (16.8), $n$ = 40
Maintenance: pretest, 23.5 (19.5), post-test, 32.9 (21.3), $n$ = 42

There was a significant weekly leisure-time exercise behaviour main effect found for stage of exercise ($F(2, 99) = 14.05$, $p < 0.0001$, $n2 = 0.22$). A *post hoc* Tukey's test showed: precontemplation/contemplationt and preparation did not differ in terms of weekly leisure-time exercise behaviour ($p > 0.05$, $d = 0.35$), however both differed significantly from those in action/maintenance ($p < 0.01$, $ds = 1.06$ and 0.71, respectively)

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
180 (31%) out of 580 volunteered. 113 (62.8%) participated (I1, 37; I2, 38; C, 38). 108/113 completed the study (I1 = I2 = C = 36). 81/108 (75%; 81/113, 71.7%) responded at 7 months (I1, 30; I2, 24; C, 27)

**Reasons**
67/180 before randomisation: two were males, 51 answered one or more of the Physical Activity Readiness Questionnaire items affirmatively, 14 were older than 50 years. No reasons mentioned for five drop-outs after randomisation

No reasons reported for drop-outs after 7 months, no significant biometric or demographic differences between 32 drop-outs and 81 participants at 7-months follow-up. Proportion of drop-outs unrelated to treatment group ($\chi^2 = 3.94$, df = 2, $p > 0.10$; $c = 0.22$)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated



*continued*

## Data extraction table *contd*

***contd***
**S305, Cardinal (1996)**[58]

***Additional comments***

**Authors' comments**
"The main difference between I1 and I2 was their latent content with nearly identical manifest content" (I1, promoting small increases in routine physical activity; I2, encouraging gradual progress). No explanation why I1 is effective compared to C and I2 not

**Authors' reported limitations**
Length of intervention (31 days), self-report outcome measures, low generalisability (only 31% response, only females), written materials not appealing to everyone

**Comment (RR)**
Other outcomes, results show greater improvements in preparation/action and maintenance; for all participants, irrespective of condition (the authors state that this finding supports the construct validity of the stage-of-exercise measure), has no relevance to effectiveness of intervention

S101: reports outcomes at 1 and 7 months for 81 responders at last follow-up only. Results reported here for 1-months assessments are from S305, reporting results of 108/113 responders, except for the stage-of-exercise outcome, which was only reported in S101

**S101**
The authors' report: "a general pattern that favoured I1 over I2 and C was identified and, interestingly, C over I2". C over I2 seems correct, but I1 over C can only be said with respect to physical activity scores (reported in S305 but not in S101), SoE scores seem to favour C over I1 and I2 at 7 months

**S439**
No additional information

**Validity of SoE scale** (S244, S442, S59)
All three papers show the scale's ability to differentiate between participants' classified into the five stages (construct validity), no other validity assessments presented

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S480, Cash (1997)**[59]

**Country**
USA

**Aim**
To compare the effects of different exercise strategies (i.e. 'Just Move' programme, 'Lifestyle Exercise' programme, group seminars, and no exercise intervention) and stage of exercise on reported physical activity, self-motivation, and stage of exercise in worksite employees

**Model**
TTM

**Theoretical basis**
In this investigation, interventions were applied according to Prochaska's TTM of behaviour change (S248, S255). Materials were distributed to individuals in all five stage subgroups of change and not just for those in the action and maintenance stages

**Study type**
RCT

**Design**
Quasi-experimental study with three dependent variables: stage of exercise, physical activity (7-day Recall Questionnaire), and self-motivation (Self-Motivation Inventory) and one manipulable exercise promotion strategy variable with four levels: written literature ('Just Move' programme), stage matched written literature ('Lifestyle Exercise' programme), group seminars and no exercise intervention (control group)

Participants were randomly assigned to one of four groups, stratified by self-reported pre-experimental stage of exercise involvement. Participants were assessed with multiple dependent measures at pre-, mid- (4 weeks) and post- (8 weeks) intervention time periods: stage of exercise, activity assessment (7-day Recall Questionnaire) and Self-Motivation Inventory. The data were obtained by self-report mail surveys. The study was summarised as a 4 stage of exercise × 4 intervention conditions repeated-measure factorial design

**Setting**
Workplace

**Length of intervention**
8 weeks

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
900 Full-time employees at a university in the north-east during the summer of 1996

**Inclusion criteria**
Not stated

**Exclusion criteria**
Individuals with potential serious health risk, assessed with the revised Physical Activity Readiness Questionnaire

**Behaviours targeted**
Physical activity

***Intervention details***

**Intervention group**
I1: 'Just Move' programme, written literature. This programme was designed to help worksite employees adopt and adhere to healthy and lifelong exercise habits. The programme provides ideas on ways to motivate and support participants in their exercise efforts and maintenance of healthy lifestyles. Participation is specific to each individual's current exercise level and offers different levels of intervention materials to all participants over an 8-week period. The programme offers a wide range of flexibility and is based on each individual's private needs and concerns. The written literature covered a wide range of exercise topics such as: 'Here's what you need to do', 'Moving safely', 'Tips For staying on the exercise track', 'Step up to a new you', and 'Spring fling'. Participants received the programme by campus mail in week 1 and additional literature was mailed during weeks 2–8 of the study

I2: 'Lifestyle Exercise' programme, stage-matched written literature (S653). The programme covered the following attributes: stage of exercise feedback, activity to encourage stage of exercise improvement, exercise success stories, and lifestyle exercise guidelines

I3: Group seminars. Conducted by primary investigators once a week (1 hour). In the first meeting, participants received a copy of the 'Tips for staying on the exercise track' information sheet from the 'Just Move' programme booklet. Following sessions: follow-up on the previous week's action step(s), note the participants' exercise progress, provide encouragement and assistance, help the participants overcome any barriers, and remind the participants about the following week's meeting

*continued*

## Data extraction table *contd*

***contd***
**S480, Cash (1997)**[59]

***Intervention details* contd**

**Comparison group**
No exercise intervention, control group. After the conclusion of the study (8 weeks) C was given the opportunity to participate in the exercise promotion interventions

**Classification into stages**
Cardinal's SoE scale: precontemplation, contemplation, preparation, action, maintenance

Algorithm not described

**Validity of measure**
Construct validity was determined by investigating self-report SoE scale scores of 43 males and 37 female college students. A significant difference was reported in the stages on all measures with the exception of the percentage of body fat variable (S244, S652, S653). Test–re-test reliability (Spearman ρ, $r = 1.00$) was established with the SoE scale using a 12-participant sample (S653)

S244: The ability of the SoE scale to differentiate between participants classified into each of the theoretically posited stages was studied in a sample of 178 female adults. Results showed that the scale was able to significantly and meaningfully differentiate between participants classified by stage in terms of exercise energy expenditure, physical activity energy expenditure, and VO(2peak)

**Training of educators**
Not stated

***Baseline characteristics***

**Gender**
57.6% female

**Age**
Mean age (SD):
I1: 44.8 (8.72) years
I2: 44.7 (9.89) years
I3: 44.1 (8.33) years
C: 44.2 (9.81) years

**Stage of change**
Mean stage of exercise (SD):
I1: 2.98 (1.17); I2: 3.09 (1.02); I3: 2.98 (1.14); C: 3.07 (1.12)

**Target behaviour**
62.8% currently exercises:
I1: 53.5%; I2: 74.4%; I3: 60.5; C: 62.8%

Mean 7-day recall scores (SD):
I1: 13.34 (6.01); I2: 12.93 (4.92); I3: 13.64 (6.01); C: 12.46 (4.52)

***Results***

**Statistical techniques**
The study was summarised as a 4 stage of exercise × 4 intervention conditions repeated measure factorial design and analysed using ANOVA (for data analysis the precontemplation stage was omitted due to the fact that only one participant was initially classified in that stage of exercise and he dropped out before mid-intervention). If participants in I3 missed more than one group meeting (without meeting the investigator individually for a review) data were not included in the study

Descriptive and inferential statistics were used to report participants' pre-, mid- and postintervention in terms of stage of exercise on reported physical activity, self-motivation, and SoE in worksite employees. Participants were compared within a 4 × 4 repeated measure factorial design and analysed by ANOVA procedures when testing the hypotheses. For all data the level of significance was set at the 0.05 level. *Post hoc* comparisons were conducted using Tukey's test and simple main effects (S651)

For analysing the effects of exercise promotion strategies on behaviour change movement between the SoE, action and maintenance participants were not included because the duration of the study was less than 6 months and the SoE scale did not indicate the specific month in which exercise participation began

**Behaviour change**
Activity assessment (7-day Recall Questionnaire (S654)). Participants were asked to self-report their 7-day physical activity levels (i.e. moderate hard and very hard intensity)

Mean 7-day recall scores (SD):
I1: pretest, 13.34 (6.01); post-test, 15.13 (5.59)
I2: pretest, 12.93 (4.92); post-test, 16.42 (8.58)
I3: pretest, 13.64 (6.01); post-test, 16.71 (8.61)
C: pretest, 12.46 (4.52); post-test, 16.01 (7.73). NS

There was a significant increase in physical activity over time ($F(2, 318) = 17.54$, $p < 0.0001$); but not between groups

*continued*

# Data extraction table *contd*

***contd***
**S480, Cash (1997)**[59]

***Results* contd**

**Stage movement**
Mean SoE, study completers only (SD):
I1: pretest, 3.00 (1.18); post-test, 3.22 (0.79). No significant increase over time in I1
I2: pretest, 3.08 (1.02); post-test, 3.38 (0.74). No significant increase over time in I2
I3: pretest, 2.95 (1.16); post-test, 3.24 (0.83). Significant increase over time: $F(2, 318) = 7.20$, $p < 0.05$
C: pretest, 3.02 (1.13); post-test, 3.17 (1.00). No significant increase over time in C

Percentages with improved stage-of-change status after 8 weeks:
I1, 29.26%; I2, 30.00%; I3, 36.58%; C, 24.39%. Significance not reported

Numbers who relapsed/maintained/progressed after 8 weeks:
I1, 0/29/12 ($n = 41$); I2, 0/28/12 ($n = 40$); I3, 0/26/15 ($n = 41$); C, 1/30/10 ($n = 41$). Significance not reported

**Health**
Not stated

**Intermediate outcomes**
Self-Motivation Inventory (S655): a 40-item questionnaire used to assess physical activity tendencies

Mean Self-Motivation Inventory scores (SD):
I1: pretest, 116.26 (8.29); post-test, 127.56 (16.40);
I2: pretest, 120.51 (6.88); post-test, 123.40 (11.40);
I3: pretest, 119.00 (9.30); post-test, 127.65 (15.76);
C: pretest, 121.09 (11.03); post-test, 120.85 (8.26). NS

There was a significant increase in self-motivation over time ($F(2, 318) = 11.20$, $p < 0.0001$) but not between groups

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
900 employees were contacted, 172 (19.11%) returned a completed initial questionnaire (I1 = I2 = I3 = C = 43). At mid- and postintervention, 163 (94.2%) participants returned a completed questionnaire (I1 = 41, I2 = 40, I3 = 41, C = 41)

**Reasons**
Nine non-respondents after randomisation: six due to job and personal time constraints or medical complications (i.e. bronchitis, pregnancy) that prohibited them from continuing in the study. The other three did not respond, despite reminder memos

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Comment**
Only one intervention (I2) was stage-based

**Authors' conclusions**
Support was shown for the TTM of behaviour change with the findings that participants in the maintenance stage of exercise group were engaged in more exercise in comparison to participants in the contemplation, preparation, and action SoE groups at pre-, mid- and post-interventions. Participants in all groups were engaged in higher physical activity levels at postintervention. However, no statistically significant differences were reported among the four groups. Participants in three of the four groups (i.e. I1, 'Just Move' programme; I2, 'Lifestyle Exercise' programme; and I3, group seminar) demonstrated higher self-motivation scores at postintervention. However, no statistically significant differences were reported among the four groups. Participants in all groups improved in stage of exercise movement at postintervention. However, no statistically significant differences were reported among the four groups

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S022, Crane (1998)**[67]

**Country**
USA

**Aim**
To evaluate the impact of a telephone outcall intervention (based on the TTM) on screening mammography behaviour among lower income, older women

S489: To test the design and feasibility of this project

**Model**
TTM

**Theoretical basis**
The telephone intervention was based on the TTM or stage-of-change model (Prochaska, S312), which posits that individuals progress through five stages in the adoption of a new behaviour, including precontemplation, contemplation, action and maintenance. Relapse and relapse risk were added (S601, S602). In the case of mammography, a series of behavioural steps may be required to accomplish behaviour change

Intervention included several components, each tailored to the stage of change of the woman. These components were: (1) basic information about mammography (stage 1); (2) counselling directed at specific barriers or concerns using a menu of 40 loosely scripted responses; (3) positive reinforcement to prevent relapse (for action/maintenance); (4) information about transportation and costs; (5) encouragement to talk to doctor an get a CBE or do BSE

**Study type**
Clustered RCT

**Design**
An RCT (residences were the unit of randomisation) testing the impact of two outcall interventions delivered by Cancer Information Services Telephone Information Specialists, compared to controls. Debriefing and follow-up interviews were conducted by the Survey Research Laboratory (University of Illinois). 6-month follow-up interviews (16 minutes; attitude and behaviour change, self-report). 2-year follow-up interviews (attitude and behaviour change, self-report)

**Setting**
Community

**Length of intervention**
One phone-call. Follow-up up to 2 years. Outcall protocol described in detail in S489

***Inclusion/exclusion criteria***

**Participants**
Physiological risk

**Population**
19,389 households from low-income and minority neighbourhoods throughout Colorado were contacted and 3080 eligible woman enrolled

**Inclusion criteria**
Female residents of contacted households, 50 years and older, English-speaking, Colorado residents and not previously diagnosed with breast cancer and no current symptoms of breast cancer

**Exclusion criteria**
Serious overriding health problems rendering the mammogram recommendation less appropriate and follow-up difficult (e.g. terminally ill or hard of hearing). And women who had obtained prophylactic double mastectomies

**Behaviours targeted**
Getting a CBE and practising BSE

***Intervention details***

**Intervention group**
I1: a telephone outcall promoting screening mammography using an interactive barriers counselling protocol based on the stage-of-change model

I2: a telephone outcall preceded by a mailed 'invitation' to participate in this programme

I1 + I2: The intervention included several components each tailored to the stage of change of the women. The components were: (1) the provision of basic information about mammography (particularly emphasised for precontemplators); (2) elicitation of each women's specific barriers or concerns about mammography and counselling directed at those barriers using a menu of over 40 loosely scripted responses; (3) positive reinforcement to prevent relapse for those in action or maintenance; (4) information about transportation and cost, including referrals to free services under the Breast and Cervical Cancer Mortality Prevention Act of 1990 and referrals to specific mammography facilities using a state-wide directory; and (5) encouragement to talk to their doctors about getting a mammogram, as well as to get a CBE and to practise BSE. Prior to ending the call, intentions to get a mammogram were reassessed

*continued*

# Data extraction table *contd*

***contd***
**S022, Crane (1998)**[67]

***Intervention details* contd**

**Comparison group**
A control telephone interview, containing questions related to health practices and use of health information resources

**Classification into stages**
Precontemplation: Never had a mammogram and no plans to have a mammogram in the next 6 months

Contemplation: Never had a mammogram/not in the past 2 years and plans to have a mammogram in the next 6 months

Relapse: Had mammogram but not in the past 2 years and no plans to have a mammogram in the next 6 months

Relapse risk: Had mammogram in the past 2 years ando plans to have a mammogram within next 1–2 years;

Action: Had mammogram in the past 2 years and plans to have a mammogram within next 1–2 years, but not more than one in past 4 years

Maintenance: Had mammogram in the past 2 years and plans to have a mammogram within next 1–2 years, and more than one in past 4 years

14 decisional balance items were developed (cognitive pros and cons to mammography) (S603, S604)

**Validity of measure**
Not stated

**Training of educators**
The telephone information staff received 2 days of training and completed a 6-week practice period in which 128 outcalls were completed. On ten separate occasions throughout the study period, investigators monitored calls (standard quality assurance form)

S489: Each information specialist received a training manual that provided a general overview of the project, as well as a review and explanation of the mammography intervention protocol, follow-up mail-outs, and control group interview. Training included role-playing, critique of audio-tapes, and practice with the computer-assisted telephone interviewing system

***Baseline characteristics***

**Gender**
100% women

**Age**
50–54 years: I1, 12.3%; I2, 12.2%; C, 10.6%
55–59 years: I1, 16.6%; I2, 15.5%; C, 12.1%
60–64 years: I1,13.5%;I2, 16.5%; C, 17.1%
65–69 years: I1, 16.8%; I2, 16.5%; C, 17.5%
70–74 years: I1, 16.8%; I2, 16.1%; C, 16.8%
75–79 years: I1, 11.8%; I2, 13.2%; C, 12.6%
80+ years: I1, 12.2%; I2, 9.9%; C, 13.4%

**Stage of change**
Precontemplators: I1, 13.4%; I2, 10.0%; C, 16.4%
Contemplators: I1, 10.1%; I2, 9.0%; C, 6.6%
Action: I1, 7.8%; I2, 7.1%; C, 7.3%.
Maintenance: I1, 55.4%; I2, 58.1%; C, 54.5%
Relapse: I1, 13.4%; I2, 15.8%; C, 15.1%

**Target behaviour**
Not stated (mammography behaviour was measured to classify women into stages, but not reported separately; BSE appears not to be assessed at the baseline)

***Results***

**Statistical techniques**
Type I error for individual tests: 0.05. *P*-values not adjusted for multiple comparisons. Mantel–Haenszel $\chi^2$ test for association between ordered categorical variables. Cochran Mantel–Haenszel test for tests of an effect of study group on stage of change at follow-up, stratified by stage of change at the baseline. Multiple logistic regression to determine ORs and independence of predictors of mammography behaviour

**Behaviour change**
Only women who were due for a mammogram in the 6-month follow-up period included in the analysis (non-stratified). Receipt of mammography during 6 months follow-up: I1, 20.1%; I2, 21.3%; C, 20.8% (NS). Physical exam during 6-month follow-up: I1, 36.4%; I2, 38.7%; C, 36.9% (NS). Had CBE in past 12 months: I1, 47.6%; I2, 47.2%; C, 45% (NS). Same findings using an annual mammography schedule. Mammography adherence at 2-years follow-up (stratified by baseline behaviour): Never had mammography at the baseline: I1, 23.5%; I2, 21.7%; C, 18.4% (NS). Had mammogram > 2 years ago at the baseline: I1, 51.1%; I2 46.8%; C 44.8% (NS). Had mammogram < 2 years ago at the baseline: I1, 89.4%; I2, 92.2%; C, 85.9 ($p$ = 0.01). Pairwise comparisons showed only difference between I2 and C statistically significant

**Stage movement**
I1: precontemplation, 24.5%; relapse, 20.7%; contemplation, 36.7%; action, 6.9%; maintenance, 11.3%
I2: precontemplation, 17.7%; relapse, 21.6%; contemplation, 41.0%; action, 7.2%; maintenance, 12.5%
C: precontemplation, 32.8%; relapse, 20.5%; contemplation, 27.7%; action, 6.1%; maintenance, 13.0%

*continued*

# Data extraction table *contd*

***contd***
**S022, Crane (1998)**[67]

***Results* contd**

**Stage movement *contd***
There is a significant shift from precontemplation to contemplation in I1 and I2 ($p < 0.005$), no apparent difference between groups in action, maintenance, or relapse stage of change. Stratified analyses (for baseline differences) showed no significant differences, although subanalyses of precontemplators at the baseline showed that I2 and I1 were more likely to be contemplators at follow-up compared to C and I2 was more likely to have moved to action compared to I1 and C ($p = 0.02$)

**Health**
Not stated

**Intermediate outcomes**
Intention to have mammogram: I1: yes, 26.4%; probably, 29.2%; ?, 4.4%; probably not, 21.9%; no, 18.1%
I2: yes, 30.0%; probably, 31.7%; ?, 3.7%; probably not, 22.3%; no, 12.3%
C: yes, 24.7%; probably, 23.0%; ?, 6.3%; probably not, 25.4%; no, 20.6%

There was a significant shift towards greater intentions to get a mammogram in I1 and I2 compared to C ($p = 0.002$). This shift appears greater in I2 than I1 (no test)

Decisional balance score: I1, 32.1; I2, 32.3; C, 30.9 ($F(2, 884) = 5.79$, $p = 0.003$)

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
A random subset of women (145) received a 2-week debriefing interview that assessed the short-term reaction to and acceptance of the outcalls. Results are presented in S489

S22: The outcalls varied on a number of attributes: length of call, caller, type and nr of barriers/issues addressed in the call, and the time period of the study. There were no differences in receipt of a mammogram at 6-month follow-up by length of call, individual caller or the time period. Receiving a mammogram during the 6-month follow-up was negatively associated with barriers/issues: 'No doctor's recommendation' (12.7% got a mammogram versus 23.0% who did not bring up this issue); 'Mammogram is not necessary' (10.8% versus 23.5%); 'Doesn't like doctors' (10.6% versus 21.9%); 'Fatalism/we're all going to die sometime' (4.9% versus 21.8%) and 'Too old for mammogram' (8.7% versus 21.6%). Total number of barriers/issues was also negatively related to receipt of a mammogram

S489: The sampling and outcall strategies were designed specifically to access low-income and minority women. A higher proportion of African–American women was reached, still this was less than expected. Hispanic neighbourhoods were specifically targeted, though the proportion enrolled fell short of that predicted. Enrolment with respect to income was more successful, the study reached women with incomes considerably lower than for the state as a whole

Examination of the effort required to reach women through an outcall mechanism suggests that the strategy is both labour intensive and potentially expensive. While the outcall counselling protocol itself required about 14 minutes to deliver, an additional 26 minutes was required to identify each eligible and consenting woman. Further, six households needed to be called for each enrolled woman

Two project investigators monitored outcalls: Information specialists were rated very highly for most aspects of the calls, including adherence to protocol. Overall, 86% of the calls were rated as 'very effective' in promoting mammography; an additional 14% of the calls received a 'somewhat effective' rating. Quality measurements obtained from debriefing interviews with call recipients ($n = 129$) indicated that 90–95% of recipients were treated courteously, had no trouble understanding the information presented, felt that the call was not too personal, and that the caller seemed to know what she was talking about. Additionally, 90–95% of call recipients felt that the caller listened carefully to their concerns and really cared if they got a mammogram

***Withdrawals/economic evaluation***

**Number per group**
6-month response rate: 75% with little variation by study group (no exact numbers for randomisation or baseline per group, or total given). Response rate at 2-years follow-up: 81% of 6-month responders (61% of baseline)

S509: The response rate to the 6-months follow-up was 75% ($n = 2212$) for the single outcall study (S22)

**Reasons**
Not stated. Respondents were more likely to be younger (< 70 years), and recently had a mammogram (responders, 56% in maintenance stage; non-responders, 43%). Non-responders were more likely to refuse demographic questions at the baseline. Responders at 2 years were more likely to be younger and at higher stages of change for mammography

**Economic evaluation**
Yes

*continued*

# Data extraction table *contd*

***contd***
**S022, Crane (1998)**[67]

***Withdrawals/economic evaluation* contd**

**Economic methods**
Not stated

S489: Upon study completion, a detailed cost analysis will be conducted (see S509)

S509: This study involves the comparison of a multiple outcall strategy promoting screening mammography with strategies involving a single outcall alone, an advance card plus single outcall, and no intervention. Data for the three comparison groups come from S22. S509 is not an RCT! Because of differences in recruitment between the study group and comparison groups, analysis required controlling for baseline differences between the groups, using stratification and statistical controlling using multiple logistic regression

Cost analyses used computer recorded times for delivery of the computerised outcalls as well as logs of time spent preparing mailings to subjects in the 'advance card' group. Printing and postage costs were actual per-item costs. Personal costs used the nation-wide average hourly wage of Cancer Information Services in 1994 ($13/hour) plus fringe benefits rate of 26% ($3.50/hour) and overhead/indirect cost rate of 45% ($7.50/hour)

**Cost outcomes**
Not stated

S509: Although the multiple outcall intervention was more costly to deliver ($14.84 per participant compared with about $7.00 for the single outcall interventions), it cost considerably less per participant converted from non-adherent to adherent. When 40% of the population is non-adherent at the baseline, the costs of delivering the program to 1000 participants are $5768, $6868 and $10,088 for the single outcall, advance card plus a single outcall, and multiple outcall interventions, respectively. The cost per participant who changed are $288, $390 and $154, respectively. When 100% of the population is non-adherent at the baseline (which might occur if participants were recruited on the basis of their medical records rather than from a community setting), the overall cost of the programme delivery increase, but the cost per participant who changed are reduced, to $131, $177 and $90, respectively. The multiple outcall intervention is consistently the most cost-effective intervention of the three

***Additional comments***

**Author's conclusion**
Neither I1 nor I2 were effective in stimulating mammography behaviour at 6-month follow-up. However, I2 had a small impact on mammography behaviour after 2-year follow-up, but this effect was isolated to those who were adherent at the baseline

**Authors' reported limitations**
Self-report of mammography behaviour; study was aimed at minority and low-income women, but majority of participants were non-Hispanic whites

**S489: Authors' conclusion**
This approach successfully extended the Cancer Information Services' audience; however, its labour intensity may limit its application. Strategies for increasing the efficiency of outcall efforts are suggested

**Comment**
S509 is a separate study evaluating the (cost)-effectiveness of a multiple outcall intervention, without any control group. Data from S22 are used for the comparison groups

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S255, DiClemente (1991)**[49]

**Country**
USA

**Aim**
To test the TTM of change that posits a series of stages through which smokers move as they successfully chance the smoking habit

**Model**
TTM

**Theoretical basis**
S135: The interventions are stage-based

S255: This study will provide the most extensive test to date of the stages-of-change model with a large sample of smokers volunteering for a minimal intervention smoking cessation research programme

**Study type**
RCT

**Design**
RCT. Participants were randomly assigned to one of four interventions stratified by stage. All interventions were done by mail or phone contact or both. After respondents returned pre-tests they were randomised and sent materials. At each assessment, respondents were asked to provide names of significant others who could validate their smoking patterns. Approximately 1 to 6 months after pretest, respondents were sent follow-up questionnaires similar to the post-test battery

Follow-up assessments continued every 6 months for the next 2 years

Participants were offered $5 for completing questionnaires as well as an opportunity for ten bonus prizes amounting to $2, 000 at each round of data collection

S135: Assessment at pre-intervention, 1, 6, 12 and 18 months. The 1-month assessment was for intervention purposes

**Setting**
Volunteers to adverts

**Length of intervention**
Only 6-months follow-up data were used in the current analysis, in as much as pre-test stage was most relevant to the first 6 months after assessment, and interventions continued through this time period

S135: 6-month intervention period

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Volunteers for a research project on minimal interventions for smoking cessation at 2 sites: Texas ($n$ = 691) and Rhode Island ($n$ = 775). Participants responded to newspaper, radio and other media advertisements seeking participants to test materials developed for smokers in various stages of change

S135: 756 volunteers in Rhodes Island

**Inclusion criteria**
Only those still smoking (precontemplators, contemplators, and those prepared for action)

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking cessation

*continued*

# Data extraction table *contd*

***contd***
**S255, DiClemente (1991)**[49]

***Intervention details***

**Intervention group**
S255: very limited details on interventions:

All interventions were done by mail or phone contact or both

I1: Transtheoretical manuals

S420/135: Individualised transtheoretical theory of change (TTT). Five manuals were developed and field tested based on the TTM and available data from a longitudinal study of natural change. The five manuals are: (1) precontemplation; (2) contemplation; (3) action; (4) maintenance; and (5) relapse. The manuals use all constructs of the model, not just the stage construct. Based on their pretest scores, participants were sent the manual matched to their individual stage of change and manuals for all subsequent stages. Participants who took action and relapsed were sent the 'Relapse' manual following assessment at either the 1- or 6-month follow-up depending on when they relapsed

I2: Transtheoretical manuals and individualised written feedback based on pretest, post-test, and 6-month questionnaires

S420/135: Interactive (ITT). Besides the TTT manuals from I1, participants were sent the series of three computer-generated reports at the start of treatment and at the 1- and 6-month follow-ups

The 2–3-page, single-spaced reports were divided into three sections: (A) a description of the person's stage of change, their pros and cons of quitting smoking, feedback, when necessary, about their under-evaluating the pros of quitting and over-evaluating the cons; (B) feedback on their use of up to six change processes, how they compared normatively with self changers who were most successful in progressing to the next stage, and how they compared ipsatively with their previous assessment; and (C) a description of tempting situations, with feedback on how to enhance their self-efficacy in their most tempting situations. The reports were printed and mailed to participants immediately upon receipt of their mailed questionnaires. Participants who did not return a mailed questionnaire at either the 1- or 6-month follow-up did not receive a report for that follow-up. If participants did not respond, they were assessed by phone surveys using short-forms of the questionnaire

I3: Transtheoretical manuals and individualised written feedback plus a series of four personalised counsellor calls at pretest, post-test, 3 months and 6 months

S420/135: Personalised individualised transtheoretical theory. This intervention included both the TTM based manuals of I1 and the interactive computer generated progress reports of I2. In addition, participants received a series of short calls from counsellors to provide personalised feedback. The calls followed a protocol for social support in stressful decisions (S605). The telephone counselling protocols were stage matched and basically followed the outline of the expert system reports. The reports enabled the counsellors to reinforce even small signs of progress, such as increases in the pros of quitting or in the use of appropriate processes of change. The goal of each call was to help participants progress to the next stage of change rather than to pressure participants to action if they were adequately prepared. The counsellor also had the flexibility to counsel on life stresses if they were assessed as barriers to progressing through the stages. The calls were delivered at the start of treatment and at 1-, 3- and 6-month follow-ups. Except for the 3-month call, the counsellors had the computer reports available to help them counsel clients about the progress or lack of progress they were making on key variables. The calls were approximately 15 minutes in duration

**Comparison group**
C: American Cancer Society/ALA materials and manuals

S420/135: Standardised (ALA+). Three separate manuals were employed: (1) *Freedom from Smoking in 20 days*, a 64-page manual oriented towards cessation from the ALA; (2) *A Lifetime of Freedom from Smoking*, a 28-page manual oriented towards maintenance of smoking cessation from the ALA; and (3) *Fifty Most Often Asked Question*, a 22-page informational booklet from the American Cancer Society. The entire package of manuals was sent to the participants

**Classification into stages**
S255:
Introduction: A stages-of-change scale (URICA; S99) measures participants' attitudes toward change on 32 items that represent precontemplation, contemplation, action or maintenance statements and yields stage scores and profiles
Precontemplation stage: smoking and not seriously considering quitting within the next 6 months
Contemplation stage: smoking and seriously considering quitting within the next 6 months; however, they were not considering quitting within the next 30 days, had not made a quit attempt of 24 hours in the past year, or both
Preparation stage: seriously considering quitting within the next 6 months, and planning to quit within the next 30 days. In addition they had made a 24-hour quit attempt in the past year

The stage classification algorithm was mutually exclusive so that all smoking respondents were classified in only 1 stage. Intention to quit in the next 6 months was used to identify precontemplators. Then both intention to quit in the next 30 days and quit attempt in the past year were used to subdivide contemplators from prepared respondents

S99: The stages are conceptually defined as follows:
Precontemplation: the person is entering into a therapy situation but does not think s/he has a problem or knows s/he does not want to change; may feel pressured by others to be there; may admit to having a problem, but has no desire to change. S/he is either not aware of or is ignoring the problem
Contemplation: The person is beginning to be aware that a problem exists or that s/he is bothered by something about him/herself. S/he is struggling to understand the problem (i.e. cause, solution); is seeking more information; but has not made a commitment to change
Decision making: The person has decided s/he is ready to change; has committed him/herself; is willing to pay the price (i.e. money, time, effort, discomfort); is ready to take responsibility; but has not started working on the problem (i.e. has not begun to change the problem behaviour or environment)
Action: The person has actively started to change the behaviour or the environment; is struggling to change; has not been very successful on his/her own and needs help. S/he has not attained the desired change
Maintenance: The person has already changed and made significant gains but is either slipping or coming in to prevent a relapse. S/he might have found it difficult to maintain the changes (i.e. new behaviours, new attitudes) on his/her own, and is therefore seeking help. S/he has already attained the desired change and is better off than s/he was initially

In the reality of therapy, these stages are not assumed to be discrete nor is movement in therapy necessarily unidirectional and successive



*continued*

## Data extraction table *contd*

***contd***
**S255, DiClemente (1991)**[49]

***Intervention details* contd**

**Validity of measure**
S255: Evidence for the validity of the stage classification is strong.[72] Stage classifications for smoking cessation are consistently related to self-efficacy efficacy[73,74] to a decision-making construct[75] and to the processes of change for smoking cessation[15,72] in a consistent and theoretically compatible manner

S99: An initial pool of 125 items representing the five stages was reduced to a final test of 32 items on the basis of principal component analysis, Cronbach's coefficient alpha and item analysis results. One of the five initial stages was eliminated based on the analyses. The resulting four stages (precontemplation, contemplation, action and maintenance) are represented by high loadings on distinct components. Cronbach's coefficient alpha for the four scales range from 0.88 to 0.89. A cluster analysis was performed on the standardised scores for each participant on each of the four scales. The resulting 18-cluster solution produced seven major and two minor client profiles that are highly distinct

**Training of educators**
S135: Counsellors in I3 were advanced doctoral students in clinical psychology who were trained and supervised by PhD-level clinicians

***Baseline characteristics***

**Gender**
S255: Texas, 64% female; Rhode Island, 62% female

S135: 62% female

**Age**
S255: Texas, mean age (SD): 40 (11) years; Rhode Island, mean age (SD), 43 (12) years

S135: Mean age (SD): 43 (12) years

**Stage of change**
S255: precontemplation, 166 (11.3%); contemplation, 794 (54.2%); preparation, 506 (34.5%)

S135: precontemplation, 93 (12.3%); contemplation, 435 (57.5%); preparation, 228 (30.2%)

**Target behaviour**
S420: Point prevalence abstinence at pretest ($n$ = 756): I1, 0.0; I2, 0.0; I3, 0.0; C, 0.0

S135: Average number of cigarettes per day: 27

***Results***

**Statistical techniques**
S255: Only stage effects will be analysed. Only 6-months follow-up data were used in the current analysis

Comparisons were made across groups of precontemplators, contemplators, and prepared respondents on a number of smoking history and change variables, using regression and logistic regression procedures. Whenever there was a conceptually similar group of measures, MANOVA was used in a preliminary analysis. Because of the large numbers of comparisons being made, an alpha level for significant differences of 0.01 was chosen to reduce experiment-wise error rate, and a more conservative Tukey procedure was used for *post hoc* analyses

S135: $\chi^2$ tests were performed to compare the four groups at each assessment. The Levy (1975) version of the Tukey follow-up test was used for pairwise comparisons of the interventions

**Behaviour change**
Smoking history questionnaire: number of previous quit attempts, current level of smoking

S255: No data presented by treatment group

S420: Point prevalence abstinence at pretest/6-/12-/18-month follow-ups ($n$ = 756):
I1: 0.0/7.0/8.2/18.5
I2: 0.0/16.2/20.6/25.2
I3: 0.0/13.9/17.6/18.0
C: 0.0/6.7/9.2/11.0

S135: Point prevalence abstinence: a self-report measure of participants who have not smoked for at least 24 hours at each follow-up; Prolonged abstinence: a self-report measure of participants who reported not smoking at two consecutive follow-ups (those who have progressed from 'action' to 'maintenance'). Cotinine validation: a standard for validating self-report measures of smoking cessation (authors state this is inappropriate for studies like these)

Data are presented in graphs. Data for precontemplation, contemplation and preparation stage separately by intervention group:

Point prevalence abstinence at pretest/6/12/18 months (%):
I1: precontemplation, 0.0/0.0/0.0/5.0; contemplation, 0.0/9.3/8.4/15.4; preparation, 0.0/5.6/11.1/29.4
I2: precontemplation, 0.0/10.0/20.0/17.6; contemplation, 0.0/15.7/18.0/25.0; preparation, 0.0/19.2/25.5/28.0
I3: precontemplation, 0.0/9.5/4.4/5.3; contemplation, 0.0/11.1/15.8/15.6; preparation, 0.0/21.3/27.1/27.9
C: precontemplation, 0.0/0.0/5.0/11.1; contemplation, 0.0/6.4/9.2/10.8; preparation, 0.0/10.2/11.1/11.6

*continued*

# Data extraction table *contd*

***contd***
**S255, DiClemente (1991)**[49]

***Results* contd**

**Behaviour change *contd***
Graph: Point prevalence abstinence at 6/12/18 months (%):
I1: 14.0/8.0/18.8; I2: 16.8/20.8/26.0; I3: 6.6/18.0/18.4; C: 6.6/9.2/11.2

I1 and C were basically equivalent, both at 6- and 12-month follow-up, I1 was significantly better than C at 18 months ($p < 0.05$). I2 was outperforming I1 and C at each of the three follow-ups ($p < 0.01$). I3 was better than I1 and C (no $p$-value), but not significantly better than I2. At 18 months I3 is only significantly better compared to C, and I2 is significantly better than I3

Prolonged abstinence (at 12 and 18 months):
Graph: Prolonged abstinence at 12/18 months (%):
I1: 2.8/6.8; I2: 10.8/14.0; I3: 6.4/10.6; C: 2.8/5.4

At 18 months: I2 signifiantly better than I1 and C ($p < 0.05$) at 12 and 18 months, and I2 significantly better than I3 at 18 months (no $p$-value). I3 significantly better than C at 12 and 18 months ($p < 0.05$)

**Stage movement**
S255: No data presented by treatment group

S135: No data presented

**Health**
Not reported

**Intermediate outcomes**
Smoking Abstinence Self-Efficacy (SASE; S41) measures the smokers' level of confidence that s/he would not smoke in 20 challenging situations (1 = not at all, to 5 = extremely confident)

Perceived Stress Scale (PSS) (S606, S607) is a global measure of how much perceived stress respondents have experienced within the past month

Fagerstrom Tolerance Questionnaire (FTQ) (S608) measures physical dependence on nicotine

Smoking Decisional Balance Scale (SDB)[75] assesses ten pros and cons of smoking

Smoking Processes of Change Scale (SPC)[15,72] measures the ten processes of change (coping activities used to modify smoking behaviour) from the TTM with four items each

No data presented by treatment group

S135: No data presented

**Adverse effects**
Not reported

**Other outcomes**
Not reported

**Implementation measures**
Level of manual use:

S255: No data presented by treatment group

S135: No data presented

***Withdrawals/economic evaluation***

**Number per group**
S255: 1466 respondents were included in the baseline assessment; 1301 respondents were included at 1 month and 1301 at 6 months. No numbers per treatment group reported

S135: 756 respondents randomised (unclear why this number differs from 775 Rhode Island participants reported in S255). Attrition rates averaged 5.5% across treatment conditions (I1, 4.1%; I2, 6.2%; I3, 7.1%; C, 4.6%). 527 participants provided data at all five assessment periods

**Reasons**
S255: Not reported

S135: Point prevalence abstinence rates are slightly higher for 527 participants completing all assessments compared to all respondents. Additional analysis comparing participants who completed the 18 month follow-up assessment with those who failed to return the questionnaire showed that: Respondents were more likely to be married than non-responders (84% versus 70%), older 943 versus 41 years), more highly educated (14.3 versus 13.8 years of schooling), and lighter smokers (26.5 versus 29.9 cigarettes per day)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated



*continued*

## Data extraction table *contd*

***contd***
**S255, DiClemente (1991)**[49]

***Additional comments***

**S255: Authors' conclusion**
The results overwhelmingly support the stage categories, stage × processes of change interactions, stage × self-efficacy and decisional balance differences, and stage-specific predictions of 1 and 6 months cessation activity

**S420**
Review of expert systems, presents some results from same trial, including 756 respondents (see above)

Results at an intermediate time point using only one outcome measure (point prevalence abstinence) are reported here. S135 provides a detailed description of the complete study

**S135**
Presents some results from the same trial, including 756 respondents (see above)

**Authors' conclusion**
When point prevalence rates were used, the stage-based I2 more than doubled the quit rates of C at each of the three follow-ups. When prolonged abstinence rates were used, I2 came close to tripling the maintenance rates of C. These results suggest that interactive computer feedback on stage-related variables has the potential to outperform the best self-help programme previously available

**Authors' reported limitations**
Men, minorities and smokers with less education and income levels are underrepresented

**S310**
Presents one paragraph of design and results of the same trial: A comparison of the expert system intervention (the expert system condition: I2 or I3, unclear which condition is meant) and related manuals to one of the best available sets of action-oriented self-help manuals for smoking cessation (C) demonstrated that the expert system was more than twice as effective (25% point prevalence abstinence at 18 months compared to 11%) (S135)

**S333**
Same trial, using results of 388 participants, again no results by treatment group reported

**S68**
Same trial, using results of the 790 participants from Texas, again no results by treatment group reported

**S132**
Same trial, using results of 544 participants, again no results by treatment group reported

**Comment**
Unclear why results from 691 Texas volunteers were never published, authors report a series of technical and methodological problems (S135)

**Request to authors for more information**
Response (DiClemente, 2001): Authors refer to S135 for full details of this trial, no more information available

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S021, Dijkstra (1999)**[43]

**Country**
The Netherlands

**Aim**
First, to investigate the efficacy of two different tailored smoking cessation self-help interventions (multiple tailoring and single tailoring) and one standardised smoking cessation self-help guide compared to a no-information control group and with each other

Second, to analyse to what extent the self-help interventions were able to change the relevant cognitive determinants in a sample of smokers with low readiness to change. Again, the interventions were compared with the no-information control condition and to each other

**Model**
TTM

**Theoretical basis**
Self-help interventions stimulate smokers to quit by changing the cognitive determinants of smoking cessation. Bandura's social cognitive theory, among others, defines the perceived positive and negative outcomes of quitting and perceived self-efficacy as central cognitive determinants of motivation and behaviour

Hence, self-help interventions are expected to increase the perception of positive outcomes of quitting, decrease the perception of the negative outcomes of quitting, and increase perceived self-efficacy. Furthermore, Bandura's social cognitive theory, and others, describes (in)attention as a means of blocking or processing potentially motivating information, for example, information on smoking and smoking cessation. In the TTM, the processes of change – operationalised as the self-reported frequency with which domain-specific information is the focus of attention – are considered to be independent cognitive variables. Hence, self-help interventions are expected to increase the use of attentional processes. Several studies support the relation between expected outcomes, self-efficacy, and processes of change, on the one hand, and motivation to quit and actual quitting on the other hand. However, no data are available on cognitive changes due to self-help interventions among smokers with low readiness to quit

**Study type**
RCT

**Design**
Smokers were randomly assigned to one of four conditions offering: (1) three (multiple) consecutive tailored letters (MT condition), (2) a single tailored letter (ST condition), (3) a standardised self-help guide (SHG condition), or (4) no self-help materials (CO condition). Participants were send a pretest questionnaire, and 6 months after the intervention a post-test questionnaire

**Setting**
Community

**Length of intervention**
6–7 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Cigarette smokers with low readiness to change, recruited by advertisements in local newspapers throughout The Netherlands ($n$ = 843)

**Inclusion criteria**
Cigarette smokers with low readiness to change, i.e. not planning to change within the next 6 months

**Exclusion criteria**
Smokers who stated having plans to quit smoking within the next 6 months or only smoked a pipe or cigar

**Behaviours targeted**
Smoking

*continued*

# Data extraction table *contd*

***contd***
**S021, Dijkstra (1999)**[43]

***Intervention details***

**Intervention group**
I1: Tailored intervention. Computerised system used to generate three consecutive tailored letters. The computerised systems to generate the tailored letters were adapted from previous evaluations of minimal interventions among smokers who were planning (S610) and who were not planning (S609, S611) to quit. A detailed description of the tailored interventions is published elsewhere (S611)

I2: Tailored intervention. Computerised system used to generate a single tailored letter. See I1

I3: Self-help guide. 46-page colour self-help manual developed for use in a community smoking cessation project. Its structure was derived from a self-help guide developed in the USA (S612) and the language and content were adapted to the Dutch population (S613)

**Comparison group**
Control: no information

Also, I1, I2 and I3 were compared to each other

**Classification into stages**
Stages of change were assessed by confronting smokers with different plans with regard to smoking cessation. Four stages were distinguished: immotives, precomtemplators, contemplators and preparers. Smokers who had quit during the past 24 hours were considered in the action stage. Only those with low readiness to change were included in the study, i.e. immotives and precontemplators. Stage transition was assessed by dichotomising changes in stage: forward transition was scored as 1, versus no transition or backward transition, which was scored as 0

**Validity of measure**
Not stated

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
62.8% female

**Age**
Mean age: 41.7 years

**Stage of change**
78.1% classified as immotives (21.9% precontemplators)

**Target behaviour**
Smoking behaviour: On average they smoked 21.5 cigarettes per day; 69.8% had engaged in a quit attempt in their lives

Baseline comparisons showed that smokers in I3 smoked significantly ($p < 0.05$) fewer cigarettes per day (mean = 20.0) than in C (mean = 22.8)

***Results***

**Statistical techniques**
The research sample comprised only smokers who stated having no plans to quit within the next 6 months. Hypothesis with regard to effectiveness and cognitive changes: (1) only the tailored interventions (I1 + I2) would lead to more changes than C; (2) both tailored interventions (I1 + I2) would lead to more changes than the standardised self-help guide (I3); and (3) the tailored intervention with three tailored letters (I1) would lead to more changes than the tailored intervention with one tailored letter (I2)

Logistic regression was used for the binary outcome measures (stage transition, 7-day quit) and linear regression for the quantitative outcome measures (intention to quit). In the case of a significant main effect of one of the variables sex, age, education, stage, partner (having or not having a smoking partner) or lifetime quit (having or not having engaged in a quit attempt in their life), the variable was included in the analyses as a covariate. The factor 'condition' was dummy coded. For all tests, $p < 0.05$ was used. Because the intention to quit was not a meaningful measure anymore for participants who had quit smoking, participants who reported having restrained from smoking during the past 7 days were excluded from all analyses on intention to quit

To test whether the conditions led to differential outcomes and to differential cognitive changes, first, overall *F* tests were conducted for the three outcome measures and the six cognitive measures. Second, contrasts between the four conditions were computed

In the analyses on the cognitive changes, the T1 scores on the cognitive measures were entered as covariates. To rule out the cognitive changes were being caused by changes in behaviour, smokers who at T2 stated having refrained from smoking during the past 7 days were removed from these analyses

To study to what extent the effectiveness of the conditions differed for subgroups of smokers, several interactions were tested; that is the two-way interactions of condition with sex, age, education, stage, partner, lifetime quit and the number of cigarettes a day were entered in the equations. In the case of significant interactions ($p < 0.10$) remaining, the analyses were stratified

With regard to stage transition, there was a significant stage × conditions interaction, $p < 0.001$. Thus, the analyses with regard to stage transition were stratified according to stage, i.e. immotives and precontemplators. Baseline comparisons showed that smokers in I3 smoked significantly ($p < 0.05$) fewer cigarettes per day (mean = 20.0) than in C (mean = 22.8). Hence, in all analyses the number of cigarettes smoked per day was included as a covariate

Last observation carried forward analysis (using T1 scores of each smoker who dropped out as a substitute for T2) revealed that none of the results changed quantitatively; only minor changes in Beta's, ORs and *p*-values emerged (the authors called this an 'ITT' analysis)

*continued*

# Data extraction table *contd*

***contd***
**S021, Dijkstra (1999)**[43]

***Results* contd**

**Behaviour change**
Quitting behaviour was measured with a point prevalence measure: 'Have you been smoking during the past 7 days? (even one puff)' (yes/no)

7-day quit (%) by condition:
I1: 3.2%; I2: 4.4%; I3: 3.5%; C: 5.5%. Overall *F* test: NS

ORs: I1 versus C, 1.94, NS; I2 versus C, 1.34, NS; I3 versus C, 1.75, NS; I1 versus I3, 1.11, NS; I2 versus I3, 0.77, NS; I1 versus I2, 1.45, NS. (No CIs reported)

**Stage movement**
Stage of change and stage transition:

Stage transition for immotives/precontemplators (%): I1, 42.1%/25.6%; I2, 26.1%/35.0%; I3, 20.5%/19.0%; C, 14.3%/40.0%. Overall *F* test: $p < 0.001$, NS

ORs for immotives/precontemplators: I1 versus C, 4.48/0.52, $p < 0.001$, NS; I2 versus C, 2.07/0.82, $p < 0.05$, NS; I3 versus C, 1.54/0.36, $p < 0.05$, NS; I1 versus I3, 2.91/1.47, $p < 0.001$, NS; I2 versus I3, 1.34/2.30, NS/NS; I1 versus I2, 2.17/0.44, $p < 0.01$/NS. (No CIs reported)

Quitting behaviour, stage movement and intention: Means and *F* tests were calculated for the four conditions on the three outcome measures. Only the overall tests for stage transition and intention to quit were significant

1: I1, I2 and I3 compared with C. For immotives, both I1 and I2 led to significantly more stage transition than C ($p < 0.001$, and $p < 0.05$, respectively), whereas I3 did not. For precontemplators, none of the experimental conditions was more effective than C – in fact, I3 led to significantly less stage transition, $p < 0.05$
2: I1 and I2 compared to I3. For immotives, only I1 was significantly more effective, $p < 0.001$. For precontemplators, no significant difference were observed
3: I1 compared to I2. Only in immotives was I1 significantly more effective, $p < 0.01$

**Health**
Not stated

**Intermediate outcomes**
Intention to quit was measured with a composite of four 10-point scales: 'Do you intent to quit smoking': 1, 'within the next month', 2, 'within the next 6 months'; 3, 'within the next 5 years', 4, 'ever'?

Mean intention to quit scores by condition: I1, 4.35; I2, 3.98; I3, 3.80; C, 3.55. Overall *F* test: $p < 0.01$

Betas of contrasts between conditions for Intention to quit: I1 versus C, 0.79 ($p < 0.001$); I2 versus C, 0.43 ($p < 0.10$); I3 versus C, 0.24 (NS); I1 versus I3, 0.55 ($p < 0.05$); I2 versus I3, 0.19 (NS); I1 versus I2, 0.37 ($p < 0.10$)

1: I1, I2 and I3 compared with C. I1 led to significantly high intention to quit ($p < 0.001$), I2 was borderline significant ($p < 0.10$), whereas I3 was not significantly different
2: I1 and I2 compared to I3. Only I1 led to significantly higher intention than I3, $p < 0.05$
3: I1 compared to I2. I1 was borderline significantly more effective than I2, $p < 0.10$

Pros of quitting (12 items referring to the positive consequences of behaviour change):

Mean scores at T2 by condition: I1, 1.44; I2, 1.36; I3, 1.33; C, 1.31. Overall *F* test: $p < 0.05$

Betas of contrasts between conditions for pros of quitting: I1 versus C, 0.14 ($p < 0.01$); I2 versus C, 0.05 (NS); I3 versus C, 0.02 (NS); I1 versus I3, 0.12 ($p < 0.05$); I2 versus I3, 0.03 (NS); I1 versus I2, 0.09 ($p < 0.10$)

Cons of quitting (ten items referring to the negative consequences of behaviour change):

Mean scores at T2 by condition: I1, 0.93; I2, 0.95; I3, 1.02; C, 0.99. Overall *F* test: NS

Betas of contrasts between conditions for cons of quitting: I1 versus C, –0.06 (NS); I2 versus C, –0.04 (NS); I3 versus C, 0.03 (NS); I1 versus I3, –0.09 ($p < 0.10$); I2 versus I3, –0.07 (NS); I1 versus I2, –0.02 (NS)

Self-efficacy (12 items referring to the perceived ability to refrain from smoking in social, emotional, and habitual situations):

Mean scores at T2 by condition: I1, 0.16; I2, –0.41; I3, –0.42; C, –0.45. Overall *F* test: $p < 0.001$

Betas of contrasts between conditions for Self-efficacy: I1 versus C, 0.61 ($p < 0.001$); I2 versus C, 0.05 (NS); I3 versus C, 0.03 (NS); I1 versus I3, 0.58 ($p < 0.001$); I2 versus I3, 0.01 (NS); I1 versus I2, 0.56 ($p < 0.001$)

Attentional change processes: three experiential processes were assessed: consciousness raising (four items); environmental re-evaluation (four items); and social liberation (four items):

Mean scores at T2 by condition for consciousness raising/environmental re-evaluation/social liberation: I1, 1.48/0.80/2.31; I2, 1.33/0.71/2.30; I3, 1.18/0.69/2.32; C: 1.09/0.63/2.30. Overall *F* test: $p < 0.001$/$p < 0.05$/NS

Betas of contrasts between conditions for consciousness raising/environmental re-evaluation/social liberation: I1 versus C, 0.39/0.17/–0.00 ($p < 0.001$/$p < 0.01$/NS); I2 versus C, 0.24/0.08/–0.02 ($p < 0.01$/NS/NS); I3 versus C, 0.09/0.06/0.01 (NS/NS/NS); I1 versus I3, 0.31/0.11/–0.02 ($p < 0.001$/$p < 0.10$/NS); I2 versus I3, 0.16/0.02/–0.03 ($p < 0.05$/NS/NS); I1 versus I2, 0.15/0.09/0.01 ($p < 0.10$/NS/NS)

*continued*

# Data extraction table *contd*

***contd***
**S021, Dijkstra (1999)**[43]

***Results* contd**

**Intermediate outcomes *contd***
Cognitive changes: Regarding the 'cons of quitting' and 'social liberation', none of the between condition comparisons were significant at the 0.05 level

1: 'Pros of quitting'. I1: led to significantly higher scores than C ($p < 0.01$), whereas I2 and I3 did not. I1 led to significantly higher scores than I3 ($p < 0.05$), whereas I2 did not. I1 led to a borderline significantly higher score than I2, $p < 0.10$
2: 'Self-efficacy'. I1 led to significantly higher scores than C ($p < 0.001$), whereas I2 and I3 did not. I1 led to significantly higher scores than I3 ($p < 0.001$), whereas I2 did not. I1 led to significantly higher scores than I2, $p < 0.001$
3: 'Consciousness raising'. I1 and I2 led to significantly higher scores than C ($p < 0.001$, and $p < 0.01$, respectively), whereas I3 did not. I 1 and I2 led to significantly higher scores than I3, $p < 0.001$, and $p < 0.01$, respectively. I1 led to a borderline significantly higher score than I2, $p < 0.10$
4: 'Environmental re-evaluation'. I1 led to significantly higher scores than C ($p < 0.01$), whereas I2 and I3 did not. I1 led to a borderline significantly higher score than I3 ($p < 0.10$), whereas I2 did not. I1 and I2 did not lead to significant differences

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
1000 were sent pretest questionnaires. 915 (91.5%) returned the pretest questionnaire (T1). 843 (84.3%) respondents were randomised to either one of the three interventions or control (I1, 214; I2, 206; I3, 215; C, 208). Attrition from T1 to T2 was 11% ($n = 93$; I1, 12.6%; I2, 12.2%; I3, 6.9%; C, 12.5%). Therefore at T2 750 participants (I1, 187; I2, 180; I3, 201; C, 182)

**Reasons**
72/915 were excluded at T1 because the respondents smoked only a pipe or cigar or had plans to quit smoking within the next 6 months
Logistic regression analysis with attrition as the dependent variable revealed that drop-outs had a significantly ($p > 0.05$) lower self-efficacy at T1

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Self-help materials currently available (in The Netherlands) are not effective among smokers who are not planning to quit within the next 6 months, but tailored interventions can be effective, especially among immotives

**Comment**
Randomisation procedure not detailed. No intention-to-treat data presented, though authors note that such analysis did not lead to qualitative changes in the nature of the results

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S219, Glasgow (1995)**[62]

**Country**
USA

**Aim**
To evaluate the short-term effects of a low-intensity worksite heart disease risk reduction programme using a matched pair design with worksite as the unit of analysis

**Model**
TTM

**Theoretical basis**
The intervention model for the Take Heart programme uses the stage-of-change model (S614, S615) as a framework for assisting worksites and employees through various behaviour change stages. For employees in precontemplation or contemplation stages the aim was to stimulate consideration of the risks of high cholesterol and smoking and ways to reduce these risks by making changes in nutrition and tobacco use behaviours. For employees in later stages, assistance in altering dietary and/or tobacco use behaviours was provided, as appropriate, and assistance in maintaining these behaviours

**Study type**
Clustered-matched RCT

**Design**
Randomised trial comparing 13 early intervention worksites and 13 matched (type of industry: manufacturing/sales versus other; number of employees: 125–150/151–250/251–750; level of employee participation in baseline assessment, and previous health promotion activities) delayed intervention worksites. The study had adequate power (power of 0.90 to detect a difference of 10 mg/dl in cholesterol (alpha = 0.05, two-tailed, paired *t*-test)) even with worksite as the unit of analysis

**Setting**
Workplace

**Length of intervention**
2-year intervention period

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Employees at eligible worksites

**Inclusion criteria**
Worksites: between 125 and 750 employees and located within 96 km (60 miles) of Eugene, OR

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking cessation and dietary fat intake

***Intervention details***

**Intervention group**
Early intervention: A 'kick-off' event was planned by each worksite to familiarise employees with the programme. Intervention activities were developed by means of a 4 × 2 matrix that listed examples under each of four activity classes (motivational/incentive, educational/skills training, policy/environmental, and maintenance) for both tobacco and nutrition. This 'Take Heart menu' is part of a 72-page guidebook provided to steering committee members to help plan worksite activities. Each worksite was encouraged to conduct at least two activities from each of the eight cells of the matrix during the 2-year intervention period

- Motivational and incentive activities: designed to provide encouragement and/or increase awareness (e.g. carbon monoxide feedback for smokers and weight loss contests); a variety of materials with Take Heart logo was distributed (hats, insulated lunch bags, key chains) to facilitate attendance and enhance the visibility of project
- Educational and skills training: distribution of self-help behaviour change materials, presentation and discussion of videos (e.g. on lowering cholesterol, environmental tobacco smoke) and several taste testing and food label reading demonstrations and discussions

Activities required no more than 15–20 minutes and offered at times (lunch hours, break times) and locations (outside cafeteria, employee lounge) selected to facilitate participation

- Policy and environmental change: reviewing existing policies related to tobacco use at worksite and inclusion of low-fat items in vending machines and cafeterias
- Maintenance: Activities were co-ordinated, whenever possible, with community or national events to facilitate maintenance

*continued*

## Data extraction table *contd*

***contd***
**S219, Glasgow (1995)**[62]

***Intervention details* contd**

**Comparison group**
Delayed intervention: No details reported

**Classification into stages**
Not stated

**Validity of measure**
Not stated

**Training of educators**
An employee who knew the worksite well acted as the research team contact person and solicited a cross section of employees to participate in a steering committee. The steering committee was then oriented and assisted by an research team facilitator and by written guidelines in promoting, planning and implementing intervention activities. I worksites were invited to send at least two representatives to a Take Heart orientation breakfast at which the programme was described. Employee steering committees met monthly and selected and publicised activities and events, involved co-workers and lobbied for changes in worksite health promotion policies

***Baseline characteristics***

**Gender**
Percentage (SD) female employees: I, 30% (20); C, 38% (24)

**Age**
Not stated

**Stage of change**
Not stated

**Target behaviour**
Cohort data/cross-sectional data:
Mean smoking prevalence (SD): I, 0.19 (0.13)/0.22 (0.11); C, 0.19 (0.09)/0.23 (0.09)
Mean fat intake (SD): I, 33.18 (8.25)/35.21 (8.54); C, 37.14 (10.18)/37.36 (9.78)

***Results***

**Statistical techniques**
All analyses were conducted on SPSS-x; the worksite was the unit of analysis. After initial descriptive statistics (means, SD, distributional statistics) had been calculated, paired *t*-tests were used to conduct primary analyses. This process reflected the experimental design, which involved pairing and then randomising worksites to conditions

Cohort data represent the 1222 employees with data at both assessments. Cross-sectional represent data from all respondents

**Behaviour change**
Attempts to quit smoking or reduce fat intake over the previous year, and current tobacco use. (Smoking status: 'Have you smoked a cigarette, even a puff, during the past 7 days?'. The Block diet history was used at the baseline; at follow-up the abbreviated Block fat screening measure was used)

Cohort data/cross-sectional data:
Mean change in smoking prevalence (SD): I, 0.03 (0.04)/0.04 (0.06); C: 0.03 (0.05)/0.05 (0.07). NS
Mean smoking cessation at follow-up (among baseline smokers) (SD): I, 0.25 (0.27)/0.30 (0.15); C, 0.27 (0.20)/0.31 (0.13). NS

Mean change in fat intake (g) (SD): I, 2.97 (3.36)/1.96 (3.60); C, 4.54 (3.36)/2.64 (3.92). NS
Mean change in smoking quit attempts, percentage (SD): I, 66% (21)/53% (15); C, 76% (19)/50% (0.09). NS
Mean change in attempts to reduce fat (scale 0–4) (SD) (cohort data only): I, –0.13 (0.32); C, –0.20 (0.14). NS

**Stage movement**
Stage of change for tobacco- and dietary-related behaviour change:
Mean change in smoking stage of change, percentage progressing (SD) (cohort data only): I: 48% (55); C: 49% (41). NS
Mean change in eating stage of change, percentage progressing (SD) (cohort data only): I: 15% (10); C: 12% (5). NS

**Health**
Cholesterol assessment

Cohort data/cross-sectional data:
Mean change in cholesterol (mg/dl) (SD): I, –0.81 (7.81)/2.70 (8.06); C, –0.39 (6.80)/2.90 (7.64). NS
Mean change in cholesterol (mg/dl) (SD), participants > 200 mg/dl at the baseline: I, 7.39 (10.70)/2.70 (8.17); C, 6.78 (7.28)/4.20 (7.96). NS

**Intermediate outcomes**
Perceived support from supervisors and co-workers for tobacco- and dietary-related behaviour change

Mean change in support for health behaviours (10-point scale) (SD):
- from supervisor: I, 0.52 (0.51)/0.47 (0.67); C, –0.05 (0.40)/0.01 (0.35). $p < 0.01/< 0.06$
- from co-worker: I, 0.30 (0.43)/0.24 (0.57)/0.04 (0.33)/0.04 (0.33). NS
- Total: I, 0.41 (0.45)/0.35 (0.60); C, 0.005 (0.33)/0.03 (0.31). $p < 0.03$/NS

*continued*

# Data extraction table *contd*

***contd***
**S219, Glasgow (1995)**[62]

***Results* contd**

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Programme implementation/process data in I were recorded by staff in two ways: (1) intervention activities and attendance at committee meetings were coded after each meeting; (2) an activity report was completed to record employee participation and length and type of event. No data reported here. The employee steering committees implemented the intervention menu approach as recommended, and there were substantially more improvements in the number and types of health promotion activities offered in I versus C (reported by Glasgow and Terborg, unpublished data)

***Withdrawals/economic evaluation***

**Number per group**
42 worksites were contacted: 27 agreed, and one withdrew (after baseline assessment) after takeover by another company (reduced its employees to < 25)

Participation rates varied from 26 to 83% (1991 = baseline mean: 48%) across worksites. 2791 employees participated at the baseline, mean participation rates were 38% for I and 58% for C. In 1993, 2622 employees took part, estimated participation rates: 40% for I and 57% for C. 1222 (47%) employees were available for longitudinal cohort evaluations

**Reasons**
As a result of confidentiality agreements there is no information on how many baseline respondents were still employed at follow-up or on characteristics of non-respondents

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' comment**
Results were similar across cohort and cross-sectional samples, and in no case was the interpretation of an effect (or absence of effect) different for cross-sectional versus cohort data

**Authors' conclusions**
At the conclusion of the intervention, I and C did not differ on changes in smoking rates, dietary intake or cholesterol levels. There were considerable variability in outcomes among worksites within each condition. This intervention did not produce short-term improvements beyond secular trends observed in control worksites

Authors' explanations for lack of effects: (1) activities were not appropriate kinds; (2) more-intensive or longer-term interventions may be needed; (3) unclear how many employees actually too part in activities; (4) employee assessment may have been sufficiently reactive to produce behaviour changes in both conditions; (5) most pessimistic conclusion is that even well-designed, multiple faceted worksite health promotion programmes do not produce meaningful improvements in employee behaviour; (6) most important conclusion is the considerable variability across worksites within conditions

**Author' reported limitations**
Only 48% of employees participated in assessments

**Request for more information from authors**
No reply

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S073, Goldstein (1999)**[55]

**Country**
USA

**Aim**
To evaluate the efficacy of a brief medical office-based intervention to increase the physical activity level of sedentary middle-aged and older adults compared to usual care and to assess the degree to which changes in physical activity levels are maintained over 8 months of follow-up

S485: Addresses the acceptability and feasibility of physician-based activity counselling and presents data on physician's evaluation of the activity counselling training and the support materials provided by the PAL project

**Model**
TTM

**Theoretical basis**
For PAL project, a medical office-based physical activity counselling intervention for adults aged 50 and above was developed, using a patient-centred model of counselling (S657) based on the principles of the TTM of change (S248), social-cognitive theory (S658), and health education theory (S659)

The PAL intervention also drew on information about the health behaviour of middle-aged and older adults to help tailor the content of messages delivered by providers and the content of printed materials for the patients

For the PAL project, the principles of TTM were integrated with a patient-centred counselling approach which emphasised interviewing skills that permit tailoring of the counselling message. Patient assessment includes previous experience with physical activity, knowledge and beliefs about physical activity, stage of motivational readiness for physical activity, and barriers and facilitators to change. The counselling strategy utilises the 'five As' (address the agenda, assess, advice, assist and arrange follow-up)

**Study type**
Clustered RCT

**Design**
Randomisation by practices to prevent carry-over effects of the intervention to control participants. Practices were matched on whether they were solo or group practices. At the baseline, 6 weeks and 8 months following the initial office visit patients were interviewed via telephone to obtain data on level of physical activity, quality of life, and psychosocial factors relevant to physical activity. At 6 weeks and 8 months patients evaluations of the intervention components were also obtained. Physicians completed a brief pre-intervention questionnaire on their counselling practices and again after completion of patient follow-up visits

All practices were reimbursed $400 for participation. Physicians in I were reimbursed an additional $100 for attending the training session and $40 for each patient seen for a follow-up visit

**Setting**
Primary care

**Length of intervention**
A routine initial office visit and a follow-up appointment scheduled within 4 weeks of the initial appointment

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Physicians: 34 physicians from 24 practices (12 solo, 12 group)

Patients: ambulatory patients, aged over 50 years, who were scheduled for routine visits (non-acute care) with the participating physician over the intervention period (4–7 weeks)

**Inclusion criteria**
Ambulatory patients, over 50 years

**Exclusion criteria**
Patients who were too active (moderate exercise for ≥ 30 minutes at least 5 days each week or vigorous exercise for ≥ 20 minutes on at least 3 days per week). Not ambulatory, and those unable to provide information on the telephone

**Behaviours targeted**
Physical activity

*continued*

# Data extraction table *contd*

***contd***
**S073, Goldstein (1999)**[55]

***Intervention details***

**Intervention group**
All: At initial appointment study was explained and patient was interviewed to obtain information on stage of motivational readiness for physical activity, physical activity preferences and barriers to becoming physically active

I: Information collected was placed on patient's chart and used to guide counselling to be appropriate to the patient's stage of readiness. Physician was asked to counsel the patient for about 5 minutes and give a written exercise prescription and a manual with instructions to read the section in the manual appropriate to the patient's stage of motivational readiness for physical activity. Participants were also encouraged to read subsequent sections of the manual when they felt ready to move on

Prior to follow-up appointment research staff provided exercise prescriptions for patient's chart. At follow-up physician was expected to provide activity counselling and complete new exercise prescription for patient, give patient attractive poster with tips on adoption and maintenance of physical activity

Manual consisted of five colour-coded sections, one for each stage of physical activity adoption. Provided guidance on health benefits, benefits and barriers, enhancing confidence to become and remain active, and tips on becoming and staying physically active

The content was based on behavioural and social-cognitive concepts (e.g. social support, cues and prompts) and stage-specific processes (e.g. precontemplators/contemplators were given information on health benefits, while preparers were given information on planning regular physical activities)

After follow-up patients received five monthly mailings including another copy of manual, and four newsletters which provided information on specific types of moderate activities (walking, gardening, dancing), tips for those thinking about becoming physically active and for those who were, as well as local resources and quizzes about physical activity. At month 1, newsletter on health benefits; month 2, newsletter on walking; month 3, new copy of manual; month 4, newsletter on dancing; month 5, newsletter on biking and gardening ($n$ = 17 physicians, 12 practices and 181 patients)

**Comparison group**
Physician meeting for usual care ($n$ = 17 physicians, 12 practices and 174 patients)

**Classification into stages**
Seven questions assessed current stage of motivational readiness for physical activity. This instrument was a modified version of a standardised questionnaire to assess stage for vigorous exercise; to address the criteria for moderate physical activity as defined by the US CDCP and ACSM. The five stages of motivational readiness are:

Precontemplation: individuals who are not physically active and do not intend to start
Contemplation: individuals who are not physically active but intend to start in the next 6 months
Preparation: individuals who participate in physically activity irregularly (< 5 days per week for at least 30 minutes each day)
Action: individuals who participate in regular physically activity (≥ 5 days per week for at least 30 minutes each day) for less than 6 months
Maintenance: individuals who participate in regular physically activity (≥ 5 days per week for at least 30 minutes each day) for 6 months or longer

**Validity of measure**
Previous studies have demonstrated the reliability (kappa index over a 2-week period of 0.78 (S145)) and concurrent validity of the stages of motivational readiness instrument for vigorous exercise (S258)

S145: Used a slightly different scale. Conclusion: scores on efficacy items significantly differentiated employees at most stages. No additional validity information regarding this four-item scale. The scale was refined, adding one item: preparation; test–re-test results are based on this five-item scale

S258: Used a slightly different scale. Conclusion: scores on physical activity behaviour items significantly differentiated employees among the stages. No additional information on validity

S138: A similar measure of the SoE adoption has been shown to be reliable (S656) and significantly related to instruments measuring the processes of change, self-efficacy, and decision making for exercise and the 7-day Physical Activity Recall Questionnaire (S115, S145, S258, S496, S656). No validity data presented in S138

**Training of educators**
17 Physicians in the intervention group attended a 1 hour training session on physical activity counselling (manual reviewed and protocol explained). Role play scenarios were used to give the physicians an opportunity to practice their counselling techniques with feedback from members of the research team. Physicians were provided with a 28-page manual, a desk prompt with summary information on counselling, and an office poster on physical activity promotion. The manual included a glossary of exercise terminology, a review of the health benefits of physical activity, and information on risk assessment prior to developing an exercise prescription; as well as described principles of behaviour change and stages of motivational readiness as applied to physical activity counselling, gave specific instructions and examples on how to write an exercise prescription, and offered suggestions on how to help patients overcome roadblocks to participation in physical activity; and provided a list of community recourses on physical activity programmes

*continued*

# Data extraction table *contd*

***contd***
**S073, Goldstein (1999)**[55]

***Baseline characteristics***

**Gender**
Physicians: I, 24% female; C, 24% female
Patients: I, 65% female; C, 64% female

**Age**
Mean age (SD):
Physicians: I, 44.6 (9.8) years; C: 43.7 (7.3) years
Patients (SD): I, 65.4 (9.0) years; C, 65.8 (9.3) years

**Stage of change**
I: precontemplation, 13%; contemplation, 31%; preparation, 56%
C: precontemplation, 17%; contemplation, 33%; preparation, 50%

**Target behaviour**
Mean PASE score (SE): I, 108.53 (5.26); C, 108.82 (5.02)

***Results***

**Statistical techniques**
Fisher's exact tests and Welch *t*-test were used to compare differences in demographic characteristics and baseline activity counselling between I and C physicians and to compare patient demographic characteristics between the two groups. PASE scores were square root transformed to correct for heteroscedasticity and non-normality. Linear mixed effects models were applied to the PASE scores while logistic mixed effects models were used for the proportion in preparation and action, the proportion in Action, and the proportion who met CDCP and ACSM recommendations for vigorous or moderate exercise. The models were fitted using the SAS GLIMMIX Macro with physician practice entered as a random effect nested within Group in accordance with the experimental design. The intervention effect was assessed for the 6 weeks and 8 months physical activity outcomes individually and also in longitudinal models taking the effect of repeated measurements into account. Age, gender, number of medical conditions, time since baseline, and baseline response were entered as covariates in all the models

S485: $\chi^2$ analyses were used to compare I and C physicians on demographic characteristics and baseline activity counselling. Descriptive statistics (means and SD) were obtained for the physicians' evaluation of PAL training programme, and barriers to implementing exercise counselling. ANCOVAs were conducted to compare I and C on physicians' assessment of patients' exercise levels, specific components of exercise counselling and confidence in providing exercise counselling. Finally, the percentage of I patients who reported receiving activity counselling and the patients' evaluation of the exercise counselling and PAL materials are presented

**Behaviour change**
PASE (PASE: 11-item self-report; three dimensions: leisure time, household, occupational activity within past week; participants are asked to recall the frequency, duration and type of leisure time activity they engaged in over the past 7 days; whether or not they engaged in light or heavy housework, home repairs, lawn work, gardening or care-giving activity; and occurrence, duration and type of volunteer or paid work)

Mean baseline PASE score (SE): I, 108.53 (5.26); C, 108.82 (5.02)
Mean 6 weeks PASE score (SE): I, 119.56 (5.90); C, 122.31 (5.57)
Mean 8 months PASE score (SE): I, 112.58 (5.79); C, 111.03 (5.55)

There were no significant differences between I and C groups on PASE scores at 6 weeks ($p = 0.94$) or at 8 months ($p = 0.74$). No changes when accounted for influence of repeated measurements in longitudinal model or when the change in PASE scores in the subgroup in precontemplation/contemplation at the baseline was examined

**Stage movement**
Stage of motivational readiness for physical activity (modified for moderate activity)

Baseline: I, 56% in preparers/action (SE: 0.04), 0% in action (SE: 0.00); C, 50% (0.04), 0% (0.00)
6 weeks: I: 89% in preparers/action (SE: 0.02), 49% in action (SE: 0.04); C, 74% (0.03), 42% (0.04)
8 months: I: 79% in preparers/action (SE: 0.03), 48% in action (SE: 0.04); C, 88% (0.03), 43% (0.04)

At 6 weeks: 89% of I in preparers/action versus 74% of C ($p < 0.001$; OR = 3.56; 95% CI, 1.79 to 7.08). 49% of I in Action versus 42% in C ($p = 0.13$; OR = 1.47; 95% CI, 0.88 to 2.43). Of those in precontemplators/contemplators at the baseline, 84% ($n = 62$) of I moved into preparers/action versus 68% ($n = 55$) of C ($p = 0.01$; OR = 3.27; 95% CI, 1.32 to 8.07)
At 8 months: 79% of I were in preparers/action versus 88% of C ($p = 0.07$; OR = 0.50; 95% CI, 0.20 to 1.07). 48% of I were in Action versus 43% in C ($p = 0.35$; OR = 1.25; 95% CI, 0.77 to 2.02). Of those in precontemplators/contemplators at the baseline, 70% ($n = 51$) of I moved into preparers/action versus 83% ($n = 64$) of C ($p = 0.16$; OR = 0.41; 95% CI, 0.11 to 1.46)
Longitudinal analyses that take all 3 time points into account: odds of I being in preparers/action was 1.29 times higher compared to C ($p = 0.28$; 95% CI, 0.82 to 2.04). Similarly, although not statistically significant, I more likely to be in Action: ($p = 0.08$; OR = 1.36; 95% CI, 0.96 to 1.93)

**Health**
Quality of life (SF-36). Not reported

*continued*

# Data extraction table *contd*

***contd***
**S073, Goldstein (1999)**[55]

***Results* contd**

**Intermediate outcomes**
Psychological constructs relevant to physical activity adoption and maintenance (processes of change, self-efficacy, pros and cons).
Not reported

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Patients evaluations of the intervention components at 6 weeks and 8 months reported elsewhere; as well as physicians' evaluation of acceptability, usefulness and feasibility of the physician manual and training (S485). Physicians favourably endorsed the training and support materials, and training produced significant improvements in confidence in delivering physical activity counselling

Copies of exercise prescriptions were obtained for 99% of patients in I. Exercise prescriptions obtained from practices after follow-up visits indicated that 139 patients (77%) received follow-up physical activity counselling and suggested that there were difficulties in arranging and providing follow-up counselling for some participants

93% (141/151) of patients in I who provided data at 6 weeks reported receiving physical activity counselling from physician during initial visit. However, only 67% recalled receiving the written exercise prescription at initial visit. Only two patients in C reported receiving an exercise prescription

S485: Evaluation of the PAL programme by I physicians (scale 1–5). Overall rating favourable (mean = 4.1; 1 = very poor; 5 = very good); training session moderately useful (mean = 4.1; 1 = not useful at all; 5 = very useful); training had improved their ability to provide exercise counselling to their older patients (mean = 3.8; 1 = not at all; 5 = very much); estimated that patients increased their activity levels (mean = 3.6; 1 = strongly disagree; 5 = strongly agree). They did not strongly endorse the integration of the intervention materials into office routine (mean = 3.4; 1 = strongly disagree; 5 = strongly agree); but they would recommend programme to colleagues (mean = 4.0; 1 = strongly disagree; 5 = strongly agree)

Generally, the physicians found that all the PAL materials were useful, and endorsed the age appropriateness of materials

Physicians did not rate barriers such as insufficient time, forgetting to counsel, etc., as limiting factors to counselling

Changes in physician confidence in providing activity counselling (eight items: adapt counselling; assess exercise history; negotiate plan; identify resources; turn setbacks into learning; help cope with triggers for relapse; counsel in cost-effective way; integrate counselling into regular patient visits): three counselling behaviours (negotiate plan; identify resources; turn setbacks into learning) showed a significant ($p < 0.05$) increase in confidence, when I compared to C. The summary score (mean of all eight) showed a significant difference between groups over time

Changes in exercise counselling behaviours: Most physicians reported counselling ≥ 75% of their patients across all counselling behaviours ('five As'). Exercise counselling was delivered to 179/181 (99%) of I patients, as corroborated by copies of exercise prescriptions. Scores on exercise components delivered to all patients (seven items: willingness to help patient; personalise benefits of exercise; negotiate with patient; provide an exercise prescription; provide printed materials; identify resources for exercise; arrange a follow-up) showed no significant differences between groups over time on any of the items, nor on the summary score

Evaluation of activity counselling by the patients: 93% (141/151) of I patients who provided data at 6 weeks reported receiving activity counselling from their physician during initial visit; on average physicians spent 8.9 minutes (SD = 0.19) on counselling; and it was moderately useful (mean = 3.3; 1 = not at all useful; 5 = extremely useful). Among I patients who had a scheduled follow-up appointment prior to 6 weeks assessment (82/152 = 54%), the majority kept the appointment (70/82 = 85%). Patients rated follow-up visit as moderately useful (mean: 3.1); 97% (66/68) reported that physician asked them about exercise and 77% (52/67) said their physician gave advice about how to exercise. At 8 months, patients in I were significantly more likely to report an increase in satisfaction (as a result of their doctor's attention to physical activity) with care, compared to C ($t = 4.55$, $p < 0.01$)

Evaluation of PAL materials by patients: 97% of I patients at 6 weeks reported receiving the manual, and 94% of those stated they read it. Most found it 'very easy to read' (99/135 = 73%), and a majority kept the manual (134/142 = 94.1%). Mean usefulness: 2.7. A majority of I patients reported receiving an exercise prescription from their physician at initial visit (95/141 = 67%), which they rated as moderately useful (mean = 3.4). Patients reported moderate adherence to exercise prescription (mean = 3.6, SD = 0.1; 1 = not at all; 5 = completely). 52% (32/62) of those attending their follow-up appointment before the 6-week assessment reported receiving a new exercise prescription, and 44% (29/66) reported receiving the activity poster. 52% (77/148) reported receiving newsletters and these were rated as somewhat useful (mean = 2.7)

*continued*

## Data extraction table *contd*

***contd***
**S073, Goldstein (1999)**[55]

***Withdrawals/economic evaluation***

**Number per group**
Physicians: no drop-outs reported. Patients: 2674 names were obtained, 2145 were contacted and 529 could not be reached. Data on demographics and exercise participation were obtained from 1702 patients, 443 refused to provide information. 858 were too active and 400 did not meet other eligibility criteria (e.g. ambulatory status, ability to complete interview): 444 were eligible. 89 (20%) refused, 355 were enrolled (80% of eligible and 13% of names received)

S485: Pre- and postintervention data were available on 12 physicians in I and 15 in C

**Reasons**
No drop-outs mentioned after randomisation

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

A detailed description of the integrated approach utilised in PAL is provided elsewhere (S500, S488)

Patients evaluations of the intervention components at 6 weeks and 8 months reported elsewhere; as well as physicians' evaluation of acceptability, usefulness and feasibility of the physician manual and training (S485)

**Authors' conclusions**
The results showed that at 6 weeks I were more likely to be in advanced stages of motivational readiness for physical activity than C. This effect was not maintained at 8 months and the intervention did not produce significant changes in PASE scores. Results suggest that more intensive, sustained interventions may be necessary to promote the adoption of physical activity among sedentary, middle-aged, and older adults in primary care medical practices

**Authors' reported limitations**
(1) Physicians in C may have provided physical activity counselling to their patients (all physicians very motivated)
(2) Physical activity assessment may have functioned inadvertently as cues for physical activity in both I and C
(3) PASE measure may not have been as sensitive to change as needed
(4) Inclusion of participants in the preparation stage may have created a ceiling effect
(5) Poor generalisability of findings (participants represented only 13% of possible population)

**Comment**
Comparison with project PACE (non-randomised similar project) discussed

Reimbursement of $40 for each follow-up appointment could have acted as an incentive

**S485: Authors' conclusion**
Physician and patients indicated the PAL project offered an acceptable and feasible approach to promote physical activity in older adults

**S488**
A review of studies that have targeted physicians as agents of behaviour change, including a detailed description of PAL approach. No additional information

**S500**
Review examining the health effects of physical activity and healthy eating, prevalence of these behaviours, prevalence of physician counselling in these areas, and the efficacy of physician counselling behaviour

Presents promising theoretical approaches relevant to the role of physicians as agents of behaviour change, followed by an application of these approaches to patient education. No additional information

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S165, Graham-Clarke (1994)**[57]

**Country**
Australia

**Aim**
To evaluate the impact of the Fresh Start programme, a multiple risk factor intervention programme for the reduction of cardiovascular disease risk factors in general practice patients, using Prochaska and DiClemente's TTM

**Model**
TTM

**Theoretical basis**
Prochaska and DiClemente's model of behaviour change was modified to three major stages of change: preparation (includes precontemplation, contemplation and preparation), action and maintenance (focus on behavioural processes of change). Three sub-programmes for reduction of cardiovascular disease risk factors: smoking cessation programme; a healthy eating programme; and a physical activity programme. Programmes include application of both cognitive and behavioural strategies and techniques to improve patient skills at overcoming barriers to change and to motivate, reinforce, and foster self-management of a healthy lifestyle

**Study type**
RCT

**Design**
80 GPs (75 practices as unit) were randomly allocated to one of three conditions: routine care, lifestyle counselling using videos and lifestyle counselling using videos and self-instructional materials. GPs were asked to enrol up to 20 patients (number and way of recruitment left entirely to GP). Assessment of patients' cardiovascular disease risk conducted at the baseline, after 4–6 months and again at 12–18 months. Patients were asked to complete a questionnaire (risk behaviours, medication use, perceived health status and demographics). At the baseline questionnaires were administered by GP, subsequent (4- and 12-month) questionnaires send directly to patient by Department of Public Health, with reminder for patient to return to GP for follow-up assessment

**Setting**
Primary care

**Length of intervention**
Length of intervention unclear; patients were asked to return to GP for follow-up assessments, last follow-up assessment 18 months after the baseline

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
758 patients with at least one modifiable cardiovascular disease risk factor (overweight, high blood pressure, elevated cholesterol, smoking)

**Inclusion criteria**
Both sexes, 18–69 years old, who had at least one modifiable cardiovascular disease risk factor (overweight: body mass index > 25 kg/m$^2$; high blood pressure, systolic blood pressure > 140 mmHg and/or diastolic blood pressure > 95 mmHg and/or currently on medication for hypertension; elevated cholesterol: total cholesterol > 5.5 mmol/l; smoking: self-report)

**Exclusion criteria**
Suffering from a chronic debilitating disease, not able to speak and write English, or not available for 12 months follow-up

**Behaviours targeted**
Physical activity, smoking and eating

***Intervention details***

**Intervention group**
I1: Lifestyle counselling using videos. GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk. Following assessment and feedback, GPs were asked to offer the patient the Fresh Start programme, and to tailor the programme according to the patient's risk factor profile (*n* = 270)

I2: Lifestyle counselling using videos and self-instructional materials. GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk. Following assessment and feedback, GPs were asked to offer the patient the Fresh Start programme, and to tailor the programme according to the patient's risk factor profile. Additionally, GPs were provided with three self-help booklets for patients, targeting risk factor behaviours and supplementing the videos (*n* = 233)

*continued*

# Data extraction table *contd*

***contd***
**S165, Graham-Clarke (1994)**[57]

***Intervention details* contd**

**Comparison group**
Routine care: GPs were asked to assess patients for risk factors for cardiovascular disease (overweight, high blood pressure, elevated cholesterol, smoking) and provide them with feedback on their risk, followed by GPs routine care ($n$ = 255)

**Classification into stages**
Not clear

GPs were asked to offer the patient the Fresh Start programme, and to tailor the programme according to the patient's risk factor profile

Physical activity was assessed by four questions: three questions on current physical activity levels and one question to determine the patients' intentions to change their current activity levels (no intention to increase their physical activity levels; thinking of increasing; or intended to increase). At follow-up assessments (4 and 12 months) an additional category was included to determine whether patients believed they had increased their physical activity levels

No description of how patients were classified into stages

Table 1 of S165: Preparation: getting ready to exercise; action: exercising. Maintenance: keeping going

In discussion (p. 142 of S165) "In the present study, patients were asked to indicate their current level of activity and state their intention to change that level of activity; however, this did not provide enough information to adequately 'stage' the patients"

**Validity of measure**
Not stated

**Training of educators**
I1 + I2: GPs were trained to use the programme at a pre-trial workshop which was supplemented by individual detailing of specific aspects of the programme in their own consultation rooms. In addition, each GP was provided with a detailed guide and instructional video, and a set of four patient videos which included an introductory motivational video and three risk behaviour videos (smoking, eating, physical activity)

***Baseline characteristics***

**Gender**
I1: 45% female; I2: 47% female; C: 54% female

**Age**
Mean (SD):
I1: 51.5(11.0) years; I2: 50.0 (11.8) years; C: 54.5 (10.9) years

**Stage of change**
See intermediate outcomes (intention to change)

**Target behaviour**
Physical activity:
I1: 35% sedentary/missing; 44% low; 11% moderate; 10% high
I2: 34% sedentary/missing; 48% low; 13% moderate; 6% high
C: 35% sedentary/missing; 48% low; 8% moderate; 9% high

***Results***

**Statistical techniques**
All preliminary analyses were conducted using the patient as the unit of analysis. The cluster effect on outcome (practice as unit of randomisation) was examined only if a significant effect was found

Data analysis had three major aims: (1) to describe baseline physical activity levels of patients; (2) to determine if interventions had differential effects on patients' physical activity levels; (3) to determine if interventions had differential effects on patients' intentions to change their level of physical activity

Descriptive analyses of baseline data were conducted to identify differences in physical activity participation and stages of change between intervention groups, between genders and between age groups. $\chi^2$ tests and analysis of variance were used to analyse baseline data where appropriate. The Mantel–Haenszel statistic was used where trends existed in categorical data

Energy expenditure scores were modelled against age and sex to determine whether these values should act as covariates in subsequent analysis. Baseline activity status and stage of change were included in the regression model

Data were analysed using repeated measures analysis of variance. Baseline measures were substituted for missing values at 4 months and 12 months. Frequency of positive progression of intention to change (jumping one (or more) categories forward since baseline; assuming a hierarchy ranging from no intention to have changed) was analysed using the $\chi^2$ statistic

**Behaviour change**
Self-reported physical activity and energy expenditure (METs). Baseline METs (SD): I1, 13.43 (3.5); I2, 14.18 (3.2); C, 15.02 (3.5). No differences between groups over 12 months. Adjusting for age, sex and baseline stage of change showed a signifcant increase in energy expenditure across 12 months ($F(2, 1024) = 40.86$, $p = 0.0001$), due to improvements among least active patients at the baseline

*continued*

# Data extraction table *contd*

***contd***
**S165, Graham-Clarke (1994)**[57]

***Results* contd**

**Stage movement**
See intermediate outcomes (intention to change)

**Health**
Not reported

**Intermediate outcomes**
Intention to change, baseline:
I1: 53% intend, 25% thinking; 22% no intention
I2: 53% intend, 28% thinking; 19% no intention
C: 37% intend, 31% thinking; 32% no intention

After 4 months: I1, 23% progressed; I2, 17% progressed; C, 27% progressed ($\chi^2$ = 7.523, df = 2, $p$ = 0.023)

After 12 months: I1, 20% progressed; I2, 22% progressed; C, 21% progressed (NS)

**Adverse effects**
Not reported

***Other outcomes***
Not reported

**Implementation measures**
Participation rates were measured by question completion

Not reported

***Withdrawals/economic evaluation***

**Number per group**
Of the 758 patients enrolled, 71% (543) completed at least one of the four physical activity questions at the baseline, and 44% (334) and 50% (382) provided follow-up information at 4 and 12 months, respectively. Participation rates did not differ between groups

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Results suggest that the staged approach to increasing physical activity in general practice was not successful. Methodological limitations (implementation of the programme; the use of the MET energy expenditure classification system; appropriate measures of impact; and the cluster effect), limitations of the physical activity intervention and problems with the interpretation, modification and use of the TTM in clinical settings are discussed

**S326**
Data not added, only background

**Request for more information from authors**
No reply

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S458, Gritz (1993)**[44]

**Country**
USA

**Aim**
To compare a state of the art provider delivered smoking cessation intervention (consisting of surgeon- or dentist-delivered advice to stop smoking, a contracted quit date, tailored written materials, and booster advice sessions) with a usual care advice control condition in an RCT

**Model**
TTM

**Theoretical basis**
Not stated explicitly. In the description of the interventions is stated: Participants' receptivity to quitting was discussed in the experimental intervention; and in the booster sessions advice was tailored to the participants current smoking status (abstainer, relapser, continuing smoker)

**Study type**
RCT

**Design**
S513: A prospective RCT. Eligible participants were randomised into either a control (usual care) or experimental (intervention) group

Participants were stratified by hospital site and type of medical treatment; radiation only, total laryngectomy, or surgery other than total laryngectomy (with or without radiation). Baseline interviews were administered to both sets of participants before medical treatment began. Standardised advice protocols were designed for the delivery of smoking cessation advice. Participants received initial advice 2 to 3 days before discharge and, to radiation-only patients, prior to treatment initiation. The protocol required 6-monthly booster advice sessions for experimental participants as part of regular medical or dental post-treatment care. Follow-up data were collected at 1, 6 and 12 months after initial advice

**Setting**
Outpatient clinic

**Length of intervention**
12 months

***Inclusion/exclusion criteria***

**Participants**
Patients with existing disease

**Population**
186 patients with newly diagnosed, first primary squamous cell carcinomas of the oral cavity, pharynx, and larynx from ten participating hospital-based medical and dental clinics in the Southern California area

**Inclusion criteria**
Tobacco use within the past year

S513: Patients over 18 years of age with newly diagnosed, first primary squamous cell carcinomas of the head and neck. Life expectancy of more than 1 year; tobacco use within the past year; absence of gross psychopathology; medical follow-up by local providers; English speaking and reading; and agreement to undergo treatment

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
All: Standardised advice protocols were designed to guide head and neck surgeons and maxillofacial prosthodontists in delivering smoking cessation advice. Providers delivered initial advice to surgical patients 2–3 days before hospital discharge and, to radiation-only patients, prior to treatment initiation

I: The protocol then called for providers to give 6-monthly booster advice sessions to experimental participants as part of regular medical or dental post-treatment care

S458: The experimental intervention consisted of an enhanced initial advice session augmented by six booster sessions, which were integrated into the first 6-monthly medical visits post-treatment. The initial advice session contained the same basic components as the control advice session, but providers supplemented the usual care advice with a discussion of the respondent's receptivity to quitting; a statement of confidence in the respondent's ability to stop; presentation of the three self-help booklets; a discussion of tobacco withdrawal; a discussion to determine a target quit date, including joint signature of the quit smoking contract; and an affirmation of continuing provider support during follow-up care

The six booster sessions consisted of debriefing respondents regarding their smoking cessation efforts prior to the visit and then tailoring advice to the respondent's current smoking status (abstainer, relapser, continuing smoker) according to the provider advice guidelines

Written materials: three booklets (two self-help guides to smoking cessation and maintaining abstinence; and a social support booklet for the patient's spouse, family member or other caretaker), a smoking cessation/abstinence contract, and reminder postcards (mailed in conjunction with the six booster sessions)

*continued*

# Data extraction table *contd*

***contd***
**S458, Gritz (1993)**[44]

***Intervention details* contd**

**Comparison group**
Received standardised 'usual care' advice from doctors (faculty and resident surgeons and dentists) regarding smoking and its contingent risks, as well as the benefits of cessation for head and neck cancer patients (see above)

**Classification into stages**
Stages were classified according to stage of change theory (reference to S248 and S248: no additional information)

Four stages: precontemplator (not currently thinking about stopping smoking); contemplator (thinking of stopping within 1 year), action (quit within the past 6 months) and maintenance (quit for 6–12 months)

**Validity of measure**
Not stated

**Training of educators**
Introduction to study design and procedures at a 2 hour training session. Training included a baseline questionnaire, a didactic presentation about the study, a video tape of a surgeon colleague delivering advice, and role playing. Written guidelines were given in a decision-tree algorithm format for the initial smoking cessation advice session (I and C) and for the six booster sessions (I only). Providers received individual 'brush-up' reminders throughout the trial in an effort to maintain adherence to advice-giving protocols

***Baseline characteristics***

**Gender**
30.7% female (of study completers)

**Age**
Mean age (SD): 57.8 (9.5) years (of study completers)

**Stage of change**
21.0% precontemplators; 38.6% contemplators; 40.4% action/maintenance (of study completers)

**Target behaviour**
Current smoker: 84.2%
Former smoker: 15.8%

Mean number of cigarettes smoked per day (SD): 24.0 (12.4) (of study completers)

***Results***

**Statistical techniques**
Logistical regression models were used to asses the importance of baseline predictors of 12-month continuous abstinence status

**Behaviour change**
Smoking behaviour (cessation/relapse history and dosage). Smoking cessation: patient who have quit at least once ('ever quit'); those not smoking at a given follow-up ('point prevalence'); and those abstinent starting with their initial cessation and continuing throughout the trial ('continuous abstinence')

There were no significant differences between I and C at any follow-up on any of the three smoking cessation outcomes. The mean quit rates were (1 month, $n$ = 169; 6 months, $n$ = 139; 12 months, $n$ = 114):

(1) Ever quit (1 month/6 months/12 months): I, 80.0%/84.3%/91.4%; C, 79.8%/82.6%/89.3%
(2) Point prevalence (1 month/6 months/12 months): I, 69.4%/71.4%/69.0%; C, 76.2%/73.9%/78.6%
(3) Continuous abstinence (1 month/6 months/12 months): I, 69.4%/64.3%/63.8%; C, 75.0%/71.0%/76.8

Participants who were still smoking at 12 months ($n$ = 30) had significantly reduced their consumption, from 25.4 cigarettes/day (SD = 12.8) at the baseline to 12.5 (SD = 8.1) at 12 months ($t$ = 7.67; $p$ = 0.0001). There were no differences between I and C

**Stage movement**
Not stated specifically

**Health**
Not stated, though see withdrawal/reasons

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated, though see withdrawal/reasons

**Other outcomes**
Predictors of 12-month continuous abstinence were medical treatment, stage of change, age, nicotine dependence, and race

*continued*

## Data extraction table *contd*

***contd***
**S458, Gritz (1993)**[44]

***Results* contd**

**Implementation measures**
(1) Providers: 110 doctors attended the training session, of whom 103 were head and neck surgeons and seven were prosthodontists, and of whom 26 were attending physicians and 84 were residents

(2) Delivery: Participants completed exit checklists after initial smoking cessation advice. These checklists were used to ensure the delivery of each intervention component and to ensure that contamination did not occur. There was some evidence of contamination, i.e. advice meant only for the intervention participants was delivered to control participants. Specifically, setting a target quit date and discussing withdrawal symptoms were reported by control participants – 72.5% and 48.5%, respectively

***Withdrawls/economic evaluation***

**Number per group**
186 patients were recruited and randomised; 114 (61.3%) completed the 12-months follow-up

**Reasons**
72 non-completers: (a) death (*n* = 33); (b) progressive illness precluded participation (*n* = 4); (c) refused further participation (*n* = 16); (d) lost to follow-up (moved, address unknown) (*n* = 14); (e) provider non-compliance (initial advice not delivered) (*n* = 4); and (f) subsequently determined not to satisfy eligibility criteria (illiterate) (*n* = 1)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusions**
Recommend systematic brief advice to stop smoking for head and neck cancer patients, with a stepped care approach for patients less able to quit. A stepped care approach might include adjunctive pharmacological treatment, materials aimed at precontemplators, and special attention to primary radiotherapy patients

**Authors' reported limitations**
Contamination of the control condition during the initial assessment. The inclusion of recent ex-smokers via the eligibility criterion "tobacco use within the past year" may have accounted for the lack of intervention effect

**S248**
No additional relevant information

**S513**
This describes the aims, study design, and patient accrual and characteristics from the ongoing trial

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S380, Gritz (1998)**[64]

**Aim**
To characterise gender differences in smoking and smoking cessation among participants in the Working Well Trial, a large worksite cancer prevention study

S493: To assess whether a sustained 2-year comprehensive cancer control worksite health promotion intervention (the Working Well Trial) addressing dietary change and smoking cessation, delivered by a participatory strategy that targeted individuals and the worksite environment, would be more effective than a minimal intervention in achieving both individual behavioural and environmental changes

**Model**
TTM

**Theoretical basis**
S380: Not stated

S370: This article examines the internal consistency of three core constructs of the TTM as applied to smoking cessation: stage of change, processes of change, and decisional balance. The TTM posits that processes of change and the pros and cons of smoking predict progressive movement through the stages of change

This study provides both a cross-sectional replication and a prospective test of this hypothesis

S371: The trial uses the transtheoretical stage of change model to guide a sustained 2-year multiple risk factor intervention

**Study type**
Prospective randomised matched-pairs trial

**Design**
A randomised matched-pair design, with the worksite as the unit of assignment and analysis. 114 worksites formed 57 matched pairs using factors such as: presence of a cafeteria, worksite size, type of smoking policy, worksite type, percentage females, percentage blue-collar employees, and response rate

S493: The study was conducted in four study centres: the Brown University School of Medicine/Miriam Hospital, The Dana-Farber Cancer Institute/University of Massachusetts, the University of Florida and the MD Anderson Cancer Centre. Cross-sectional surveys of individuals and surveys of key informants were conducted in each worksite at the baseline and follow-up. Data were collected from individual employees with self-administered surveys containing standard items in all study centres. Baseline data were collected from September to December 1990; and follow-up data from September to December 1993

Florida and Brown mailed surveys to each employee in the worksite, Dana-Farber mailed surveys to a random sample of employees in each worksite, and MD Anderson administered questionnaires to employees at mandatory worksite meetings. Follow-up reminders were sent to maximise response rates

**Setting**
Workplace

**Length of intervention**
The Working Well Trial is a 5-year trial. The second and final survey is at the end of the study, about 2.5 years after randomisation

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
28,000 workers from 114 worksites. A majority were employed in blue-collar occupations in a large variety of worksites (light manufacturing, communications, public services, and utilities) in different regions of the country, and were in an educational stratum of 'high school or less'. Smoking cessation intervention in 90 worksites, including 17,836 responders to baseline survey. Final assessment: 87 worksites, with 15,582 respondents. Companies ranged in size from 49 to 1700 workers (mean = 316). 49% of baseline respondents completed the second survey

**Inclusion criteria**
Permanent employees who worked at least 50% of full-time work week, and having worked at the workplace for at least 6 months. Among the reasons for loss of follow-up two additional inclusion criteria are mentioned: must have smoked at some time, and must have had a long-term cessation opportunity

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking and dietary change

*continued*

# Data extraction table *contd*

***contd***
**S380, Gritz (1998)**[64]

***Intervention details***

**Intervention group**
I: Comprehensive health promotion programme including strategies to encourage smoking cessation (details elsewhere: S371). Interventions were targeted to individuals (posters, interactive events, self-assessment) and to the organisation/environment (prohibit or restrict smoking at work)

S371: The essence of the operating principles (serving as an intervention plan) can be shown as a two-dimensional matrix. The matrix consists of two intervention target levels, (A) individual and (B) organisational/environmental; and three distinct intervention components, (1) promotion/awareness building, (2) action/skills training and (3) maintenance/relapse prevention.
A1 = increase awareness of need for change and motivation to attempt change in individual health behaviours
A2 = increase individual skills that enable successful behaviour change
A3 = increase the likelihood that individual behaviour changes will be sustained
B1 = increase management and worker awareness of environmental change benefits and support for making such changes
B2 = increase ability to formulate policy and to implement policy change; and increase ability to design and implement environmental alterations
B3 = increase the likelihood that policy and environmental changes will be institutionalised

Several working groups were formed to develop specific intervention strategies based on the theoretical model. These groups developed specific process objectives and a common core of intervention strategies. Core interventions directed at individuals include: (a) a kick-off event, (b) information/education/motivational materials, (c) self-assessments, (d) self-help materials, (e) campaigns and contests and (f) direct education. Core interventions targeted at the environment included: (a) consultation on the formation of smoking policy, (b) changes in food offerings and/or nutrition education in cafeterias and vending machines, and catering policy

Participatory strategies are being operationalised by involving workers (company representatives serve as a worksite co-ordinator; employee advisory boards are formed; research staff, co-ordinators and employee advisory board members collaborate in planning and implementing intervention activities.)

Sample activities: Exhibits, demonstrations, guest speaker, taste test (kick-off event); posters, brochures, newsletters, door prizes, balloons (information); questionnaires, health risk survey to assess eating, smoking or other health behaviour, self-tests (self-assessment); at home videos or print materials for self-help behaviour change (self-help); cook-offs, poster contest, incentive to participate in awareness, action, or maintenance events (contests); groups or classes on skill building, social support, knowledge, attitude, and behaviour change (direct education); tag on food items that meet the Working Well Trial criteria for fat or fibre (point of purchase); foods which follow the Working Well Trial guidelines for fat and fibre available at company meetings or events (catering policy); reduce or eliminate smoking at the workplace (smoking policy); penalty for not adhering to a stated company policy (enforcement)

S493: Florida did not include a smoking intervention (smoking was banned at all worksites) but did target cancer screening practices. The other three centres targeted smoking and nutrition and 1 additional risk factor (Dana-Farber: occupational exposure to carcinogens; Brown: exercise; MD Anderson: smokeless tobacco)

**Comparison group**
C1: Any health promotion activities that occurred at the worksites were documented. Received summary results of baseline survey, and

C2: same as C1 plus two of the three study centres (S493: three of the four centres) offered an optional minimal intervention that consisted of the distribution of widely available print materials such as posters and brochures

**Classification into stages**
Readiness for smoking cessation was assessed using the stages-of-change algorithm. Three stages were used in the analyses: precontemplation (not thinking about quitting in the next 6 months)/contemplation (planning to quit smoking within the next 6 months or planning to quit within the next month, but have not made at least one 24 hour quit attempt in the past 12 months)/preparation (planning to quit within the next month and having made at least one 24-hour quit attempt in the previous 12 months), two additional stages (action (having quit smoking for at least 48 hours, but less than 6 months)/maintenance (having been abstinent for 6 months or more)) were assessed but not used in the analyses. Stages of change were calculated as a nominal and continuous variable. The processes of change scale short form was used to measure how affective, cognitive or evaluative changes, as well as behavioural changes, are made as smokers move closer to a decision to stop smoking (six dimensions, two combined: behavioural and experimental processes)

S85: Items used to classify respondents into one of five stages of change for fat intake and for fibre/fruit and vegetable (F + V) intake are based upon: self-rated diet, length of time following a healthy diet (if applicable), intentions to make dietary changes, reported past attempts to make dietary changes, and success with change. An algorithm was developed based on combinations of these five items, for low-fat eating and for high-fibre/F + V consumption. The algorithms were used to classify respondents into 1, and only one, of five stages of change: precontemplation, contemplation, preparation, action or maintenance, for fat, fibre and F + V. Item wording and methods for stage assignment followed the procedures described in S30

S30: Definitions of stages (assignment to stage was done sequentially, beginning with maintenance. Once an individual was assigned to a stage, the remaining response codes were not processed):
Maintenance: Healthy diet (= low/very low fat, or high/very high fibre) for ≥ 6 months. (Item: self-rated diet)
Action: Healthy diet for < 6 months or tried to change with some success in the last 6 months. (Items: self-rated diet; reported changes – attempts, success)
Preparation: Tried to make healthy diet changes in last 6 months but not successful, or definitely plan to change. (Items: self-rated diet; reported changes: attempts, success; behavioural intentions to change diet)
Contemplation: Maybe/probably plan to change diet in the next 6 months; and no attempts to change in the last 6 months. (Items: self-rated diet; behavioural intentions to change diet; reported changes: attempts, success)
Precontemplation: No plans to change diet in the next 6 months; and no attempts to change in the last 6 months. (Items: self-rated diet; behavioural intentions to change diet; reported changes: attempts, success)

*continued*

# Data extraction table *contd*

***contd***
**S380, Gritz (1998)**[64]

***Intervention details* contd**

Self-rated diet:
How high in fat is your overall diet? (1 = very high, to 5 = very low)
If low or very low: For how long have you followed a diet that is low in fat? (1 < 1 month, to 4 ≥ = 1 year)
How high in fibre is your overall diet? (1 = very high, to 5 = very low)
If high or very high: For how long have you followed a diet that is high in fibre? (1 < 1 month, to 4 ≥ = 1 year)

Behavioural intentions to change diet (this section introduced by "The following questions ask about changes you may have made, or may make, in the way you eat"):
Over the next 6 months, do you plan to cut down on fats? (1 = definitely yes, 5 = definitely no)
Over the next 6 months, do you plan to eat more F + V? (1 = definitely yes, 5 = definitely no)

Reported eating habits changes – attempts, success:
Have you tried to make any changes to lower the fat in your diet in the past 6 months? (yes/no)
If yes: How successful were you in making those changes? (1 = extremely successful, 5 = not successful)
Have you tried to make any changes to increase the fibre in your diet in the past 6 months? (yes/no)
If yes: How successful were you in making those changes? (1 = extremely successful, 5 = not successful)

**Validity of measure**
Validity of stages-of-change scale not reported. The processes of change scale short form has been validated elsewhere (S312)

S312: Validity of stages-of-change scale not reported

S30: No data on validity of stage-of-change measure

**Training of educators**
Not stated

S371: Training sessions are held for employee advisory board members to familiarise them with the goals of the project, their own roles and responsibilities, and basic information regarding smoking and nutrition

***Baseline characteristics***

**Gender**
At the baseline of 17,836 respondents, 5523 (31%) were female and 12,313 (69%) were male. Initial survey: 4663 (30%) female and 10,919 (70%) male

**Age**
Not stated

**Stage of change**
Not stated

**Target behaviour**
Not stated

S493:
Percentage energy from fat: I, 36.71; C, 36.70
Dietary fibre (g/1000 kcal): I, 8.03; C, 7.96
Servings of fruit and vegetables per day: I, 2.60; C: 2.58
Smoking: not reported

***Results***

**Statistical techniques**
Worksites were randomised after forming pairs within study centre based upon study centre-specific stratification factors (presence of cafeteria, worksite size and type, type of smoking policy, percentage females, percentage blue-collar workers and response rate). Worksite was used as unit of analysis

All available data were employed in the regression models. Block and block by treatment arm enter all regression models as random effects. Mixed model logistic regression employing penalised quasilikelihood methods was used to examine the effect of intervention, by gender, on follow-up smoking cessation, and smoking prevalence. ORs and 95% CIs of specific treatment arm by gender contrasts, adjusting for education and occupation are reported. The Rao–Scott correction was employed to correct for effects of worksite randomisation in contingency table analyses

S493: Because the worksite was the unit of both randomisation and analysis, data from the 111 participating worksites were pooled to test the hypotheses. Evaluation of the effects of the intervention was based on the difference between intervention and control worksite means within each worksite pair, with adjustment for the baseline worksite mean as a covariate

*continued*

# Data extraction table *contd*

***contd***
**S380, Gritz (1998)**[64]

***Results* contd**

**Behaviour change**
Long-term (6 months) quitters; 7-day abstinence rate; mean number of cigarettes per day; mean number of quit attempts

No results by intervention group presented

S371: The smoking endpoint is quit rate: defined as 6 months or more of continuous abstinence of smokers reported at the end of the trial

S493: Nutrition outcomes: nutrient intakes of fat, fibre, and F + V, using an 88-item semi-quantitative food-frequency questionnaire with portion sizes (176 items in total). Outcome variables: percentage energy from fat, grams of fibre per 1000 kcal, and daily servings of F + V

Smoking outcomes:
- 6-month abstinence rate, measured by self-reported abstinence for the 6 months prior to the survey (denominator: employed for a minimum of 6 months, and were current smokers or had quit smoking during the 2-year intervention)
- Worksite smoking prevalence. Current smokers were defined as those who had smoked at least 100 cigarettes in their lives and currently smoked at least 1 cigarette per day, or who defined themselves as current smokers

Percentage energy from fat at the baseline/follow-up:
I: 36.71/34.64 (difference: –2.07); C: 36.70/35.00 (difference: –1.70)
Difference (I – C and follow-up minus baseline): –0.37 (adjusted: –0.35, SE = 0.16), $p < 0.05$

Dietary fibre, g/1000 kcal at the baseline/follow-up:
I: 8.03/8.61 (difference: 0.58); C: 7.96/8.41 (difference: 0.45)
Difference (I – C and follow-up – baseline): 0.13 (adjusted: 1.7, SE = 0.87), NS

Servings of F + V at the baseline/follow-up:
I: 2.60/2.80 (difference: 0.20); C: 2.58/2.60 (difference: 0.02)
Difference (I – C and follow-up – baseline): 0.18 (adjusted: 5.6, SE = 1.3), $p < 0.001$

6-month abstinence rate (% of quitters in total):
I: 13.8%; C: 12.3%
Difference (I – C, 95% CI): 1.53 (–1.0, 3.7). NS

Smoking prevalence (% smokers in total):
I: 21.2%; C: 21.8%
Difference (I – C, 95% CI): –0.66 (–3.0, 1.2). NS

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Encouragement for quitting (social support): not reported

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

S493: A process evaluation was designed to (1) assess the extent to which the intervention was delivered (based on data from the senders, i.e. project staff) (to assess the delivery of the intervention, the mean proportion of process objectives achieved in each worksite was summed and was divided by the number of worksites); (2) assess the extent to which the intervention was received (based on data from the receivers, i.e. employees). Two indices for each risk factor were created to calculate receipt of the intervention: (1) awareness of intervention activities; (2) activities directed toward behaviour change. For both indices, items were scored 1 or 0; the items were added and were divided by the total number of items

Delivery: Kick-off participation (50% of employees), 68%

Percentage process objectives achieved for nutrition/smoking:
No. of worksites: 55%/43%
Interactive Kick-off activity: 96%/72%
Posters: 82%/81%
Video/single session presentation 84%/67%
Self-assessment activity: 88%/85%
Self-help programme 78%/81%
Multisession direct education: 69%/58%
Campaign: 78%/72%
Total: 82%/74%

*continued*

# Data extraction table *contd*

***contd***
**S380, Gritz (1998)**[64]

***Results* contd**

Receipt of intervention (I – C difference):
Smoking awareness: 0.14; SE = 0.03; $p$ = 0.00; 95% CI, 0.08 to 0.22
Nutrition awareness: 0.17; SE = 0.02; $p$ = 0.00; 95% CI, 0.13 to 0.22
Smoking action: 0.13; SE = 0.02; $p$ = 0.00; 95% CI, 0.10 to 0.17
Nutrition action: 0.26; SE = 0.02; $p$ = 0.01; 95% CI, 0.22 to 0.29

***Withdrawals/economic evaluation***

**Number per group**
90 worksite randomised, three dropped out prior to final assessment. Overall response rate to the baseline survey was 69% (average worksite response rate, 72%) and 71% to the final survey (average worksite response rate, 75%)

S493: 114 worksites were originally recruited; three did not participate because of economic dislocations (I = 2, C = 1). For pairwise analyses, three pairs were excluded, leaving 108 worksites

**Reasons**
The percentage of matches were affected by (1) normal annual worksite attrition (mean = 7.9%, range = 0–30%); (2) a selection in 1 study centre (24 worksites) of a random sample of employees at the baseline and a new random sample of employees at final; (3) non-respondents to either or both surveys; and (4) smoking characteristics (e.g. must have smoked at some time, must have had a long term cessation opportunity)

**Economic evaluation**
Yes

**Economic methods**
Not stated

S371: Cost data are assessed in terms of the costs of the implementing each intervention activity at a worksite and the cost per unit of effectiveness of that implementation. These costs are monitored according to the bearer of the costs (i.e. worksite, study centre, worker)

Costs are represented in terms of personnel, travel, telephone and materials/incentives. The actual cost of the intervention (independent of programme development and research costs) will be used to compute cost-effectiveness, defined as the cost per unit of behaviour and organisational change

S493: Not stated

**Cost outcomes**
Not stated

S371: No data reported

S493: Not reported

***Additional comments***

Whether intervention is based on Stages of change not clear from this report (see S370 and S371: intervention is stage-based). See also S370, S371, S62 and S493. Here only results to assess gender differences; all results and baseline characteristics are reported for men and women separately. Study limitations mentioned by the author: relevant for blue-collar workers; intervention period may not be long enough; effects are smaller using entire worksite population (including less highly motivated and non-responders)

**S370**
The analysis uses data from one out of four study centres, encompassing 26 worksites. This study uses only baseline data; no data on the effectiveness of the intervention are presented. It does state: "Two year follow-up results of the Working Well Trial revealed no significant smoking cessation differences between intervention and control worksites" (S493)

**S371**
This describes the design of the Working Well Trial; no data are presented here

**S493: Authors' conclusion**
Significant but small differences were observed for nutrition. Positive trends, but no significant results, were observed in trial-wide smoking outcomes. The observed net differences were small owing to the substantial secular changes in target behaviours

**S85**
Examines associations of stage of change with diet prospectively and addresses whether: (1) baseline stage of change predicts participation; (2) forward changes in stage movement were greater in treatment worksites; and (3) change in stage was associated with adoption of healthful diets. The study used data from a cohort of 11,237 employees (S493 included data from over 28,000 workers). There is no explanation where this cohort is derived from. Data from S85 are therefore not included.

Authors' conclusion: Findings indicate that persons in later stages of change reported higher participation levels. Employees from intervention worksites who were in pre-action stages at the baseline were much more likely to shift into action and maintenance stages than controls. Changes in dietary stage of change were associated with decreases in fat intake and increases in fibre and F + V intake. Net change in change due to the intervention was modest. Stage of change appears to be useful for understanding mediators of health promotion intervention effectiveness

**S30**
This presents data from the baseline survey of 17,121 employees in the Working Well Trial

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S001, Harland (1999)**[37 *]

**Country**
UK

**Aim**
"To evaluate the effectiveness of combinations of three methods to promote physical activity"

**Model**
TTM/motivational interviewing

**Theoretical basis**
"Motivational interviewing is a technique for negotiating behaviour change (S618) ... that uses the stages of change model of behaviour change" (S248, S258, S660, S661)

**Study type**
RCT

**Design**
RCT. Baseline assessment with postintervention follow-up at 12 weeks and 1 year. Four intervention groups: brief (one interview) or intensive (six interviews over 12 weeks) motivational interviewing based on the stages-of-change model of behaviour change, with or without financial incentive (30 vouchers entitling free access to leisure facilities) compared to controls. Outcome assessors were blind to allocated group

**Setting**
Primary care

**Length of intervention**
Brief motivational interviewing: one session; intensive motivational interviewing: six interviews (40 minutes each) over 12 weeks. Last follow-up 1 year postintervention

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
523 adults aged 40 to 64 years, from one urban general practice

**Inclusion criteria**
All patients aged 40 to 64 years who were registered at the practice on 1 January 1995 and satisfied the inclusion criteria were eligible to participate

**Exclusion criteria**
Exclusion criteria related primarily to safe exercise testing (see Table 1 of S001), which gives further details of the exclusion criteria and numbers excluded). Patients unable to complete a submaximal exercise test were excluded (patients with cardiovascular or respiratory disease causing raised risk), as were patients undertaking regular vigorous exercise at least three times a week over the previous 6 months

**Behaviours targeted**
Physical activity

***Intervention details***

**Intervention group**
All: "Participants received their baseline results (blood pressure, weight for height, activity level and aerobic capacity, smoking, and alcohol consumption) and a pack containing information on the benefits of physical activity, other lifestyle factors (smoking, alcohol, weight, and diet), recommended activity levels for men and women of different ages, and 19 leaflets on leisure facilities and activities available locally. Brief advice was given, comparing the individual's results with recommended levels and highlighting details in the information pack"

I1: Brief interviewing: one motivational interview within two weeks of their baseline assessment

I2: Brief interviewing with financial incentive: same as I1 plus 30 vouchers (entitling free access to leisure facilities) at the interview

I3: Motivational interviewing: six motivational interviews over 12 weeks, the first within 2 weeks of the baseline assessment. Motivational interviewing aims to promote safe, effective physical activity but does not prescribe particular activities

I4: Motivational interviewing with financial incentive: same as I3 plus 30 vouchers (entitling free access to leisure facilities) at the interview

ALL: Each interview was scheduled to last for 40 minutes and took place at the practice or local leisure centre

**Comparison group**
Control group: no further intervention

**Classification into stages**
Not stated

[*] *Sections of text reproduced with permission from the BMJ Publishing Group (*BMJ *1999;**319**:828–32)*

*continued*

# Data extraction table *contd*

***contd***
**S001, Harland (1999)**[37]

***Intervention details* contd**

**Validity of measure**
Not stated

**Training of educators**
"A health visitor (LF), who was trained in motivational interviewing, delivered the motivational interviews"

***Baseline characteristics***

**Gender**
I1: 64% female
I2: 58% female
I3: 59% female
I4: 55% female
C: 56% female

**Age**
I1: 40–44 years, 27%, 45–49 years, 16%, 50–54 years, 23%, 55–59 years, 15%, 60–64 years, 19%
I2: 40–44 years, 19%, 45–49 years, 30%, 50–54 years, 16%, 55–59 years, 21%, 60–64 years, 14%
I3: 40–44 years, 31%, 45–49 years, 22%, 50–54 years, 14%, 55–59 years, 13%, 60–64 years, 20%
I4: 40–44 years, 19%, 45–49 years, 26%, 50–54 years, 20%, 55–59 years, 15%, 60–64 years, 19%
C: 40–44 years, 26%, 45–49 years, 21%, 50–54 years, 20%, 55–59 years, 12%, 60–64 years, 21%

**Stage of change**
Not stated

**Target behaviour**
Physical activity score:
I1: 0, 62%; 1, 19%; 2, 8%; 3, 7%; 4, 4%; 5, 1%
I2: 0, 58%; 1, 18%; 2, 14%; 3, 4%; 4, 3%; 5, 4%
I3: 0, 56%; 1, 20%; 2, 10%; 3, 9%; 4, 3%; 5, 3%
I4: 0, 70%; 1, 15%; 2, 10%; 3, 1%; 4, 4%; 5, 1%
C: 0, 65%; 1, 19%; 2, 8%; 3, 5%; 4, 1%; 5, 3%

***Results***

**Statistical techniques**
"The null hypothesis was that changes in self reported physical activity at follow up would be the same in the intervention and control arms. A successful outcome was defined as moving up one or more levels of physical activity score from baseline to follow up. 107 participants per group would be required to detect a difference between success rates of 40% to 60% at 80% power and 5% significance level. Analysis, on the basis of intention to treat, was done with SPSS. The Chi-squared test for differences in proportions was used to compare success rates across the five groups at follow up. If these showed significance ($p < 0.05$), then the success rate in all intervention groups combined was compared with that in the control group. The rates within the intervention groups were compared by investigating the effect of extra interviews (interventions 1 and 2 combined versus interventions 3 and 4 combined), introduction of vouchers (interventions 1 and 3 combined versus interventions 2 and 4 combined), and interaction between extra interviews and vouchers, using logistic regression analysis. Confidence intervals for differences in proportions were calculated"

Behaviour change:
Increased physical activity score at 12 weeks: I1, 36%, I2, 28%, I3, 35%, I4, 55%, C, 16%
Percentage difference (95% CI for difference) compared with control group: I1, 20% (8 to 33); I2, 12% (0 to 25); I3, 19% (6 to 32); I4, 39% (25 to 53)

The proportions with improved physical activity scores differed significantly in the four intervention groups combined, compared with the controls (38% (123) versus 16% (13), $p = 0.001$)

Within the intervention groups, no significant effect was due to the introduction of vouchers ($p = 0.84$) or more than one interview ($p = 0.26$), but there was a significant interaction between these interventions ($p = 0.01$): the highest proportion of participants with increased physical activity scores (55%) was in the group offered both multiple interviews and vouchers. This was 39% (95% CI 25% to 53%) more than in the control group. The proportion of participants with an improvement in vigorous activity was significantly higher in the four intervention groups combined than the control group (29% (94) V 11% (9), $p < 0.001$; difference 18%, 10% to 26%). However, within the four intervention groups there were no significant effects due to interviews ($p = 0.4$), vouchers ($p = 0.21$), or the interaction between them ($p = 0.09$). The improvement in moderate activity was significantly greater in the four intervention groups than the control group (30% (98) versus 13% (11), $p = 0.002$; difference 17%, 8% to 26%). However, there was no significant effect due to interviews ($p = 0.80$), vouchers ($p = 0.27$), or the interaction effect between them ($p = 0.16$). Increased physical activity score at 1 year: I1, 23%; I2, 26%; I3, 31%; I4, 27%; C, 23%. percentage difference (95% CI for difference) compared with control group: I1, 0% (–12 to 12); I2, 3% (–10 to 15); I3, 8% (–5 to 21); I4, 4% (–10 to 17). Increases in physical activity reported at 12 weeks by participants in the intervention group were not maintained at 1 year, regardless of the intensity of intervention. Only the increase in vigorous activity in the intervention groups was close to statistical significance. The data were consistent with small positive or negative effects of intervention groups compared with controls

*continued*

# Data extraction table *contd*

***contd***
**S001, Harland (1999)**[37]

***Results* contd**

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Uptake of interventions:
Among participants in the intervention group (I1–I4), 341 (82%) attended at least one interview. Attendance was higher in the interventions that included vouchers (I2 and I4) than the other interventions (86% (180) versus 77% (161)). Among participants offered six interviews (I3 and I4), the median number of interviews attended was three

Of the 180 participants receiving vouchers (I2 and I4), 41% (74) used at least one. Use of vouchers was higher in the intensive intervention (I4) than the BI (I2) (44% (45) versis 27% (29)). In total, 670 vouchers were exchanged; 69% (463) at the leisure centre nearest to the practice, 29% (196) at the local swimming pool, and 2% (11) at another swimming pool

***Withdrawals/economic evaluations***

**Number per group**
"In all, 2974 patients were approached (96% of those aged 40–64 years): 1308 opportunistically and 1666 by post. Of these, 477 (16%) were excluded and 734 agreed to participate. In total, 217 men and 306 women were enrolled and randomised ($n$ = 523). The response rate at 12 weeks was 81% ($n$ = 424). Response at one year was 85% ($n$ = 442); 61% (321) attended the repeat assessment and 23% (121) completed the postal questionnaire. Differences in response rates at 12 weeks and one year between intervention groups were not significant"

I1: 105 randomised; 81 interviewed; 96 12-week questionnaire; 96 1-year follow-up
I2: 106 randomised; 91 interviewed; 88 12-week questionnaire; 88 1-year follow-up
I3: 104 randomised; 14 × 1, 22 × 2, 12 × 3, 14 × 4, 13 × 5 and 5 × 6 interviews; 88 12-week questionnaire; 88 1-year follow-up
I4: 102 randomised; 14 × 1, 13 × 2, 20 × 3, 20 × 4, 19 × 5 and 3 × 6 interviews; 79 12-week questionnaire; 79 1-year follow-up

**Reasons**
I1: Nine lost (three moved, four refused, two not contacted)
I2: 18 lost (two moved, ten refused, four not contacted, two missing data)
I3: 16 lost (three moved, eight refused, four not contacted, one missing data)
I4: 22 lost (one died, three moved, ten refused, six not contacted, two missing data)
C: 12 lost (one died, one moved, seven refused, three not contacted)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusions**
"The most effective intervention for promoting adoption of exercise was the most intensive. Even this did not promote long term adherence to exercise. Brief interventions promoting physical activity that are used by many schemes in the United Kingdom are of questionable effectiveness"

**Limitations mentioned by authors**
"Opportunistic recruitment was effective initially but led to diminishing returns as the number of eligible patients fell from 20 to three per surgery over a year. About a third of these patients were excluded, the majority on health grounds. Postal recruitment enabled further participants to be enrolled, but they were more likely to be in employment and in better health. Participants were recruited from an area with high levels of socio-economic disadvantage. As physical activity, and perceived barriers to physical activity, vary with socio-economic status, the effectiveness of the interventions may vary in different population subgroups. The baseline assessment received by participants in the control group represents a considerable intervention and may have diluted the apparent results of the intervention"[11]

**Major limitation**
Stage of change never mentioned

**Comment**
Opportunistic recruitment seemed to have targeted those with most to gain. Postal recruitment: likely to have included those who were most motivated. It would be useful to know how many from each type of recruitment were included in the trial

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S378, Havas (1998)**[60]

**Country**
USA

**Aim**
To increase fruit and vegetable consumption among women served by the WIC programme in Maryland

**Model**
TTM

**Theoretical basis**
The project was based on Prochaska and DiClemente's stage model of change

**Study type**
RCT (crossover design)

**Design**
Randomised crossover design. 16 WIC sites were unit for randomisation. 4 months after completion of phase 1, intervention sites became control sites, and vice versa (phase 2). Baseline and postintervention surveys 2 months after last nutrition session. One year after postintervention survey another follow-up survey (Controls had intervention by this time)

**Setting**
Community

**Length of intervention**
2 years. 6-month intervention period

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Women served by 16 WIC sites located in Baltimore city and 6 Maryland counties

The WIC programme is federally funded, involves approximately 7.1 million low-income participants, and operates in all 50 US states

**Inclusion criteria**
Women had to be enrolled in the WIC programme or have children enrolled; at least 18 years of age; have the intention of remaining enrolled at the site for at least 6 months

**Exclusion criteria**
Not stated

**Behaviours targeted**
Fruit and vegetable consumption

***Intervention details***

**Intervention group**
Three components:
(1) Nutrition sessions conducted by peer educators, focusing on building skills and providing social support
(2) Printed materials and visual reminders (guidebook with story line: five clue cards with questions; a tip sheet with ideas; a booklet of recipes; a children's activity book; a videotape; a refrigerator magnet; calendar reminder sheets; and attractive posters of fruits and vegetables)
(3) Direct mail.

Peer educators delivered two types of education: (a) brief messages regarding increasing fruit and vegetable consumption at enrolment, and (b) a series of three group discussion sessions 45 minutes/small groups/over 6 months (the first sessions focused on self-assessment, the value of eating fruit and vegetables and personal goal setting; the second session focused on identifying and overcoming perceived barriers; the third session stressed maintenance strategies. Each session included a food demonstration to build skills and allow trying new foods.

Direct mail: four different tailored (pregnancy status, baseline stage of change, attendance at sessions, and individual goals) letters were sent to participants by peer educators over 6 months, accompanied by a tip sheet and clue card

1443 respondents

**Comparison group**
Normal WIC programme, generally less than 10 minutes of nutrition education at the bi-monthly voucher pick-up

1679 respondents

*continued*

# Data extraction table *contd*

***contd***
**S378, Havas (1998)**[60]

***Intervention details* contd**

**Classification into stages**
S378: Used stages of change for five or more servings per day: classification not reported

S431: Stages of change were measured for two behavioural outcomes: (1) eating five or more servings of fruit and vegetables a day and (2) eating more fruit and vegetables. Eating more fruit and vegetables referred to increasing the consumption of fruits and vegetables compared to the amount eaten in the past

Items used to stage participants for five or more servings per day were as follows:
1. How many servings of fruits and vegetables (including 100% juice) are you eating a day?
2. For about how long have you been eating this number of servings of fruits and vegetables a day? (< 1 month, 1–3 months, 4–5 months, ≥ 6 months)
3. Are you thinking about, planning to eat, or already eating five or more servings of fruits and vegetables a day?

Participants were categorised into the five stages for eating five or more servings as follows:
Precontemplation: Currently eating less than five servings a day and not thinking about eating five or more servings a day
Contemplation: Currently eating less than five servings a day and thinking about starting to eat five servings a day in the next 6 months or reporting eating less than four in question 1 and already eating five in question 3
Preparation: Currently eating less than five servings a day and definitely planning to start eating five servings a day in the next month or reporting eating between four and five in question 1 and already eating five in question 3
Action: Currently eating five or more servings a day and has been eating this number of servings for less than 6 months
Maintenance: Currently eating five or more servings a day and has been eating this number of servings for 6 months or longer

Items used to stage participants for eating more fruits and vegetables were as follows:
1. How many servings of fruits and vegetables (including 100% juice) are you eating a day?
2. For about how long have you been eating this number of servings of fruits and vegetables a day? (> 1 month, 1–3 months, 4–5 months, ≥ 6 months)
3. Are you thinking about, planning to eat, or already eating five or more servings of fruits and vegetables a day?

Participants were categorised into the five stages of change for eating more fruits and vegetables as follows:
Precontemplation: Currently eating less than five servings a day (Q1) and not thinking about eating more fruits and vegetables (Q3)
Contemplation: Currently eating less than five servings a day and thinking about starting to more in the next 6 months
Preparation: Currently eating less than five servings a day and definitely planning to start eating more fruits and vegetables in the next month
Action: Eating less than five servings a day, already eating more (Q3) and doing it for less than 6 months or eating five or more and doing it for less than 6 months
Maintenance: Eating less than five servings a day, already eating more (Q3), and doing it for more than 6 months or eating five or more and doing it for 6 months

**Validity of measure**
Cronbach alpha values for stage-of-change scale and four other scales ranged from 0.80 to 0.92, indicating high levels of internal response consistency

**Training of educators**
Peer educators were hired and trained, they were responsible for all contacts with participants. Peer educators attended at least 2.5 days of training for orientation/recruitment and each of the three sessions to be taught, and they had to demonstrate competency in teaching the session (through role-play) before teaching at the WIC sites. Educators were observed during training and as they taught their sessions at WIC to ensure quality

***Baseline characteristics***

**Gender**
100% female

**Age**
18–24 years: I, 39.7% (22.7–50.8); C, 41.3% (27.1–55.5)
25–29 years: I, 26.3% (19.2–29.6); C, 26.7% (19.7–36.7)
30+ years: I, 34.0% (24.4–52.1); C, 32.0% (20.2–50.0)

**Stage of change**
S378: 14.1 precontemplation; 32.1% contemplation; 36.0% preparation; 2.9% action; 14.6% maintenance

S431: Eating five or more fruits and vegetables – classification:
I: precontemplation, 12.8%; contemplation, 32.4%; preparation, 37.2%; action, 3.1%; maintenance, 14.5%
C: precontemplation, 15.4%; contemplation, 31.7%; preparation, 35.2%; action, 2.8%; maintenance, 15.0%

Eating more fruit and vegetables – classification:
I: precontemplation, 5.1%; contemplation, 11.5%; preparation, 35.8%; action, 9.9%; maintenance, 37.8%
C: precontemplation, 5.4%; contemplation, 11.0%; preparation, 30.8%; action, 10.3%; maintenance, 42.6%

**Target behaviour**
Mean daily servings of fruit and vegetables (SE): I, 3.88 (0.11); C, 4.20 (0.10)

*continued*

# Data extraction table *contd*

***contd***
**S378, Havas (1998)**[60]

***Results***

**Statistical techniques**
Sample size calculations based on ability to detect a difference of 0.5 servings between I and C (intrasite correlation of 0.2, pre-post-test correlation of 0.11 and error variances based on NHANES II data). Intention-to-treat analyses, using 'last value carried forward' (1 site not included in analyses). I and C were compared initially on demographic and other baseline characteristics by means of paired *t*-tests or Pearson $\chi^2$ tests ($p < 0.05$). Analyses of dietary intake data were based on change between baseline and 8 months. Comparisons between I and C participants (within site) on change in individual consumption and other outcomes were made at both the site and individual levels. Analyses at the site level were based on either site means or site proportions, both treated as continuous in analyses of the 15 sites. Paired *t*-tests were used to compare I and C on mean change within site in terms of intake, attitude, self-efficacy, knowledge and social support scores. Individual-based analyses were also carried out. Individuals were used as the unit of analysis, but site was included as a random effect, as recommended by Murray. Results were similar to those of site-based analyses and are not presented

**Behaviour change**
Mean daily consumption was assessed by summing responses to seven questions concerning frequency of consuming fruit and vegetables

Change at 8 months (SE): I: 0.56 (0.11); C: 0.13 (0.07); $p = 0.002$

Women who were White, > 30 years, high school graduates, married, not working, or non-smokers showed significantly greater increases in consumption

**Stage movement**
S378: At post-survey, there had been significantly more movement to higher stages among participants in I (versus C) who were in the precontemplation, contemplation, and preparation stages at the baseline (data not shown)

S431: Difference in distribution at post-test, Eating 5 or more-classification:
I: precontemplation, –5.0%; contemplation, –4.0%; preparation, +1.8%; action, +4.7%; maintenance, +2.4%
C: precontemplation, –2.8%; contemplation, +2.9%; preparation, –0.3%; action, +0.9%; maintenance, –0.6%

Difference in distribution at post-test, eating more fruit and vegetable classification:
I: precontemplation, –1.9%; contemplation, –4.0%; preparation, –8.8%; action, +11.8%; maintenance, +2.9%;
C: precontemplation, 0.0%; contemplation, +1.0%; preparation, –3.5%; action, +0.8%; maintenance, +1.6%

**Health**
Not stated

**Intermediate outcomes**
Mean 8 months change (SE) in attitudes; self-efficacy; perceived barriers:
Attitude: I, 0.49 (0.09); C, 0.15 (0.06); $p = 0.0030$
Self-efficacy: I, 0.93 (0.15); C, 0.19 (0.12); $p = 0.0006$
Perceived barriers: I, –0.69 (0.19); C, –0.48 (0.16); $p = 0.4164$

Significantly greater positive changes in attitudes and self-efficacy occurred among I than among C. Perceived barriers did not change significantly

**Adverse effects**
Not stated

**Other outcomes**
Mean 8 months change (SE) in knowledge, social support and responsibility:
Knowledge: I, 0.41 (0.04); C, 0.16 (0.03); $p < 0.0010$
Social support: I, 0.21 (0.06); C, 0.04 (0.04); $p = 0.283$
Responsibility: I, 0.10 (0.04); C, 0.13 (0.03); $p = 0.5976$

Knowledge of recommendations to eat five or more fruits and vegetables a day: At the baseline, 41% of I and C were aware of the recommendation. On post-survey, 57% of I and 46% of C ($p < 0.0001$)

Other knowledge questions, social support and responsibility for food shopping and preparation: Significantly greater positive changes in other knowledge questions and social support occurred among I than among C. Responsibility did not change significantly

**Implementation measures**
Attendance at the nutrition sessions varied considerably by site. Overall, 19% (range 8–31%) attended all three sessions, 14% (range 9–21%) attended two sessions, 20% (range 15–27%) attended one session, and 46% (range 31–58%) attended no sessions. There was a strong relationship between attendance and changes in consumption: women who attended no sessions increased consumption by 0.15 (0.15); one session, 0.68 (0.21); two sessions, 0.91 (0.25); three sessions, 1.25 (0.22) ($p$ (for trend) = 0.02)

S83: 23 attended the four focus groups for non-attenders: most women intended to come but scheduling conflicts and lack of transportation interfered. 15 women participated in four focus groups for those who had attended once. In general they had a positive opinion of session, main reason not to attend was scheduling conflicts and lack of transportation, a few admitted they preferred staying at home. Two focus groups in black urban sites and one for black women who attended two or three sessions: 18 women participated in these sessions, they had similar positive comments

*continued*

## Data extraction table *contd*

***contd***
**S378, Havas (1998)**[60]

***Withdrawals/economic evaluation***

**Number per group**
16 WIC sites randomised, one site dropped out (not included in analyses): I, 1443; C, 1679. About 85% of women met eligibility criteria. Overall, the acceptance rates were 66% (range = 55–85%) during the intervention phases and 87% (range = 68–100%) during the control phases). Overall, 75% of I completed the post-survey (range = 60–86%), as did 76% of C (range = 55–93%)

**Reasons**
One site dropped-out because the peer educator did not follow quality control guidelines during control phase

Reasons for not completing the post-survey included withdrawal from WIC, change of residence, disconnected telephone, and lack of interest. Non-completers were more likely to be young ($p < 0.001$), black ($p < 0.001$), single ($p < 0.03$), employed ($p = 0.001$) and in school ($p = 0.05$); also, in the case of I, they were likely not to have attended the nutrition sessions ($p < 0.0001$)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

1-year follow-up results not extracted because this was beyond the RCT period (crossover design, controls had received intervention)

**S378: Authors' conclusions**
Greater increases in consumption were found in I than in C, and positive movement was found along the stages of change among I. Statistically significant changes were only found among whites and those with at least a high school education

Authors' reported limitations: Most deprived populations not reached, non-attendance was considerable

**S431: Authors' conclusion**
The intervention increased positive movement through the stages of change, I participants moved forward in stage status or maintained target behaviour better than C participants. The intervention was designed to improve knowledge, feelings of self-efficacy, and attitudes and reduce perceived barriers; women with the largest changes in the psychosocial variables also shared the greatest positive stage movement

**S83**
Because of the high drop-out rate after 6 months, the intervention period was changed from 12 months originally proposed to 6 months. S83 describes mainly process evaluation (extent, fidelity and quality of implementation)

**S431**
This focused on the effect of the intervention on the stages of change of the participants. Stages of change were measured for two specific target behaviours: eating five servings of fruit and vegetables a day and eating more servings of fruit and vegetables a day. The effectiveness of the intervention across groups depended on which staging measure was used. Results extracted here are those from S378, using the stages of change for eating five or more servings (i.e. the first staging definition)

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S084, Kristal (2000)**[39]

**Aim**
To examine how a dietary intervention programme affected mediating factors for dietary change

Analyses addressed three questions: (1) Did the nutrition intervention affect mediating factors? (2) Did changes in mediating factors affect dietary intake of fat, fibre and fruits and vegetables? (3) Could the effect of the intervention on dietary behaviour be explained by changes in mediating factors?

**Model**
Classic model of Anderson (S616)

**Theoretical basis**
In the Working Well Trial, authors proposed a simple framework for organising components of these models (social cognitive theory, the theory of reasoned action, the TTM and its stages-of-change construct, and the PRECEDE/PROCEED model) that was based on the classic model of Anderson (S616)

Key categories of constructs in this framework, which we term psychosocial factors, are predisposing factors (e.g. skills, knowledge, beliefs in diet and disease relationship), enabling factors (e.g. social support, perceived norms, availability of healthful foods), and change-related factors (e.g. intentions, stage of dietary change). The theoretical models underlying the intervention were primarily social cognitive theory and the stages-of-change construct from the TTM. The intervention focused on providing employees with practical and personally relevant information, helping them to develop skills and enhance their motivation to change

**Study type**
Clustered RCT

**Design**
Worksites were randomised to I or C. Evaluation was based on mailed questionnaires completed at the baseline and at 1 and 2 years' postrandomisation

**Setting**
Workplace

**Length of intervention**
2 years

***Inclusion/exclusion criteria***

**Participants**
Physiological risk

**Population**
Employees in 28 selected worksites (no details reported)

**Inclusion criteria**
Not stated

**Exclusion criteria**
Not stated

**Behaviours targeted**
Intake of fat, fibre and fruits and vegetables

***Intervention details***

**Intervention group**
In year 1, a series of five nutrition classes were offered during work hours at intervention worksites, and self-help nutrition materials (S617) were mailed to employees at their homes. In year 2, personalised feedback (based on stage of dietary change and food frequency questionnaire responses) were mailed to intervention participants who completed the year 1 dietary assessment, and posters and brochures promoting low-fat, high-fibre eating were placed in worksite cafeterias. In both years, employees in I worksites received a quarterly newsletter with information about screening and nutrition

**Comparison group**
Control group (no details reported)

No numbers of participants for each condition reported

**Classification into stages**
Stage of dietary change was based on an algorithm developed by Glanz (S30), which uses items that assess self-rated diet, length of time following a healthy diet, intentions to make dietary changes, past attempts to change, and success with past efforts. Respondents were classified into five stages: precontemplation, contemplation, preparation, action and maintenance for two separate dimensions: low-fat eating and high fibre/fruit and vegetable consumption

*continued*

# Data extraction table *contd*

***contd***
**S084, Kristal (2000)**[39]

***Intervention details* contd**

**Classification into stages *contd***
For analyses, five categories were collapsed into three (precontemplation, contemplation or preparation), action and maintenance

S317: Questions and algorithm used to assign stages of change for a low-fat diet:
Q1. 'How high is your overall diet in fat?'
Low/very low: 'How long have you followed a diet low in fat?':
Less than 1 month/1–5 months: action stage. 6–11 months/1 year or more: maintenance stage
In the middle/high/very high/don't know: go to question 2

Q2. "In the past 6 months, have you tried to eat less fat?":
Yes: 'How successful were you?':
Very successful/somewhat successful: preparation stage
Not successful: go to question 4
No: go to question 3

Q3. "Are you seriously thinking about eating less fat over the next 6 months?"
Yes: "Go to question 5"
No: precontemplation stage

Q4. 'Do you plan to continue trying to eat less fat over the next 6 months?'
Yes: preparation stage
No: contemplation stage

Q5. 'How confident are you that you can change your diet to eat less fat?'
Very confident/somewhat confident: preparation stage
Not very confident/don't know: contemplation stage

**Validity of measure**
Validated by Glanz (S30)

S30: No data on validity of stage-of-change measure

**Training of educators**
Not stated

***Baseline characteristics***

**Gender**
100% male

**Age**
Mean age: 58.5 years

**Stage of change**
Not stated

**Target behaviour**
Mean fat intake: 36.6% of total energy

Mean fibre intake: 9 g per day

Mean fruit and vegetable intake: 3.43 servings per day

***Results***

**Statistical techniques**
Analyses are based on 1758 male employees who completed dietary assessments at all three survey time points (women excluded because only 5%). Sample sizes for specific analyses vary, with a loss of up to 6% due to missing data. All analyses and statistical tests were adjusted for intra-worksite correlations using the software packages SUDAAN and SAS's Proc Mixed

The first set of analyses examined whether the intervention affected changes in mediating variables. To examine the effect of the intervention on predisposing and enabling scale scores, the intervention effect (change from baseline in I – C) was calculated. Using multiple regression models to adjust intervention effects for baseline values and covariates (age, education, body mass index, and employment status (active versus retired)). To examine the effects of the intervention on shifts through stages of dietary change, the proportion of participants who fell into each of 9 possible categories of the $3 \times 3$ contingency table of baseline versus follow-up stage of change was calculated. Using generalised multinomial logit models to estimate the relative odds of shifts through stage of change contrasting I and C worksites, which allowed to test for intervention effects controlled for covariates

The second set of analyses examined whether changes in mediating variables predicted changes in diet. In the analyses, changes in mediating factors from baseline to year 1 were used to predict change in diet from baseline to year 1, and change from baseline to year 2 was used to predict change in diet from baseline to year 2. To examine the effect of changes in predisposing and enabling scale scores on dietary change, regression models were used to estimate the effect of a one-unit change in scale scores with changes in fat, fibre, fruits and vegetables. Authors fit regression models with both treatment groups combined, but estimated the treatment-specific effects by including both treatment and its interaction with main effects in the model. To examine the effects of shifts through stages of change on dietary change, first participants were categorised into the nine possible categories of change in stage. Authors fit multiple regression models predicting dietary change, using dummy variables to capture stage of change, and controlled for baseline diet and covariates. The authors fit these models for both treatment groups combined, including terms for treatment group and interactions

*continued*

# Data extraction table *contd*

***contd***
**S084, Kristal (2000)**[39]

***Results* contd**

**Statistical techniques *contd***
The third set of analyses examined the extent to which changes in predisposing and enabling scale scores and movement through stages of change explained the effects of the dietary intervention. Using multiple regression models to calculate the intervention effect controlled for: (1) covariates only; (2) covariates and mediating factors at the baseline; (3) covariates, baseline and change in mediating factors. The comparison of the intervention effect calculated with and without control for changes in mediating factors addresses how much of the intervention effect was explained by changes in the set of mediating factors

**Behaviour change**
Dietary intake was assessed using a mailed, self-administered Food Frequency Questionnaire. Principal outcomes were percentage of energy (% en) from fat, grams of fibre per 1000 kcal, and servings per day of fruits and vegetables. Fruit and vegetable consumption was calculated following the approach used by the national 'Five a Day for Better Health' programme. Servings of vegetables was the sum of responses to the question 'How often did you eat vegetables, not counting potatoes and salads', plus the Food Frequency Questionnaire items 'potatoes (not including fried)' and 'green salad'. Servings of fruit was the sum of the question 'How often did you eat fruit, not counting juice', plus the Food Frequency Questionnaire item 'fruit juice'

No exact data were reported

Data by stage of change:
For fat, there were no significant changes among precontemplation-participants at follow-up, modest decreases among those in action, and large decreases among those in maintenance. The pattern of results was similar in I and C, although effect sizes were smaller in C (*p*-values for interactions: year 1 = 0.04; year 2 = 0.14). For both I and C, effect sizes were larger in year 2 than in year 1. Results for fibre and for fruit and vegetable intakes were generally similar to those for fat. For fibre, effect sizes tended to be larger in I in year 1 only (*p*-values for interactions: year 1 = 0.06; year 2 = 0.50), and this result was similar for fruits and vegetables (*p*-values for interactions: year 1 = 0.07; year 2 = 0.63)

Control for baseline values of mediating factors reduced the intervention effects for fat modestly but had almost no effect on intervention effects for fibre and for fruits and vegetables. Additional control for changes in mediating factors reduced all intervention effects substantially. At year 1, intervention effects were reduced by 39% for fat, 34% for fibre, and 50% for fruits and vegetables. After control for mediating factors, the intervention effect for fat was no longer statistically significant, and the intervention effects for fibre and fruits and vegetables were only borderline statistically significant. In year 2, only the intervention effect for fibre was statistically significant, and it was reduced by 55% and no longer statistically significant after control for mediating factors. Thus, changes in mediating factors explained substantial proportions of the effects of the intervention on dietary change

**Stage movement**
Stage of change (P = pre-action; A = action; M = maintenance):

Fat stage of change, from baseline to year 1 (estimates from graph):

I (*n* = 823):
Backwards: A/P, 6.8%; M/A, 6.8%; M/P, 2.3%
No change: P/P, 10.9%; A/A, 25.5%; M/M, 21.8%
Forward: P/A, 10.9%; A/M, 10.0%; P/M, 3.2%

C (*n* = 871):
Backwards: A/P, 8.2%; M/A, 6.8%; M/P, 4.1%
No change: P/P, 15.9%; A/A, 22.7%; M/M, 21.4%
Forward: P/A, 10.9%; A/M, 5.9%; P/M, 3.2%

Fibre stage of change, from baseline to year 1 (estimates from graph):

I (*n* = 818):
Backwards: A/P, 6.2%; M/A, 9.0%; M/P, 5.2%
No change: P/P, 15.9%; A/A, 15.2%; M/M, 25.2%
Forward: P/A, 11.0%; A/M, 7.9%; P/M, 5.2%

C (*n* = 873):
Backwards: A/P, 8.0%; M/A, 9.0%; M/P, 6.9%
No change: P/P, 21.0%; A/A, 15.2%; M/M, 22.8%
Forward: P/A, 8.3%; A/M, 6.2%; P/M, 2.8%

Statistical modelling of shifts through stages of change showed that I participants were, in general, significant more likely than C to move into later stages of dietary change (data available from authors, not reported)

Fruit and vegetable change of change: not reported

**Health**
Not stated

**Intermediate outcomes**
I. Predisposing factors (individuals' beliefs and attitudes about a behaviour, motivation to engage in the behaviour, and knowledge about specific actions that constitute the behaviour):
Ia. Perceived benefits of a healthful diet (two items)
Ib. Motivation to eat a healthful diet (one item)
Ic: Knowledge of fat and fibre in foods (five items)

No exact data presented



*continued*

# Data extraction table *contd*

***contd***
**S084, Kristal (2000)**[39]

***Results* contd**

**Intermediate outcomes *contd***
For the predisposing scale, scores in I increased significantly at year 1 and increased further in year 2; there were no changes in C. At both years, intervention effects on the predisposing scale score were statistically significant ($p < 0.001$) and not affected by adjusting for covariates

II. Enabling factors (promote or impede practice of a behaviour, including barriers, norms and social support):
IIa: Perceived barriers to eating a healthful diet (two items)
IIb: Perceived norms for healthful eating (two items)
IIc: Social support to eat low-fat foods (two items)

No exact data reported. For the enabling scale, scores in I did not change, but were significantly decreased at both years in C. The intervention effect on enabling scale scores reached significance at the year 2 follow-up and was only slightly reduced by controlling for covariates

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
About 10% of retired employees and about 25% of active employees attended classes

***Withdrawals/economic evaluation***

**Number per group**
28 worksites were randomised, including 1758 male employees, women were excluded because they constituted less than 5% of total cohort. Sample sizes for specific analyses vary, with a loss of up to 6% due to missing data

Of the 4845 eligible male employees, 57.0% completed dietary assessments at the baseline. Of these, 63.6% (1758) completed dietary assessments at both year 1 and year 2 follow-ups

**Reasons**
Compared to men who completed baseline but not follow-up surveys, participants included in this analysis were somewhat older, more likely to be white and retired, and had lower fat and higher fruit and vegetable intake

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

Details of the main outcomes of this trial have been published (S503, S504). At the year 1 follow-up, there were modest but statistically significant intervention effects on intake of fat (–0.9% en), fibre (0.5 g/1000 kcal), and fruits and vegetables (0.2 servings/day). Employees at intervention worksites made significant, positive dietary changes; there were no changes in C. At the year 2 follow-up, however, net intervention effects for fat and fruits and vegetables were small and no longer significant. Although all changes in I were maintained, employees at C made significant changes, thereby muting the intervention effect. After control for mediating factors most of the intervention effects were lost, thus, changes in mediating factors explained substantial proportions of the effects of the intervention on dietary change

**Authors' reported limitations**
Potential response bias; reliability of the measures of predisposing and enabling factors was only fair; and self-reported diet from a food frequency questionnaire rather than 24 hour recalls or an objective, biological measure

**S498**
Describes participants' baseline data including dietary information, medical history, and demographics

**S503**
Analyses included both male and female participants, therefore results above are only taken from S84

At the year 1 follow-up, there were modest but statistically significant intervention effects on intake of fat (–0.9% en), fibre (0.5 g/1000 kcal), and fruits and vegetables (0.2 servings/day). At 2 years, due to significant positive changes in control worksites, intervention effects were smaller, significant for fibre only. Intervention effects were larger in younger (< 50 years), active employees and class attendees

**S504**
The Next Step Trial was a trial of worksite colorectal cancer screening promotion and nutrition interventions. S504 describes results of the screening promotion intervention only

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S227, Lennox (1998)**[45]

**Country**
UK

**Aim**
Assess the effects of training (1-day stages-of-change workshop for health professionals) on patient smoking outcomes

**Model**
TTM

**Theoretical basis**
The training was based on the stages-of-change model of behavioural change (S248)

The main implication of the TTM for health professionals is that different interventions are appropriate for different stages of change

The training also included a short introduction to the techniques of motivational interviewing (S618), a consulting technique often used along with the stages-of-change approach, and particularly relevant for respondents at the precontemplation and contemplation stages

**Study type**
Cluster RCT

**Design**
Cluster RCT, with two sets of respondents: health professionals and smoking patients. The unit of randomisation was the general practice. Health professionals from half of the participating practices were invited to attend the training intervention, while the other half acted as untrained controls. Smokers on the lists of participating practices were identified by postal questionnaire to a random sample of adults on practice lists. Patient outcome data were collected by postal questionnaire sent at 8 and 14 months after the workshops

This was a pragmatic trial: smokers were not formally recruited into the study, and were not told that their practice was involved in a smoking study; smokers may or may not have attended their practice during the follow-up period, and attendance(s) could have been at any time during the follow-up period; smoking may or may not have been raised as an issue during consultation

16 practices were pair-matched according to list size, staff numbers and social deprivation, and randomly and blindly allocated to C or I

**Setting**
Primary care

**Length of intervention**
A 1-day workshop for health professionals and the intervention took place during normal practice visits by smokers in the 14-months study period

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
A random sample of adult smokers on the participating practices' lists. All general practices in Aberdeen city were invited to participate. Patients stating that they were current regular smokers (smoking every day or most days) constituted the smoking respondents

**Inclusion criteria**
Practices: willing to participate in one day workshop ('all or most' GPs and all practice nurses and attached health visitors would attend); willing to commit time to smoking cessation training

**Exclusion criteria**
Practices: involved in an other health promotion initiative; staff member attended pilot workshop; impending large-scale staff changes; staff members worked for more than one participating practice

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
Smoking education by trained health professionals

**Comparison group**
Smoking education by untrained controls

**Classification into stages**
S227: The questionnaire also collected baseline data on readiness to change smoking behaviour (S515)

S515: The contemplation ladder is a graphical presentation of a ladder, with ten rungs which are numbered from 0 (below bottom rung) to 10 (above top rung). Each rung on this ladder represents where various smokers are in their thinking about quitting. Respondents are asked to circle the number that indicates where s/he is now. Next to the numbers 0, 2, 5, 8, and 10 is extra information: 0, No thought of quitting; 2, 'Think I need to consider quitting someday'; 5, 'Think I should quit, but not quite ready'; 8, 'Starting to think about how to change my smoking patterns'; 10, 'Taking action to quit (e.g. cutting down, enrolling in a programme')

*continued*

# Data extraction table *contd*

***contd***
**S227, Lennox (1998)**[45]

***Intervention details* contd**

**Validity of measure**
S515: Analyses of data collected from more than 400 smokers at two worksites before and during a 10-month intervention indicate that the Ladder scores were significantly associated with reported intention to quit, number of previous quit attempts, perceived co-worker encouragement to quit, and socio-economic status. Ladder scores predicted subsequent participation in programmes designed to educate workers about their smoking habit and its contingent risks. The Ladder did not predict biochemically validated abstinence of 24 hours or more. To assess its ability to distinguish between groups known *a priori* to differ in readiness, the Ladder was administered to 36 participants in a clinic-based smoking cessation programme. As predicted, clinic patients scored significantly higher than the workers on the ladder

**Training of educators**
Health professionals were given a one day workshop focusing on the stages-of-change model. It was emphasised that different interventions are appropriate for different stages of change. The training also included a short introduction to the techniques of motivational interviewing

The workshops were devised and run by two of the authors (a senior health promotion officer experienced in group work with primary healthcare teams, and a GP). The emphasis was on an interactive approach, with work in groups and in pairs, and some self-reflection. Some didactic teaching on the stages-of-change model was also included

***Baseline characteristics***

**Gender**
Not stated

**Age**
Not stated

**Stage of change**
Not stated

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
Analyses were carried out for all smoking respondents irrespective of whether or not they had attended their practice during the 14-month follow-up period. Sample size was calculated on assumption that continuous abstinence from 8 to 14 months would be 5% in C and 8% in I (all respondents irrespective of attendance). Assuming that complete follow-up data would be obtained from 75% of smokers contacted, 1410 respondents in each group would be required to detect this difference at the 5% significance level with 80% power

Initially, comparisons of binary outcomes (whether smoking had been mentioned in a consultation, whether a cessation attempt was made, point abstinence, and continuous abstinence) between I and C were assessed using $\chi^2$ tests. Logistic and multiple logistic regression analyses were carried out where appropriate for these outcome measures. Comparison of the continuous outcome of change in readiness to change scores were carried out using *t*-tests and multiple linear regression

In order to adjust for potential confounders, adjustment was made for age, sex and deprivation score in the regression analyses, as well as for an indicator for the intervention group

Because randomisation was by practice rather than by patient, potential intrapractice clustering had to be taken into account. A generalised linear mixed model approach used regression techniques which added the general practice, as a random factor nested within the treatment groups, to the other fixed-effect factors

Intervention patients were less affluent than controls, and regression techniques were therefore used to adjust for deprivation

**Behaviour change**
Cessation attempts; point prevalence of abstinence (defined as not having smoked a cigarette in the previous 24 hours); and continuous abstinence from 8 to 14 months (defined as reporting point abstinence at both 8 and 14 months)

Smokers attempting to give up over 14 months of follow-up (number (%) 'yes'):
I: 503 (56.6%)
C: 434 (55.5%)
$\chi^2 = 0.22$, $p = 0.64$; difference: 1.1%; 95% CI, –3.67 to 5.87

Point prevalence of abstinence at 8/14 months (number (%) 'yes'):
I: 74 (8.0%)/100 (11.1%)
C: 80 (9.4%)/93 (11.7%)
$\chi^2 = 1.11/0.13$, $p = 0.29/0.72$; difference, –1.4%/–0.6%; 95% CI, –4.03 to 1.23/–1.50 to 0.30

Continuous abstinence between 8 and 14 months (number (%) 'yes'):
I: 32 (3.6%)
C: 37 (4.7%)
$\chi^2 = 1.25$, $p < 0.26$; difference, –1.1%; 95% CI, –3.03 to 0.83

*continued*

# Data extraction table *contd*

***contd***
**S227, Lennox (1998)**[45]

***Results* contd**

**Behaviour change**
Lack of significant differences in outcomes between I and C was not due to lack of power

**Stage movement**
Change in smokers' readiness to change their smoking behaviour

Raw data showed a significantly greater change in readiness to change in I (measured from baseline to 14 months): on a 11-point scale, mean change was 0.60 (I) as opposed to 0.27 (C) ($p = 0.04$, difference = 0.33 (95% CI, 0.01 to 0.65)). This became non-significant after allowing for clustering using a generalised linear mixed model (intracluster correlation: 0.013, $p = 0.11$)

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
33 of 37 GPs (89.2%), 15 of 16 practice nurses (93.7%) and all 16 health visitors attended the intervention workshops

Over the 14-month follow-up period, 674 from 898 I (75.0%) and 611 from 795 C (76.9%) attended their practice at least once. Smokers in I were more likely than smokers in C to recall smoking having been mentioned in a consultation during the 14-month follow-up period. This difference was significant ($p < 0.10$) for GP consultations, but not for consultations with practice nurses or health visitors

Smokers recalling smoking having been mentioned during consultation with health professionals over 14-months follow-up (attenders only, number (%) 'yes'):
I: GPs, 420 (79.4%); practice nurses, 104 (83.2%); health visitors, 28 (73.7%)
C: GPs, 355 (74.9%); practice nurses, 77 (76.2%); health visitors, 24 (68.6%)
GPs, $\chi^2 = 2.88$, $p = 0.09$; practice nurses, $\chi^2 = 1.69$, $p = 0.19$; health visitors, $\chi^2 = 0.23$, $p = 0.63$

***Withdrawals/economic evaluation***

**Number per group**
26 practices were approached, four declined and six of the 22 volunteering were excluded. 16 practices were randomised

I: Eight practices; 6631 patients surveyed; 5022 (76%) patients responding, 1381 (27% of responders) smokers identified; 941 (68% of identified smokers) smokers responding to 8-month questionnaire and 898 (65% of identified smokers) smokers responding to 14-month questionnaire

C: Eight practices; 6631 patients surveyed; 5217 (79%) patients responding, 1207 (23% of responders) smokers identified; 864 (72% of identified smokers) smokers responding to 8-month questionnaire and 795 (66% of identified smokers) smokers responding to 14-month questionnaire

33 of 37 GPs (89.2%), 15 of 16 practice nurses (93.7%) and all 16 health visitors attended the intervention workshops

**Reasons**
Before randomisation four practices declined to participate: Involved in an other health promotion initiative ($n = 2$); unwilling to commit time to smoking cessation training ($n = 2$) and six were excluded before randomisation: staff member attended pilot workshop ($n = 4$); impending large scale staff changes ($n = 1$); staff members worked for more than one participating practice ($n = 1$)

Smokers: there was no significant difference between the two arms in response rate, age, sex, addiction score or readiness to change smoking behaviour. Intervention patients were less affluent than controls

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

| ***contd***<br>**S227, Lennox (1998)**[45] |
|---|
| ***Additional comments*** |
| **Authors' conclusion**<br>Patients in I were more likely than controls to recall smoking having been mentioned in a consultation but there were no significant effects of the intervention on patient smoking outcomes 14 months after the workshops<br><br>**Possible explanations for lack of effects**<br>(1) Health professionals' motivation to change behaviour<br>(2) Degree of training may not have been sufficient<br>(3) Time available for health professionals may have been too short<br>(4) Organisational improvements are also necessary |

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S479, Lutz (1996)**[36]

**Country**
USA

**Aim**
To develop and evaluate the effectiveness of nutrition newsletters at three levels of tailoring designed to help HMO clients increase the number of fruit and vegetables they eat each day, using computer-tailoring technology. The purpose of this study was to assess the relative impact of tailored messages with and without tailored goal-setting information to improve participants' fruit and vegetable consumption

**Model**
TTM, social cognitive theory, health belief model and goal-setting theory

**Theoretical basis**
Components from three theoretical frameworks were used to guide tailoring of newsletter content: specific constructs, such as self-efficacy, from social cognitive theory (S619); stage of readiness to change from the TTM of change (S248) ; and perceived barriers and benefits from the health belief model (S620, S621). Goal-setting theory also guided the development of the tailored newsletter with a goal-setting component (S622)

**Study type**
RCT

**Design**
A four-group RCT (stratified by stage of change) with pre- and postintervention measures. The predetermined sample size (4469 mailed, 20% response, 20% attrition: 715/4 = 178 participants per condition) would have provided over 80% power to detect a difference of 0.5 servings at alpha = 0.05 (estimated SD = 2.316). Actual power with 573/4 = 143 participants per condition: 80% power to detect a difference of 0.59 servings

**Setting**
Community

**Length of intervention**
Newsletters were mailed once a month for 4 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
A North Carolina HMO population: 4469 HMO clients who work for one of ten employer groups covered by the HMO who agreed to have their employees participate in this study

**Inclusion criteria**
At least 18 years, one member per household

**Exclusion criteria**
Following a special diet that would prevent them from eating more fruit and vegetables. Having chewing problems or any other medical condition that would prevent them from changing their current diet to eat less fat and eat more fruit and vegetables. Been advised by doctor to limit intake of fruit and vegetables. Planning to move away from North Carolina in the next 6 months

**Behaviours targeted**
Fruit and vegetable consumption

***Intervention details***

**Intervention group**
All I: Four-monthly newsletters, for the two tailored newsletters (I2 and I3), baseline survey responses served as basis and a short, postage-paid survey included in the first three issues of the tailored newsletters served to provide additional information for tailoring

I1: Non-tailored or generic newsletter. Non-tailored nutrition information and emphasis on non-quantitative goal of 'eat more fruit and vegetables'

I2: A computer-tailored newsletter. Tailored nutrition information, feedback on baseline eating habits and attitudes related to increasing fruit and vegetable intake, follow-up newsletter surveys for tailoring over time and emphasis on non-quantitative goal of 'eat more fruit and vegetables'

I3: A computer-tailored newsletter with tailored goal-setting information. Tailored nutrition information, feedback on baseline eating habits and attitudes related to increasing fruit and vegetable intake, follow-up newsletter surveys for tailoring over time, emphasis on specific, difficult goal of 'five a day', tailored goal-setting information and tailored subgoals based on baseline eating habits

**Comparison group**
C: No newsletter

*continued*

# Data extraction table *contd*

***contd***
**S479, Lutz (1996)**[36]

***Intervention details* contd**

**Classification into stages**
Stage of change was assessed using a modified format of the questions and staging algorithm developed for National Cancer Intitute's '5 A Day for Better Health' initiative (S623):
Precontemplation: not seriously thinking about eating more fruit and vegetables. Additionally participants were asked to choose a reason for 'Not seriously thinking about eating more fruit and vegetables in the next 6 months' (see question 3)
Contemplation: seriously thinking about eating more in the next 6 months
Preparation: planning to eat more in the next 30 days
Action: eating five or more servings a day for 6 months or less
Maintenance: eating five or more servings a day for more than 6 days

Survey questions:
1. Not counting salad or potatoes, about how many servings of vegetables do you eat per day or per week?
1A. Not counting juice, about how many servings of fruit do you eat per day or per week?
1B. How often do you usually eat (drink): orange juice, grapefruit juice/other 100% fruit juices, not counting 'fruit drinks'/green salad/other potatoes, including boiled, baked, mashed and potato salad? (Response options: Never or hardly ever/Less than once a week/1–2 times a week/3–4 times a week/5–6 times a week/Every day/More than once a day)
2. About how long have you been eating this many servings of fruit and vegetables? (Less than 1 month/1–3 months/4–6 months/Longer than 6 months)
3. Are you seriously thinking about eating more servings of fruit and vegetables starting sometime in the next 6 months? (Yes/no, I've thought about it, but decided not to/No, I've thought about it before, but never got around to it/No, I've never thought about it/No, I'm already eating enough fruit and vegetables)
4. Are you planning to eat more servings of fruit and vegetables during the next month? (Yes/no)

Algorithm for assigning stage of change:
Maintenance: Q1 + Q1A + Q1b ≥ 5, and Q2 = longer than 6 months
Action: Q1 + Q1A + Q1b ≥ 5, and Q2 = 6 months or less
Preparation: Q1 + Q1A + Q1b < 5, and Q3 = yes, and Q4 = yes
Contemplation: Q1 + Q1A + Q1b < 5, and Q3 = yes, and Q4 = no
Precontemplation: Q1 + Q1A + Q1b < 5, and Q3 = no

**Validity of measure**
Not reported

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
64.4% female

**Age**
Average age: 39.3 years (range 18–65) years

**Stage of change**
Precontemplation: 27%
Contemplation 2%
Preparation: 49%
Action: 3%
Maintenance 19%

**Target behaviour**
Mean intake of fruit and vegetables (SE): 3.4 (0.09) servings per day, with 21% eating five or more servings a day

Mean variety per week score (SE): 6.4 (0.13)

*continued*

# Data extraction table *contd*

***contd***
**S479, Lutz (1996)**[36]

***Results***

**Statistical techniques**
Descriptive statistics were used to assess relationships between demographic characteristics and the dietary and psychosocial variables of interest. *t*-tests were used to examine differences between dichotomous and continuous variables. *F* tests for continuous and categorical variables with multiple levels, and $\chi^2$ tests for categorical variables. All analyses were performed using SAS for windows (version 6.10)

Both daily intake and weekly variety measures were skewed to the right. Attempts were made to achieve a more normal distribution by transforming the data using a square root, log(1 + fruits and vegetables) and ln(1 + fruits and vegetables). For analysis of the primary hypotheses related to daily intake and weekly variety, these data transformations appeared to have minimal impact on differences in postintervention intake and variety seen among intervention groups, unadjusted for other variables. Therefore, results were reported using untransformed data. For the secondary hypotheses related to stage of change and self-efficacy, a square root transformation was used to achieve a more normal distribution of daily fruit and vegetable intake

For each outcome measure of interest, baseline levels of the variable were controlled for in the analyses

Other independent variables were only included in the final analyses if they were considered potential confounders of the associations seen between intervention group and the outcome measure. For a variable to be included in the model it had to correlate significance with both intervention group and the outcome measure. The demographic variables gender, age, educational level, race (black/white), marital status, presence of children in the household, income and employment status were all considered for inclusion in the final models developed for assessing changes in daily fruit and vegetable intake, weekly variety, daily fruit and vegetable eating behaviours, stage movement and level of self-efficacy

Primary hypotheses: fruit and vegetable consumption. Analyses looking at changes in the dependent dietary variables among intervention groups were conducted for those participants completing both baseline and postintervention surveys. Multiple ANCOVA was used with the dependent measures of daily fruit and vegetable intake and weekly variety because of the significant correlation between these two outcome variables at the baseline and postintervention. The results of the multivariate tests were examined first, and the dependent variables were tested using univariate analyses only if significant results were seen. ANCOVA was used to assess differences among intervention groups regarding change in daily fruit and vegetable intake and change in variety of fruit and vegetable eaten in a week. *Post hoc* analyses using Tukey's honestly significant difference test were conducted when ANCOVA was significant. Analyses to examine changes in daily fruit and vegetable intake and weekly variety eaten per week among intervention groups were conducted with the entire baseline sample ($n$ = 710) using the standard of intent to treat (non-respondents to post-test contributed data to their original group and non-respondents experienced no change in daily intake or weekly variety scores)

Secondary hypotheses: Contemplation and preparation were combined when looking how baseline stage of change related to demographic characteristics and baseline fruit and vegetable intake. Action and maintenance were combined for analyses looking at stage movement. Stage movement among intervention groups was looked at using binomial probabilities and logistic regression. The binomial distribution was used for those who exhibited a change in stage from pre- to post-test ($n$ = 292) to determine if a significantly greater number of people were advancing in stage versus regressing in stage than would be expected by chance. Logistic regression was used to test how stage movement varied among groups based on participants' baseline stage of change

**Behaviour change**
Daily fruit and vegetable intake, variety of fruit and vegetables eaten each week, specific fruit and vegetable eating behaviours (how often participants include a piece of fruit or glass of juice at breakfast) measured by pre- and postintervention food frequency questionnaires

Changes in daily intake: The MANCOVA test yielded a significant Wilks' lambda ($F$ = 2.7, $p$ = 0.01), indicating significant differences among intervention groups for daily intake and weekly variety

ANCOVA showed significant differences among groups ($F$ = 5.22, $p$ < 0.002). Tukey's HSD test showed significantly higher fruit and vegetable intake at postintervention for I1 to I3 compared to C, differences between I1, I2 and I3 not significant:

Mean baseline (SE)/mean follow-up (SE) daily fruit and vegetable intake ($n$ = 573):
I1, 3.4 (0.18)/4.1 (0.19); I2, 3.3 (0.19)/4.1 (0.21); I3, 3.3 (0.19)/4.1 (0.21); C, 3.5 (0.20)/3.6 (0.16). Intention-to-treat analysis ($n$ = 710): overall test was significant ($F$ = 5.21, $p$ < 0.001), Tukey's honestly significant difference test revealed significantly higher post-test fruit and vegetable intake scores for I2 and I3 compared to C, differences between I1 and I2/I3 not significant

Overall ANCOVA significant differences among groups ($F$ = 10.16, $p$ < 0.0001). Tukey's honestly significant difference test showed significantly higher post-test scores for I1 to I3 compared to C, differences between I1, I2 and I3 not significant

Mean baseline (SE)/mean follow-up (SE) total variety consumed per week:
I1, 6.4 (0.29)/7.8 (0.29); I2, 6.5 (0.30)/7.9 (0.30); I3, 6.4 (0.29)/8.5 (0.29); C, 6.7 (0.29)/6.9 (0.25). Intention-to-treat analysis: overall test was significant ($F$ = 10.15, $p$ < 0.0001), Tukey's honestly significant difference test showed that I1 to I3 scores were significantly higher than C scores

Changes in the seven fruit and vegetable eating behaviours: No differences among groups regarding post-test eating behaviours, unadjusted for any other variables

**Stage movement**
First approach: Using binomial probabilities (looks at differences in direction, not magnitude) ($n$ = 573): 29% moved forward; 22% regressed and 49% stayed in the same stage. Of those who did change ($n$ = 292) using binomial probabilities to test for differences in stage movement (H0 = those who changed were just as likely to move forward as backward), the overall test was significant ($p$ < 0.01) indicating that significantly more moved forward than expected by chance

Those in I1 and I2 showed significant positive movement in stage ($p$ < 0.01), and those in C were more likely to regress (not significant)

Second approach (taking into account baseline stage of change): For those in precontemplation/contemplation/preparation, a two-category variable was created (moved forward/stayed the same or regressed) and for action/maintenance, a two-category variable was created (moved forward or stayed the same/regressed). Logistic regression showed (using C as reference group) that for those in precontemplation/contemplation/preparation, I1 to I3 were significantly more likely to experience forward stage movement compared to C; and for those in action/maintenance, no significant differences were found between groups



*continued*

## Data extraction table *contd*

***contd***
**S479, Lutz (1996)**[36]

***Results* contd**

**Health**
Not stated

**Intermediate outcomes**
Self-efficacy to eat more fruit and vegetables: no significant differences changes over time between groups

Self-efficacy toward eating at least five servings of fruit and vegetables each day: overall test was significant ($F = 3.6$, $p < 0.001$), Tukey's honestly significant difference test showed only significant increase for I2 compared to C; no significant differences between I1/I3 and C

Outcome expectations, motivation to change, and perceived barriers: not reported in chapters 2, 3 and 4 of thesis

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Level of study participation (e.g. reading newsletter, mailing back follow-up newsletter surveys)

No tables, data are from text:
81% of 422 who received 'Take 5' newsletters and completed post-test remembered receiving at least 3 of 4 newsletters (64% of all receiving newsletters). I3 were significantly more likely to remember receiving more newsletter issues, compared to I1 and I2 ($\chi^2 = 8.65$, $p < 0.01$)

For all who remembered receiving at least three newsletters, 71% read most or all of each issue

I2 and I3 received surveys with the newsletter to enhance tailoring. Response rates were higher in I3 (about 25% each survey) than I2 (26%, 19% and 13%)

***Withdrawals/economic evaluation***

**Number per group**
4469 clients were mailed, 16% of eligible clients returned a completed baseline survey. 710 randomised. Follow-up response rate was 81% (surveys completed by 573 of baseline study participants)

**Reasons**
One person was excluded because another household member had already enrolled

Non-respondents ($n = 137$) compared to respondents ($n = 573$) were more often female (70.8% versus 62.8%, $p = 0.08$), lower educated (50.7% 2–12 grade/49.3 > 12 grade versus 37.2%/62.8%, $p < 0.01$), more often non-white (24.8% black/71.5% white/3.7% other versus 18.1%/80.0%/1.9%, $p = 0.08$) and less often married (55.5% versus 68.9%, $p < 0.01$)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
For those completing pre- and post-test ($n = 573$), I1 to I3 had significantly higher daily intake and variety scores compared to C. There were no significant differences in intake and variety at follow-up among I1, I2 and I3. Few differences in the seven daily fruit and vegetable eating behaviours were seen among groups. Newsletters can be an effective approach for improving fruit and vegetable consumption of interested HMO clients. In this study, a computer-tailoring system did not significantly enhance the impact of the nutrition newsletters on fruit and vegetable intake

**Authors' reported limitations**
Sample size gave only 50% power to detect intake differences as small as 0.2 servings among groups. Generalisibility is limited by the mail recruitment approach, only 16% of those invited took part, participants tended to be well educated and have higher income status than average for North Carolina, and possibly more motivated

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S452, Morgan (1996)**[46]

**Country**
USA

**Aim**
To test the effectiveness of an office-based smoking cessation programme tailored to midlife and older smokers

**Model**
TTM

**Theoretical basis**
Study utilises an approach both specifically tailored to older smokers and integrated into routine care. Hypothesis: a cessation guide that addressed the known barriers, concerns and motivations for quitting among older smokers would be superior to a generic guide. Tailoring included attention to the graphic and style preferences of older adults as well as inclusion of content specific to older smokers, especially the benefits of quitting at any age (see Intervention)

**Study type**
RCT (clustered)

**Design**
Primary care practices were recruited to participate in a 2-year RCT comparing usual care with brief quit-smoking advice and counselling for midlife and older smokers (aged 50–74 years)

Entire practices (physicians and key non-physician office staff) were randomised. Several strategies to facilitate provider adherence to research and intervention protocols were used (e.g. patient enrolment aids, cues and reminders for office staff, practical intervention aids, regular staff contacts and small gifts). Practices ranged from 5 to 50 weeks (average: 36 weeks) for patient accrual. Original estimates of effect size and expected variance among practices indicated that a minimum number of five patients per practice was required. Practises accruing fewer than five patients were excluded

All patients meeting inclusion criteria completed a questionnaire about smoking habits prior to seeing a healthcare provider

Physicians completed a questionnaire following the close of enrolment regarding perceptions of their effectiveness giving quitting advice, and the programme's effectiveness and feasibility. Patients in I were telephoned by programme staff between 2 and 4 weeks after their office visit for brief follow-up counselling and to check on provider adherence to the treatment protocol. Follow-up telephone interviews were conducted by professional interviewers 6 months after enrolment

**Setting**
Outpatient clinic

**Length of intervention**
2-year study. Results 6 months after enrolment are reported only

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Smokers, aged 50–74 years, visiting a primary care practice

**Inclusion criteria**
Practices: willingness to participate, absence of a formalised smoking intervention programme, and provider projections of ability to accrue 25 age-eligible patients within 3 months

Patients: Ages between 50 and 74 years, seeing the physician for a non-crisis visit and were smokers (having had a cigarette in the previous 7 days). Participants were assured that they did not have to quit smoking, or even try, to participate, thus motivation was not an inclusion criterion

**Exclusion criteria**
Practises: Accruing fewer than five patients

**Behaviours targeted**
Smoking

*continued*

# Data extraction table *contd*

***contd***
**S452, Morgan (1996)**[46]

***Intervention details***

**Intervention group**
Immediate intervention: received on-site training to implement a modified National Cancer Institute smoking cessation intervention. The National Cancer Institute programme comprises four steps: ask about smoking at every opportunity; advise all smokers to stop, assist the patient to stop smoking; arrange for follow-up support. Physicians were trained to praise patients for previous quit efforts, provide personalised feedback linking smoking to symptoms, discuss the health benefits of quitting for older smokers, and give a clear message to stop smoking. Patients were give a copy of a smoking cessation guide tailored to older smokers ('Clear Horizons') and asked: 'If we give you some help, are you willing to try to quit?'

Smokers in the precontemplation stage, who declined help, received brief guide-based counselling to overcome quitting barriers. Smokers in the contemplation stage received brief guide-based counselling to set up a quit plan and quit date and, when indicated, a prescription for nicotine gum. All smokers were to be sent a follow-up letter drafted by the Clear Horizons office from their physician within 1 week of their visit

Smokers received a brief follow-up Clear Horizons Quitline counselling call from project staff within 2–4 weeks of the intervention visit to reinforce their efforts, explore barriers, and discuss their quit plans

The *Clear Horizons* guide is designed specifically for long-term heavy smokers, aged 50 years and older. The guide was designed to address individuals at all stages of smoking and is divided into several sections: deciding to quit, preparation, initial cessation, and maintenance

**Comparison group**
Delayed intervention practices were instructed to provide usual care to their older smokers over the accrual and follow-up period

**Classification into stages**
Not stated

**Validity of measure**
Not stated

**Training of educators**
Physicians and key office and clinical staff in both conditions were provided 45 to 60 minutes on-site training by masters- or doctoral-level psychologists and health educators. Training included a presentation of background and rationale for the project including the special needs of older smokers, training objectives, goals for the practice, and data collection guidelines

***Baseline characteristics***

**Gender**
56% female
I: 54.5%
C: 57.6%

**Age**
Average age: 60.1 years
I, 60.9; C, 59.5

**Stage of change**
Not stated

**Target behaviour**
Average number of cigarettes per day: 20.1 (SD = 12.1)
I, 19.0; C, 20.9

***Results***

**Statistical techniques**
Descriptive statistics were computed for all baseline and follow-up measures. To identify covariates of selected process and outcome measures, bivariate comparisons were conducted using $\chi^2$ tests for categorical variables, Mantel–Haenszel $\chi^2$ analysis for ordinal variables, and *t*-tests for continuous variables. Standard logistic regression models were computed for each condition as well as a combined model. A correlated logistic regression model that accounts for dependencies among respondents within a given practice (because practice was the unit of randomisation) was also utilised. The dependencies are measured on the log-odds scale as in standard logistic regression. Thus, the model includes the parameters of the standard logistic regression and two other parameters describing dependencies within control groups and within intervention groups

**Behaviour change**
Self-reported quit rates

Abstinent (not having smoked a cigarette in the previous 7 days): I, 17.8%; C, 9.3% ($n$ = 573; $p < 0.005$)

Counting all non-responders as smokers: I, 15.4%; C, 8.2% ($n$ = 659; $p < 0.005$)

**Stage movement**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S452, Morgan (1996)**[46]

***Results* contd**

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Patient reports of interactions with physician at 2–4-weeks follow-up (I only, *n* = 259):
Doctor recommended that you stop smoking: 88.4%
Doctor gave you 'Clear Horizons' guide: 95.8%
Received a letter about quitting plans from doctor since visit: 35.1%
Someone talked to you about quitting methods in the guide (optional): 44.8%
Set a quit date (optional): 37.1%
Doctor prescribed nicotine gum (optional): 30.9%
Doctor gave sample of nicotine gum (optional): 31.7%
Doctor asked you to set another appointment to talk about quitting (optional): 38.6%

Primary care providers opinions on feasibility and effectiveness (I only, 14 practices): 79% of physicians reported spending between 3 and 10 minutes per patient implementing the counselling intervention; 43% thought patients were often/always receptive to advice to quit. Providers rated the protocol as practical and helpful; 93% expressed increased confidence in counselling older patients to stop smoking

***Withdrawals/economic evaluation***

**Number per group**
81 practices expressed interest, 49 met criteria and agreed to participate and were randomised (I, 23; C, 26). After exclusion of practises accruing fewer than five patients: I, 18; C, 21. Numbers of patients: I, 279; C, 380. Of the 659 patients who completed the baseline questionnaire, 573 (87%) were contacted at the 6-months follow-up

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Smoking abstinence was significantly increased by training physicians and key office and clinical staff to intervene with older smokers. BIs tailored to this age cohort can be successfully and efficaciously integrated into routine care

**Comment**
Intervention was tailored to known barriers, concerns and motivations for quitting among older smokers; unclear how readiness to change was used in the tailoring. Stages of change not explicitly assessed. Although precontemplators were treated different from contemplators

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S418, Oliansky (1997)**[65]

**Aim**
To determine the effectiveness over time of the Substance Abuse Brief Screening and Intervention Project, which was designed to identify people as 'at risk' for substance abuse and then provide brief educational or motivational interventions to encourage behaviour change in ambulatory care settings. The goal was to reduce or stabilise the consumption of alcohol, drugs and/or tobacco use through behavioural changes as a result of the interventions

**Model**
TTM

**Theoretical basis**
Clinic A developed the PERM, a BI protocol which combines solution-focused therapy principles with Prochaska's transtheoretical stages of change. This approach matches a patient's stage of change with a specific sequence of questions designed to empower the patient to take responsibility for their alcohol, tobacco, and/or drug use

**Study type**
RCT

**Design**
Clinic A and B: patients were randomly assigned to I or C based on odd–even medical record numbers. Clinic B: patients were randomly assigned to one of the two paediatric physicians for I and C

At initial screening, substance use in the past year and in the past month were assessed for baseline rates. Past year use was used to determine which patients were at risk for substance abuse

Quasi-experimental and longitudinal design

**Setting**
Community-based clinics

**Length of intervention**
One interview, assessments after 1 and 3 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Patients 'at risk' for substance abuse, from three community-based urban clinics in the Detroit area (patients were all seeking primary care). The SUSI was used to determine which patients were at risk for alcohol, tobacco and/or drug abuse. The SUSI is an 18-item survey which was developed for this project and based on the AUDIT (S625) and the CAGE (S624) questionnaires

Clinics A and C focused on adults aged 18–55 years

Clinic C screened only female patients

Clinic B directed its efforts toward male and female adolescents ages 12–18 years

**Inclusion criteria**
Clinic A: Ages 18–55 years; primary care patients; scoring within 6–25 range on the SUSI

Clinic B: Ages 12–18 years; scoring 6–25 on the SUSI, or with family use (patients scoring 1–5 and reported regular substance use by someone in their household were deemed at risk; patients who reported family use and scored 0 were not included in the analysis). Written consent from a parent for the adolescent patients

Clinic C: Ages 18–55 years; female patients; scoring within 6–25 range on the SUSI

**Exclusion criteria**
Not stated

**Behaviours targeted**
Consumption of alcohol, drugs and/or tobacco

*continued*

# Data extraction table *contd*

***contd***
**S418, Oliansky (1997)**[65]

***Intervention details***

**Intervention group**
BI. Each clinic (A, B and C) devised their own BI to be used

The BI for adolescents (clinic B) and for the female adult population (clinic C) were primarily educational in nature, providing information regarding the harmful effects of substances that the patient reported using. Reduction of use was encouraged through the use of a contract which outlined a specific goal formulated by the patient

Clinic A developed the PERM, a BI protocol which combines solution-focused therapy principles with Prochaska's transtheoretical stages of change. This approach matches a patient's stage of change with a specific sequence of questions designed to empower the patient to take responsibility for their alcohol, tobacco, and/or drug use

Clinic A: 10 minutes solution-focused interview, conducted by a resident or psychologist, establishing written goals related to each patient's substance use; verbal reinforcement from physician. Follow-up: I and C contacted by phone at 1 and 3 months for SUSI reassessment

Clinic B: Brief education intervention provided by a registered nurse consisting of pamphlets, motivational interview, contract of personal goals, and/or video; verbal reinforcement from physician

Clinic C: Educational intervention provided by bilingual programme assistant with healthcare experience; consisting of info about damaging effects of ATOD, identification of barriers to decreasing ATOD, development of personal plan to overcome barriers and decrease ATOD, verbal reinforcement from physician

**Comparison group**
No intervention. Baseline SUSI assessment and demographics. Follow-up: I and C contacted by phone at 1 and 3 months for SUSI reassessment

**Classification into stages**
Clinic A: Stage of change algorithm (given to I only)

**Validity of measure**
Not reported

**Training of educators**
Not stated

In addition to the variations in BI at the three clinics, the project staff at each site had diverse educational backgrounds. The screening and intervention were administered by clinical psychologists at clinic A, a registered nurse at clinic B, and a health educator at clinic C

***Baseline characteristics***

**Gender**
Clinic A: 51% female
Clinic B: 52% female
Clinic C: 100% female

**Age**
Mean age (range):
Clinic A: 35.3 (19–53)
Clinic B: 15.7 (13–18)
Clinic A: 25.2 (17–49)

**Stage of change**
Not reported

**Target behaviour**
Clinic A/B/C: mean SUSI score at the baseline:
Past year use: 14.95/7.67/7.31
Past month use: 10.83/5.33/0.46

***Results***

**Statistical techniques**
In the comparison analysis between baseline and the 1 month follow-up, the baseline SUSI score which reflected substance use in the past month was utilised, rather than the past year score, in order to provide better comparability

To determine whether the BI provided at the clinics were effective in reducing or stabilising substance use, paired comparison *t*-test analyses were conducted on the SUSI mean scores for I and C at each clinic from baseline to 1-month follow-up, and then from 1- to 3-month follow-up

*continued*

# Data extraction table *contd*

***contd***
**S418, Oliansky (1997)**[65]

***Results* contd**

**Behaviour change**
Substance use: The SUSI was used to determine which patients were at risk for alcohol, tobacco and/or drug abuse. The SUSI is an 18-item survey which was developed for this project and based on the AUDIT (S625) and the CAGE (S624) questionnaires

Mean SUSI scores across time for I and C at clinic A:
I: Baseline, 10.39; 1 month, 7.46 (13 pairs); $p$ = 0.03/1 month, 7.80; 3 month; 7.00 (10 pairs); NS
C: Baseline: 10.28; 1 month, 8.61 (18 pairs); NS/1 month, 9.07; 3 month, 7.36 (14 pairs); NS

Mean SUSI scores across time for I and C at clinic B:
I: Baseline, 3.46; 1 month, 1.15 (13 pairs), $p$ = 0.05/1 month, 1.25; 3 months, 1.58 (12 pairs); NS
C: Baseline, 6.63; 1 month, 4.31 (16 pairs), NS/1 month, 4.46; 3 month, 7.46 (13 pairs); NS

Mean SUSI scores across time for I and C at clinic C:
I: Baseline, 0.00; 1 month, 0.71 (7 pairs); NS/1 month, 0.71; 3 month: 0.43 (7 pairs). NS
C: Baseline, 1.00; 1 month, 0.67 (6 pairs); NS/1 month, 0.67; 3 month: 0.00 (6 pairs). NS

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
565 patients were screened (clinic A, 132; clinic B, 182; clinic C, 251). 87 were classified as 'at risk': clinic A, 41 (31%); clinic B, 33 (18%); clinic C, 13 (5%)

The rates of participants lost to follow-up were 39% at clinic A, 24% at clinic B and 0% at clinic C

**Reasons**
The very low rate of eligible patients in clinic C is probably attributable to the disproportionate number of pregnant women included in the screening

The attrition rates at clinics B and C (39 and 24% lost to follow-up) are not unusual when dealing with very mobile, urban populations such as these, where losing contact with patients because of a change of address and phone disconnection is a common dilemma for care providers and researchers. There was no indication that those lost to follow-up were significantly different in any way from the rest of the participants

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Important**
Only BI in clinic A is stage-based

**Authors' conclusion**
The decreased substance use among patients at clinic A and B indicated that the BI that were provided to the general adult and adolescent participants had a beneficial impact on their substance use behaviours. In addition, the reduction in substance use appears to have been maintained across 3 months without a return to baseline use patterns. The follow-up phone calls at 1 and 3 months to re-administer the SUSI probably served to augment the BI

**Comment**
Results from clinic A are very minimal and certainly not more favourable than clinic B

During phase 2 all three clinics will be using the PERM with male and female adult patients, evaluation of phase 2 will be published later

**Request to authors for more information**
Reply (Oliansky, 2001): Data of the phase 2 study were never published and not available

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S234, Pallonen (1994)**[47]

**Country**
Finland

**Aim**
To examine longitudinally how well manuals based on the TTM were accepted by smokers and to determine their efficacy in accelerating the smoking cessation process

**Model**
TTM

**Theoretical basis**
The TTM emphasises the matching of the content of an intervention with a smoker's readiness to quit. The model postulates five stages of change. Progress through the stages is mediated by experiential and behavioural processes, e.g. decisional balance between the pros and cons of smoking, and ability to resist temptations to smoke. A set of five self-help manuals has been developed for each stage of change to instruct a smoker to use these dynamic constructs

**Study type**
RCT

**Design**
Prior to assignment to the three conditions, smokers were classified according to Prochaska (S135) into three stages of change: precontemplators, contemplators and prepared smokers. After stage was determined, two-thirds were randomly allocated to a treatment condition and one-third to a usual care condition. Prepared smokers who were in the treatment condition were offered a 6-week, eight-session clinic. Precontemplators, contemplators, and those prepared smokers who refused the cessation clinic were assigned to a manual condition resulting in a higher portion of the precontemplators compared to the usual care condition. The smaller proportion of contemplators in this group than in the usual care condition is due to the exclusion of the cessation clinic participants, who were mostly contemplators

Participants in the manual condition were assessed at the 6th, 12th, 18th, and 24th month by mailed surveys. Similar measures took place in the usual care condition only at the 12th and 24th month to reduce potential measurement reactivity

Only participants in the manual and usual care condition were considered in this minimal intervention study

**Setting**
Community

**Length of intervention**
24 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
375 middle-aged (ages: 42, 48, 54 and 60 in 1984) Finnish men from rural and urban settings (study started in 1988)

**Inclusion criteria**
Men, smoking at least 10 cigarettes a day (from random sample of all men aged 42, 48, 54 and 60 years in 1984)

**Exclusion criteria**
None stated

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
Manual condition ($n$ = 149). The intervention consisted of five 10–20-page self-help manuals designed for each stage of change (S135, S628). One of these manuals corresponding to the current stage of change observed at the baseline and at each follow-up assessment was mailed to a participant bi-annually after an assessment. If smoking stage did not change from one 6-month assessment to the next no manual was mailed at that time

**Comparison group**
Usual care condition ($n$ = 116). Annual mail surveys (12th and 24th month) constituted the only communication with the intervention centre

*continued*

# Data extraction table *contd*

***contd***
**S234, Pallonen (1994)**[47]

***Intervention details* contd**

**Classification into stages**
Smokers were classified at the baseline (S135) into three stages of change: precontemplators (not thinking about quitting in the next 6 months), contemplators (planning to quit within the next 6 months), and prepared smokers (planning to quit in the next 30 days and had had at least one 24-hour quit attempt in the past year). At the 12- and 24-month assessments, the action stages included ex-smokers who had refrained from smoking for less than a year. The maintenance stage at the 24-month follow-up consisted of ex-smokers who had abstained for more than 1 year

Due to annual assessments only in the usual care group, it was not possible to distinguish between the action and maintenance stages at the 1-year measure. The baseline preparation stage was merged with the contemplation stage due to the small number of prepared smokers in the panel (I, $n$ = 5; C, $n$ = 13)

**Validity of measure**
Not stated specifically

**Training of educators**
Not stated

***Baseline characteristics***

**Gender**
100% male

**Age**
Mean (SD): 51.8 (5.5) years

**Stage of change**
Precontemplators: I, 70.0%; C, 54.3%
Preparation: I, 4.0%; C, 11.2%

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
2-year treatment differences in point prevalence quit rates were analysed in the longitudinal panel data using the GSK method for categorical data with repeated measure (S626, S627) using the CATMOD procedure in SAS. The method utilises weighted least-squares estimates to describe the distribution of response profiles under different treatments and time points and assumes that the frequencies associated with all possible response profiles follow a product multinomial distribution. Separate $\chi^2$ tests for main effects and interactions are summarised in the form of an ANOVA table. The dichotomous dependent variable in these analyses was smoking status and the independent variables included baseline stage, treatment group, and an interaction term for time of treatment. Treatment differences among prolonged abstainers and stage changes were assessed by $\chi^2$ tests. Stage change probability over 2 years were obtained by cross-tabulating the stage distributions at 1- and 2-year surveys

**Behaviour change**
Smoking quit rates: 7-day point prevalence abstinence (not having smoked during the past 7 days) and prolonged abstinence (7-day point prevalence abstinence both at the 1- and 2-year assessments)

(1) 7-day point prevalence quit rates at year 1/2 for precontemplators and contemplators:
I: precontemplators, 7.6/7.6%; contemplators, 25.0%/28.9%
C: precontemplators, 1.6%/6.4%; contemplators, 13.2%/22.6%
There was a significant time × intervention effect ($\chi^2$ = 4.42, $p$ < 0.05), favouring I. There was a significant time × baseline stage interaction ($\chi^2$ = 14.61, $p$ < 0.001) – quit rates at year 1 and 2 were significantly higher among contemplators than among precontemplators in both conditions

(2) Prolonged abstinence at year 2:
I, 10% (15/149)
C, 6.0% (7/116)
There was no significant difference between I and C in the number of prolonged abstainers at year 2, $p$ > 0.10. The stage effect was significant, $p$ < 0.01. Prolonged abstinence among baseline contemplators (14.3%) was three times higher than that among baseline precontemplators (4.8%)

**Stage movement**
Probability of stage changes at the 1- and 2 year surveys:
(1) Baseline precontemplators, 71.1% and 74.5% of baseline precontemplators in I and C, respectively, stayed as precontemplators during the 2 years; no significant difference between I and C ($p$ > 0.10)
(2) Baseline contemplators, stage movement among baseline contemplators was significantly greater in I in year 1 ($p$ < 0.05) and year 2 ($p$ < 0.10). Over the 2 years, 24.4% in I and 45.3% in C made no stage changes

**Health**
Not stated

**Intermediate outcomes**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S234, Pallonen (1994)**[47]

***Results* contd**

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Exposure to manuals:
32.4% in year 1 and 31.2% in year 2 reported having read none or only some of the manuals mailed to them. Similar proportions (30.3% year 1, 30.5% year 2) reported having read most of the manuals, and 37.2% in year 1 and 38.3% in year 2 reported having read all the manuals. Amount of material read was not related to baseline stage of change or to stage of change at either annual assessment, or with being a quitter or a smoker

Usefulness of manuals:
53.2% in year 1 and 49.6% in year 2 rated the manuals as either not useful or only a little useful in their quit attempts, and 19.1% in year 1 and 14.4% in year 2 rated the manuals as quite helpful or very helpful at both assessments. Baseline stage of change was not related to usefulness rating at year 1 ($p > 0.10$) or year 2 ($p > 0.10$). But, at year 1, stage of change and usefulness rating were significantly related ($p < 0.05$), those in early stages of change at that time were more likely to rate the manuals as less useful than those in a more advanced stage of change. Those who reported having read most or all of the manuals rated them as more useful than those who had not read them at all or read them only a little, $p < 0.05$ at year 1, $p < 0.001$ at year 2

***Withdrawals/economic evaluation***

**Number per group**
482 smokers were randomised to three conditions: cessation clinic ($n = 62$); self-help manuals ($n = 263$); and usual care ($n = 157$). 30 in the manual condition and 15 in the usual care condition refused or provided incomplete data at the baseline on essential smoking status variables. 375 participants remained (I, 233; C, 142)

Additionally, 108 were lost to a 2-year follow-up and two men later participated in a cessation clinic. 265 participants were present at the baseline, year 1 and year 2 assessments (I, 149; C, 116)

**Reasons**
108 lost to 2-year follow-up, and two later participated in a cessation clinic

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusions**
Smokers who are mailed stage-based manuals to their home quit smoking more and made more quit attempts than those who did not receive the manuals. Although manuals may accelerate the smoking cessation process, the manuals alone may not constitute a sufficient long-term intervention

**Authors' reported limitations**
The effects of differential exposure to intervention, participant characteristics, measurement reactivity, and secular trends were discussed as potential confounds

**S388**
No additional information

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S172, Pallonen (1998)**[48]

**Country**
USA

**Aim**
To evaluate the ability of the computer-based interventions to engage and to retain the interest of adolescents in a school setting

**Model**
TTM

**Theoretical basis**
As a new intervention approach to adolescent smoking authors implemented two smoking cessation interventions which both employed the personal computer

The first intervention, the interactive and individualised cessation expert system was a modified version of the expert system used among adult smokers (S420, S255). The system was based on the TMC (S629)

The theoretical content of the TMC intervention used in the study is similar to the expert-system intervention originally developed among adult smokers (S420, S630)

The content of the adolescent expert system input, including several scale items and output, were revised to be more age appropriate based on previous research (S238, S631)

**Study type**
RCT

**Design**
A 2 (interventions) × 4 (assessments) design was applied

Students were assigned to an intervention condition based on smoking status at that time. The expert system determined student's stages of change at the beginning of the first session

Assessments were done at the baseline (a classroom-based 30-minute self-administered paper-and-pencil survey), during the three intervention sessions (data were integrated in the user interaction with the computer), and at 6 months (follow-up questionnaire, same as the baseline)

**Setting**
School

**Length of intervention**
6 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
704 (80% of all potential cases) 10th and 11th grade students who participated in vocational training in three high schools in Rhode Island, of which 135 were current smokers who were assigned to one of two interventions

**Inclusion criteria**
Current smokers

**Exclusion criteria**
Parental refusal

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
TMC-based expert system cessation programme; On first contact, participants are compared in their feedback report to successful and unsuccessful quitters within the same stage of change (normative feedback). During subsequent contact, individuals are compared both to other individuals and their own previous performance (ipsative feedback). Each assessment and feedback section at each intervention session were provided in small, logically meaningful segments of the four TMC constructs: (1) stage of change, (2) decisional balance, (3) processes of change and (4) self-efficacy or temptations to smoke. Feedback is provided as text on the computer monitor's screen

The first intervention session was offered 2 months after the baseline survey in school in space dedicated to the project. The expert system determined student's stages of change at the beginning of the first session and assigned students to an intervention condition based on smoking status at that time. The remaining two sessions were offered at 2-month intervals in a similar fashion as section 1

**Comparison group**
Action-orientated cessation programme. Original ALA (1988) clinic programme was shortened and modified into three sessions and altered for a personal computer monitor screen presentation. Changes in text of the program were kept minimal to retain the order and presentation of the core concepts as similar to the original program as possible. The sessions were administered in the same schedule as the TMC program to minimise the novelty effect differences between the two interventions. The feedback from the action-orientated programme was pre-determined and based on the assumption that the smoker was prepared to quit smoking. Session 1 provided mostly health education information, support, and motivation to quit. Session 2 focused on preparation and commitment for the quit day. Participants were recommended to quit after session 2. Session 3 dealt with tempting situations after smoking cessation

*continued*

# Data extraction table *contd*

***contd***
**S172, Pallonen (1998)**[48]

***Intervention details* contd**

**Classification into stages**
Stages of change was determined by previously used dichotomous questions in adults (S135) and adolescents (S631)

Smokers in the precontemplation stage were not thinking about quitting smoking in the next 6 months

The contemplation stage included smokers who were thinking about quitting within the next 6 months

Smokers in the preparation stage were ready to quit within the next 30 days and had at least one serious quit attempt during the past 6 months

The action stage included those who had quit smoking within the past 6 months

The maintenance stage included current ex-smokers who had quit more than 6 months ago

Algorithm for stages of change:
Q1. Which of the following best describes your current smoking?
I have never smoked (non-smoker)
I have tried smoking a few times (non-smoker)
I used to smoke regularly but I quit (go to Q2)
I am a smoker (go to Q2)

Q2. Have you stopped smoking cigarettes?
Less than 6 months ago (maintenance)
More than 6 months ago (action)
No (go to Q3)

Q3. Are you seriously considering quitting smoking within the next 6 months?
No (precontemplation)
Yes (go to Q4)

Q4. Are you planning to quit smoking in the next 30 days?
No (contemplation)
Yes (go to Q5)

Q5. When was the last time you seriously tried to quit smoking?
More than 6 months ago (contemplation)
Less than 6 months ago (preparation)

**Validity of measure**
Stages of change was determined by previously used dichotomous questions in adults (S135) and adolescents (S631)

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
Total: 40.1% female

**Age**
Total: mean age 16.5 years (SD = 0.9 years, range = 14.8–21.0 years)

**Stage of change**
Stage-of-change distribution at session 1 (%, completers only): 42.0% precontemplators; 30.3% contemplators and 27.7% preparers; 0% action; 0% maintenance. (Not presented by group)

**Target behaviour**
Mean number of cigarettes smoked in the last 24 hours/7 days at session 1 (completers only): I, 10.6/64.3; C, 10.4/62.5

***Results***

**Statistical techniques**
A 2 (interventions) $\times$ 4 (assessments) design was applied. Longitudinal analyses focused on behaviour changes during the three-session intervention which was measured at the 6-month follow-up session. Analyses of categorical variables in the panel data utilised the GSK method for categorical data with repeated measures. This method utilises weighted least squares estimates to describe the distribution of response profiles under different treatments and time points, and assumes that the frequencies associated with all possible response profiles follow a product multi-nominal distribution. Separate $\chi^2$ tests for main effects and interactions are summarised in the form of an ANOVA table. Changes in continuous variables were analysed by a repeated measures ANCOVA and with appropriate follow-up comparisons. Potential initial differences were removed by using Session 1 data as a covariate

Students who attended only one session were excluded from analyses

*continued*

# Data extraction table *contd*

***contd***
**S172, Pallonen (1998)**[48]

***Results* contd**

**Behaviour change**
Cigarette smoking status: ever smoked and current smoking (four categories: never smoked; tried a few times; used to but quit; smoker). Quit rates: calculated as the number of quitters/number of quitters and current smokers. Quit attempts: assessed with four open-ended questions: the number of (a) 24 hours and (b) 7-day quit attempts during the last 2 months and the number of (c) 24 hours and (d) 7-day quit attempts since the last contact (6–8 months ago)

Smoking status was verified by 5 ml saliva sample – continine extract

Quit attempts: No significant difference between I and C:

Overall mean number of 24 hours quit attempts during the last 2 months: 1.6 (SD = 3.0) and 7-day quit attempts: 0.6 (SD = 2.0); nearly 80% reported no attempts. (Comment: mean number of 24-hour quit attempts is higher than mean number of 7-day quit attempts; this should probably be the other way around)

Overall mean number of 24 hours quit attempts during the whole postintervention period: 1.7 (SD = 2.6) and 7-day quit attempts: 0.5 (SD = 1.2) (Comment: again, this should probably be the other way around)

Quit rates: The overall quit rates did not differ significantly by treatment condition at any of the four intervention assessments

**Stage movement**
Session 1 ($n$ = 135): precontemplation, 42%; contemplation, 30.3%; preparation, 27.7%
Session 2 ($n$ = 108): precontemplation, 37%; contemplation, 25.9%; preparation, 22.2%; action, 14.8%; relapse, 30%
Session 3 ($n$ = 99): precontemplation, 43.4%; contemplation, 16.2%; preparation, 20.2%; action, 20.2%; relapse, 34.3%
6 months ($n$ = 69): precontemplation, 52.2%; contemplation, 24.6%; preparation, 17.4%; action, 4.3%; maintenance, 1.4%; relapse, 40.6%

No distribution by group reported

The overall stage of change distribution did not differ significantly by treatment condition at any of the four intervention assessments

**Health**
Not stated

**Intermediate outcomes**
Decisional balance (pros and cons of smoking/quitting) and temptations to smoke (analogues to the self-efficacy concept, and assesses situations where participants are tempted to smoke cigarettes)

There was a significant ($p$ < 0.001) increase in the cons of smoking from session 1 to 6 months, but there was no difference between I and C or stage of stage of change. The level of temptations remained unchanged during the intervention and follow-up periods and did not differ by program

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Participation rate in the three intervention sessions:
I: 11.4%, one session; 26.1%, two sessions; 62.5%, three sessions
C: 12.7%, one session; 12.8%, two sessions; 74.5%, three sessions

***Withdrawals/economic evaluation***

**Number per group**
Of the 704 baseline survey students, 84.1% ($n$ = 592) participated in the first computer intervention session; of these 22.8% ($n$ = 135) were smokers. 135 students were randomised (I, 88; C, 47). Students who attended only one session were excluded, leaving 119 students (I, 78; C, 41)

At 6-months follow-up: $n$ = 69, no condition-specific data provided

**Reasons**
Loss to follow-up: could not be contacted/did not attend subsequent sessions

**Economic evaluation**
No

**Economic methods**
Not stated specifically, but "Costs to replicate this text-based program would include one or more low level Windows PC(s), an ID diskette for each participant, and supervisor's time"

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S172, Pallonen (1998)**[48]

***Additional comments***

**Authors' conclusions**
I resulted in more quit attempts for those in the precontemplation stage, whereas C resulted in more quit attempts for those in the preparation stage (see comment below). Computer-based intervention is good for (school-aged) children in terms of (high) participation rates. Computer-based interventions are easy to implement and offer consistency across populations

**Authors' reported limitations**
The (study) focus was mainly on program feasibility instead of efficacy, and the sample size, particularly after attrition, was far from adequate for detecting even large intervention effects. the high frequency of relapse might be a product of using too few booster sessions

**Comment**
This was a non-significant trend to which the authors provide descriptive data only

**S238**
No additional information, only baseline data, no mention of interventions

**S43**
No additional information, no data by treatment condition

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S061, Peterson (1999)**[54]

**Country**
USA

**Aim**
To evaluate the effect of a stage-based exercise intervention in a randomised trial of adults working in a corporate setting

**Model**
TTM

**Theoretical basis**
TTM of behaviour change. Successful change depends on engaging the right process at the right stage. According to this theory, tailoring interventions to match a person's readiness (or stage of change) is essential

**Study type**
RCT

**Design**
Employees received an invitation letter, with baseline questionnaire. 784 replied and were randomly assigned to three groups. Approximately 2 weeks after the baseline questionnaire deadline participants in I1 and I2 received materials, through interoffice mail. 6 weeks after materials received, employees were sent a follow-up questionnaire

**Setting**
Workplace

**Length of intervention**
6-week intervention period

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
784 employees of a large telecommunications company

**Inclusion criteria**
Not stated

**Exclusion criteria**
Not stated

**Behaviours targeted**
Exercise behaviour

***Intervention details***

**Intervention group**
I1: Generic intervention. Approximately 2 weeks after baseline questionnaire deadline, employees received non-tailored materials based on information from the 'Report of the Surgeon General' on physical activity. The message focused on the known benefits of exercise and the amount of exercise required for health benefit

I2: Stage-based intervention. Baseline questionnaires were examined to determine stage of change. Approximately 2 weeks after baseline questionnaire deadline, employees received 2-page written messages tailored to their individual stage of change. Separate messages were developed to be used between each of the three stages (to assist contemplators in becoming preparers; to assist preparers in becoming action takers; and to assist action takers in becoming maintainers). The messages contained stage-based information, motivational information, exercises designed to initiate change processes (goal-setting exercises, relapse prevention exercises, etc.), and graphics. Messages content was developed foe each stage of change using the specific cognitive and behavioural processes utilised in each stage as described by Prochaska

**Comparison group**
Control group. Did not receive any materials, only questionnaires

**Classification into stages**
A stage of readiness to change measure was used to determine the exercise stage of readiness that most accurately described each employee's intention to change

S138: This describes only four stages: precontemplation/contemplation/preparation and action. S115 uses the same algorithm but describes it better

S115: Precontemplators: those who did not exercise and do not intend to start in the next 6 months. Contemplators: those who did not exercise, but who intended to start in the next 6 months. Preparers: those who exercised some, but not regularly. Actors: those who exercised regularly, but who had done so for less than 6 months. Maintainers: those who exercised regularly and who have done so for 6 months or longer. Regular exercise is operationalised as equal to 3 days or more per week for 20 minutes or more each day

S61: In the present study, precontemplators were grouped with contemplators

*continued*

# Data extraction table *contd*

***contd***
**S061, Peterson (1999)**[54]

***Intervention details* contd**

**Validity of measure**
The measure used was developed and validated by Marcus (S138)

S115: The kappa index of reliability over a 2-week period was 0.78. Concurrent validity was demonstrated by its significant association with the 7-day Recall Physical Activity Questionnaire

S138: A similar measure of the stages of exercise adoption has been shown to be reliable (S656) and significance related to instruments measuring the processes of change, self-efficacy, and decision making for exercise and the 7-day Physical Activity Recall Questionnaire (S115, S145, S258, S496, S656). No validity data presented in S138

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
60.4% female

**Age**
79.3% were < 45 years

**Stage of change**
Not reported

**Target behaviour**
Mean self-reported physical activity level (SD):
I1: 39.43 (21.12)
I2: 36.90 (18.77)
C: 36.80 (21.59)

***Results***

**Statistical techniques**
ANOVA was used to examine differences before and after physical activity measures, with between-group differences evaluated using the Duncan follow-up test. Between-group baseline demographic differences were evaluated using the $\chi^2$ test. Additionally, ORs were calculated on the stage improvement by group. The portion of each group who recalled receiving and reading the written materials they were sent was evaluated using the $\chi^2$ test. The magnitude of each $\chi^2$ was determined by the Mantel–Haenszel $\chi^2$ test

**Behaviour change**
Self-reported physical activity (7-day Physical Activity Recall Questionnaire). Summed exercise time was converted to metabolic equivalents and expressed in kilocalories per kilogram of body weight per week

Mean changes in self-reported PAL project (SD): I1, +0.66 (1.43); I2, +4.94 (1.29); C, –3.12 (1.34). Differences between the three groups are significant ($p < 0.05$)

**Stage movement**
I1: 65.7% remained in the same stage, 18.9% progressed in the direction of maintenance; and 15.4% moved at least one stage towards precontemplation

I2: 59.8% remained in the same stage, 33.3% progressed in the direction of maintenance; and 6.9% moved at least one stage towards precontemplation

C: 69.2% remained in the same stage, 14.1% progressed in the direction of maintenance; and 16.8% moved at least one stage towards precontemplation

There was a significant difference among the three groups in magnitude and direction of stage movement ($\chi^2 = 25.15$, df = 4, $p < 0.0001$)

ORs revealed that I2 were 2.1 times (??% CI, 1.43 to 3.12; $p < 0.0001$) more likely to progress at least one stage than C; and I1 was 1.3 times (??% CI, 0.83 to 2.11; $p < 0.0001$) as likely to make the same movement as compared to C. When I2 was compared to I1, it was 1.6 times (??% CI, 1.11 to 2.29; $p < 0.01$) more likely to progress. (??%: percentage for CI not mentioned)

**Health**
Not reported

**Intermediate outcomes**
Not reported

**Adverse effects**
Not reported

**Other outcomes**
Not reported

*continued*

## Data extraction table *contd*

***contd***
**S061, Peterson (1999)**[54]

***Results* contd**

**Implementation measures**
In I2, 92.5% reported that had received the message, compared with 82.8% in I1 ($\chi^2$ = 7.46, df = 1, $p$ < 0.006)
In I2, 92.5% had read the information, compared with 79.3% in I1 ($\chi^2$ = 12.44, df = 1, $p$ < 0.0001)

***Withdrawals/economic evaluation***

**Number per group**
784 randomised (numbers per group not stated). 527 (67%) completed the postintervention questionnaire (I1, 168; I2, 174; C, 185).
527 respondents used in analyses

**Reasons**
No reasons stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated. Authors do report "the relatively low cost of producing the intervention", no details given

***Additional comments***

**Authors' conclusion**
Stage-based tailored messages appear to be more effective at increasing short-term activity levels than either generic messages or no information at all

**Authors' reported limitations**
Possible threat of contamination (all employees from same company), self-reported data, short duration of the study (6 weeks), and only 67% response rate

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S027, Rakowski (1998)**[68]

**Country**
USA

**Aim**
To compare the effectiveness of a stage-matched, tailored intervention of mailed educational materials with standard materials (the same for all women) and no materials, in increasing mammography

**Model**
TTM

**Theoretical basis**
The TTM guided the design of the intervention. Two strategies: targeting (less committed stages (precontemplation, relapse, contemplation): information to counter perceived cons and reinforce pros of target behaviour) and tailoring (providing person-specific feedback to individuals within a stage group)

**Study type**
RCT

**Design**
1864 women were recruited for the baseline survey, through a staff-model HMO with five sites in Rhodes Island and south-eastern Massachusetts. Analyses are based upon 1397 women who participated in all four telephone surveys

Randomisation of participants into one of the three intervention groups occurred by a computer-based algorithm after completion of each day of interviewing. Therefore, neither the interviewer nor the women were aware of group assignment when baseline interview occurred. Randomisation was done within medical departments (family practice; internal medicine; and obstetrics/gynaecology) so that one-third of the women from each department were assigned to each intervention group. After recruitment/baseline survey there was a first follow-up call 3–5 months later. The third survey was a 1-year follow-up after the baseline, the final phone survey occurred 7–9 months after the 1-year follow-up. Telephone calls at the baseline and follow-ups were conducted by computer-assisted interviewing

**Setting**
Community

**Length of intervention**
Women in I1 and I2 received intervention materials after baseline assessment and first follow-up survey, which was 3–5 months later

The third survey was a 1-year follow-up after the baseline interview. And the final phone survey occurred 7–9 months after the 1-year follow-up

***Inclusion/exclusion criteria***

**Participants**
Physiological risk

**Population**
Women aged between 40 and 74 years who had a medical visit for any reason in the departments of family practice, internal medicine or obstetrics/gynaecology during the 8 months prior to the date of selection. Women were recruited through a staff-model HMO with five sites in Rhodes Island and south-eastern Massachusetts

**Inclusion criteria**
Women aged between 40 and 74 years

**Exclusion criteria**
Listed in the HMO's cancer tumour database. Personal history of breast cancer; being evaluated or followed for possible breast cancer; pregnant or nursing; worked in one of the primary care departments of the HMO in which intervention was going to occur, or non-English speaking

**Behaviours targeted**
Mammography

***Intervention details***

**Intervention group**
I1: Standard materials. Women received mailed intervention packets (two-sided folder with pockets for materials) after both the baseline interview and first follow-up. All women received the same materials: (1) mammography question and answer sheet; (2) 'breast health guide' emphasising mammography, BSE and CBE as three-part plan; (3) tip sheet page, emphasising importance of regular medical check-ups. Same materials at first follow-up, plus BSE shower card

I2: Stage-matched materials. Women received mailed intervention packets (two-sided folder with pockets for materials) after both the baseline interview and first follow-up. Four different packets: (1) precontemplation/relapse/risk of relapse; (2) contemplation; (3) action; (4) maintenance. I2 also received an expert system computer-generated letter, tailored to be an individualised response to information provided during the interview. Other elements: (1) question and answer sheet; (2) information sheet; (3) tip sheet; (4) BSE shower card (3 and 4 same for all stages and same (S420) in the Standard package). Second package, after first follow-up survey, contained personalised letter and stage-matched materials



*continued*

# Data extraction table *contd*

***contd***
**S027, Rakowski (1998)**[68]

***Intervention details* contd**

**Comparison group**
No education materials: only four surveys

**Classification into stages**
Precontemplation: never has had a mammogram and does not plan to have one within next 2 years
Relapse: has had one or more, but is now off-schedule and does not plan to have one within next 2 years
Risk of relapse: currently on schedule, but does not plan to have one on a time frame that will keep her on schedule
Contemplation: never has had one, but plans to have one in coming 2 years; (or) is off schedule after prior mammogram, but intends to have one in coming 2 years
Action: has had one on schedule and intends to have another on a time frame that will keep her on schedule; (or) has one scheduled
Maintenance: Has had at least two on schedule and intends to have another on a time frame that will keep her on schedule

**Validity of measure**
Not stated

**Training of educators**
First, prior to recruiting each dept was visited during regularly scheduled staff-meeting to explain project objectives and activities, questions answered and mammography education needs/interest survey distributed. Second: shortly after recruitment during regularly scheduled department meeting (1 hour and earned a continuing medical education credit); contents: (a) basic concepts of TTM, (b) discussion of age 40–49 screening controversy, (c) discussion of interviewing technique, (d) video showing role plays, and (e) review of data collected at the baseline, emphasis on barriers. Each department received final summary of baseline results (self-reported screening rates and anticipated barriers), and recommendations for patient–provider communication

***Baseline characteristics***

**Gender**
100% female

**Age**
Not stated (between 40 and 74 years)

**Stage of change**
Not stated

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
Analyses are based upon 1397 women who participated in all four telephone surveys

The effect of the intervention was examined in a two-step procedure. First, bivariate associations were computed ($\chi^2$ test and bivariate logistic regression) to contrast the rates of mammography across the three study groups. In the next step, multiple logistic regressions examined the association of intervention group and receipt of screening, adjusting for the covariates listed above (screening intention, time of most recent mammogram, time of most recent Pap test, age, decisional balance and commitment to screening process of change).
A significance level of $p \leq 0.05$ was used

**Behaviour change**
Percentage screened: I1, 58.5%; I2, 63.6%; C, 54.9% (overall $\chi^2 = 7.16$; df = 2, $p < 0.05$). Single-variable logistic regression showed a significant OR for I2 versus C (OR = 1.43; 95% CI, 1.10 to 1.86). I1 versus C was not significant (OR = 1.15; 95% CI, 0.89, 1.50). Single-variable logistic regression showed no significant difference for I2 versus I1 (OR = 0.81; 95% CI, 0.62 to 1.05). Multivariate analysis showed similar results, although the difference between I2 and I1 was now significant (OR = 0.74; 95% CI, 0.56 to 0.99)

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Results given excluding those with a screening appointment (intention)

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S027, Rakowski (1998)**[68]

***Withdrawals/economic evaluation***

**Number per group**
The response rate for the baseline survey was 73.5% (*n* = 1864). 42 excluded and 425 drop-outs after the baseline assessment, resulting in 1397 women for analyses

**Reasons**
42 excluded because of incomplete mammography history in HMO records. 123 women unenrolled from the HMO during the study and 302 were lost to follow-up due to refusal, being under observation for breast problems, not being able to be contacted or having died

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Stage-matched tailored materials may be a means to encourage screening mammography. Such interventions can be implemented by telephone and mail

**Comments**
Only I2 is a stage-matched intervention. No comparison to baseline data (no baseline data presented). No analysis of stage movement presented. There was no significant difference in receipt of mammography after the baseline interview between I2 (stage-matched materials) and I1 (standard materials)

Data from S4 and S202 not used because they were based on different sample size (*n* = 1323)

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S353, Resnicow (1997)**[50]

**Country**
USA

**Aim**
To examine the use, impact, and interaction of the intervention's sub-components as well as possible mediating variables related to successful quitting

S447: To test a culturally sensitive, low-intensity smoking cessation intervention for low-socio-economic adult African–Americans

**Model**
TTM

**Theoretical basis**
Participant's stage of change was computed using three items asked at the baseline. Participants were classified according to one of three stages; precontemplation, contemplation and preparation. The staging algorithm used was based on that used by Prochaska, but the wording of individual items differed somewhat from previous studies (S94, S135, S633)

The 'Kick It' guide (a 24-page, four-colour self-help booklet written at fifth-grade reading level) contained four sections with each chapter corresponding to one of the major stages of change delineated by Prochaska, that is, precontemplation, contemplation, preparation, action and maintenance (S94, S248, S254, S632). Similarly, a two-part 'Kick It' video is designed for use by people at different stages of change: part 1 is aimed at those in the precontemplation and contemplation stages, and part 2 is aimed at those in the action and maintenance stages. A tailored 'booster call' was also provided, e.g. for individuals who had quit prior to the call, counselling focused on relapse prevention

**Study type**
Cluster RCT

**Design**
A cluster randomisation (by site) design was employed using sites from three institutional settings: healthcare facilities, public housing developments and churches

**Setting**
Community

**Length of intervention**
6–7 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
9311 individuals were recruited between June and December 1992 from six healthcare settings; four large, low-income public housing developments; and 16 predominantly black churches of varying denomination and size. Of these 1244 (42%; I, 703; C, 541) enrolled in the study

S353 presents only analyses including 650 intervention participants

**Inclusion criteria**
African–American adults (> 18 years of age), current smokers, providing an address or telephone number within New York City

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
*n* = 650. Received the 'Kick It' guide, a two-part 'Kick It' video (part 1 – for precontemplators and contemplators to initiate a quit attempt; part 2 – for action and maintenance, providing instruction on how to quit, how to stay quit, and how to start over for those who did not initially succeed), a booster call (received after 1–2 months), quit contract, and an invitation to enter two separate prize-draw contests – entry criteria for both was 30-day abstinence

S447: Received a culturally sensitive, multicomponent self-help cessation kit, which included a printed cessation guide, companion cessation video and several quit aids (e.g. toothpick, stress-reduction card, and mints). In addition over the course of the 6 month intervention phase they received periodic (approximately bimonthly) mailings related to smoking and other health concerns. Also scheduled to receive one booster call

The 'Kick It' guide is a 24-page, four-colour self-help booklet, divided into four sections: 'Why should you quit', 'How to quit', 'Staying quit', and 'Starting over', with each chapter corresponding to one of the major stages of change delineated by Prochaska: precontemplation, contemplation, preparation, action and maintenance

Booster calls: The goal was two-fold: to encourage the use of intervention materials, and provide brief motivational counselling. The content of the counselling was determined by the participant's stage of change. Additionally, perceived obstacles and fears related to quitting were discussed and possible coping strategies and solutions were offered

*continued*

# Data extraction table *contd*

***contd***
**S353, Resnicow (1997)**[50]

***Intervention details* contd**

**Comparison group**
*n* = 504. Received previously developed printed health education materials (e.g. American Heart Association, National Cancer Institute, National Heart Lung and Blood Institute, American Diabetes Association and the New York State Department of Health) related to substance use, HIV/AIDS, diet, heart disease, and cancer (but no materials that exclusively addressed tobacco use or tobacco-related cancers) and a 10-minute cholesterol education video developed for African–Americans

**Classification into stages**
Participant's stage of change was computed using three items asked at the baseline:
(1) Do you plan on making any changes in your smoking habits in the next 6 months (yes/no)
(2) How much do you want to quit smoking in the next 6 months? (range: not at all, to very much)
(3) How many times in the past year have you been able to stay off of cigarettes for at least 24 hours?

The three items were used to classify participants into one of three stages: precontemplation, contemplation and preparation. Individuals answering 'no' to the former question or 'not at all' to the latter questions were coded as precontemplators; those planning on making changes and responding either 'a little', 'medium', or 'very much' to the second question but not reporting a serious quit attempt in the past year were coded as contemplators; and those planning on making changes, responding either 'a little', 'medium', or 'very much' to the second question, and reporting at least one serious quit attempt in the past year were considered in the preparation stage

**Validity of measure**
Not stated

**Training of educators**
Counsellors (booster call) received approximately 6 hours of training and their first two or three calls were monitored by a senior investigator

***Baseline characteristics***

**Gender**
I: 58% female; C: 65% female

**Age**
Mean age
I: 44.0 years; C: 46.4 years

**Stage of change**
S353 (I only): precontemplators, 49%; contemplators, 32%; preparers, 20%

S447: Total: precontemplators: 34%; contemplators: 45%; preparers: 21%

I: 32% precontemplators; C: 35% precontemplators

(Comment: the data on precontemplators from S353 and S447 seem to contradict each other)

**Target behaviour**
Cigarettes per day (range = 1–67): I, 15.3; C, 16.5

***Results***

**Statistical techniques**
S353: Univariate analyses examined the relationship between the five exposure variables ('Kick It' manual, 'Kick It' video, booster call, quit contract, and prize contests) and 6-month point prevalence abstinence

Subsequent, multivariate logistic analyses entered all five variables simultaneously. Several covariates were entered into the model, e.g. age, gender, cigarettes per day at the baseline, education, minutes until first cigarette upon waking, baseline stage of change, and work status. With the exception of stage of change and age, none of the covariates were associated with quitting ($p > 0.20$) and were dropped from the model

Interaction terms for the five intervention elements (e.g. booster × video) as well as element by stage of change were also examined – all were non-significant ($p > 0.05$) and dropped from subsequent analyses

The ten possible pairs of intervention components (e.g. booster call × contest) were examined. Forward stepwise regression was used to eliminate variables

To control for the effects of non-independence within sites (i.e. intracluster correlation) multivariate analyses using SAS GLIMMIX were conducted, using recruitment site as a random-effect term

S447: Univariate analyses for treatment and comparison participants by organisational channel were conducted using $\chi^2$ analyses

Multivariate logistic regression (OR and 95% CI) analyses follow, adjusting treatment effects for several demographic variables including age, gender, education, marital status, employment status (used as proxy for income) and several smoking variables: cigarettes smoked per day at the baseline, stage of change, quitting efficacy, and time to first cigarette upon waking

*Post hoc* analyses are presented comparing the effects of the intervention among individuals for whom booster call was (Tx2) and was not (Tx1) completed

To control for the effects of non-independence within sites (i.e. intracluster correlation) multivariate outcome analyses were conducted, allowing for fixed (treatment condition) and random (site of recruitment) effects in a logistic model. For primary outcome analyses, treatment condition was nested within site. For secondary analyses, where individuals receiving and not receiving the booster call could be found in the same site, treatment was not nested within site, although site was still considered a random effect

Both: 1244 respondents were randomised; analyses included data from 1155 (93%) respondents with complete follow-up interviews. S353 reported only data from I (*n* = 650)

*continued*

# Data extraction table *contd*

***contd***
**S353, Resnicow (1997)**[50]

***Results* contd**

**Behaviour change**
S353: Analyses only included results from the intervention group, therefore no comparisons between I and C reported. Results focus on correlations between the intervention's subcomponents and successful quitting:

Point prevalence abstinence in smoking ('Do you currently smoke cigarettes?'): Not reported specifically – see S447

In univariate analyses, four of the five components were significantly associated with quitting: contests (OR = 3.0; CI, 1.70 to 5.38), contract (OR = 2.6; CI, 1.31 to 5.30), video (OR = 2.1; CI, 1.27 to 3.39), booster call (OR = 2.0; CI, 1.22 to 3.29)

In multivariate analyses, two components were significantly associated with quitting: contests (OR = 2.38; CI, 1.22 to 4.63) and contract (OR = 1.75; CI, 0.78 to 3.94), and the booster call was borderline significant (OR = 1.70; CI, 0.98 to 2.93)

Analyses examining the odds of quitting for the ten possible pairs of intervention elements indicated two pairs, booster and contest (OR = 6.1; CI, 2.67 to 14.14) and Contract and Video (OR = 3.7; CI, 1.22 to 11.41) were significantly associated with quitting

S447: Univariate analyses: Point prevalence quit rates at 6 months: I, 11.2%; C, 7.9%. $\chi^2 = 3.5$, $p = 0.06$

However, for participants in I who did receive the booster call abstinence rates were significantly ($p < 0.05$) higher (16.4%) than for those in C, as well as for those in I who could not be reached for the booster call (8.9%)

Quit attempts among participants still smoking at 6-month follow-up (I: 580; C: 463): I, 13.1%; C, 10.2%. $\chi^2 = 2.2$, $p = 0.14$

However, smokers in I who received the booster call were significantly ($p < 0.05$) more likely to have attempted quitting in the past 6 months (22.5%) than those in C (10.2%) and those in I who did not receive the booster call (9.2%)

Multivariate analyses: Point prevalence quit rates at 6 months:

For the entire treatment group, the odds of quitting were not significantly different than C (OR = 1.36; 95% CI, 0.87 to 2.11) – data not shown. Among the group with booster call, the odds of being abstinent at 6 months were significantly greater than C (OR = 2.03; 95% CI, 1.2 to 3.6)

Quit attempts among participants still smoking at 6-month follow-up (I, 580; C, 463):

For the entire treatment group, the odds of making quit attempt were not significantly different than C (OR = 1.36; 95% CI, 0.68 to 2.72). Among those with booster call, the odds of reporting a quit attempt in the past 6 months were significantly greater than C (OR = 2.3; 95% CI, 1.2 to 4.1), as well as than those without booster call (OR = 2.6; 95% CI, 1.5 to 4.4)

**Stage movement**
Not reported

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
I: Approximately 60% of respondents reported having read most of the guide; 32% some; and 8% none

I: Approximately 36% of respondents reported having watched most of the video; 27% some; and 37% none

Participants in I were scheduled to receive booster calls; calls were completed for 201 (31%). Major reasons not reached: no phone number provided ($n = 199$), and not home/no answer after three attempts ($n = 104$). Of those reached, eight declined to participate

I: Quit contracts were received from 52 out of 650 participants (8%)

I: 84 of the 650 participants (13%) entered at least one contest, including 20 who entered both

***Withdrawals/economic evaluation***

**Number per group**
1244 (I, 703; C, 541) participants at the baseline. Complete follow-up interviews were obtained from 1155 (93%): I, 650; C, 505. Due to missing data for some variables, sample size for the analyses in S353 ranges from 618 to 650

S447: Complete follow-up interviews were obtained from 1154 (93%): I, 650; C, 504

**Reasons**
S353: 53 (of 703 respondents) were lost to follow-up

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S353, Resnicow (1997)**[50]

***Additional comments***

**S353: Authors' conclusions**
Despite the positive effects observed for individual elements, quitting was not significantly greater in I versus C. One explanation is inadequate intervention delivery (in the case of the booster call) or use (in the case of the contract, contest and video) – see limitations. Future research should focus on developing strategies to increase use of existing interventions rather than searching for the 'perfect' intervention. Intervention ought to contain multiple motivational and cessation strategies

**Authors' reported limitations**
(1) Follow-up data collected only at 6-month post-test
(2) Quit rates determined by self-report and not validated by collateral report or biochemical methods
(3) Only one-third of participants originally scheduled to receive the booster call were reached
(4) Inadequate intervention delivery, e.g. of the 650 participants, only 52 (8% sent in quit contracts, 84 (13%) entered a contest, 201 (31%) were reached for the booster call, and only 36% reported watching most of the video

**Comment**
Separate *post hoc* analyses reported for those attending booster sessions and those not attending. These groups were self-selected, not random

**S447: Authors' conclusions**
Although no significant effects were observed for the entire treatment cohort, *post hoc* analyses suggest that culturally sensitive self-help smoking cessation materials plus a single phone contact can produce short-term cessation rates

**Authors' reported limitations**
(1) Reporting intervention results separately (those who did and did not receive booster call) violates the 'intention-to-treat' principle – when combined no significant effects emerged
(2) Follow-up data collected only at 6-month post-test
(3) Only point prevalence quit rates were assessed, and not longer term abstinence
(4) Quit rates determined by self-report and not validated by collateral report or biochemical methods
(5) Only one-third of participants originally scheduled to receive the booster call were reached

**Comment**
I and C were not comparable on several variables. That is, I and C were significantly different with regards to age, gender, education, and number of cigarettes smoked per day. These variables were included as covariates in all outcome analyses

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S478, Scales (1998)**[66]

**Country**
USA

**Aim**
To assess the effectiveness of a lifestyle behaviour change programme

**Model**
TTM

**Theoretical basis**
The programme was matched with the motivational needs of patients attending a traditional early outpatient cardiac rehabilitation programme. The health-related behaviours (perceived stress, physical activity, dietary fat intake and adherence to prescribed medications) of patients attending the traditional programme were compared with a 'stage-matched' intervention

**Study type**
RCT

**Design**
Patients were assigned at random, using a random-numbers table, to one of two conditions (I and C) by someone who had no contact with them. A true experimental design with repeated measures (baseline and 12 weeks), comparing two treatments, with dependent variables: perceived stress, physical activity, dietary fat intake and adherence to medication

Information was gathered through questionnaires, a 45-minute structured interview, food records and biological assessment

**Setting**
Outpatient clinic

**Length of intervention**
12 weeks

***Inclusion/exclusion criteria***

**Participants**
Existing disease

**Population**
Patients with diagnosed coronary artery disease, referred by a cardiologist or primary care physician to the Presbyterian New Heart Outpatient Cardiac Rehabilitation Program

**Inclusion criteria**
Diagnosed coronary artery disease. Eligible patients included those who had entered the programme following angina symptoms, a myocardial infarction, percutaneous transluminal coronary intervention, or coronary artery bypass graft surgery

**Exclusion criteria**
Participation in another study that may have confounded results

**Behaviours targeted**
Stress, exercise, fat intake, medicine compliance

***Intervention details***

**Intervention group**
I: Motivational interviewing and skills-based counselling (integrated within the framework of the TTM of behaviour change) in addition to the traditional programme (motivational interviewing + skills-based training + traditional programme). Included all the components of C, plus a multiple behaviour, stage-matched approach to lifestyle change. This involved a 1-hour motivational interview and three 30-minute skills-based counselling sessions. The motivational interview was designed to strengthen the commitment of those who were ready (preparation, action and maintenance phases) and to built motivation in those who were less ready to change (precontemplators and contemplators). If patients in I were ready to change (over the next 30 days), skills-based counselling was offered, during weeks 2, 3 and 7. Further appropriate strategies were applied to support the patient in their efforts to change the specified behaviours (goal setting, behavioural contracting, setting up a reward management system, training in self-monitoring skills, and brief follow-up assessment with the provision of swift feedback on progress)

**Comparison group**
Traditional programme. Supervised exercise sessions (1 hour, three times per week) and a series of eight 45-minute didactic lectures with group discussion on topics related to heart disease.

With an option to participate in additional behavioural interventions designed to change lifestyle, to include personal feedback from a dietician at the start of the programme, cooking demonstrations, and classes in smoking cessation, weight control and stress management

*continued*

# Data extraction table *contd*

***contd***
**S478, Scales (1998)**[66]

***Intervention details* contd**

**Classification into stages**
A four-item algorithm adapted from the work of Prochaska and DiClemente[98] was used to determine the patient's readiness to change specified health-related behaviours (manage stress, exercise, avoid dietary fat, and quit smoking)

The first item asked patients if they were currently changing the specified behaviour. If yes, they were asked if they had been doing so for more than 6 months. If no, they were asked if they intended to do so within the next 30 days. If 'no' to the next 30 days, they were asked if they intended to do so in the next 6 months

Precontemplators: those who did not intend to change in the next 6 months
Contemplators: those who intended to change in the next 6 months
Preparers: those who intended to change in the next 30 days, or in some cases, had made some changes
Actors: those who had changed the behaviour within the previous 6 months
Maintainers: those who had maintained the change for 6 months

**Validity of measure**
These measures have been shown to possess adequate reliability and validity in previous studies (S145, S312, S445, S516, S633)

S145: The first study (instrument development) was based on a four-item version. Conclusion: scores on efficacy items significantly differentiated employees at most stages. No additional validity information regarding this four-item scale. The scale was refined, adding one item, preparation; this five-item scale showed that total scores on the self-efficacy items reliably differentiated employees at different stages. Proportion of variance accounted for was 0.28. Test–re-test reliability (kappa index) for the stages-of-change instrument over a 2-week period was 0.78 ($n$ = 20)

S312: Validity of stage-of-change scale not reported

S445: No validity information presented

S516: Paper focuses on weight control.

Reliability: "The stages construct has been found reliable across a wide range of other problem behaviours" (S145, S312, S8). Construct validity: "Individuals in the four stages of change differ on several dimensions of the TTM in accordance with the predictions of the model, including decisional balance and the processes of change" (S635, S636). S478 and S516, both focus on a five-stage version. Practicality and location: "The stages of change algorithm (S634) is easy to administer and score". No additional information presented. The URICA, a 32-item version to measure four stages of change is described and information on its validity is presented. Other scales to measure readiness to change diet are described as well

**Training of educators**
Not stated

***Baseline chracteristics***

**Gender**
Total: 29% female
I: 27.6% female
C: 31.3% female

**Age**
Mean age (SD):
Total: 59.6 (10.4) years
I: 59.8 (11.4) years
C: 59.4 (9.6) years

**Stage of change**
Not stated

**Target behaviour**
Cigarette smoking:
I: 3.4% persistent smokers, 58.6% quit smokers (17.6% of quit smokers tempted to smoke), 37.9% never smokers
C: 6.2% persistent smokers, 71.9% quit smokers (34.8% of quit smokers tempted to smoke), 21.9% never smokers

Mean pack years (No. of cigarette packs smoked × No. of years smoked) smoked (persistent smokers + quit smokers): I, 29.2 (26.2); C, 33.7 (27.8)

Perceived stress: 16.0 (SD = 6.9)

Physical activity: 229.2 (SD = 27.1) MET hours/week

Dietary fat intake: 21.5% (SD = 9.8) of total calories consumed

Mean adherence to prescribed medication on the four -and six-item MAS-4/MAS-6: I, 75.0%/79.3%; C, 78.1%/83.3%

*continued*

## Data extraction table *contd*

***contd***
**S478, Scales (1998)**[66]

***Results***

**Statistical techniques**
At the baseline and at 12 weeks, inferential statistics were used to compare the results of the two groups on the measured dependent variables. Data were analysed by using the SPSS package (1986). A repeated measures MANCOVA analysis was used to determine whether or not there was a significant difference between the two groups on the composite dependent variable. Univariate ANCOVA was also used to determine if there were significant differences between the groups on each of the dependent variables. Baseline levels were treated as covariates. The progress of the smokers was presented as descriptive data because the number of smokers was small

The remaining measures for both groups were also analysed using descriptive rather than inferential statistics

**Behaviour change**
Physical activity (modified Physical Activity Recall, Lo-PAR), dietary fat intake (3-day food records), adherence to prescribed medications (surreptitiously measured 7-day pill count, adherence rates were calculated as percentage of the prescribed doses that were missing when remaining pills were counted (this did not take place as intended!); also assessed with MAS-4 and MAS-6, smoking (self-report and the Fagerstrom Nicotine Dependence Scale

Mean scores for physical activity and dietary fat intake at the baseline and 12 weeks (SD):

Physical activity:
I: pretest, 233.0 (26.5); post-test, 275.7 (38.1)
C: pretest, 226.7 (28.1); post-test, 260.7 (33.6). NS

Dietary fat (%):
I: pretest, 18.0 (8.2); post-test, 17.5 (6.6)
C: pretest, 24.3 (10.3); post-test, 22.3 (8.9). NS

Mean scores for adherence to prescribed medication at the baseline and 12 weeks:
MAS-4: I, pretest, 75.0%; post-test, 85.1%; C, pretest, 78.1%; post-test, 82.0%. NS
MAS-6: I, pretest, 80.0%; post-test, 89.8%; C, pretest, 83.3%; post-test, 86.4%. NS

Smoking cessation:
I: One male smoker at the baseline, changed from five cigarettes/2 weeks to ten cigarettes/2 weeks (nicotine dependence score: pretest, 1; post-test, 2)
C: One male smoker at the baseline, changed from four cigarettes/day to ten cigarettes/day (nicotine dependence score: pretest, 4; post-test, 5).; one female smoker at the baseline, changed from ten cigarettes/day to six cigarettes/day (nicotine dependence score: pretest, 6; post-test, 6)

**Stage movement**
Motivation (stage of readiness) to change: (a) manage stress; (b) exercise; (c) avoid dietary fat; (d) adhere to prescribed medications; (e) quit smoking

Motivational stages to stage, at the baseline and at 12 weeks (data are estimates from graphs) (PC, precontemplation; C, contemplation; P, preparation; A, action; M, maintenance; NA, not applicable)

Manage stress:
I: Pretest, 3% PC/3% C/20% P/20% A/46% M/8% NA; post-test, 0% PC/0% C/0% P/60% A/20% M/20% NA
C: Pretest, 0% PC/3% C/21% P/18% A/52% M/6% NA; post-test, 0% PC/0% C/0% P/36% A/56% M/8% NA

Exercise:
I: Pretest, 0% PC/0% C/70% P/22% A/8% M; post-test, 0% PC/0% C/4% P/86% A/10% M
C: Pretest, 0% PC/0% C/68% P/32% A/0% M; post-test, 3% PC/0% C/3% P/91% A/3% M

Avoid dietary fat:
I: Pretest, 0% PC/4% C/8% P/40% A/48% M; post-test, 0% PC/0% C/0% P/70% A/30% M
C: Pretest, 0% PC/0% C/36% P/36% A/28% M; post-test, 0% PC/0% C/8% P/60% A/32% M

Take prescribed medication:
I: Pretest, 4% PC/0% C/18% P/26% A/52% M; post-test, 0% PC/0% C/4% P/42% A/54% M
C: Pretest, 0% PC/4% C/8% P/30% A/58% M; post-test, 0% PC/0% C/12% P/30% A/58% M

Quit smoking:
I: Pretest, 0% PC/0% C/3% P/16% A/43% M/38% NA; post-test, 0% PC/0% C/4% P/18% A/42% M/36% NA
C: Pretest, 0% PC/2% C/2% P/22% A/44% M/20% NA; post-test, 0% PC/2% C/2% P/22% A/44% M/20% NA

*continued*

# Data extraction table *contd*

***contd***
**S478, Scales (1998)**[66]

***Results* contd**

**Health**
Perceived emotional stress (10-item Perceived Stress Scale, PSS-10), cardiovascular risk factors (Arizona Heart Institute Test), biological assessment (blood pressure, body mass index, waist–hip ratio)

Mean scores for perceived stress at the baseline and 12 weeks (SD):
I: Pretest, 16.5 (5.6); post-test, 9.5 (7.2)
C: Pretest, 15.8 (8.0); post-test, 13.4 (7.3). $F(1, 55) = 8.37$, $p = 0.005$

Arizona Institute Heart Test scores:
I: Pretest, 39.6 (8.9); post-test, 33.2 (9.0)
C: Pretest, 43.4 (9.1); post-test, 39.6 (8.3). $F(1, 57) = 7.56$; $p = 0.008$

Blood pressure, mm/Hg (systolic/diastolic):
I: Pretest, 119.61/75.18; post-test, 120.86/75.61
C: Pretest, 126.56/77.13; post-test, 124.13/74.15. NS/NS

Body mass index:
I: Pretest, 27.15; post-test, 26.60. C: pretest, 27.74; post-test, 27.63. NS

Waist–hip ratio:
I: Pretest, 0.90; post-test, 0.90. C: pretest, 0.92; post-test, 0.91. NS

**Intermediate outcomes**
Not stated

**Adverse effects**
Follow-up cardiac events, emergency room visits and hospitalisation:

Cardiac or sudden death/non-fatal myocardial infarction/percutaneous transluminal coronary intervention/coronary artery bypass graft/emergency room visit only/hospitalization: I, 1/0/1/0/3/1; C, 0/0/0/0/3/1

**Other outcomes**
Not stated

**Implementation measures**
12 weeks assessment only: Patient satisfaction (an adaptation of the Seattle Angina Questionnaire) and attendance in the exercise sessions and education classes, participation in optional classes (cooking demonstrations, smoking cessation, weight control and stress management), enrolment in outpatient maintenance cardiac rehabilitation programme:

Exercise sessions attended: I, 71.65%; C, 63.11%. NS
Attendance rate for education classes: I, 79.08%; C, 60.94%. $t(55.46) = 2.29$, $p = 0.29$
Completion of 12 week rehabilitation programme: I, 69%; C, 59%
Enrolment into maintenance programme: I, 57.1%; C, 53.1%. NS

Participation in optional classes:
Cooking demonstrations: I, 34.5%; C, 3.1%. $p = 0.001$
Stress management: I, 3.6%; C, 0.0%. Not applicable
Weight control: I, 10.7%; C, 6.3%. Not applicable
Smoking cessation: I, 0.0%; C, 0.0%. Not applicable

Patient satisfaction scores: I, 90%; C, 86%. NS

***Withdrawals/economic evaluation***

**Number per group**
61 patients were randomised (I, 32; C, 29). One drop-out (I). Some patients prematurely terminated participation in the cardiac rehabilitation programme, but were included in the 12-week data analysis because they had adhered to the study protocol

**Reasons**
One patient (I) died from complications independent of the study and was excluded from analyses

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S478, Scales (1998)**[66]

***Additional comments***

**Comments**
**'**Not stated' means not stated in the pages we copied from the microfiches (pp. 60–115: chapter 3, 'Methodology', and chapter 4, 'Results')

**Authors' reported limitations**
(1) The study sample was not representative of the population at large
(2) The Arizona Heart Test and satisfaction questionnaire have not been validated, therefore results cannot be generalised to other populations
(3) The interaction of patients may have influenced results

**Authors' conclusion**
Integrating motivational interviewing and skills-based counselling into a traditional early outpatient cardiac rehabilitation programme helps motivate patients to adopt a more healthful lifestyle

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S510, Sinclair (1999)**[51]

**Country**
UK

**Aim**
To assess the cost-effectiveness of intensive pharmaceutical intervention in assisting people to stop smoking

S225: focuses on the pharmacy personnel's perceptions of the value and utility of the training workshops and on changes in job satisfaction as a consequence of attending the training

S214: The focus of this paper is the effect of the training on the knowledge and attitudes of the workshop participants

**Model**
TTM

**Theoretical basis**
Training of pharmacy personnel based on the stages-of-change model

Intervention-pharmacists tailored their advice to match the client's stage of change. For example, a 'pre-contemplator' is not a suitable candidate for NRT – they will benefit more from advice about the dangers of continued smoking that aims to move them through the stages of change. A person in the 'preparation' or 'action' stage is ready to receive practical help, and may benefit from the sale of NRT with appropriate on-going advice

S225: This study set out to develop and evaluate an interactive training workshop for community pharmacists and pharmacy assistants based on the stages-of-change model. The training did not include motivational interviewing techniques to encourage smokers to move from precontemplation to contemplation (see S227). However, it did include specific content and recommendations pertaining to maintenance and relapse

**Study type**
RCT

**Design**
All pharmacies in Grampian (Scotland, not Aberdeen; 76 pharmacies) were invited to participate. Pharmacies agreeing to take part were randomised to I or C. Smokers were recruited on an opportunistic basis. Eligible smokers either asked for advice on smoking cessation or bought an over-the-counter anti-smoking product for their own use. A variety of questionnaires were used to collect client information at 1, 4 and 9 months after recruitment

S225: Pharmacy recruits were stratified by type (national multiple or proprietor-owned) and ranked according to the pharmacist's level of motivation (as defined by the date on which their 'willingness to participate' proforma was received). They were then randomised to either I or C by sequential allocation

S225: Participants (of the workshops) were followed up at 0, 2 and 12 months to monitor their perceptions off the value and utility of the training

S214: An RCT design, employing both quantitative and qualitative methods, was used to evaluate the training

**Setting**
Primary care

**Length of intervention**
Assessments at 1, 4 and 9 months

S214: Assessments after 2 and 12 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Not stated

**Inclusion criteria**
S510: Eligible smokers either asked for advice on smoking cessation or bought an over-the-counter anti-smoking product for their own use

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking

*continued*

# Data extraction table *contd*

***contd***
**S510, Sinclair (1999)**[51]

***Intervention details***

**Intervention group**
Staff from pharmacies attended one of seven health promotion workshops held to explain the stage of change' model. Pharmacists tailored their advice to match the client's stage of change

**Comparison group**
Standard advice and support with respect to smoking cessation and NRTs

**Classification into stages**
Not stated

**Validity of measure**
Not stated

**Training of educators**
S225: A 2-hour training package. The training, which was facilitated by health promotion personnel, focused on the stages-of-change model using case studies of pharmacy customers, and on communication skills for negotiating change and providing ongoing support and encouragement

***Baseline characteristics***

**Gender**
Not stated

**Age**
Not stated

**Stage of change**
Not stated

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
S510: Not stated

S225: Differences between pharmacists and their assistants were assessed using $\chi^2$ tests; Pearson correlations were used to measure the strength of association between 2- and 12-month results

**Behaviour change**
9-month continuous abstinence rate:
I: 12.0% (26/217)
C: 7.4% (19/257); $p < 0.089$

1-month point prevalence of cessation:
I: 29.9%
C: 23.6%; $p = 0.12$

4-month continuous abstinence rate:
I: 16.1% (26/217)
C: 10.9% (19/257); $p < 0.094$

Purchase of NRT:
I: 97.7% (212/217)
C: 92.6% (238/257)

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S510, Sinclair (1999)**[51]

***Results* contd**

**Implementation measures**
S225: A self-completion questionnaire (the impact questionnaire) was developed to monitor the participants' (pharmacists/assistants) immediate impression to the workshop; as well as self-completion postal questionnaire (2- and 12-months post-training follow-ups) to monitor the participants' perception of the value and utility of the training and to assess their perceived self-efficacy to counsel customers. 16 months after the training a sub-sample of 20 personnel was selected from those available to assess their perceptions of the value and utility of the training

Impact questionnaire:
95% rated the training as a 'very good' or 'good' learning experience and a worthwhile use of their time. 98% thought that they would be able to use what they had learned in their work

2-/12-month postal follow-ups:
82.4%/89.9% had utilised the training (at 2 months, pharmacists significantly more likely than assistants to have utilised training in practice: 92.3 versus 75.0%, $p = 0.03$; at 12 months, 94.6% versus 85.7%, NS)

At each of the follow-ups over 90% agreed/strongly agreed that the 'cycle of change' model was a good way of understanding stopping smoking; almost three-quarters felt that the training had made a difference to the way they counselled customers who were trying to stop smoking and that it had helped them to help these customers; and around 80% felt confident in their ability to assess the stage of change their customer was at by asking them a few questions (no details regarding these questions!) and to tailor the advice they gave to customers to their current stage of change (no details regarding tailoring!)

Telephone interviews:
The majority of pharmacists (9/10) and assistants (7/10) were extremely positive about the training. It fulfilled a training need; the workshop was a more effective training method; it provided information and a new understanding of the psychological background of smokers. Almost all (nine pharmacists; nine assistants) felt that the training had helped them to help their customers; it provided an orderly approach: greater understanding and empathy towards smokers and increased counsellor confidence and the incidence of counselling. The majority (seven pharmacists; nine assistants) felt that the training had increased their job satisfaction, in particular, through more effective interaction with customers

**Economic methods**
For the purposes of cost-effectiveness analysis, the alternatives considered here are: advice to stop smoking given by pharmacy personnel trained in the stage of change model (I), or advice to stop smoking given by personnel who have not had this training (C). The outcome measures used are: the number of quitters (continuous cessation) at 9 months and an estimate, based on previous studies, of the life-years gained by smoking cessation. Incremental cost-effectiveness ratios, that is, cost of producing one additional unit of effectiveness (e.g. a quitter or a life-year) by using intensive rather than standard pharmaceutical support

Perspective: Not limited to the health service viewpoint, but wider societal

The most obvious cost to the NHS arose from the organisation of the training sessions and trainee's out-of-pocket expenses, including staff costs and travel (NRT was a cost of the intervention to the client and cost of materials and documentation was borne by the research project but would not ultimately be a cost to the NHS)

For trainees, lost working time was valued at participants' wage rate, and travel time was valued at 0.4 times their wage rate (standard convention). Leisure time of pharmacy personnel who attended the training outside normal working hours was also valued at their wage rate, and travel time was valued at 0.4 times their wage rate

Sensitivity analysis: Costs and benefits are reported in detail, so that other workers can adjust the costs and benefits as necessary to apply to their own local setting

Discounting: Not necessary, as all costs and benefits fall in 1 year (1995 prices)

Training costs: An opportunity costs questionnaire was developed to collect information on the costs of attending the training workshop: alternative activity, lost income, means of travel and travel time

NRT purchase and counselling costs: A customer registration postcard and 1-month customer questionnaire monitored which product (if any) had been purchased. The duration of product use was monitored at 1-, 4- and 9-month follow-ups. Information on the duration of initial and subsequent consultations was gathered during semi structured telephone interviews with a representative sub-sample of 20 intervention pharmacy personnel and a quota sample of 50 clients (25 I, 25 C)

Clients time was valued at the average gross hourly earnings (excluding overtime pay) for all full-time employees: £8.32

The consultation times given by clients were also used as a proxy for the input of pharmacy personnel

**Cost outcomes**
Training costs: (I only) £2844.30
Organising costs (invitation letter, £10.00; postage, £34.00; telephone, £5.00): £49.00
Operating costs (health promotion consultancy fee, £1260.00; trainer travel expenses, £79.00; training materials, 30.00; refreshments, £67.00; venues, 0): £1436.00
Pharmacy travel expenses (car at 33p per mile, £393.08; private use hire, £80.00; public bus fare, 0.50): £473.58
Lost working time (2-hour daytime sessions: nine pharmacists at £9.93 per hour × 1.0 = £178.74. Seven assistants at £3.19 per hour × 1.0 = £44.66): £223.40
Lost leisure time (2-hour evening sessions: 31 pharmacists at £9.93 per hour × 0.4 = £246.26. 47 assistants at £3.19 per hour × 0.4 = £119.94): £366.20
Travel time (average 1.3 hours: 40 pharmacists at £9.93 per hour × 0.4 = 206.54. 54 assistants at £3.19 per hour × 0.4 = 89.58): £296.12
NRT purchase and counselling costs: I, £12, 071.46; C, £14, 121.13
I: NRT purchases: £10,076.57 (212 clients, £47.53 per NRT user). Health promotional material and pharmacy client documentation: £617.00. Clients counselling time (92.6 hours at £8.32): £770.43. Pharmacy personnel time (pharmacists: 0.5 × 92.6 hours × £9.93 = £459.76. Assistants: 0.5 × 92.6 hours × £3.19 = £147.70): £607.46
C: NRT purchases: £12,463.50 (238 clients, £52.37 per NRT user). Clients counselling time (111.4 hours at £8.32): £926.85. Pharmacy personnel time (pharmacists: 0.5 × 111.4 hours × £9.93 = £553.10. Assistants: 0.5 × 111.4 hours × £3.19 = £177.68): £730.78

*continued*

# Data extraction table *contd*

***contd***
**S510, Sinclair (1999)**[51]

***Results* contd**

**Total costs:**
I: £14,915.76 (NHS: organising and operating costs (£1485.00) + pharmacy travel expenses (£473.58) + promotional materials and client documentation (£617.00) = £2575.58)/(pharmacy: pharmacy training time (£885.72) + pharmacy counselling time (£607.46) = £1493.18)/(customer: anti-smoking products (£10,076.57) + customer counselling time (£770.43) = £10,847.00)
C: £14,121.13 (pharmacy: pharmacy counselling time = £730.78)/(customer: anti-smoking products (£12,463.50) + customer counselling time (£926.85) = £13,390.35)

Incremental cost-effectiveness ratios for the intervention: £300.00 per quitter and £83.00 per life-year

***Withdrawals/economic evaluation***

**Number per group**
62 pharmacies were recruited, 81.6% (62/76). One I pharmacist was also in charge of an outlet allocated to C, this pharmacy was transferred to I; 6 weeks into the study one C pharmacy withdrew due to pressure of work. After a further 11 weeks, one I pharmacy withdrew because of major staff changes (no clients had been recruited by either pharmacy). Thus, 31 I and 29 C pharmacies participated

I: 94 personnel participated (54 assistants and 40 pharmacists) in training

C pharmacies identified 120 personnel (80 assistants, 40 pharmacists)

Initially 492 clients (I, 224; C, 268) were recruited. At 9 months, 474 clients (96%) were available for follow-up (I, 217; C, 257)

S225: All 94 workshop participants completed the impact questionnaire. 93 were available at 2 months when 91 questionnaires were completed (97.8%). At 12 months, 87 personnel were available and 80 questionnaires were completed (91.9%)

**Reasons**
C: One pharmacy-withdrawal due to pressure of work
I: One pharmacy-withdrawal because of major staff changes
Clients: 18 drop-outs (I, 7; C, 11), no reasons reported

**Economic evaluation**
Yes

***Additional comments***

**Authors' conclusion**
The intervention was associated with higher smoking cessation rates, confirming that community pharmacy personnel have the potential to make a significant, cost-effective contribution to smoking cessation

**S225: Authors' conclusion**
The majority of pharmacists and pharmacy assistants thought that: the model was a good way of understanding smoking cessation; the training was a good learning experience and a good use of their time; they had been able to utilise the training; it had made a difference to the way they counselled customers; had helped them to help their customers; and had increased their job satisfaction

**S214**
The training had a significant effect for at least a year, since at both follow-ups, the I-pharmacy teams had a greater knowledge and understanding of the model and a more positive attitude about the outcome of smoking cessation counselling provided in community pharmacies than their control counterparts. No information regarding the smokers provided

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S350, Steptoe (1999)**[63] *

**Country**
UK

**Aim**
"To measure the effect of behaviourally oriented counselling in general practice on healthy behaviour and biological risk factors in patients at increased risk of coronary heart disease"

**Model**
TTM

**Theoretical basis**
Behaviourally oriented counselling was based on the stage of change model. "This model categorises patients into stages of readiness to change behaviour (from precontemplation through contemplation, preparation, and action, to the maintenance of change), with different types of advice and skill training being appropriate at different stages"

**Study type**
Cluster RCT

**Design**
"Cluster randomised controlled trial. Twenty general practices were allocated to intervention and control conditions using the minimisation technique to balance groups for the Jarman score of social deprivation, ratio of patient to practice nurse hours per week, and fund-holding status (including wave of entry)"

"The target sample size was 100 patients per practice. Taking intracluster correlations of risk factors into account, it was calculated that this would detect a drop in smoking prevalence from 50% to 41%, and a decrease of 0.27 mmol/l in total serum cholesterol concentration with 90% power at the 5% significance level." Patients were reassessed at 4 and 12 months

**Setting**
Primary care

**Length of intervention**
I: three counselling sessions if they had two risk factors and two counselling sessions if they had only one risk factor (20 minutes each at most); between sessions one or two telephone contacts

***Inclusion/exclusion criteria***

**Participants**
Physiological risk

**Population**
20 interested practices out of 42 training practices linked with the dept of General Practice at St Georges Hospital Medical School. 883 men and women selected for the presence of one or more modifiable risk factors: regular cigarette smoking, high serum cholesterol concentration (6.5–9.0 mmol/l), and high body mass index (25–35) combined with low physical activity

**Inclusion criteria**
"Patients were recruited on the basis of one or more modifiable cardiovascular risk factors" (According to S228: each practice was asked to recruit 100 patients with at least two out of three risk factors for coronary heart disease, people with one risk factor are included according to S228): "regular cigarette smoking (more than one cigarette per day), high serum cholesterol concentration (6.5–9.0 mmol/l), or combined high body mass index (25–35) and low physical activity (fewer than 12 episodes of vigorous or moderate exercise for at least 20 minutes in the past 4 weeks, according to criteria based on the national fitness survey)." Patients had to be aged between 18 and 69 years, be available for 12 months and have adequate written and spoken English

**Exclusion criteria**
"Patients were excluded if they were on active follow up or drugs for coronary heart disease, had had cardiovascular disease or peripheral vascular disease, had a serious chronic illness, or were prescribed a special diet or lipid lowering drugs"

**Behaviours targeted**
Smoking, fat intake, exercise



*continued*

# Data extraction table *contd*

***contd***
**S350, Steptoe (1999)**[63]

***Intervention details***

**Intervention group**
"After recruitment and baseline assessment patients were counselled by practice nurses in smoking cessation, dietary fat reduction, and increasing physical exercise as appropriate using behaviourally oriented methods

The goal in the smoking intervention was complete abstinence, and counselling was supported by nicotine replacement therapy when appropriate. Patients with increased serum cholesterol concentration were counselled to reduce dietary fat intake and to increase fruit and vegetable consumption within the context of a balanced diet, without specifying targets of the proportion of energy derived from fats. Patients with combined increased body mass index and lack of regular physical activity were counselled to increase their activity levels to 12 sessions of moderate or vigorous activity per month

Patients in the intervention arm of the study were invited for three counselling sessions if they had two risk factors and for two counselling sessions if they had only one risk factor. The order in which risk factors were targeted was determined after negotiation between nurse and patient. Counselling sessions were scheduled to last no more than 20 minutes, and between sessions the nurse contacted the patient by telephone one or two times to consolidate the counselling and to encourage behaviour change"

**Comparison group**
After recruitment and baseline assessment patients were counselled by practice nurses in smoking cessation, dietary fat reduction, and increasing physical exercise as appropriate using their own usual methods, involving information provision and exhortation

**Classification into stages**
Stage of change for smoking cessation, dietary fat reduction, and increasing physical activity were assessed with measures described elsewhere (S199)

S199: Staging criteria:

Reduction of dietary intake of fat:
Precontemplation: participants had never changed to a reduced-fat diet or were not currently eating a low-fat diet and had not thought over the past month about changes that they could make to decrease their intake of fat
Contemplation: participants had thought about changing their dietary intake of fat but were not confident or only mildly confident that they would make these changes within the next month
Preparation: participants felt somewhat or very confident that they could make dietary changes within the next month
Action: participants had made these changes within the last 6 months
Maintenance: participants had made and adhered to changes for more than 6 months

Increasing exercise:
Precontemplation: participants were not currently exercising at least three times per week for at least 20 minutes each time and were not considering exercising at this level within the next 6 months
Contemplation: participants were considering exercising at the above level within the next month but they were only mildly or not at all confident that they would succeed
Preparation: participants were somewhat or very confident that they would succeed
Action: participants had been exercising at the above level for less than 6 months
Maintenance: participants had been exercising for more than 6 months

Cessation of smoking (assessment was carried out for participants who had formerly been smokers or were current smokers):
Precontemplation: participants were not considering stopping smoking
Contemplation: participants were considering stopping, but were only mildly or not at all confident that they would succeed or were somewhat or very confident that they would succeed but had not made an attempt to stop for at least 24 hours within the last year
Preparation: participants had made an attempt to stop for 24 hours or more within the last year, were considering stopping and were either somewhat or very confident that they would succeed
Action: participants had stopped smoking and had not started again within the last 6 months
Maintenance: participants had stopped smoking and had not smoked for 6 months

**Validity of measure**
Not stated

S199: Staging criteria – stage of change was assessed according to measures described in previous articles (S445, S255, S496)

S445: No validity information presented

S255: See data extraction form S255

S496: Stages of adopting exercise were measured using an 11-point scale in the shape of a ladder. Each rung had a number (0 through 10), and five rungs had also written labels to serve as anchor points:

Rung 0: 'I currently do not exercise and I do not intend to start exercising in the next 6 months' (precontemplation)

Rung 2: 'I currently do not exercise, but I am thinking about starting to exercise in the next 6 months' (contemplation)

Rung 5: 'I currently exercise some, but not regularly' (preparation)

Rung 8: 'I currently exercise regularly, but I have only begun doing so within the last 6 months' (action)

Rung 10: 'I currently exercise regularly, and have done so for longer than 6 months' (maintenance)

Labels in parentheses not on ladder. Regular exercise was defined as exercising three or more times per week for at least 20 minutes each time

Reliability of the stages-of-exercise adoption measure has been examined. The kappa index of reliability over a 2-week period was 0.78 ($n$ = 20 (S145)). Concurrent validity for this measure has been demonstrated by its significant association with the 7-day Recall Physical Activity Questionnaire (S258). S496 concludes that pros (positive perceptions of exercise), cons (avoidance of exercise) and a decisional balance measure (pros minus cons) were significantly associated with stage of exercise adoption

*continued*

# Data extraction table *contd*

***contd***
**S350, Steptoe (1999)**[63]

***Intervention details* contd**

**Training of educators**
"One practice nurse from each of the 10 intervention practices was trained in behavioural counselling on the basis of the stage of change model. Training was adapted from the Health Education Authority's package 'Helping People Change' (S637, S638). Nurses were trained both to assess a patient's readiness to change behaviour and to use attitude change, goal setting, and specific behavioural advice to enable change. Training took place over 3 days, with a retraining and refresher day after 6 months"

***Baseline characteristics***

**Gender**
I: 54.1% female
C: 54.0% female
Patients in I and C did not significantly differ in sex distribution: 406 men/477 women

**Age**
Mean age (SE of the mean):
I: 48.1(0.67) years
C: 46.0 (0.49) years
Patients in I and C did not significantly differ in age: mean 46.7 (SE: 0.4) years

**Stage of change**
S228:
Stage of change for smoking cessation:
I: 25.9% precontemplation; 50.0% contemplation; 24.1% preparation
C: 42.2% precontemplation; 44.6% contemplation; 13.2% preparation

Stage of change for dietary fat reduction:
I: 21.1% precontemplation; 6.8% contemplation; 28.1% preparation; 15.1% action; 28.8% maintenance
C: 18.2% precontemplation; 9.6% contemplation; 21.7% preparation; 23.2% action; 27.3% maintenance

Stage of change for increasing physical activity:
I: 25.3% precontemplation; 27.0% contemplation; 39.8% preparation; 5.0% action; 2.9% maintenance
C: 37.9% precontemplation; 20.1% contemplation; 27.0% preparation; 7.2% action; 7.0% maintenance

**Target behaviour**
Mean cigarettes per day: I, 20.2; C, 16.3
Mean smoking prevalence: I, 28.9; C, 44.3
Mean fat score: I, 30.8; C, 27.9
Mean No. of exercise sessions: I: 5.29; C: 4.84

***Results***

**Statistical techniques**
"Statistical comparison of intervention and control groups was carried out with weighted means for each practice thereby taking account of cluster effects"

**Behaviour change**
The smoking outcome measures were abstinence as verified by measurement of cotinine at 4 and 12 months together with reported number of cigarettes smoked per day. Dietary fat intake was assessed with the dietary instrument for nutritional education. Physical activity was measured as the number of episodes of vigorous or moderate activity (as defined in the national fitness survey assessment instrument) completed in the past 4 weeks

Differences in change from the baseline (95% CI):
Cigarettes per day: 4 months, 4.5 (2.1, 7.0); 12 months, 5.2 (1.1, 9.3)
Difference in quit rate: 4 months, 7.4 (–0.6, 20.1); 12 months, 9.4 (–9.6, 28.3)
Fat score: 4 months, 4.8 (1.6, 8.0); 12 months, 2.8 (0.1, 5.5)
No. of exercise sessions: 4 months, 3.7 (1.3, 2.6); 12 months, 3.9 (1.0, 6.8)

Greater reductions in dietary fat and the reported number of cigarettes smoked per day, and increases in physical activity, were recorded in the intervention than control groups

The smoking quit rate was 7.4% (95% CI: –0.6 to 20.1) greater in the intervention than control groups at 4 months

The differences favouring intervention in dietary fat, physical activity, and the number of cigarettes smoked per day were maintained at 12 months. The smoking quit rate at 12 months was 9.4% (–9.6 to 28.3) greater in the intervention than control groups

**Stage movement**
Data related to motivational stage of change will be described elsewhere (not in S350, no reference given, not in S199)

*continued*

## Data extraction table *contd*

***contd***
**S350, Steptoe (1999)**[63]

***Results* contd**

**Health**
The physical assessment measures were calculation of body weight and body mass index, and total serum cholesterol concentration and blood pressure

Behaviour changes were not translated into differences in biological risk factors. The only difference was in systolic blood pressure, where the decrease at 4 months was greater in the intervention than control groups

The reduction in systolic blood pressure in the intervention group was sustained at 12 months. Total serum cholesterol concentration was reduced to a similar extent in intervention and control groups at 12 months

**Intermediate outcomes**
Not reported

**Adverse effects**
Not reported

**Other outcomes**
Not reported

**Implementation measures**
Of the 316 patients in the intervention group, 298 (90.2%) attended at least one counselling session, 230 (72.8%) attended two, and 176 (55.7%) attended three

***Withdrawals/economic evaluation***

**Number per group**
42 practices were invited, 27 expressed interest and 22 were still interested after visit explaining study. 20 practices were randomised (two held in reserve). A total of 316 intervention and 567 control patients were recruited. Overall, 626 (70.9%; I, 204; C, 422) of the 883 patients entering the trial completed the 4-month assessment, and 520 (58.9%; I, 169; C, 351) were assessed at 12 months

**Reasons**
Failure to complete the trial was not related to sex, education, occupation, or family history of cardiovascular disease. Patients lost to follow-up were younger than those who completed the study. They were also more likely to be smokers and less likely to have entered the study on the basis of cholesterol concentration or body mass index and exercise criteria. Participants who smoked and those with a serum cholesterol concentration < 6.5 mmol/l tended to drop out more in the intervention than control groups at 4 and 12 months

There were no differences in response related to age, sex, or number of risk factors

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S350, Steptoe (1999)**[63]

***Additional comments***

**Authors' conclusions**
"Behavioural counselling by practice nurses for lowering fat intake and increasing physical activity led to changes in target behaviours after 4 months, which were sustained at 12 months. More extended counselling to help patients sustain and build on behaviour changes may be required before differences in biological risk factors emerge"

**Authors' reported limitations**
"The smoking results were compromised by the differential drop out of smokers from the intervention group. Authors reported considerable difficulties in recruitment and retention to this study, and the drop-out rate was higher than that found in previous trials in general practice. The greater drop-out rate for the intervention group may have resulted from its more demanding nature. Recruitment and retention required the commitment of all staff and not only the study nurses, but many health professionals in primary care are ambivalent about advising patients in lifestyle change. The changes in behaviour did not lead to differential reductions in biological risk factors." Possible explanations: reporting bias, or insufficient power

**Comment**
It is not clear whether the same nurse delivered intervention and control counselling in each practice. If so, it might be the case that controls were also given counselling which might reflect some of the training the nurse had received

**S228**
Details added on study design. Data on baseline target behaviour are different in S228 from S350, data reported here are from S350. Data on baseline stage of change are from S228

**S199**
This provided staging criteria

**Request for more information from authors**
(Data related to stage movement described elsewhere)

A reference was supplied: Steptoe A., Kerry S, Rink E, Hilton S. Stage of change in fat intake, physical activity and cigarette smoking in a randomized trial of behavioral counseling for adults at increased risk of coronary heart disease. *Am J Public Health*, 2001;**91**:265–69. Article was ordered but not received at time of writing

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S453, Swanson (1999)**[41]

**Country**
USA

**Aim**
To evaluate the effect of motivational interviewing on outpatient treatment adherence among psychiatric and dually diagnosed inpatients

**Model**
Motivational interviewing

**Theoretical basis**
Motivational interviewing (S639) is a method that utilises the stages of change to motivate substance abusers to change their addictive behaviours

**Study type**
RCT

**Design**
Consenting patients were interviewed regarding demographic and historical data, and then administered the URICA to measure readiness to change. The therapist then consulted a random number table to determine group assignment. Patients assigned to C (standard treatment) were thanked for their participation and returned to the unit

For patients assigned to I (standard treatment plus motivational interviewing), the URICA was immediately scored and a discussion followed regarding the meaning of the results in light of the patients' presenting problems and their own perceptions of their stage of change. After this discussion, I patients were informed that they would be meeting with the therapist again at some point, and returned to the unit. 1 or 2 days before discharge, I patients received a 1-hour motivational interviewing

The dependent measure was the proportion who attended their first aftercare appointment

**Setting**
Hospital

**Length of intervention**
Additionally to standard treatment: a 15-minute session and a 1-hour session

***Inclusion/exclusion criteria***

**Participants**
Existing disease

**Population**
Psychiatric inpatients at two inner-city private, not-for-profit hospitals. Patients were on a voluntary status in the hospital after admission due to potential danger to themselves or others or due to grave disability

**Inclusion criteria**
All patients admitted during a 4-month period

**Exclusion criteria**
Diagnosis of dementia or mental retardation, and those who spoke little or no English. Patients who were acutely psychotic, manic and/or hostile were initially excluded, until there was significant reduction of their symptoms

**Behaviours targeted**
Appointment attendance

***Intervention details***

**Intervention group**
Standard treatment plus motivational interviewing: Received standard treatment plus a 15-minute session of feedback on their URICA scores at the beginning of each hospitalisation and 1 hour motivational interview 1 or 2 days before discharge. Specifically, URICA feedback included: (a) a brief description of the instrument; (b) the results in terms of profiles identified in previous research and composite scores, (c) an interpretation of these results based on the stages-of-changes model (the research therapists were provided with a script so that they could explain the profile or composite score that best described the patient), and (d) a discussion of the patient's views of the results and how they may influence his/her commitment to adhere to treatment recommendations. Such feedback, given in a neutral manner, is an integral part of motivational interviewing (S639)

The five principles of motivational interviewing are: (a) express empathy, (b) note discrepancies between current and desired behaviour, (c) avoid argumentation, (d) refrain from directly confronting resistance, and (e) encourage self-efficacy, or the patient's beliefs that he/she has the ability to change

**Comparison group**
Standard treatment: received an intake assessment by a multidisciplinary team, resulting in an individualised treatment plan, which identified psychiatric, psychological, medical, and social needs. During the hospitalisation, the patient worked with his/her team to accomplish the treatment plan objectives via pharmacological and psychosocial methods. Before discharge, all patients were provided an outpatient psychiatric clinic appointment, and the importance of attending this appointment was emphasised routinely. Although patients in standard treatment were administered the URICA, they were not given any feedback on the results

*continued*

# Data extraction table *contd*

***contd***
**S453, Swanson (1999)**[41]

***Intervention details* contd**

**Classification into stages**
URICA (S149):

Each stage of change is assessed with eight Likert-type items, each ranging from 1 to 5, with higher scores indicating greater endorsement of a particular stage. The four stages assessed were: (a) precontemplation (when individuals are denying the existence of a problem); (b) contemplation (when change and its pros and cons are being considered); (c) action (when actual steps towards change are taken); and (d) maintenance (when an individual attempts to sustain improvement). URICAs were completed based on the problem (i.e. psychiatric illness or substance abuse) that the patient considered to be of primary importance

S149: Replication of an earlier study (S99, S255 (see data extraction), S265). Stages of change scales: four scales operationally defining the four theoretical stages of change: precontemplation, contemplation, action, and maintenance. The four scales have 32 items, with eight items measuring each scale. The questionnaire has a five-point Likert format in which a score of 1 indicates strong disagreement and a score of 5 shows strong agreement

Precontemplation:
1. 'As far as I'm concerned, I don't have any problems that need changing'
5. 'I'm not the problem one. It doesn't make sense for me to be here'
11. 'Being here is pretty much of a waste of time for me because the problem doesn't have to do with me'
13. 'I guess I have faults, but there's nothing that I really need to change'
23. 'I may be part of the problem, but I don't really think I am'
26. 'All this talk about psychology is boring. Why can't people just forget about their problems?'
29. 'I have worries but so does the next person. Why spend time thinking about them?'
31. 'I would rather cope with my faults than try to change them'

Contemplation:
2. 'I think I might be ready for some self-improvement'
4. 'It might be worthwhile to work on my problem'
8. 'I've been thinking that I might want to change something about myself'
12. 'I'm hoping this place will help me to better understand myself'
15. 'I have a problem and I really think I should work on it'
19. 'I wish I had more ideas on how to solve my problem'
21. 'Maybe this place will be able to help me'
24. 'I hope that someone here will have some good advice for me'

Action:
3. 'I am doing something about the problems that had been bothering me'
7. 'I am finally doing some work on my problems'
10. 'At times my problem is difficult, but I'm working on it'
14. 'I am really working hard to change'
17. 'Even though I'm not always successful in changing, I am at least working on my problem'
20. 'I have started working on my problems but I would like help'
25. 'Anyone can talk about changing; I'm actually doing something about it'
30. 'I am actively working on my problem'

Maintenance:
6. 'It worries me that I might slip back on a problem I have already changed, so I am here to seek help'
9. 'I have been successful in working on my problem but I 'm not sure I can keep up the effort on my own'
16. 'I'm not following through with what I had already changed as well as I had hoped, and I'm here to prevent a relapse of the problem'
18. 'I thought once I had resolved the problem I would be free of it, but sometimes I still find myself struggling with it'
22. 'I may need a boost right now to help me maintain the changes I've already made'
27. 'I'm here to prevent myself from having a relapse of my problem'
28. 'It is frustrating, but I feel I might be having a recurrence of a problem I thought I had resolved'
32. 'After all I had done to try to change my problem, every now and again it comes back to haunt me'

**Validity of measure**
URICA (S149), a psychometrically sound instrument designed to measure readiness for, or stage of, change (S312). No additional information reported

S149: The original sample ($n$ = 155 (S99)) results demonstrated that the four components (scales) accounted for 58% of the total variance. The four scales with their respective coefficient alphas were as follows: precontemplation, 0.88; contemplation, 0.88; action, 0.89; maintenance, 0.88. Cluster analysis revealed nine distinct client profiles which accounted for 90% of the sample

S149: 327 adult psychiatric outpatients. The four components (scales) accounted for 45% of the total variance. Factor loadings ranged from 0.32 to 0.72 for precontemplation; from 0.38 to 0.70 for contemplation; from 0.31 to 0.70 for action; and from 0.48 to 0.69 for maintenance. Factor loadings were less than in the original study and one of the action items had a 0.63 loading on the contemplation stage component and 0.31 loading on the action stage component. The four scales with their respective alpha coefficients were as follows: precontemplation, 0.79; contemplation, 0.84; action, 0.84; maintenance, 0.82. Overall, the principal component, internal consistency, and cluster profile analyses demonstrated a replication of the original findings. Four distinct stages (precontemplation, contemplation, action, maintenance) and eight client stage profiles emerged

*continued*

## Data extraction table *contd*

***contd***
**S453, Swanson (1999)**[41]

***Intervention details* contd**

**Training of educators**
Therapists were four upper-level undergraduate psychology students. Training in motivational interviewing included the assignment of relevant readings followed by 6 hours of didactic instruction. Authors modelled the approach, and each therapist rehearsed and role played motivational interviewing techniques with feedback. In addition, the therapists received supervision on a daily basis

***Baseline characteristics***

**Gender**
Proportion female: I, 36%; C, 37%

**Age**
Mean age (SD):
I: 32.87 (9.03) years
C: 34.87 (8.90) years

**Stage of change**
Not stated. There were no significant differences between I and C on pre-treatment level of motivation as assessed by the URICA

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
$\chi^2$ analyses were used to test for differences between the two groups on categorical variables and the proportion of patients attending their first appointment. Independent *t*-tests were used to test for differences on continuous pre-treatment variables. For all analyses, statistical significance was set at $p < 0.05$ (two-tailed tests)

**Behaviour change**
Proportion who attended first aftercare appointment. Attendance was assessed by calling or sending research assistants to the various referral sites and having on-site personnel check attendance databases

Number of patients attended first outpatients sessions (%):
Dually diagnosed: I, 20 (42%); C, 7 (16%), $\chi^2 = 7.68$; $p < 0.01$
Psychiatric: I, 10 (63%); C, 5 (42%). NS
Total: I, 30 (47%); C, 12 (21%), $\chi^2 = 8.87$; $p < 0.01$

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
235 patients were approached about entering the study and 170 (72%) met all criteria. 121 (71%) were enrolled (I, 57; C, 64)

**Reasons**
65 ineligible: 29 (12.3% did not speak English; 17 (7.2%) too severely psychotic or manic; nine (3.8%) dementia; five (2.1%) mentally retarded; three (1.3%) deaf; and three (1.3%) medically unstable (unclear why this adds up to 66)

Primary reason ($n = 41$, 24%) for not being enrolled when eligible was a discharge during a weekend (no research staff available) or within 3 days of admission (too brief to implement the protocol); eight (4.7%) refused to participate, two of which gave a reason: one felt the information might be used to keep him hospitalised longer than he wished and the other had 'no problems' to discuss

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S453, Swanson (1999)**[41]

***Additional comments***

**Authors' conclusion**
The addition of a brief (1-hour and 15-minute) intervention based on motivational interviewing to an already intensive inpatient treatment programme (on average 14 days) may lead to substantially enhanced treatment adherence among psychiatric and dually diagnosed patients when considered together

**Authors' reported limitations**
Generalisibility is limited by the fact that no formal attention control group was used; the study only reported on attendance at the first outpatient clinic appointment, therefore it remains unclear whether motivational interviewing could increase longer term outpatient treatment adherence; the performance of therapists was not systematically monitored, therefor the therapist's adherence to the protocol cannot be assessed

**Comment**
URICA scores are not reported, although it was reported that they did not differ significantly at the baseline. Unclear how stages were used in the intervention. Appointment attendance is only an intermediate outcome towards the change in health behaviour

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S368, Velicer (1999)**[52]

**Country**
USA

**Aim**
To compare interactive and non-interactive smoking cessation interventions

**Model**
TTM

**Theoretical basis**
The expert-system intervention is based on the TTM. Most of the measures were TTM measures used to generate the interactive progress report. These measures included the ten processes of change, the pros and cons for a decisional balance and situational temptations

**Study type**
RCT

**Design**
A 2 intervention (interactive or non-interactive) × 4 contacts (one, two, three or six contacts) × 4 occasions (0, 6, 12 and 18 months) design was used. The interactive intervention was stage-matched expert-system reports plus manuals and the non-interactive intervention was stage-matched manuals. Contact occurred at 3-month intervals

**Setting**
Workplace

**Length of intervention**
18 months

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Adults in four offices of a managed care system (*n* = 2882)

**Inclusion criteria**
Smokers, aged between 18 and 75, and competence in English

**Exclusion criteria**
Serious illness

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
I1–I4: Interactive. Participants completed smoking cessation questionnaires and received individualised and detailed (computerised) feedback reports containing information about their progress and referred them to sections in their stage-matched self-help manuals (*n* = 1429)

The interactive expert system is described in detail elsewhere (S420, S630). It involves a series of individualised computer reports. An assessment is completed on the key variables of the TTM, the scores are compared with those of a reference group, and any previous scores for that individual and a complex set of decision rules determine the most relevant intervention materials for that individual, which are then assembled into a feedback report. The 2–4-page single-spaced reports are divided into four sections: (1) a description of the participant's current and previous stage of change, his or her pros and cons of quitting and feedback when necessary about their undervaluing the pros and overvaluing the cons of quitting; (2) feedback on the participant's use of up to six change processes that describe how he or she compared ipsatively with his or her previous assessment; (3) a description of tempting situations, with feedback on how to enhance self-efficacy in the most tempting situations; and (4) a section on strategies for taking small steps to progress to the next stage, such as having those in the contemplation stage delay the first cigarette of the day by an extra 30 minutes as a method of modelling smokers in the preparation stage. The feedback reports also referred participants to sections of the stage-matched self help manuals that were most relevant to their individual progress

I5–I8: Non-interactive. Self-help manuals were based on research on how self-changers progress through each stage of change and how they recycle through the stages if the relapse. The manuals instruct users about their particular stage of change and the processes they can use to progress to the next stage. On the basis of their pretest scores, participants were sent the manual matched to their individual stage of change and the manuals for all subsequent stages. In the multiple-contact conditions, a different manual was mailed on each occasion. Each smoker in each different stage at the baseline received the same package of material; the only difference was the number of manuals received at each occasion (*n* = 1453)

Both: I1–I4 and I5–I8 treatments were delivered in one of four doses: one, two, three or six mailings, at 3-month intervals

I1: Interactive/one mailing (*n* = 357)
I2: Interactive/two mailings (*n* = 359)
I3: Interactive/three mailings (*n* = 353)
I4: Interactive/six mailings (*n* = 368)
I5: Non-interactive/one mailing (*n* = 362)
I6: Non-interactive/two mailings (*n* = 366)
I7: Non-interactive/three mailings (*n* = 357)
I8: Non-interactive/six mailings (*n* = 360)

*continued*

# Data extraction table *contd*

***contd***
**S368, Velicer (1999)**[52]

***Intervention details* contd**

**Comparison group**
I1 to I8 are compared with each other

**Classification into stages**
A battery of measures based on the TTM were given to all participants at the baseline and at 6, 12, and 18 months. Specific stage-of-change instrument not reported

6-month prolonged abstinence is the same as being in the maintenance stage at that assessment (see 'Measures')

A general health survey was mailed that staged respondents on 15 different behavioural risk factors (see 'Procedure')

**Validity of measure**
"All measures have been shown to demonstrate adequate reliability and validity in previous smoking cessation studies"

**Training of educators**
Not applicable

***Baseline characteristics***

**Gender**
56% female

**Age**
Mean (SD):
Total: 38.4 (12.5) years
I1: 38.4 (12.0) years
I2: 38.6 (12.9) years
I3: 38.5 (12.2) years
I4: 39.7 (12.9) years
I5: 38.7 (12.6) years
I6: 38.9 (11.9) years
I7: 37.7 (12.6) years
I8: 38.4 (12.6) years

**Stage of change**
Precontemplation, 37%; comtemplation, 45%; and preparation, 18%

**Target behaviour**
Cigarettes per day (SD):
I1: 19.7 (12.6)
I2: 20.9 (14.0)
I3: 18.3 (11.8)
I4: 20.7 (12.1)
I5: 19.8 (13.2)
I6: 19.8 (10.5)
I7: 19.5 (12.0)
I8: 21.9 (12.8)

*continued*

# Data extraction table *contd*

***contd***
**S368, Velicer (1999)**[52]

***Results***

**Statistical techniques**
The $\chi^2$ statistic was used to examine differences between the two groups (I1-4 and I5-8). An ANOVA was performed on baseline scores of five variables (cigarettes per day, age, education, time to first cigarette, No. of 24 hours quit attempts/year) to test whether there were any pre-existing differences between any of the eight groups

Planned comparisons were performed using Levy's procedure (S640) to compare primary outcomes for each of the eight groups

**Behaviour change**
Point prevalence abstinence: a self-report measure of participants who have not smoked for at least 24 hours at each follow-up (S644)

A 7-day point-prevalence abstinence was also measured as an alternative

24-hours point-prevalence abstinence (%) at 6/12/18 months (7 days):
I1: 12.4 (13.0)/18.2 (16.5)/22.5 (21.7)
I2: 11.6 (11.5)/14.0 (12.9)/20.1 (19.5)
I3: 16.6 (15.7)/20.6 (19.8)/23.3 (23.2)
I4: 12.0 (11.1)/15.9 (15.6)/21.6 (21.3); I1–4: 13.2 (12.8)/17.2 (16.2)/21.6 (21.3)
I5: 9.9 (9.7)/14.4 (14.2)/16.7 (16.2)
I6: 9.7 (8.5)/13.8 (12.5)/16.0 (14.6)
I7: 8.0 (7.1)/13.8 (12.5)/16.0 (14.6)
I8: 11.8 (10.7)/14.3 (13.7)/18.3 (16.0); I5–8: 9.9 (9.0)/13.4 (12.8)/16.5 (15.5)

The overall test comparing I1 to I4 and I5 to I8 was significant at 6 months ($\chi^2 = 6.10$, $p < 0.05$), 12 months ($\chi^2 = 5.97$, $p < 0.05$) and 18 months ($\chi^2 = 7.97$, $p < 0.05$). I1 to I4 outperformed I5 to I8 for all four levels of dose. In all four of the comparisons, the difference at 18 months was significant, $p < 0.05$

Dose–response relationship: Although multiple-contact conditions were slightly superior to a single-contact condition overall, there was little difference, $p > 0.05$. Thus, there was no clear dose–response relationship

Prolonged abstinence: individuals are counted as former smokers if they have been abstinent for a prolonged period of time, such as 30 days or 6 months

30-days prolonged abstinence (%) at 6/12/18 months (6 months):
I1: 7.9 (–)/14.6 (3.4)/20.0 (9.8)
I2: 9.6 (–)/12.8 (4.8)/14.7 (8.1)
I3: 12.3 (–)/17.7 (7.9)/21.4 (11.2)
I4: 8.3 (–)/14.0 (4.9)/17.3 (8.2)
I1 to I4: 9.4 (–)/14.8 (5.2)/18.4 (9.3)
I5: 6.8 (–)/12.0 (5.3)/13.6 (7.2)
I6: 6.8 (–)/11.1 (3.6)/12.8 (6.4)
I7: 4.4 (–)/10.7 (2.1)/11.7 (4.7)
I8: 7.3 (–)/10.8 (3.7)/14.5 (7.5)
I5 to I8: 6.3 (–)/11.1 (3.7)/13.1 (6.4)

Comparison for four outcome measures (1 = point prevalence, 2 = 7-day abstinence, 3 = 30-day abstinence, 4 = 6-month abstinence) collapsed over number of contacts: the overall difference between I1 to I4 and I5 to I8 was significant ($p < 0.05$) at 18 months for 7-day point-prevalent abstinence, 30-day sustained abstinence, and 6-month prolonged abstinence

Cotinine validation: the standard for validating self-report measures of cessation. The authors object to the use of this instrument

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Ten processes of change (S254): not reported

Pros and cons for a decisional balance (S8, S642): not reported

Situational temptations (S643): not reported

**Adverse effects**
Not stated

**Other outcomes**
Comparison for four outcome measures (1 = point prevelence, 2 = 7-day abstinence, 3 = 30-day abstinence, 4 = 6-month abstinence) collapsed over number of contacts: the overall difference between I1 to I4 and I5 to I8 was significant ($p < 0.05$) at 18 months for 7-day point-prevalence abstinence, 30-day sustained abstinence, and 6-month prolonged abstinence

**Implementation measures**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S368, Velicer (1999)**[52]

***Withdrawals/economic evaluation***

**Number per group**
19,236 participants were contacted, 4653 were identified as smokers, and 85% (*n* = 3967) were recruited at the baseline. 2882 were randomly assigned to one of the eight treatment groups. The remaining 1085 participated in a separate intervention study (S641)

Follow-up at 6 months (lost to follow-up/refused): I1, *n* = 306 (42/9); I2, *n* = 276 (48/28); I3, *n* = 278 (54/29); I4, *n* = 292 (39/25); I5, *n* = 294 (54/11); I6, *n* = 309 (43/16); I7, *n* = 299 (54/12); I8, *n* = 304 (45/11)

Follow-up at 12 months (lost to follow-up/refused):
I1, *n* = 270 (65/20); I2, *n* = 250 (66/36); I3, *n* = 253 (70/38); I4, *n* = 245 (61/50); I5, *n* = 285 (53/21); I6, *n* = 281 (59/28); I7, *n* = 282 (62/21); I8, *n* = 272 (69/18)

Follow-up at 18 months (lost to follow-up/refused):
I1, *n* = 245 (75/35); I2, *n* = 224 (79/46); I3, *n* = 224 (82/55); I4, *n* = 220 (56/80); I5, *n* = 252 (63/44); I6, *n* = 251 (71/45); I7, *n* = 257 (78/30); I8, *n* = 256 (72/31)

**Reasons**
Two reasons: (1) lost to follow-up – those not able to be contacted by telephone or mail; (2) refused – participants who declined further participation in the study

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusions**
The results of this study indicate that disease state management programmes for smoking cessation using proactive recruitment procedures, interactive treatment procedures and stage-matched materials designed for an entire population of smokers can be successfully implemented and produce high impact rates in a managed care setting

This study supports three conclusions: (1) a proactive stage-matched intervention can produce high participation rates; (2) an interactive (expert system) intervention outperformed a non-interactive (stage-matched manuals) intervention for each of the four contact conditions; and (3) although multiple-contact conditions were slightly superior to a single-contact condition overall, there was little difference, and no clear dose-response relationship emerged

**Comment**
All interventions were stage-based. There was no comparison with non-stage-based interventions or no treatment

**S310**
No additional information

## Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S330, Wang (1994)**[53]

**Country**
Taiwan

**Aim**
The study assessed the feasibility and effectiveness of a stages-of-change model in cigarette smoking cessation counselling

**Model**
TTM

**Theoretical basis**
Health professional were given two lessons on the stage-of-change model for cigarette smoking and received specific guidelines for clinical counselling on cigarette smoking cessation. The cigarette smoking stages-of-change model developed by Prochaska and Goldstein (S645) indicates that most people follow a cyclic pattern in behaviour change, with relapse being the rule rather than the exception

**Study type**
RCT

**Design**
Second- and third-year residents, as well as part-time and full-time physicians of the depatment of family medicine participated; they were numbered and randomly assigned to one of three groups by number of years in practice. Clinic patients were interviewed using structured questionnaires. First interview in period May–July 1991, follow-up interviews 6 months later. At follow-up physicians recorded stage changes of each patient. Counselling was carried out at each clinic visit

**Setting**
Primary care

**Length of intervention**
6 months

***Inclusion/exclusion criteria***

**Participants**
Physicians and patients

**Population**
Clinic patients who smoked at least one cigarette a day. 93 patients were recruited, 82 of which completed the second questionnaire 6 months after the first interview

**Inclusion criteria**
Patients who smoked at least one cigarette a day

**Exclusion criteria**
Not stated

**Behaviours targeted**
Smoking

***Intervention details***

**Intervention group**
I1: Physicians (group 1) were given two lectures on the stages-of-change model for cigarette smoking and received specific practice guidelines for clinical counselling on cigarette smoking cessation

I2: Physicians (group 2) did not receive stages-of-change training but did receive a poster to be placed in the examination room to remind the doctor to conduct smoking cessation intervention in their clinic practice

**Comparison group**
Control group. No intervention, i.e. physicians received no lecture nor reminder and continued to practise in their usual style

*continued*

# Data extraction table *contd*

***contd***
**S330, Wang (1994)**[53]

***Intervention details* contd**

**Classification into stages**
No stage-of-change measure reported. The authors do present a "stage-of-change model in cigarette smoking" modified from Prochaska and Goldstein (S645):

1. Precontemplation: Individuals:
   1. Have no intention to change in the foreseeable future
   2. Demoralise their abilities to change
   3. Do not want to consider quitting cigarette smoking
   4. Are uninformed or under-informed about the risks of cigarette smoking
   5. Tend to defend their risky behaviour and refuse to change
   6. Avoid communications designed to help them stop smoking
   7. Overestimate the benefits of smoking (pros) and underestimate the hazards (cons)
2. Contemplation. Individuals:
   1. Are seriously thinking about changing in the next 6 months
   2. Evaluate the pros and cons of smoking as about equal
   3. Estimate the cons of smoking slightly higher than the pros
   4. Are quite ambivalent about quitting
   5. Doubt the long-term benefits of quitting will clearly outweigh the short-term costs
   6. When in doubt, they don't change
3. Preparation. Individuals:
   1. Are intending to change in the next month
   2. Have tried to quit in the past year
   3. Currently are taking small but significant steps toward action
   4. Delay their first cigarette a half hour longer in the morning
   5. Smoke five cigarettes less than contemplators and precontemplators
   6. Have tried to quit often
   7. Estimate the cons of smoking clearly outweigh the pros
4. Action. Individuals:
   1. Have overtly modified their risk behaviour, such as quitting smoking
   2. Completely stop smoking for 6 months and are at greatest risk for relapse
   3. Actively participate in quit smoking trials
5. Maintenance. Individuals:
   1. Work to continue a healthier lifestyle (free from the use of tobacco)
   2. Actively use processes of change to modify their environments and their experiences to prevent relapse

**Validity of measure**
Not stated

**Training of educators**
Physicians (group 1) were given two lectures on the stages-of-change model for cigarette smoking and received specific practice guidelines for clinical counselling on cigarette smoking cessation

Lessons on the stages-of-change model in cigarette smoking emphasised that most people follow a cyclic pattern in behaviour change, with relapse being the rule rather than the exception. Practice guidelines emphasised how each counselling session should be conducted. Physicians were taught to realise that counselling was more effective if only one participant was dealt with on each occasion. Physicians were instructed to follow each patient's smoking status by using staged criteria in each and every counselling session

***Baseline characteristics***

**Gender**
All: 95.7% male, 4.3% female
I1: 2.6% female
I2: 7.7% female
C: 3.6% female

**Age**
All: 37.6% < 40 years, 39.8% = 40–59 years, 22.6% > 60 year

Percentages < 40, 40–59 and > = 60 years:
I1: 35.9%/43.6%/20.5%;
I2: 53.8%; 30.8%/15.4%;
C: 25.0%/42.9%/32.1%

**Stage of change**
Not stated specifically. But "Most patients ... had tried to quit smoking at least once, were willing to try once more and had a receptive attitude to cigarette smoking cessation counselling. There were no significant differences among patient histories and attitudes in the three groups"

*continued*

## Data extraction table *contd*

***contd***
**S330, Wang (1994)**[53]

***Baseline characteristics* contd**

**Target behaviour**
Daily cigarette consumption, < 10, 10–20, or > 20 cigarettes (%):
I1: 20.5%/56.4%/23.1%
I2: 23.1%/61.5%/15.4%
C: 7.1%/85.7%/7.2%

***Results***

**Statistical techniques**
All data collected were examined by either $\chi^2$ or Fisher's exact test

**Behaviour change**
Analyses examined smoking behaviour change by patients by physician group

Cigarette smoking status after 6 months (% quit): I1, 28.6%; I2, 8.3%; C, 4.3%
I1 better than I2 ($p$ = 0.054), OR = 4.40 (95% CI, 0.76 to 32.77);
I1 better than C ($p$ = 0.02), OR = 8.80 (95% CI, 1.00 to 198.53)

Change of daily cigarette consumption by those who continue to smoke (% less than before): I1, 56%; I2, 9.1%; C, 13.6%
I1 better than I2 ($p$ = 0.0020), OR = 12.73 (95% CI, 2.10 to 99.51);
I1 better than C ($p$ = 0.0066), OR = 8.06 (95% CI, 1.61 to 45.65)

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Not stated

**Adverse effects**
Not stated

**Other outcomes**
Reasons to resume smoking examined. Necessity in social encounter = 40.7%. Peer influence = 27.8%. Weight gain = 18.5%. Health not improved = 7.4%. Others = 5.6%

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
93 patients were recruited, 82 (88.2%) completed the second questionnaire at 6 months

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
These data show that counselling coupled with the concept of stages-of-change model is feasible and effective to assist with cigarette smoking cessation

**Comment**
Not clear how the intervention was implemented; how much of the intervention was stage-based

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S272, Werch (1996)**[33]

**Country**
USA

**Aim**
To examine the effects of brief nurse consultations in preventing alcohol use among inner-city youth

**Model**
TTM (multicomponent motivational stages), social learning theory, health belief model

**Theoretical basis**
The theory-based STARS programme is founded on the multicomponent motivational stages prevention model (S646) which posits a continuum of stages in alcohol-use habit acquisition and change. Intervention messages were developed from risk factors identified within three behavioural theories underpinning the multicomponent motivational stages model, including health belief model, social learning theory, and behavioural self-control theory

**Study type**
RCT

**Design**
Participants were randomly assigned to I or C by computer. Baseline and 3 months post-tests (3 months after conclusion of STARS programme) were conducted at target school: self-administered questionnaire in classrooms

**Setting**
School

**Length of intervention**
Initial consultation and 6-weekly follow-up consultations (approximately 7 weeks)

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
138 sixth to eighth grade students attending an inner-city public school in Jacksonville, Florida, during the 1994–1995 school year

**Inclusion criteria**
Written parental consent was required

**Exclusion criteria**
Not stated (sixth grade students purposely were over-sampled because fewer seventh and eighth grade students were eligible to participate due to two earlier pilot tests of alcohol use interventions at the target site)

**Behaviours targeted**
Alcohol use (prevent use)

***Intervention details***

**Intervention group**
STARS programme. Students were provided with a two-phase prevention intervention individually administered by registered nurses at the target school site including: a brief initial health consultation, and six focused weekly follow-up consultations. Intervention materials were tailored to the stage of alcohol acquisition of the participant by addressing hypothesised risk factors extracted from the three underlying behavioural theories within the multicomponent motivational stages model

Standardised health consultations were provided by four nurses using consultation protocols which included a stage definition, objective, instructions, introduction, prevention messages, a prescription recommendation, and a contract agreement to avoid future alcohol use. The consultation protocols used a checklist format, specifically designed to better ensure that all the prevention content was reviewed with the client

Follow-up consultations were designed to provide more intensive and focused coverage of prevention content by targeting two risk factor constructs per session. Follow-up consultations addressed in a more intensive fashion the majority of risk factor constructs posited by the three behavioural theories underlying the multicomponent motivational stages prevention model

Session 1 targeted the social learning theory constructs environment and situation; session two targeted social learning theory constructs behavioural capability and self-efficacy; session 3 addressed social learning theory risk factors expectations and expectancies; session 4 addressed the health belief model risk factors perceived susceptibility and severity; session 5 targeted the social learning theory construct emotional coping responses and the behavioural self-control theory construct self-reinforcement; and session 6 targeted the behavioural self-control theory constructs self-monitoring and self-evaluation

Each follow-up consultation protocol included a stage definition, objective, directions, review of prevention messages related to two targeted risk factor constructs, two or more exercises designed to enhance understanding of the prevention content and build essential resistance skills, and nurse-client contracts with summary and prescription recommendations

*continued*

## Data extraction table *contd*

***contd***
**S272, Werch (1996)**[33]

***Intervention details* contd**

**Comparison group**
Control group. No intervention

**Classification into stages**
Not stated

Comment: Stage of change in this study is assessed as the readiness to start drinking (alcohol use was very low and approximately 93% were in precontemplation stage at the baseline)

**Validity of measure**
Not stated

**Training of educators**
Nurses received an intensive half day training which included demonstrations, role playing and feedback from the project staff on how to implement the STARS intervention components

***Baseline characteristics***

**Gender**
Overall: 59% female
I: 56% female
C: 61% female

**Age**
Mean (SD):
Overall: 12.2 (1.16) years
I: 12.3 (1.24) years
C: 12.0 (1.04) years

**Stage of change**
I: 94% precontemplation
C: 93% precontemplation

**Target behaviour**
Life-time alcohol use: I, 22%; C, 29%
Alcohol frequency: I, 0.15; C, 0.15
Alcohol quantity: I, 0.15; C, 0.18
Heavy alcohol use: I, 0.03; C, 0.03

***Results***

**Statistical techniques**
Two-tailed *t*-tests were conducted comparing I and C difference scores, thereby allowing a repeated measures analysis of the outcome data

**Behaviour change**
Self-reported alcohol and other drug use (supported by 'dip stick' saliva pipeline procedure immediately prior to questionnaire). Alcohol consumption patterns were measured from five items adopted from previous government-funded alcohol and other drug use prevention research, and included items measuring lifetime use, 30-day and 7-day frequency of use, and 30-day and 7-day quantity of use. Two additional items measured heavy drinking, defined as consuming five or more drinks in a row during the past 30 days and 2 weeks (references provided, but no more information; See S62 for more details)

Percentage of participants using alcohol at post-test (no baseline data):
30-day use: I, 5%; C, 10%. NS
7-day use: I, 4%; C, 12%. NS
30-day heavy use: I, 0%; C, 5%. NS

Pretest/post-test alcohol use:
Alcohol frequency: I, pretest, 0.15; post-test, 0.16; C, pretest, 0.15; post-test, 0.39; NS
Alcohol quantity: I, pretest, 0.15; post-test, 0.13; C, pretest, 0.18; post-test, 0.25; NS
Heavy alcohol use: I, pretest, 0.03; post-test, 0.00; C, pretest, 0.03; post-test, 0.10 ($t$ = –2.33, 120 df, $p$ = 0.02)

**Stage movement**
Baseline stage distribution only reported for precontemplation: I, 94% precontemplation; C, 93% precontemplation

Post-test:
I: 97% precontemplation; 2% contemplation; 0% preparation; 2% action; 0% maintenance
C: 94% precontemplation; 0% contemplation; 2% preparation; 2% action; 3% maintenance

*continued*

# Data extraction table *contd*

***contd***
**S272, Werch (1996)**[33]

***Results* contd**

**Health**
Not stated

**Intermediate outcomes**
Cognitive, social, and behavioural risk factors associated with alcohol consumption

Pretest/post-test alcohol risk measures:

Drinking consequences (negative consequences experienced during drinking):
I: pretest, 9.41; post-test, 9.58
C: pretest, 9.05; post-test, 9.33
NS

Intentions:
I: pretest, 5.43; post-test, 6.05
C: pretest, 4.93; post-test, 6.13
NS

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

***Withdrawals/economic evaluation***

**Number per group**
138 participants randomised (I, 68; C, 70). At post-test 14 participants were lost to attrition (I, 8; C, 6)

**Reasons**
Not stated

A greater proportion of drop-outs (50%) reported a family alcohol or drug problem compared to non-drop outs (23%)

A smaller percentage of drop-outs (79%) reported to be in a pre-contemplation stage of alcohol use compared to non-drop outs (95%)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

Alcohol stage of change was reported as a measure of alcohol use

**Authors' conclusion**
A significant difference was found on heavy drinking. No differences were found between groups on other alcohol use measures. This study's findings indicate that a series of brief nurse consultations appear to reduce heavy alcohol consumption among urban school youth

**Comment**
The main conclusion should be that there is overall little difference in effectiveness between I and C. Trends in favour of I seem mainly driven by the fact that alcohol measures increased in C between pre and post-test. The extra attention on alcohol use by introducing the STARS programme at the school, without giving preventative interventions, might have caused this

This study suffered from an extreme ceiling effect. No significant differences could be expected unless C would dramatically increase alcohol consumption. I and C hardly used alcohol before and after intervention, unclear why these outcome measures were chosen

Comment: Stage of change in this study is assessed as the readiness to start drinking (alcohol use was very low and approximately 93% were in precontemplation stage at the baseline)

## Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S062, Werch (1999)**[70]

**Country**
USA

**Aim**
To test the effectiveness of stage-based strategies for preventing alcohol use among youth using primary healthcare providers

**Model**
TTM

**Theoretical basis**
S55: STARS for families is based on the Multi-Component Motivational Stages (McMOS) prevention model, which posits stages of habit acquisition that parallel, and exist in succession with, the stages of habit change described in the seminal work of Prochaska and DiClemente

**Study type**
RCT

**Design**
Participants were randomly assigned by computer to I or C within targeted schools. Baseline (beginning fall semester), post-test (concluding spring semester), and 6-month follow-up data (beginning subsequent fall semester) were collected at targeted schools

**Setting**
School

**Length of intervention**
A multicomponent intervention provided in the sixth grade and a booster programme in the seventh grade

***Inclusion/exclusion criteria***

**Participants**
Lifestyle risk

**Population**
Sixth grade students from one neighbourhood and one bussed middle school in the economically disadvantaged inner city of Jacksonville, Florida

**Inclusion criteria**
Written parental consent was required. Eligibility criteria included not having withdrawn from school and having < 50% absenteeism

**Exclusion criteria**
Not stated

**Behaviours targeted**
Alcohol use

***Intervention details***

**Intervention group**
STARS for family programme. Intervention consisted of standardised health consultations provided by seven nurses using consultation protocols. The consultation protocols used a checklist format, with as many as 12 specific risk factors addressed during the health consultation based on pre-intervention data collected using the Youth Alcohol and Drug Survey. During the spring semester, the intervention consisted of mailed prevention postcards requesting that the parents/guardians take a few minutes to read and talk about the important key fact found on the card – to help their child stay away from alcohol. Each tri-fold postcard was colour coded to identify a new key fact. Each key fact addressed a particular risk factor for each student. Based on pre-intervention student risk factor status, parents/guardians were mailed up to ten postcards, addressing the same risk factors found in the health consultations. The intervention is described in more detail elsewhere (S55)

S55: STARS for families includes: (1) a media related materials prevention strategy involving a physician-endorsed parent/guardian letter providing key facts for parents to read and discuss with their children about avoiding alcohol; (2) an interpersonal prevention strategy involving a brief one-on-one health consultation provided by a nurse about why and how the child should avoid alcohol; and (3) an environmental prevention strategy involving nine physician-endorsed weekly family-based prevention lessons including facts and activities that parents and children work on together to complete. All intervention components are matched to the specific stage status and risk/protective factors of individual youth

**Comparison group**
Minimal intervention control. Received a 15-page alcohol education booklet and were asked to read the material on their own

**Classification into stages**
Not stated

**Validity of measure**
Not stated

**Training of educators**
Not stated

*continued*

# Data extraction table *contd*

***contd***
**S062, Werch (1999)**[70]

***Baseline characteristics***

**Gender**
50% female

**Age**
Mean age (SD) of all students: 12.08 (0.96) years

**Stage of change**
Not stated

**Target behaviour**
Not stated

***Results***

**Statistical techniques**
Data were analysed using statistical procedures contained in SPSS 7.5 for Microsoft Windows 95. Because of numerous participant differences between the two schools, school site data were analysed as separate samples. Pretest alcohol use and demographic data were analysed using $\chi^2$ analyses for dichotomous variables and *t*-tests for continuous measures. MANOVAs were used for primary analyses examining follow-up alcohol use outcome data comparing experimental groups. Factorial MANOVAs were used for secondary analyses examining differential intervention effects by prior alcohol consequences as suggested by other prevention researchers (S647)

**Behaviour change**
Alcohol consumption patterns included 30 and 7 day frequency of use (scored on five- or seven-point scales ranging from 0 to 5 or more drinks); heavy drinking, defined as having consumed five or more drinks in a row during the last 30 days and 2 weeks (scored on five-point scales ranging from 0 to 10 or more times)

Mean alcohol use at follow-up for neighbourhood/bussed school (SD):

Alcohol frequency:
I: 0.12 (0.63)/0.12 (0.55)
C: 0.39 (1.57)/0.31 (1.20)
NS

Alcohol quantity:
I: 0.12 (0.70)/0.12 (0.51)
C: 0.12 (0.59)/0.24 (0.94)
NS

Heavy alcohol use:
I:0.12 (0.22)/0.05 (0.30)
C: 0.16 (0.78)/0.07 (0.45)
NS

6-month follow-up alcohol use measures were lower for I students at both schools, compared to C students, though not significantly

Subanalyses: Students with prior consequences ($n$ = 49) and no prior consequences ($n$ = 432) analysed separately, showed that bussed students in I who had prior alcohol problems had less intention to drink ($p < 0.05$)

**Stage movement**
Not stated

**Health**
Not stated

**Intermediate outcomes**
Intentions to think about, plan, try, and use alcohol in the next year (four items, scored on a four-point scale of yes, probably yes, probably no, no)

Mean intentions towards alcohol use at follow-up for neighbourhood/bussed school (SD):
Intentions: I, 5.15 (2.63)/5.52 (2.82); C, 5.24 (2.49)/5.81 (3.15). NS

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

*continued*

## Data extraction table *contd*

***contd***
**S062, Werch (1999)**[70]

***Withdrawals/economic evaluation***

**Number per group**
Of the eligible sixth-grade students, 87% were recruited. At follow-up 74% of the sample completed a questionnaire ($n$ = 481; neighbourhood school, 65%, bussed school, 80%); I, 86 drop-outs; C, 83 drop-outs

**Reasons**
Drop outs were more likely to be Caucasian ($p$ = 0.02), and to have experienced greater mean negative alcohol consequences than non-drop outs ($p$ = 0.04)

I drop-outs experienced greater alcohol problems than C drop-outs ($p$ = 0.06)

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
This study found that students from the bussed school who received I showed reductions in quantity of alcohol use and intention to drink in the future, 6 months after intervention

**Authors' reported limitations**
(1) Only two schools involved. Limiting the generalisibility
(2) Considerable attrition, particularly within the neighbourhood school sample (more white youth and those with greater alcohol problems were lost at follow-up)
(3) Intervention contamination may have occurred

**Comment**
Main conclusion: overall there were no significant differences between intervention groups at follow-up

The stage of change was not assessed, and it was not clear to what extent the intervention was stage based or the results provide evidence to (not) support stage-based interventions

# Data extraction table *contd*

***Study reference No., author (year), country of origin, aim, design details***

**S338, Woollard (1995)**[35]

**Country**
Australia

**Aim**
To assess whether a lifestyle modification programme implemented by nurse counsellors in a general practice setting would improve blood pressure control in treated hypertensive patients

**Model**
TTM, self-efficacy

**Theoretical basis**
The patients were counselled using a stage of change behavioural model and motivational interviewing. Behaviour modification techniques included a model that assessed patients readiness to change behaviour and focused on patients self-efficacy. Motivational interviewing was used as a counselling strategy (S650)

**Study type**
RCT

**Design**
RCT with three conditions. Assessments before and after 18-weeks intervention period

**Setting**
Primary care

**Length of intervention**
18-weeks intervention period

***Inclusion/exclusion criteria***

**Participants**
Existing disease

**Population**
Treated hypertensive patients in 13 general practices from a wide socio-economic range in the Perth metropolitan area

**Inclusion criteria**
Treated for hypertension, able to be contacted by telephone

**Exclusion criteria**
Not stated

**Behaviours targeted**
Alcohol, fat, salt intake, weight, smoking, exercise

***Intervention details***

**Intervention group**
All: GPs continued routine treatment of all patients throughout the programme

I1 + I2: Contacted every 4th week by the nurse counsellor throughout the 18-week period. The patients were counselled using a stage of change behavioural model and motivational interviewing to: reduce alcohol consumption, dietary fat and salt intake and weight; cease smoking; and increase leisure time physical activity

Patients were provided with an educational manual that discussed each risk factor from a perspective of both programme goals and incorporation of behaviour modification strategies

Programme objectives:
(1) Weight reduction following the Australian Nutrition Foundation guidelines
(2) In drinkers a reduction in alcohol intake to one standard drink a day (10 g) for women and two standard drinks (20 g) for men
(3) Salt restriction to less than 90 mmol/day
(4) Less than 30% daily energy dietary fat with restriction of saturated fat intake to 10%
(5) An increase in regular leisure time physical activity
(6) Smoking cessation

I1: Low intervention group. One practice appointment (a single face-to-face appointment were they were given their initial results) and five telephone counselling appointments (lasting 15 minutes)

I2: High intervention group. Six appointments in the general practice (lasting 45 minutes)

**Comparison group**
Usual GP care

*continued*

## Data extraction table *contd*

***contd***
**S338, Woollard (1995)**[35]

***Intervention details* contd**

**Classification into stages**
Measurement of stages of change (patients readiness to change their behaviour) and self-efficacy (S648). No description reported

**Validity of measure**
Not stated

**Training of educators**
Lifestyle counselling was delivered by nurses trained in behaviour modification techniques, no more details reported

***Baseline characteristics***

**Gender**
Percentage female:
I1: 44.2%
I2: 44.7%
C: 50%

**Age**
Mean age:
I1: 58 years
I2: 58 years
C: 59 years

**Stage of change**
Not stated

**Target behaviour**
Mean baseline alcohol (g/week) (95% CI):
I1: 256 (134 to 378)
I2: 182 (115 to 248)
C: 190 (128 to 252)

Fat intake: not reported

Salt intake: not reported

Smoking behaviour: not reported

Physical activity: not reported

***Results***

**Statistical techniques**
The data were analysed using $\chi^2$ ANOVA, Duncan's *t*-tests for *post hoc* comparisons and linear regression, with significance values set at $p < 0.05$. Values are expressed as mean with 95% CIs

**Behaviour change**
1-week retrospective alcohol consumption diary (S649), and 24-hour urinary sodium were measured

Change in alcohol intake (g/week) (95% CI): I1, –164 (–274 to –55); I2, –83 (–123 to–42); C, –12 (–57 to 32). No significant changes in I2 and C, but reduction in I1 versus C significant at $p < 0.05$

Fat intake: not reported

Change in sodium intake (mmol/24 hours, 95% CI): I1, –38 (–59 to–17); I2: –21 (–42 to–0.6); C, 4 (–15 to 24). No significant changes in I2 and C, but reduction in I1 versus C significant at $p < 0.05$

Smoking behaviour: not reported

Physical activity: not reported

**Stage movement**
Stage of change: not reported

*continued*

# Data extraction table *contd*

***contd***
**S338, Woollard (1995)**[35]

***Results* contd**

**Health**
Blood pressure was taken as the mean of three measurements (DINAMAP 1846 SX), on each occasion taken at 3-minute intervals after sitting quietly for 10 minutes. Height and weight were measured

Blood pressure change scores from the baseline:
Delta systolic blood pressure (mmHg, 95% CI): I1, –6 (–12 to –2); I2, –8 (–14 to –4); C, –4 (–9 to 0.5)
Delta diastolic blood pressure (mmHg, 95% CI): I1, –1 (–4 to 1.9); I2, –2 (–5 to 0.04); C, 1 (–1 to 4)

In a regression model with final systolic blood pressure corrected for initial systolic blood pressure as an independent variable and two dummy variables entered for I1 and I2 there were significant falls in systolic blood pressure and diastolic blood pressure for I2 (systolic blood pressure = 6 mmHg, adjusted $r^2 = 0.39$, $p < 0.05$; diastolic blood pressure = –5 mmHg, adjusted $r^2 = 0.38$, $p < 0.05$)

Change in weight (kg, 95% CI): C, 0.05 (–0.8 to 0.9); I1, –1 (–2.2 to –0.1); I2, –1.7 (–2.7 to –0.6). No significant changes in I1 and C, but reduction in I2 versus C significant at $p < 0.05$

**Intermediate outcomes**
Self-efficacy: Not reported

**Adverse effects**
Not stated

**Other outcomes**
Not stated

**Implementation measures**
Not stated

The programme was popular with both patients and general practitioners (unclear how this was assessed)

***Withdrawals/economic evaluation***

**Number per group**
566 treated hypertensive patients in 13 general practices were identified. 46 GPs sent patients letters and the first 219 who could be contacted by telephone were invited. 166 agreed and were randomised. Baseline results presented for 146 patients (I1, 52; I2, 46; C, 48; gender distribution in I2 reported as 26 males and 21 females, $n = 47$)

**Reasons**
Not stated

**Economic evaluation**
No

**Economic methods**
Not stated

**Cost outcomes**
Not stated

***Additional comments***

**Authors' conclusion**
Compared with C, I1 showed significant decreases in alcohol and salt intake while I2 resulted in significant decreases in both weight and blood pressure. Nurse counselling targeted to specific aspects of lifestyle can improve blood pressure control and weight in treated hypertensive patients over 18 weeks. Its longer-term effectiveness in the management of hypertension warrants further evaluation

**Comments**
Conference proceeding, not a full paper

Outcomes on fat intake, smoking and exercises not reported

No explanation for differences in effectiveness between I1 and I2

**Request for more information from authors**
No reply

*I, Intervention group; C, control group*

# Appendix 5

## Quality assessment checklist and quality assessment table

Quality assessment was carried out using an existing quality assessment tool[20] by one reviewer and checked by a second, using the following predefined criteria

(answer categories: N/S, not stated; yes; no; N/A, not applicable)

1. Method of randomisation: was the method of intervention allocation reported?
2. Concealment of allocation: was the intervention allocation concealed?
3. Blinding of participants: were participants blind to the existence of other conditions? (This item was scored as 'not applicable' if a group receiving no intervention at all was included; in this case blinding was considered not possible.)
4. Blinding of outcome assessors: were outcome assessors blinded to intervention allocation?
5. Blinding of care-providers: were care-providers or educators blind to the existence of other conditions? (Not applicable if intervention did not involve educators.)
6. Baseline comparability: were the groups similar at the baseline?

6a. Adjustment for baseline differences: if groups were not similar at the baseline, were analyses adjusted for these differences? (Not applicable if groups were similar at baseline.)

7. Completeness of follow-up: did the last follow-up include 80% or more of randomised participants?
8. Inclusion criteria: were the eligibility criteria specified?
9. Point estimates and variability: were the point estimates and a measure of variability presented for the primary outcome measure (behaviour change)?
10. Handling of drop-outs (intention-to-treat analysis): was an intention-to-treat analysis used or were differences between drop-outs and completers explained?
11. Description of statistical methods used: were the statistical methods used described?
12. Sample size calculation: was a calculation of statistical power or required sample size reported?
13. Comparability of treatment: were the groups treated identically other than the named interventions? (This item was scored as 'yes' unless it was clear from the paper that contamination of interventions may be present.)
14. Stage-of-change assessed at the baseline: were participants' stage-of-change assessed before the intervention?
15. Stage-of-change instrument validated: was the stages-of-change instrument validated?
16. Interventions tailored: were interventions tailored to individual stage of change? (Answer categories: yes; Uncl., unclear; Part., partial (e.g. only booster sessions are stage matched), HP, intervention aimed at health professionals (includes some data on participants); separate)
17. Quality of implementation reported: was the quality of the implementation recorded?
18. Details of training reported: were details of the training of the people giving the intervention reported? (Not applicable if intervention did not involve educators.)

# Quality assessment table

| Study details | Methodological quality* | Randomisation | Concealment of allocation | Blinding of | | | Baseline comparability | Adjustment for baseline differences | Completeness of follow-up | Inclusion criteria | Point estimates and variability | Drop-outs (intention-to-treat) | Description of statistical methods | Sample size calculation | Comparability of treatment | Stage-of-change assessed at baseline | Stage-of-change instrument validated | Interventions tailored | Quality of implementation | Details of training reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Participants | Outcome assessors | Care providers | | | | | | | | | | | | | | |
| ***Prevention*** | | | | | | | | | | | | | | | | | | | | |
| S025 Aveyard[69], 1999 | 9/13 | Yes | N/S | N/S | N/S | No | Yes | N/A | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| S062 Werch[70], 1999 | 7/13 | Yes | N/S | N/S | N/S | No | Yes | N/A | No | Yes | Yes | Yes | Yes | N/S | Yes | N/S | No | Uncl. | N/S | N/S |
| S272 Werch[33], 1996 | 6/12 | Yes | N/S | N/A | N/S | No | Yes | N/A | Yes | N/S | No | Yes | Yes | N/S | Yes | Yes | N/S | Uncl. | N/S | Yes |
| ***Smoking cessation*** | | | | | | | | | | | | | | | | | | | | |
| S402 Butler[34], 1999 | 9/13 | Yes | Yes | N/S | Yes | No | Yes | N/A | No | Yes | Yes | Yes | Yes | Yes | No | Yes | N/S | Yes | N/S | Yes |
| S227 Lennox[45], 1998 | 8/13 | N/S | Yes | Yes | N/S | No | No | Yes | No | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | HP | Yes | Yes |
| S353 Resnicow[50], 1997 | 7/13 | N/S | N/S | N/S | N/S | No | No | Yes | Yes | Yes | Yes | No | Yes | Yes | Yes | Yes | N/S | Yes | Yes | Yes |
| S021 Dijkstra[43], 1999 | 6/11 | N/S | N/S | N/A | N/S | N/A | No | Yes | Yes | Yes | No | Yes | Yes | N/S | Yes | Yes | N/S | Yes | N/S | N/A |
| S172 Pallonen[48], 1998 | 6/12 | Yes | N/S | N/S | N/S | N/A | Yes | N/A | No | Yes | Yes | No | Yes | N/S | Yes | Yes | N/S | Yes | Yes | N/A |
| S330 Wang[53], 1994 | 6/13 | N/S | N/S | N/S | N/S | No | Yes | N/A | Yes | Yes | Yes | N/S | Yes | N/S | Yes | Yes | N/S | HP | N/S | Yes |
| S255 DiClemente[49], 1991 | 5/13 | Yes | N/S | N/S | N/S | No | No | No | Yes | Yes | No | No | Yes | No | Yes | Yes | Yes | Yes | No | Yes |
| S452 Morgan[46], 1996 | 5/13 | N/S | N/S | N/S | N/S | No | No | No | Yes | Yes | No | Yes | Yes | N/S | Yes | N/S | N/S | Yes | Yes | Yes |
| S368 Velicer[52], 1999 | 4/12 | N/S | N/S | N/S | N/S | N/A | Yes | N/A | No | Yes | No | No | Yes | N/S | Yes | Yes | N/S | Yes | N/S | N/A |
| S290 Berman[42], 1995 | 4/13 | Yes | N/S | N/S | N/S | No | N/S | N/S | No | Yes | No | No | Yes | N/S | Yes | Yes | N/S | Part. | Yes | N/S |
| S458 Gritz[44], 1993 | 3/13 | N/S | N/S | N/S | N/S | No | N/S | No | No | Yes | No | Yes | Yes | N/S | No | Yes | N/S | Part. | Yes | Yes |
| S510 Sinclair[51], 1999 | 3/13 | N/S | N/S | N/S | N/S | No | N/S | N/S | Yes | Yes | No | N/S | N/S | N/S | Yes | N/S | N/S | Yes | Yes | Yes |
| S234 Pallonen[47], 1994 | 2/12 | N/S | N/S | N/A | N/S | No | N/S | N/S | No | Yes | No | No | Yes | No | No | Yes | N/S | Yes | Yes | N/S |
| ***Physical activity*** | | | | | | | | | | | | | | | | | | | | |
| S001 Harland[37], 1999 | 11/12 | Yes | Yes | N/A | Yes | No | Yes | N/A | Yes | Yes | Yes | Yes | Yes | Yes | Yes | N/S | N/S | Uncl. | Yes | Yes |
| S305 Cardinal[58], 1996 | 6/12 | N/S | N/S | N/S | N/S | N/A | Yes | N/A | No | Yes | Yes | Yes | Yes | N/S | Yes | Yes | Yes | Yes | N/S | N/A |
| S480 Cash[59], 1997 | 6/12 | N/S | N/S | N/A | N/S | No | Yes | N/A | Yes | Yes | Yes | No | Yes | N/S | Yes | Yes | Yes | Yes | No | N/S |
| S073 Goldstein[55], 1999 | 5/13 | N/S | N/S | N/S | N/S | No | Yes | N/A | Yes | Yes | Yes | N/S | Yes | N/S | No | Yes | Yes | Yes | Yes | Yes |
| S089 Braatz[56], 1999 | 5/13 | N/S | N/S | N/S | N/S | No | No | Yes | Yes | Yes | Yes | No | Yes | N/S | No | Yes | Yes | Uncl. | Yes | No |
| S165 Graham-Clarke[57], 1994 | 5/13 | N/S | N/S | N/S | N/S | No | No | Yes | No | Yes | Yes | N/S | Yes | N/S | Yes | N/S | N/S | Uncl. | N/S | Yes |
| S061 Peterson[54], 1999 | 3/11 | N/S | N/S | N/A | N/S | N/A | N/S | N/S | No | N/S | Yes | No | Yes | No | Yes | Yes | Yes | Yes | Yes | N/A |

## Quality assessment table *contd*

| Study details | Methodological quality* | Randomisation | Concealment of allocation | Blinding of | | | Baseline comparability | Adjustment for baseline differences | Completeness of follow-up | Inclusion criteria | Point estimates and variability | Drop-outs (intention-to-treat) | Description of statistical methods | Sample size calculation | Comparability of treatment | Stage-of-change assessed at baseline | Stage-of-change instrument validated | Interventions tailored | Quality of implementation | Details of training reported |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | Participants | Outcome assessors | Care providers | | | | | | | | | | | | | | |
| ***Dietary change*** | | | | | | | | | | | | | | | | | | | | |
| S479 Lutz[36], 1996 | 9/12 | Yes | N/S | N/A | N/S | N/A | Yes | N/A | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes | N/S | Yes | Yes | N/A |
| S288 Brug[38], 1998 | 7/13 | N/S | N/S | N/S | N/S | No | Yes | N/A | Yes | N/S | Yes | Yes | Yes | Yes | Yes | Yes | N/S | Uncl. | Yes | N/S |
| S378 Havas[60], 1998 | 7/13 | Yes | N/S | N/S | N/S | No | N/S | Yes | No | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | Part. | Yes | Yes |
| S084 Kristal[39], 2000 | 3/12 | N/S | N/S | N/A | N/S | No | No | No | No | N/S | No | No | Yes | Yes | Yes | N/S | No | Part. | No | No |
| S446 Baker[61], 1999 | 3/12 | N/S | N/S | N/A | N/S | No | Yes | N/A | Yes | N/S | N/S | N/S | N/S | N/S | Yes | Yes | N/S | Uncl. | N/S | N/S |
| ***Multiple lifestyle change*** | | | | | | | | | | | | | | | | | | | | |
| S478 Scales[66], 1998 | 8/13 | Yes | Yes | No | N/S | No | Yes | N/A | Yes | Yes | Yes | Yes | Yes | N/S | No | Yes | Yes | Yes | Yes | N/S |
| S350 Steptoe[63], 1999 | 7/13 | Yes | N/S | N/S | N/S | No | Yes | N/A | No | Yes | Yes | No | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| S219 Glasgow[62], 1995 | 6/12 | N/S | N/S | N/A | N/S | No | Yes | N/A | No | Yes | Yes | No | Yes | Yes | Yes | N/S | N/S | Uncl. | Yes | Yes |
| S380 Gritz[64], 1998 | 5/12 | N/S | N/S | N/A | N/S | No | N/S | N/S | No | Yes | Yes | No | Yes | Yes | Yes | Yes | No | Uncl. | Yes | N/S |
| S338 Woollard[35], 1995 | 5/13 | N/S | N/S | N/S | N/S | No | N/S | N/S | Yes | Yes | Yes | N/S | Yes | N/S | Yes | Yes | N/S | Uncl. | N/S | N/S |
| S418 Oliansky[65], 1997 | 4/13 | Yes | N/S | N/S | N/S | No | N/S | N/S | No | Yes | No | No | Yes | N/S | Yes | Yes | N/S | Yes† | N/S | N/S |
| ***Mammography screening*** | | | | | | | | | | | | | | | | | | | | |
| S027 Rakowski[68], 1998 | 6/12 | Yes | Yes | N/A | Yes | No | N/S | N/S | No | Yes | No | No | Yes | No | Yes | N/S | N/S | Yes | N/S | Yes |
| S022 Crane[67], 1998 | 4/13 | N/S | N/S | N/S | N/S | No | No | Yes | No | Yes | No | No | Yes | N/S | Yes | Yes | N/S | Yes | Yes | Yes |
| ***Treatment adherence*** | | | | | | | | | | | | | | | | | | | | |
| S453 Swanson[41], 1999 | 6/13 | Yes | N/S | N/S | N/S | No | Yes | N/A | Yes | Yes | No | N/S | Yes | N/S | Yes | Yes | Yes | Yes | N/S | Yes |

* *The maximum score for the 13 methodological quality items is 11 or 12 if 'blinding of care-providers' and/or 'blinding of participants' is not applicable*

† *The intervention in clinic A only was classified as fully stage-based*

# Appendix 6

# Taxonomy of non-stage-based models aimed at behaviour change

During the initial search for trials to be included in this review, several non-stage-based models and theories were identified. These are summarised below. They can be divided into two broad categories: motivational theories and action theories.[105] Motivational theories propose that motivation determines behaviour, and therefore the best predictors of behaviour are factors that predict or determine motivation (or intention). Action theories may include motivational elements, but postulate that other factors are necessary to predict behaviour.

## Motivational theories

### Health belief model

The health belief model suggests that when faced with the possibility of changing personal health behaviour, individuals consider the advantages and disadvantages of change and then take a rational decision.[106] Behaviour will depend on the individual's view of their susceptibility to the illness or danger, the perceived seriousness of the illness and the relative costs and benefits of change. Change is often considered to be the result of some trigger, or 'cue to action', such as a health campaign or life event.

### Health Action Model

The Health Action Model builds on the health belief model by incorporating the additional element of self-esteem.[107] The model suggests that individuals with high self-esteem are likely to be more receptive to health messages, since if you value yourself you are more likely to want to keep yourself well. The model identifies determinants of health decisions (e.g. self-esteem) and factors that effect health decision-making, such as knowledge. Individuals are considered to be in charge of their own health if complementary health promotion work is directed towards making the environment within which health decisions are made conducive and supportive.

### Protection motivation theory

The protection motivation theory also builds on the health belief model.[108] Like the health belief model, it proposes that health-related behaviours are a product of four psychological components: these are an individual's perception of the severity of a health condition; their susceptibility to it; the effectiveness of the proposed health behaviour; and their confidence that they can perform the behaviour. In contrast to the health belief model, which sees these components as having a direct effect on behaviour, the protection motivation theory proposes that their effect is indirect and mediated by behavioural intentions. Later versions of the protection motivation theory also incorporate an additional emotional component (fear).

### Social cognitive theory

Social cognitive theory proposes that behaviour is determined by incentives (see operant conditioning below) and expectancies.[109] Three kinds of expectancies are described in the theory: situation–outcome expectancies, outcome expectancies and self-efficacy expectancies. Situation–outcome expectancies are beliefs about how events are connected (e.g. 'smoking is bad for your health'). Outcome expectancies refer to beliefs about the consequences of performing behaviour (e.g. 'if I stop smoking, I will put on weight'). Self-efficacy expectancies are beliefs about one's ability to perform the behaviour (e.g. 'I can stop smoking'). All of these are seen to be important in health behaviours, but self-efficacy expectancies have been found to be the most important in empirical studies.[110]

### Theory of reasoned action

The theory of reasoned action is a general social psychological theory, which was developed to explain a wide range of behaviours, including health behaviours.[111] It assumes that behaviour is a function of the intention to perform that behaviour. A behavioural intention is determined by the strength of an individual's attitude towards the behaviour, and by subjective norms. Attitudes towards the behaviour are proposed to arise from a combination of beliefs about its consequences (behavioural beliefs) and evaluations of those consequences (outcome evaluations). Subjective norms are based on perceptions of the views of

other individuals or groups (normative beliefs), and the strength of the individual's desire to gain approval of these groups (motivation to comply). The theory of reasoned action only applies to behaviours that an individual can perform at will, that is, behaviours that are under volitional control.

### Theory of planned behaviour

The theory of planned behaviour is an adaptation of the theory of reasoned action, and was developed to predict behaviours that are not under volitional control.[112] It proposes that the strength of an individual's intention to engage in a behaviour, and the degree of control he or she feels he or she has over that behaviour (perceived behavioural control) are the proximal determinants of engaging in it. The perceived behavioural control construct in the theory of planned behaviour is closely related to (and originates from) the concept of self-efficacy in social cognitive theory. Perceived behavioural control is a function of beliefs about factors likely to facilitate or inhibit the behaviour (control beliefs).

## Action theories

### Operant conditioning

Operant conditioning proposes that behaviours that have positive consequences for the individual are likely to be repeated whereas those that have unpleasant consequences will become less frequent.[113] Positive consequences can take a variety of forms, from material incentives (e.g. financial rewards), through social incentives (e.g. maintaining a positive relationship) to personal incentives (e.g. achieving a desired goal). The principle that positive consequences promote repetition of behaviour is well established and has been widely and successfully used to understand behaviour and behaviour change.

### Social learning theory

Social learning theory proposes that our own behaviours are affected by our observation of other peoples' behaviour.[114] If we see someone we admire or respect being rewarded in some way for a behaviour, then we are more likely to repeat that behaviour ourselves. This model is often used to explain the uptake of risky behaviours such as smoking or excessive alcohol consumption.

### Implementation intentions

Gollwitzer has made the distinction between 'goal intentions' and 'implementation intentions'.[115] A goal intention is an intention to perform a behaviour or achieve a goal (e.g. 'I intend to take more exercise'). This is conceptually close to the behavioural intention construct in the theory of planned behaviour. By contrast, implementation intentions are explicit plans about when and where a goal intention will be achieved. Gollwitzer argues that by creating an implementation intention, people effectively transfer control of the behaviour to the environment – establishing cues to action. For example, by saying that 'I will cycle to work on Tuesdays and Fridays'.

# Appendix 7
## Excluded studies

Treasure JL, Katzman M, Schmidt U, Troop N, Todd G, de Silva P. Engagement and outcome in the treatment of bulimia nervosa: first phase of a sequential design comparing motivation enhancement therapy and cognitive behavioural therapy. *Behav Res Ther* 1999; **37**(5):405–18.
- Reply from author: intervention was not stage-matched.
- "What the therapist did was not overtly matched to stage-of-change based on questionnaires, although there is always implicit matching as those not in action are reluctant to do the work."

Stewart JE, Wolfe GR, Maeder L, Hartz GW. Changes in dental knowledge and self-efficacy scores following interventions to change oral hygiene behavior. *Patient Educ Counsel* 1996;**27**(3):269–77.
- No behaviour assessed/no stage movement.

Haddock J, Burrows C. The role of the nurse in health promotion: an evaluation of a smoking cessation programme in surgical pre-admission clinics. *J Adv Nurs* 1997;**26**(6):1098–110.
- The intervention was delivered by the researcher according to the participants' learning needs; no mention of stages-of-change to tailor the intervention.

Richmond R, Mendelsohn C. Interventions for smokers in general practice. Translating theory and research into practice. In: Slama K, editor. 9th Tobacco and Health World Conference, Paris 1994. Vol. 9. New York: Plenum Press. p. 477–80.

Richmond RL, Makinson RJ, Kehoe LA, Giugni AA, Webster IW. One year evaluation of three smoking cessation interventions administered by general practitioners. *Addict Behav* 1993;**18**:187–99.
- Reply from author: intervention was not stage-matched.
- "This was not a stage based study."

Ni Mhurchu C, Margetts B, Speller V. Randomised clinical trial comparing the effectiveness of two dietary interventions for patients with hyperlipidaemia. *Clin Sci* 1998;**95**(4):479–87.
- Reply from author: intervention was not stage-matched.
- "Stage of change was not used in the intervention because all people in the intervention groups received motivational interviewing irrespective of SOC."

Kreuter M, Oswald DL, Bull FC, Clark EM. Are tailored health education materials always more effective than non-tailored materials? *Health Educ Res* 2001;**15**:305–15.
- Reply from author: intervention was not stage-matched.
- "The tailoring assessment, which took place over the phone at enrolment, did not include stage of readiness, … The rationale for not putting stage items on the tailoring assessment was a combination of limited time for interviews, limited space for content on the tailored materials, a relative lack of variability on readiness since 'motivation' was an inclusion criteria for participation, and our experience that stage is no more important a tailoring variable than other factors."

Weinstein ND, Lyon JE, Sandman PM, Cuite CL. Experimental evidence for stages of health behavior change: the precaution adoption process model applied to home radon testing. *Health Psychol* 1998;**17**(5):445–53. [S337]
- The expert panel advised that this trial should be removed as it did not target a health-related behaviour.

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## Feedback

The HTA Programme and the authors would like to know your views about this report.

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***We look forward to hearing from you.***

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