NETSCC, HTA

5th November 2010

An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach'

EARS

(Exercise Assisted Reduction then Stop smoking)

Study Protocol

HTA no: 07/78/02
ISRCTN no: 13837944
UKCRN Study ID:
LREC no: 10/H0106/59

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LIST OF ABBREVIATIONS

CI	Confidence Interval
CO	Carbon Monoxide
DMEC	Data Monitoring and Ethics Committee
DRCP	Devonport Regeneration Community Partnership
ES	Effect Size
FTND	Fagerström Test for Nicotine Dependence
GP	General Practitioner
HT	Health Trainer
HTA	Health Technology Assessment
mCEQ	Modified Cigarette Evaluation Questionnaire
MI	Motivational Interviewing
MPSS	Mood and Physical Symptoms Scale
NARS	Nicotine Assisted Reduction then Stop
NHS	National Health Service
NRT	Nicotine Replacement Therapy
PA	Physical Activity
PAR-Q	Physical Activity Readiness Questionnaire
PCRN	Primary Care Research Network
PCT	Primary Care Trust
PI	Principal Investigator
PM	Project Manager
QALY	Quality Adjusted Life Years
RCT	Randomised Controlled Trial
SPSS	Statistical Package for the Social Sciences
SSS	Stop Smoking Services
TSC	Trial Steering Committee

2. STUDY TEAM CONTACT DETAILS

Name/Position	Address	Telephone/Fax	E-mail
Professor Adrian Taylor *Principal Investigator* *Professor of Exercise and Health Psychology*	School of Sport and Health Sciences, University of Exeter, Heavitree Road, Exeter EX1 2LU	Tel: 01392 264747 Fax: 01392 264726	A.H.Taylor@exeter.ac.uk
Dr Michael Ussher *Senior Lecturer in Psychology*	Division of Community Health Sciences, St George's, University of London, Cranmer Terrace, London SW1 0RE	Tel: 020 8725 5605 Fax: 020 8266 6470	mussher@sgul.ac.uk
Dr Paul Aveyard *Senior Lecturer and GP*	Department of Primary Care & General Practice, University of Birmingham, Edgbaston, Birmingham B15 2TT	Tel: 0121 414 8539 Fax: 0121 414 8529	p.n.aveyard@bham.ac.uk
Professor Robert West *Professor of Health Psychology and Director of Tobacco Studies*	Department of Epidemiology and Public Health, University College London, Brook House, 2-16 Torrington Place, London WC1E 6BT	Tel: 0207 679 6633 Fax:	robert.west@ucl.ac.uk
Professor Rod Taylor *Associate Professor in Health Services Research*	Clinical Research Methodology Unit, Peninsula Medical School, Noy Scott House, Barrack Road, Exeter EX2 5DW	Tel: 01392 406980 Fax: 01392 406936	rod.taylor@pms.ac.uk

Professor John Campbell *Professor of General Practice and Primary Care*	General Practice and Primary Care, Peninsula Medical School, St Lukes Campus, Heavitree Road, Exeter EX1 2LU	Tel: 01392 262740 Fax:	john.campbell@pms.ac.uk
Dr Ann Rowlands *Senior Lecturer in Sport and Exercise Physiology*	School of Sport and Health Sciences, University of Exeter, St Lukes Campus, Heavitree Road, Exeter EX1 2LU	Tel: 01392 262878 Fax: 01392 263726	A.V.Rowlands@ex.ac.uk
Dr Colin Green *Senior Lecturer in Health Economics*	Clinical Research Methodology Unit, Peninsula Medical School, Noy Scott House, Barrack Road, Exeter EX2 5DW	Tel: 01392 406915 Fax: 01392 406936	colin.green@pms.ac.uk
Dr Colin Greaves *Senior Research Fellow*	Primary Care, Peninsula College of Medicine and Dentistry, St Lukes Campus, Heavitree Road, Exeter EX1 2LU	Tel: 01392 262751 Fax:	colin.greaves@pms.ac.uk
Dr Rupert Jones *Clinical Research Fellow*	Respiratory Research, Peninsula College of Medicine and Dentistry, ITTC, Tamar Science Park, 1 Davy Road, Plymouth PL6 8BX	Tel: 01752 764293 Fax:	rupert.jones@pms.ac.uk
Professor Susan Michie *Co-Director Centre for Outcome Research and Effectiveness*	Centre for Outcomes Research and Effectiveness, Dept. of Psychology, University College London,	Tel: 020 7679 5930 Fax: 020 916 8511	s.michie@ucl.ac.uk

	1-19 Torrington Place, London WC1E 7HB		
Dr Richard Ayres *Clinical Lecturer and GP, Lead for Plymouth Teaching PCT, Medical Director for Devonport Community Regeneration Project*	Postgraduate Medical Education, Peninsula College of Medicine and Dentistry, John Bull Building, Tamar Science Park, Research Way, Plymouth PL6 8BU	Tel: 01752 437 300 Fax:	richard.ayres@pms.ac.uk
Dr Richard Byng *Senior Lecturer in Primary Care*	Primary Care, Peninsula College of Medicine and Dentistry, Tamar Science Park, Research Way, Plymouth PL6 8BU	Tel: 01752 437 300 Fax:	Richard.byng@pms.ac.uk
Tom Thompson *Project Manager*	Primary Care, Peninsula College of Medicine and Dentistry, Tamar Science Park, Research Way, Plymouth PL6 8BU	Tel: 01752 437 300 Fax:	T.P.Thompson@exeter.ac.uk
TO BE APPOINTED *Health Trainer/Researcher*			
TO BE APPOINTED *Health Trainer/Researcher*			
TO BE APPOINTED *Administration Assistant*			

3. SUMMARY OF STUDY

Title:	An exploratory trial to evaluate the effects of a physical activity intervention as a smoking cessation induction and cessation aid among the 'hard to reach'.
Short Title:	Exercise Assisted Reduction then Stop (trial acronym: EARS)
Objectives:	Primary Objective: To develop a multi-component PA intervention aimed at helping smokers (not intending to quit in the next month), among 'hard to reach' groups, to cut down. Secondary Objectives: (i) To assess via interview the acceptability of such a PA intervention as an aid to cutting down, among 'hard to reach' smokers. (ii) To assess via interview the acceptability of recruitment, assessment and randomisation procedures within a pilot pragmatic randomised controlled trial to compare the effects of a PA intervention versus brief advice (usual care) on quitting, among 'hard to reach' smokers. (iii) To obtain an estimate of the intervention (PA v brief advice) effect size, relative risk and its precision to inform sample size calculations for a fully powered trial, from a pilot randomised trial to assess carbon monoxide confirmed abstinence at 4 weeks post-quit date. (iv) To assess process measures at 4, 8 and 16 weeks post-baseline including: self-reported cigarettes smoked; number of quit attempts; self-reported quality of life; mood & physical symptoms; cravings; PA by self-report and accelerometer (in a sub-sample); pharmacological and behavioural support used; and weight. (v) To estimate the resource use and costs associated with delivery of the intervention, and to pilot methods for determining future cost-effectiveness analyses.
Design:	A randomised Controlled Trial involving 120 heavy smokers (>15 cigarettes per day) from 'hard to reach' groups who wish to cut down the number of cigarettes they smoke but do not wish to quit within the next month. Randomised equally to brief advice or PA intervention. Week 1: Screening/Baseline Assessment: demographics, height and weight, expired CO measurement, randomisation, questionnaires, accelerometer (1 week, sub sample), Week 4: Questionnaires Week 8 (or start of quit attempt): Questionnaires, height and weight, expired CO measurement, accelerometer (1 week, sub sample) Week 16 (or 4 weeks post quit): Follow Up Assessment: Questionnaires, height and weight, expired CO measurement, accelerometer (1 week, sub

	sample)
Treatment Schedule:	Brief Advice: Written and verbal information on NHS Stop Smoking Service (SSS) with information on the benefits of quitting and how to quit provided at baseline. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS. PA Intervention: Written and verbal information on NHS SSS with information on the benefits of quitting and how to quit provided at baseline. Smokers will select one of three strategies for smoking reduction and receive weekly support to attain this. Face to face physical activity support sessions will be conducted at weeks 1, 4, and 8 along with supportive phone calls in each intermediate week. The communications will involve tailored physical activity counselling, guidance on using a free pedometer to achieve SMART goals, and signposting to local exercise opportunities with subsidised access as required, with the aim of increasing the amount of regular physical activity completed by each participant for both implicit and explicit purposes as an aid to quit. Those expressing a desire to make a quit attempt will subsequently be referred to NHS SSS.
Treatment Groups:	(i) Brief Advice; (ii) Brief advice + PA Intervention

4. MAIN RESEARCH QUESTION

What is the effect of a physical activity intervention designed to aid 'hard to reach' smokers wishing to cut down, but not quit, on smoking reduction and cessation, when compared to brief advice?

5. PLAIN ENGLISH SUMMARY

5.1 BACKGROUND

NHS smoking cessation treatment aims to help people to remain abstinent after an abrupt quit attempt but even with the best available behavioural and pharmacological support as few as 22% are abstinent at 12 months. The addition of physical activity to usual care has been shown, among sufficiently large studies, to increase quit rates[1].

For an abrupt quit attempt recruitment into an NHS SSS is difficult among 'hard to reach' smokers. However, surveys suggest that between 57-66% of smokers would like to cut down but are not yet ready to quit. Nicotine Assisted Reduction then Stop (NARS) studies have shown increased quit attempts and cessation rates[2], but NICE guidelines do not recommend NRT products for smoking reduction and only one study (pre-post one group design) has suggested that physical activity may help in cessation induction[3]. Exercise Assisted Reduction then Stop (EARS) could be effective for several reasons: (1) Increasing physical activity before tackling a quit attempt may be easier; (2) physical activity related breathlessness may prompt a desire to quit; (3) it builds confidence to use physical activity to cope with cravings, stress and low mood, before and after quitting; and (4) it may attenuate the stronger reinforcement value from each cigarette, observed when smokers try to cut down. We therefore wish to examine if physical activity v brief advice enhances smoking reduction attempts and successful quitting for 4 weeks, among 'hard-to-reach' smokers from lower-socio-economic groups, building on the experiences of a wide range of professionals and residents in Plymouth.

5.2 INTERVENTION DESIGN

In Phase 1 we will establish appropriate ways to increase physical activity while reducing smoking among 'hard-to-reach' smokers, using an individually tailored counselling intervention, which can be described in a manual and replicated elsewhere. From our extensive previous quantitative and qualitative information on client preference and needs and professional views, and new information from interviews in the present study with smokers and community action-type leaders (eg, health promotion specialists) we will develop and pilot the EARS intervention targeted at 'hard to reach' heavy smokers (>15 cigarettes per day) wishing to cut down but not yet quit.

5.3 METHODS

Phase 1 will explore the utility of various approaches (eg, GP invitation, community advertising) to recruit 'hard to reach' smokers, and pilot the intervention and assessment procedures. Phase 2 will aim to provide information from which to plan a larger trial. In an exploratory trial involving 120 smokers (wishing to cut down) will be randomly allocated equally to: (i) brief advice on cutting down; (ii) physical activity intervention + brief advice; with support from an NHS SSS for those wishing to quit, with ongoing support for physical activity, for those in (ii). After baseline screening

and assessments those in (ii) will receive the EARS intervention package (Health Trainer counselling, use of pedometers and guidance into free physical activity options). Smokers wishing to quit in both conditions will be offered support by the Plymouth NHS SSS for up to 6 weeks. Those in (ii) will receive additional parallel weekly Health Trainer support to remain physically active. The smoking status of all participants will be assessed, using expired carbon monoxide measures, and self-reported continuous abstinence, at 8 and 16 weeks after baseline, and at 4 weeks after any quit attempt. This will provide information to estimate expected effects at longer follow-up points. Secondary outcomes at 8 and 16 weeks (and at 4 weeks after any quit attempt) will include: number of quit attempts; self-reported quality of life; withdrawal symptoms, cravings, readiness to quit, confidence to quit and stay quit, use of NHS SSS after quitting and pharmacological support; physical activity and weight. All assessments will be conducted by a Health Trainer/researcher (in a GP surgery or community setting). Taped interviews will be conducted with GPs, stop smoking advisors and smokers to establish information on feasibility and acceptability of the recruitment, randomisation, intervention and assessment procedures.

Smokers will be recruited with the support of the Primary Care Research Network, community advertising and community outreach workers. Trial management will be with the support of the Peninsula Medical School's accredited Clinical Trials Unit, and follow Good Clinical Practice. A 0.7 Project Manager (for 27 months) will co-ordinate the study, lead Phase 1, support recruitment in Phase 2, and help with data analysis and report writing. Two 0.7 FTE Health Trainers/researchers (for 19 months) will recruit, and do baseline screening, randomisation, all assessments and provide the PA intervention.

6. BACKGROUND AND RATIONALE

6.1 REDUCING HEALTH INEQUALITIES

NHS priorities for helping people to quit smoking focus on identifying a quit date and abrupt cessation, with pharmacological and behavioural support[4]. After one year, only about 4% of those who attempt to quit alone succeed[5], whereas that figure is almost doubled (7%) with NHS support in primary care and almost quadrupled (15%) with the support of NHS specialist stop smoking services[6]. In recent years greater resources have been directed towards helping 'hard to reach' groups to quit in an attempt to address health inequalities[7]. These groups include the unemployed, those in social class grade C2-E (among whom smoking prevalence rates reduced only 1.3% compared with 2.3% for grade AB-C1, from 2007-8[8]), people with mental health problems, ethnic minorities, and young single parents. However, it is challenging to recruit such smokers into NHS services that focus on abrupt cessation[9]. New approaches are needed to increase the number of 'hard to reach' smokers who make a quit attempt with NHS support and hence successfully quit, such as locating services in community settings with most need4, developing roles for NHS outreach workers (eg, Health Trainers)[10], and developing complex behaviour change interventions that target multiple behaviours among 'hard to reach' groups[11].

6.2 ABRUPT CESSATION VERSUS CUT DOWN THEN QUIT

Abrupt cessation is the preferred NHS approach because it is believed that if smokers cut down prior to quitting they may gain greater reward from each cigarette and hence find quitting even more

difficult[4]. Yet, in the English Smoking Toolkit Study, 57% of current smokers reported they were in the process of cutting down, of whom a quarter were using NRT, with no difference across social class5. This suggests that the majority of smokers are using other cognitive and/or behavioural approaches to cut down. In a US survey interest in reduction was highest among those who were less interested in quitting and heavier smokers [12]. There is also evidence from epidemiological studies that cutting down is associated with an increased probability of trying to quit. Recent evidence suggests that smokers who do not intend to quit in the next month, but cut down with the use of nicotine replacement therapy (NRT), are more likely to make a quit attempt and be abstinent at follow-up[2]. However, there is a lack of research on behavioural support programmes for those wishing to cut down, to inform NHS policy and practice.

6.3 WHY REDUCTION PROGRAMMES MAY WORK

There are several reasons why a reduction programme may work, namely:

(1) Increasing the length of time between cigarettes may reflect steps in moving from the identity of a heavy or moderate smoker to that of a light then non-smoker. Identity shifts are important in smoking cessation. (2) Increasingly longer periods between smoking a cigarette may progressively raise confidence to abstain, which may generate intentions to actually quit and reduce the risk of relapse. (3) With fewer and fewer cigarettes the association between environmental cues and conditioned response (to smoke) weakens, which will lead to low urges to smoke when abstinent. (4) A lower drug intake might reduce drug dependence thus increasing the ability to abstain completely. Nicotine assisted reduction then stop (NARS) programmes aim to facilitate these changes by providing a dose of nicotine to relieve cravings and withdrawal symptoms. Other behavioural strategies for reducing cravings and withdrawal symptoms may also be efficacious but little is known about their effectiveness.

6.4 PA AS AN AID TO SMOKING REDUCTION AND CESSATION

Theoretically, increasing PA may help reduction in several ways:

1) Systematic reviews of 20[1]and 14[13] studies showed that during temporary smoking abstinence, a short bout of PA (eg, a brisk 15 min walk or 5 mins of seated isometric exercise) reduces cravings and withdrawal symptoms. PA also appears to reduce reactivity to smoking cues, which have been shown to predict lapses and relapse during a quit attempt,[14] and delays ad libitum smoking[14-17]. It would therefore appear appropriate for smokers to explicitly use short bouts of PA to aid smoking reduction and quitting.

2) PA enhances mental health which has been associated with reduced smoking. Also, doing more PA may cause a shift from the identity of a smoker to that of an exerciser; consequently increasing PA may have implicit positive effects on smoking habits.

3) Increasing PA while cutting down (then quitting) may reduce weight gain. In prospective population surveys and trials weight gain and fear of weight gain is associated with quitting smoking, especially among women and initially heavier smokers[18-20], with an average of 7kg gained within a year of quitting[21]. Increasing PA has been suggested as a useful strategy to prevent weight gain[22], not only by increased energy expenditure but also through self-regulation of energy intake,

particularly emotional snacking in response to withdrawal symptoms such as depression and anxiety[23, 24]. The effects of exercise on preventing weight gain are likely dependent on the exercise dose[25].

6.5 CHRONIC EFFECTS OF EXERCISE AS AN AID TO SMOKING CESSATION

Four adequately-powered RCTs have assessed physical activity as an aid for smoking cessation after an abrupt quit attempt[1] with encouraging results. One study[22] showed that vigorous intensity structured (gym-based) exercise on three days a week over 15 weeks plus behavioural support produced significantly higher cessation rates at 12 months, relative to controls, among female smokers (Odds Ratio=2.4, 95% CIs=1.0 to 5.6). However, smokers may be more interested in moderate rather than vigorous activity. Three studies have investigated the effects of promoting moderate intensity exercise. One study showed that four sessions of supervised exercise produced higher abstinence rates, versus controls, at the end of 12 weeks of treatment (EOT) (OR=3.2, 95%,CIs=1.6 to 6.6), but not at 6 or 12 months[26]. Another study found that supervised weekly exercise for 8 weeks significantly increased abstinence rates at 3 months (OR=2.8, 95%, CIs=1.3 to 6.8), but not at 12 months, among women smokers[27]. However, women achieving at least 110 minutes/week of activity were significantly more likely to achieve cessation at 12 months. A final study, involving 3 of the researchers, found that, although there were some increases in unsupervised activity levels, physical activity counselling alone (7 sessions) did not increase abstinence rates at EOT or 12 months[28, 29]. The latter study was the only one to focus on unstructured PA, but this was equivalent to only 5-10 mins per week of cognitive–behavioural physical activity counselling, incorporating decision balance sheets, goal-setting, relapse prevention planning and self-monitoring, embedded within standard smoking cessation counselling, and advice to use 15 mg 16 h nicotine patches after quitting, throughout the treatment program. The target was to accumulate 30 mins of moderate intensity PA per day on at least 5 days per week and among those remaining in the study at 4 weeks after quitting (ie, were abstinent at the end of the intervention) those in the PA group had increased time doing moderate and vigorous intensity exercise by an average of 120 mins compared with 24 mins in the control group.

There is wide variation in the timing of the start of the exercise programme in the studies reviewed that focused on smoking cessation[1]. For those beginning exercise either on or after the quit date[26, 30-32] success rates may have been hampered by the demand to cope simultaneously with two major changes in health behaviour[31, 33, 34]. Furthermore, where the exercise programme started after a period of smoking abstinence the potential for exercise to moderate withdrawal symptoms during this period was lost[35, 36]. Increasing PA prior to any quit attempt (planned or otherwise) may address concerns about simultaneous health behaviour changes. Indeed NHS guidance for stop smoking advisors is to avoid changing diet and exercise during a quit attempt[4], and as a result advisors generally spend little time promoting PA[37], although recent evidence suggests that simultaneous health behaviour changes may not be detrimental[38]. However, a sample of advisors who did advocate simultaneous health behaviour changes had developed integrated strategies for using one behaviour change to positively support a quit attempt (Taylor et al, in press).

6.6 TRIALS INVOLVING PA PROMOTION AMONG SMOKERS

Taylor et al[39, 40] reported no effect of increasing PA on self-reported smoking but did find that smokers in a GP exercise referral scheme were more likely to increase their readiness to quit smoking. A similar finding was reported by Hardcastle et al[41] (and personal communication) in response to a PA and dietary motivational interviewing intervention, in which participants with multiple coronary heart disease risk factors (eg, mean body mass index was 34, some smokers) were offered up to 5 sessions of lifestyle counselling. The findings of these two studies are limited by the numbers of smokers involved but support the idea that physical activity interventions are acceptable to many and may implicitly change thoughts about smoking.

6.7 INTEREST IN USING PA AS AN AID TO QUITTING

109 Canadian community dwelling people with mental health problems, who were receiving smoking cessation treatment, completed a survey assessing perceived interest in physical activity and a 24-item decisional balance questionnaire reflecting potential advantages and disadvantages of becoming more physically active[42]. In the only literature to have considered the use of physical activity specifically among such smokers, 63% reported being interested in assistance in becoming more active and there were generally positive beliefs about the benefits.

Patten and colleagues [43, 44] reported on two studies involving exercise targeted at smokers with a history of alcoholism. While the studies were not strongly designed to determine the effects of exercise, they did demonstrate that the participants were willing to increase their physical activity. In one study[43], behavioural counselling plus exercise was as effective as standard treatment, or behavioural counselling plus nicotine gum in reducing cigarettes smoked, prior to quitting.

In a survey of 181 smokers attending an NHS Stop Smoking Clinic in England and Scotland, 22% of quitters reported currently using PA to control their smoking, and 34% of those who had made a previous quit attempt reported having used PA as an aid[45]. Those more ready to use PA as a cessation aid and more physically active, held more positive beliefs regarding confidence to do more PA and expected value of doing more PA to aid quitting. The survey involved participants attending stop smoking services but little is known about the acceptability of PA as an aid to cutting down. In an audit of 178 smokers in a Plymouth GP practice, in a mainly deprived area, 39% were prepared to both gradually cut down over 8 weeks and were interested in taking part in research involving exercise as an aid to cutting down.

Several cycles of collaborative action research with advisors in Plymouth and South Birmingham helped us to develop and pilot our 'Walk-2-Quit' intervention, embedded within NHS SSS. In brief this involved providing all clients with a Self-Help Guide (SHG) and a pedometer prior to quitting. A variety of cognitive-behaviour approaches were used to increase client's beliefs in the value of PA as an aid, and in their own confidence to use PA as it may best help them with quitting smoking. In a group setting, it was not possible to stage-match the intervention on an individual basis but the Transtheoretical Model [31, 46] provided the framework in which to direct focus towards changing cognitions about PA as an aid. In a later section our proposed intervention will refer to and build on this extensive feasibility work (developed for the context of supporting abrupt quitters).

Following pre-clinical research that supported the efficacy of using isometric exercise for reducing cravings after temporary abstinence[47] Al-Chalabi and colleagues[48] examined the acceptability and feasibility of using MP3 files with guided isometric exercises (eg, placing the palms of the hands together and pushing) to manage urges to smoke within a pilot randomised trial. While the study was not designed to detect differences in quit rates, about 80% of quitters reported using the isometric exercises each week, intended to continue doing so and would recommend these techniques to others trying to stop.

6.8 OTHER SMOKING REDUCTION TECHNIQUES WITH BEHAVIOURAL SUPPORT

There are several techniques which have been proposed for smoking reduction which are still under evaluation. These include:

1) Setting a smoking time at equally spaced intervals throughout the day depending on the number of cigarettes smoked (eg. a 16 a day smoker smokes on the hour every hour during a 16 hour day).

2) Identify half hour blocks where smoking occurs each day and attempt to reduce the blocks over time.

3) Rank the least to most important cigarettes of the day and aim to cut them down in order, although this can be problematic as smokers can easily identify the least and most important cigarettes but not the ones in the middle.

4) Schedule a percent reduction in cigarettes each week.

We plan to offer smokers specific choices (1or 2 from above) to take place as a reduction strategy alongside increasing PA.

6.9 SUMMARY

Much of the above research has taken place in the context of helping smokers following an abrupt quit attempt. However, given the potential mechanisms for how physical activity may be beneficial and the need to consider behavioural approaches to helping smokers to cut down, and possibly quit, the proposed study seeks to provide the first scientific study on using PA for smoking reduction, then as an aid for quitting if a quit attempt is made. Given that physically active smokers are more likely to have attempted cessation in the past year, than inactive smokers[49], it seems justified to explore if helping smokers to become physically active will lead to more quit attempts and successful quitting. In the context of health behaviour change for 'hard to reach' smokers support to overcome environmental, financial, social, cognitive and emotional barriers to increase PA and reduce smoking will be needed.

7. AIMS AND OBJECTIVES

We aim to perform an RCT of the effects of behavioural counselling to reduce smoking and increase PA to make it easier for 'hard to reach' smokers to cut down then quit, compared to brief advice on SSS and the benefits of quitting.

7.1 MAIN OUTCOME MEASURE

- Confirmed expired CO concentration (Bedfont Smokerlyzer) abstinence at 4 weeks post-quit (if a quit attempt is made).

7.2 OTHER OUTCOME MEASURES

- Self reported cigarettes smoked per day (in past week) (to derive a figure for N (%) reducing cigarettes by ≥50% and CO by ≥25%)
- Prolonged abstinence[50, 51]
- Quality of life (EQ-5D and SF12)

7.3 PROCESS MEASURES

- Confidence to quit and importance of quitting
- Subjective stress[52]
- MPSS [53]
- Strength of desire to smoke[54]
- mCEQ[55]
- Body weight

7.4 BASELINE MEASURES AND DEMOGRAPHICS

- Age
- Gender
- Marital status
- Highest education qualification
- Ethnicity/race
- Occupational status
- Co-habitation with other smokers
- Cigarettes smoked per day
- Type of cigarette smoked
- Quit attempts within the previous 8 months
- Fagerström Test for Nicotine Dependence (FTND)
- Self reports of smoking and expired CO levels

7.5 OTHER MEASURES

- Reasons for withdrawing from the study
- Reasons for missing pre and post quit support sessions
- Adverse or serious adverse events
- Number of pre- and post-quit sessions completed with the HT (and if a quit attempt is made with a SSS advisor) in the intervention arm
- Alcohol consumption

8. ETHICAL APPROVAL

R & D approval to undertake the study will be obtained from Plymouth Teaching Primary Care Trust.

9. POPULATION

9.1 PROPOSED SAMPLE SIZE

Given the lack of research involving behavioural smoking reduction interventions in the 'hard to reach' population, the effect size of our intervention is uncertain (see above). We will therefore use the pilot trial in order to provide a quantitative estimate of the intervention impact (relative to control) in order to inform the sample size estimation for a definitive trial. Using data from a recent HTA meta-analysis of trials of smoking cessation[2] we have undertaken a scenario analysis in order to examine the impact on our estimation of effect size precision given differing pilot trial sample sizes and plausible effect sizes (see table). In the case of recruiting 120 participants (60 in each arm) if 5% are successfully quit after 4 weeks of making an attempt, in the control group, then we would need an effect size of 4 for the confidence interval to not include 1.0. With a smaller ES in the pilot RCT, clearly, for the CI to not include 1.0, the N would have to be considerably larger.

Control quit rate*	Sample size^ (control:Rx)	Effect size Relative risk	Precision of effect size estimate (95% CI)**
5%	60 (1:1) 60 (1:1)	2.00 4.00	0.19 to 20.89 0.47 to 33.72
5%	120 (1:1) 120 (1:1)	2.00 4.00	0.52 to 7.63 1.18 to 13.46
5%	160 (1:1) 160 (1:1)	2.00 4.00	0.63 to 6.38 1.28 to 11.41

*based on the meta-analysis of control arm quit rates in HTA report. ^combined intervention and control group sample size

** Based on a 2-sided Fischer's exact test

We believe this sample size provides an acceptable level of precision of effect size estimation i.e. upper estimate that is within the range of relative risk reported in the HTA report. Although a larger sample size (160) would offer greater precision, we believe that would not be feasible within the constraints of the time and resources sought for this pilot study.

9.2 RECRUITMENT OF 'HARD TO REACH' SMOKERS

In searching through the literature we have identified several ways of defining 'hard to reach' but broadly it refers to sections of the community that are difficult to involve in public participation. Such sections may include: (1) Minority groups; (2) Those 'Slipping through the net '; (3) Those who are 'service resistant.'

Local data confirm that the proposed geographical location for the research has a higher prevalence of people who are unemployed, in social class C2-E, single parents, and have mental health problems, than in most other areas in the South West and the UK as we previously described. Residents also have a higher prevalence of smoking, lower use of NHS Stop Smoking Services, and lower levels of PA. We therefore implicitly expect our recruitment to be targeted at 'hard to reach'

smokers, but will also explicitly aim to recruit smokers who have these characteristics. Further liaison with the local community in Plymouth will determine if the following recruitment targets would be realistic: 75% (n=80) of the sample to be unemployed, receiving benefits, or in social class C2-E; 30% (n=36) from single parent families; 20% (n=24) with mental health problems, with some overlap between sub-groups. As noted above we will also target diverse ethnic minority groups.

A range of strategies will be explored in Phase 1 of the study, particularly through initiating a community advisory group (including smokers and community workers), to inform Phase 2. There is a wealth of experience for the best ways to try to reach the most difficult to engage with and promote health in the proposed areas of Plymouth, and we will also draw on other evidence from evaluations involving interventions delivered by HTs across the UK. Broadly, the strategies will include:

1) Networking and making links with other professionals who have offered services to 'hard to reach' groups.

2) Specifically targeting members of hard-to-reach groups and formally inviting them to participate in consultations (eg, through GP lists).

3) Outreach work in community venues where hard-to-reach groups could be identified, approached and consulted (e.g. job centres).

Regarding the targeting of ethnic minorities, we accept that this will be more challenging than in other UK locations, due to the low proportion of minorities in Plymouth, but we will involve such groups in the advisory group to ensure as heterogeneous a sample in the pilot trial as possible.

In many ways, our study implicitly focuses on 'hard to reach' smokers simply because we intend to recruit smokers who are not wishing to quit but who wish to cut down and are typically heavier smokers. NHS Stop Smoking Services have traditionally focused on those wishing to make an abrupt quit attempt, who may be more successful and hence help to meet challenging targets for quit rates. The proposed work will target those for whom NHS support is not currently available.

9.2.1 The context

Recruitment will take place in and around Devonport and Stonehouse, the two most deprived neighbourhoods in Plymouth. In 2004, Devonport's health deprivation score (within the Index of Multiple Deprivation) was 1.59; above the New Deals for Communities (NDC) average of 1.23[56], with a population of about 7000. In Devonport 49% smoke (MORI Household Survey, 2006) compared with 27% across Plymouth, and 23% nationally. In 2004, targets were set within the scope of the Devonport Regeneration Community Project (DRCP) to reduce smoking prevalence to 39% by 2010. Limited numbers accessing NHS Stop Smoking Services were thought to be due to delivery in clinical settings (eg, Nuffield Clinic, Lipson Rd) and inadequate tailoring of services for local residents. In 2007-8, only 79 patients from the two Devonport GP practices (Marlborough St Surgery and Cumberland Centre) were recorded as having set a quit date by a specialist stop smoking advisor, of whom 43% were still quit after 4 weeks, verified by standard CO monitoring. In response, as part of the DRCP in July 2008, a level 3 specialist stop smoking advisor and registered nurse were appointed, and they have developed new outreach and community development approaches to service recruitment (eg, cold approaches outside a supermarket with follow-up calls

to respondents about NHS services, visits to the Salvation Army centre, home visits, providing drop-in opportunities within non-clinical community facilities, attending local events). By the end of 2010, the Brickfields Healthy Living Centre (HLC) is expected to be completed in Devonport, to complement similar facilities (eg, Jan Cutting HLC) with access to exercise classes, catering, health promotion and community development initiatives in neighbouring areas. This information gives an indication of the prevalence and scope for conducting the proposed study among 'hard to reach' smokers in Plymouth. There is strong interest from the Public Health team (K Elliston, S. Thomas, personal communication), local GPs (R. Jones, R. Ayres, R. Byng personal communication) and NHS SSS (R. Moody – Manager of Services, M. Cheshire, personal communication) in the proposed study, as a novel approach to possibly increasing quit rates among 'hard to reach' groups.

9.2.2 Describing the study and intervention to potential participants and its impact on recruitment

An audit in 2008 of 178 smokers in a GP practice (in a mainly deprived area of Plymouth), revealed that 39% were not interested in quitting but were prepared to gradually cut down over 8 weeks, and were also interested in joining a study 'to see if physical activity is useful for helping you to reduce the amount you smoke. [The study would include support such as professional support, a self-help booklet, a free pedometer, and free access to an exercise facility]'. Initially we will begin by describing the intervention as one involving behavioural support for reducing smoking, with additional support to increase PA to be delievered by a person (Health Trainer) with local knowledge of opportunities for engaging in PA or exercise. The initially planned Patient Information Sheet is shown in Appendix X.

Recruitment will be through both Primary Care (1) and community-based (2) approaches (with approximately equal numbers from each) as follows:

(1) The HTs, with Service Support from the Primary Care Research Network (PCRN), will identify heavy smokers on GP practice lists (though not necessarily attending GP surgeries on a regular basis) in Devonport, Stonehouse and adjacent neighbourhoods. Smokers will be contacted by a letter signed by the patient's GP, inviting them to take part in the study, and a brief Information Flyer. They will be asked to return a reply slip to the GP practice or phone (to a mobile) the HT directly indicating interest in the study. The HT will contact the participant, confirm eligibility for the study, arrange a time to meet them at the GP surgery if suitable, and also mail a more detailed Patient Information Sheet. At the meeting, the study will be further explained and Informed Consent provided if appropriate. This may limit recruitment based on literacy, and we will take advice from our user advisory group on refining such an invitation.
(2) The HTs will circulate a brief Information Flyer and posters, about the study to appropriate NHS staff (eg, health visitors, specialist and non-specialist stop smoking advisors, public health workers) working outside primary care. Posters and public adverts will be circulated throughout the respective neighbourhoods (eg, pubs, media, community centres), guided by consultation with community leaders (eg, MIND centre and other charity managers) and smokers or recent quitters identified as possible champions for promoting PA and healthy living. There may be scope to identify people with specific skills and attributes who are able to engage in recruitment activities (eg, giving out flyers in pubs and job seeking centres).

Interviews in Phase 1 will inform the selection of such approaches. The PI will work closely with Dr Richard Ayes (Medical Advisor to the Devonport Community Regeneration scheme, and lead for health inequalities in Plymouth Teaching PCT), to establish a working group with relevant community stakeholders, to specifically identify recruitment strategies, and scope for intervention delivery by an HT.

A recent evaluation of the first HT service in the UK[57], specifically seeking to determine if the most disadvantaged groups were being seen, revealed that 83% were referred by a GP or practice nurse, 11% were self-referrals, 1% by a pharmacist, and 5% from 'other' sources including dietitian, midwife, GP receptionist, attendance at a health promotion event or other health promoting service. A high proportion (53% vs 24% nationally) of those seen by the HT in the central London service, were smokers, which probably reflected the gatekeepers' priorities for referral. Socio-economic characteristics of the sample indicated that recruitment had successfully reached a considerably higher proportion of people with income from benefits, living in rented accommodation, and with no qualifications, compared with London generally, and nationally. In contrast to this London HT service, we will seek to recruit 50% of the sample from the community.

9.2.3 Recruitment Rate (Phase 2)

We will recruit 3 smokers per week (12 per month for 10 months) which will result in a maximum number of 48 participants in the trial (after 16 weeks) at any one time, 24 of whom will be in the PA arm. Not all patients will be in contact with the HT at any one time, through participant choice, so we expect that this workload will be sufficient for 1.4 full-time equivalent Health Trainers. Recruitment will take from 2/2011 - 12/2011 (10 months). During the middle of the trial the Research Fellow will also be available to conduct some assessments.

9.3 INCLUSION CRITERIA

- Written informed consent
- People who are currently smoking at least 15 cigarettes a day and have done for a minimum of 3 years;
- are at least 18 years of age;
- and are not motivated to quit smoking in the next month but do wish to cut down the number of cigarettes they do smoke

9.4 EXCLUSION CRITERIA

- Are contra-indicated for moderate physical activity;
- have an injury or illness that might be exacerbated by exercise;
- are pregnant;
- or wish to use Nicotine Replacement Therapy (NRT) as an aid for smoking reduction

10. INFORMED CONSENT

Patients will receive their information sheet at least seven days prior to the screening assessment in order to allow sufficient time for consideration of participation.

At the screening visit the details and implications will be explained and the opportunity will be given for the participant to ask questions. Written informed consent will be obtained by the Researcher/Health Trainer prior to screening or any study procedures being undertaken. Participants will also be asked to agree to their GP being informed of their involvement in the study.

11. STUDY PROCEDURE

See Appendix II.

11.1 STUDY WEEK (1): SCREENING/BASELINE ASSESSMENT AND RANDOMISATION

Suitable participants will be assessed by the Researcher/HT at an agreeable location (eg, GP practice, community centre):

- Expired CO (ppm)
- Weight and height (BMI)
- Accelerometer use (1 week, in sub sample)
- Questionnaires:
    - Smoking History
    - PAR-Q
    - Demographics
    - Self reported quit attempts in past 8 months lasting at least 24 hours, use of cessation aids and length of prolonged abstinence
    - Self reported cigarettes, pipes, and cigars currently smoked in the past week
    - Current readiness to quit smoking
    - Cigarettes smoked in past week
    - FTND
    - Urge to smoke (single item)
    - Mood and Physical Symptoms Scale (MPSS) (7 items)
    - Perceived Stress Scale (PSS)
    - Confidence to quit, cut down, and importance of quitting
    - Cigarette Evaluation Questionnaire (mCEQ)
    - Self reported Physical activity (PA)
    - Alcohol consumption
    - SF36
    - Self reported use of NRT products or smoking related aids

11.2 STUDY WEEK (2) AND (3): BEHAVIOURAL INTERVENTION ARM

- Pedometer step count (diary)
- Adverse or Serious Adverse events
- Questionnaires:
    - Confidence to quit, cut down, and importance of quitting
    - mCEQ
    - Self reported PA
    - PSS
    - MPSS (7 items)
    - Urge to smoke (single item)
    - Self reported use of NRT products or smoking related aids
    - Cigarettes smoked in past week

Prolonged abstinence
Self reported cigarettes, pipes, and cigars smoked

11.3 Study Week (4): Phone Call Measure at 4 weeks post-baseline

- Adverse or serious adverse events
- Questionnaires:

  Confidence to quit, cut down, and importance of quitting
  mCEQ
  Self reported PA
  PSS
  MPSS (7 items)
  Urge to smoke (single item)
  Self reported use of NRT products or smoking related aids
  Cigarettes smoked in past week
  Prolonged abstinence
  Readiness to quit smoking
  Self reported cigarettes, pipes, and cigars smoked

11.4 Study Week (5), (6), and (7): Behavioural Intervention arm

- Pedometer step count (diary)
- Adverse or Serious Adverse events
- Questionnaires:

  Confidence to quit, cut down, and importance of quitting
  mCEQ
  Self reported PA
  PSS
  MPSS (7 items)
  Urge to smoke (single item)
  Self reported use of NRT products or smoking related aids
  Cigarettes smoked in past week
  Prolonged abstinence
  Self reported cigarettes, pipes, and cigars smoked

11.5 Study Week (8) or Start of Quit Attempt

To be conducted by the Researcher/HT in person at an agreeable location:

- Expired CO (ppm)
- Weight and height (BMI)
- Accelerometer use (1 week, in sub sample)
- Adverse or serious adverse events
- Questionnaires:

  Self reported cigarettes, pipes, and cigars smoked
  Prolonged abstinence
  Readiness to quit smoking
  Cigarettes smoked in past week
  FTND
  Urge to smoke (single item)
  MPSS (7 items)

PSS
Confidence to quit, cut down, and importance of quitting
mCEQ
Self reported PA
Alcohol consumption
SF36
Self reported use of NRT products or smoking related aids

11.6 WEEKLY (6 WEEKS) DURING QUIT ATTEMPT WITH NHS SSS SUPPORT: BEHAVIOURAL INTERVENTION ARM

To be conducted by the Researcher/HT in person at an agreeable location:

- Expired CO (ppm)
- Adverse or serious adverse events
- Pedometer step count (diary)
- Questionnaires:
  - Self reported PA
  - Self reported use of NRT products or smoking related aids
  - Urge to smoke (single item)
  - MPSS (7 items)
  - Perceived stress
  - Prolonged abstinence

11.7 STUDY WEEK (16) OR 4 WEEKS POST-QUIT IF SAME: ALL PARTICIPANTS

- Expired CO (ppm)
- Weight and height (BMI)
- Accelerometer use (1 week, in sub sample)
- Adverse or serious adverse events
- Questionnaires:
  - Self reported cigarettes, pipes, and cigars smoked
  - Prolonged abstinence
  - Readiness to quit smoking
  - Cigarettes smoked in past week
  - FTND
  - Urge to smoke (single item)
  - MPSS (7 items)
  - PSS
  - Self reported PA
  - Alcohol consumption
  - SF36
  - Self reported use of NRT products or smoking related aids

12. RANDOMISATION

Randomisation will occur following a successful screening assessment where participants will be allocated a study number and randomised equally into either (i) brief advice on cutting down; or (ii) to receive the behavioural intervention. Randomisation will be completed by random number generation using a computer held in Vesey Building, Salmon Pool, Lane, PCMD, Exeter. The

randomisation code will be kept in a sealed envelope inside a locked cabinet inside the Principal Investigator's office at the School of Sport and Health Sciences at The University of Exeter.

13. THE EARS INTERVENTION

13.1 PHASE 1: DEVELOPING AND PILOTING THE INTERVENTION

Professionals from public health, primary care, The Jan Cutting Healthy Living Centre, and NHS Stop Smoking Services working in the targeted areas of Plymouth have been consulted on the proposed study and several ideas have already emerged for developing an appropriate intervention with specific groups. The Plymouth YMCA is also keen to be involved, given the acceptability of recruiting smokers into a YMCA exercise programme in a deprived community in the US [3]. A co-applicant, Dr Richard Ayres is Medical Advisor for DRCP, and lead in Plymouth Teaching PCT for Health Inequalities has also provided valuable information. We will establish a working group, prior to the project formally beginning to identify appropriate stakeholders from the respective neighbourhoods, as well as identifying potentially suitable candidates for the HT/researcher role.

The intervention will be delivered by a Health Trainer (HT). The 2004 Department of Health White Paper *Choosing Health: Making healthy choices easier* proposed the development of a new role for improving health and reducing health inequalities – accredited HT. HTs are drawn from local communities and are trained to reach those who want to adopt healthier lifestyles (eg, reducing or quitting smoking, increasing PA), but who have little contact with services[10, 11]. HTs develop an understanding of the needs of people in deprived communities, while applying basic health behaviour change strategies. Co-applicant SM helped to develop the competences and the national training programme for HTs and is involved in their evaluation. Our intervention manual (and the subsequent intervention to be tested in the exploratory trial) will describe approaches that build on the competences that an HT would be expected to have.

13.2 WHAT IS THE BEST APPROACH TO CHANGING PA AND SMOKING?

Research on multiple health behaviour change has tended to focus on how best to change several individual behaviours. In the present context there may be two types of processes involved in how increases in physical activity influences smoking, namely implicit and explicit ones. *Implicit* processes may be involved particularly if the focus is on increasing PA, rather than smoking reduction, with an expectation that PA will, through previously identified mechanisms, influence smoking behaviour. For example, increasing PA may enhance mood and reduce stress, which reduces the urge to smoke, or additionally becoming involved in exercise initiates an identity change (perhaps through new non-smoking social networks). There is considerable research on the effectiveness of interventions for increasing PA in general (eg, [58]) though relatively little has focused on 'hard to reach' groups[11]. *Explicit* processes may be involve if the focus is on how best to cut down smoking, or support a quit attempt, specifically using PA. For example, exercise sessions (eg, seated isometric exercise, aerobic exercise) could be recommended as a coping strategy for managing cravings and withdrawal symptoms or weight management. In the former, the focus is mostly on a single behaviour and in the latter there is a need to think about increasing PA while also managing a change in smoking (ie, multiple behaviour changes). It may be that both processes play a part, but each has implications for designing an intervention, which may be influenced by the target group, and the individual's ability

to take on simultaneous multiple behaviour changes. In Phase 1 we will interview smokers from different 'hard to reach' groups about how PA could be used to reduce smoking, and their preferences for just focusing on increasing PA, with the possibility that smoking will decrease, or focusing on how best to cut down, explicitly using PA as an aid to reduce cravings and increasing the duration between cigarettes (as employed with nicotine assisted reduction to stop programmes).

The PA and abrupt smoking cessation trials, reviewed above (see [1]), largely focused on the effects of structured exercise in addition to smoking cessation advice. Less is known about promoting PA for smoking reduction, and in developing and then trying our intervention, prior to the pilot RCT, we will monitor how smokers view the utility of PA and exercise as they attempt to cut down. In particular, we will seek to identify if PA has utility to help smokers to achieve SMART goal oriented behaviour (eg, cutting down by 50% over 2-4 weeks) as described in the HT training manual[10], and at a later stage, staying quit on a weekly basis, and if increases in PA increases confidence to cut down (and make a quit attempt). As ideas emerge from target groups, academic literature will also be reviewed to consider best practice for health promotion activity among 'hard to reach' groups. For example, voucher-based reinforcement therapy has been shown to be an effective treatment across a wide range of substance use disorders, including smoking cessation [59, 60]. The intervention will eventually be defined in a manual with flexibility to tailor the intervention to participant needs and the local environment/facilities. The table below provides a guide to how the intervention may build on the typical approaches used by a HT, with an integrated approach to promoting PA as an aid to smoking reduction and quitting. We also identify specific process and outcome variables that may indicate how the intervention is working. HTs are trained to adopt a motivational interviewing (MI) counselling style (ie, client-focused, non-judgemental) which also draws on psychological theories (eg, Self-determination Theory; suggesting individual's motivation is driven by basic needs to feel competent, in control and for companionship or relatedness) to help promote health behaviour change[61].

Intervention component	**Aim**	**Content**	**Process and outcome evaluation**
Use MI principles and strategies in counselling sessions.	Develop rapport with smoker, building trust, and shared respect.	Effective communication skills. Exhibit empathy, listen, reflect, summarise.	Participant feedback on HT-led support.
Explore initial beliefs about cutting down, and quitting (eg, pros & cons, confidence, triggers for smoking).	Identify readiness to quit, and ambivalence towards quitting. Increase self-awareness and build confidence to cut down.	Smoker identifies why it is important to cut down and quit, and identifies the challenges. The role of PA as an aid may emerge.	A shift towards stronger intentions to not only cut down but also quit over the early sessions. Smoker self-monitors own smoking behaviour.
Introduce PA as a healthy behaviour and aid to cutting down and quitting.	Increase beliefs in pros of PA alone and as an aid to cutting down & quitting.	Introduce PA as a behaviour that may regulate smoking. Explore beliefs about PA.	Participant increases beliefs in PA as a coping strategy and aid to cutting down.

Set goals to reduce smoking and increase PA	Develop strategies to reduce smoking and increase PA.	Set SMART goals with smoker to reduce smoking and increase PA. Signpost to PA/exercise opportunities & remove barriers to do PA.	Goals identified and action plans developed. Self-monitoring used (eg, smoking and PA diary kept). Rewards and reinforcement contingencies established.
Review and reflect on behaviour change.	Build confidence and perceptions of control, & ability to self-regulate.	Smoker reflects on PA successes and sets new targets; perhaps to quit.	Participant increases beliefs in confidence to cut down, and quit.
Maintenance and relapse prevention. Using NHS Stop Smoking Services.	To strengthen self-regulatory skills. To identify identity shifts.	Smoker reflects on own skills and strategies for avoiding relapse, including use of PA. Ready to quit?	Participant seeks support for a quit attempt, possibly using NHS specialist support.
On-going phone support provided for quit attempt in addition to NHS support.	To reinforce participants shift to non-smoker and more physically active.	Reflect on achievements and explore future needs for support to maintain PA.	Successful quit attempt and increase in PA.

13.3 PHASE 2: EXPLORATORY TRIAL

13.3.1 Standard treatment: Brief advice for quitting

After completing baseline assessments and random assignment, all control participants will receive written and verbal information on what the NHS Stop Smoking Services offer, including some brief information on the benefits of quitting smoking and how to quit in line with NICE guidelines. No information will be given on how to cut down the number of cigarettes smoked. If smokers wish to quit at any time they will be encouraged to contact the trial staff who will arrange for a member of the NHS Stop Smoking Services to contact them for individual or group standard 6/7 week (or matched to the participants needs) behavioural and pharmacological support for a quit attempt.

13.3.2 Behavioural intervention

Phase 1 will help us to develop a participant-centred framework. As shown in the table above, we envisage that it will involve multiple components that aim to address real and perceived environmental (eg, nowhere to do PA), social (eg, no one to do it with), financial (eg, too costly), cognitive (eg, not confident to do PA), and emotional (eg, feel too tired) barriers to increase PA and reduce smoking, as considered above.

After completing baseline assessments and random assignment (by the HT/researcher), all PA participants will be offered a 45 min face to face PA support session in week 1, 4 and 8, and a

supportive phone call in each intermediate week. The communications will involve tailored PA counselling, guidance on using a free Digi-Walker SW-200 pedometer to achieve SMART goals, and signposting to local exercise opportunities with subsidised access as required. The counselling will follow principles described in the HT manual[10], adapted in response to findings from Phase 1. If a smoker wishes to quit at any time they will be offered a meeting with a specialist NHS SSS advisor for individual or group standard 6/7 week (or matched to the participants needs) behavioural and pharmacological support for a quit attempt. At the same time, those attempting to quit will receive parallel weekly telephone support to maintain (or increase) physically activity.

Behaviour change strategies will focus on self-regulation and may involve the following: (1) A choice of alternatives for reducing cigarettes smoked as discussed previously (see 6.8). (2) Identification of situations, cues and moods/affect that elicit urges to smoke; (3) Increase perceived expectancy that PA may help to regulate mood and affect (instead of a cigarette); (4) Raise awareness of PA or sedentary patterns (what, where, when, who with) overall and in relation to smoking through self-monitoring (using a pedometer and daily diary); (5) Build confidence to increase PA primarily as a lifestyle behaviour (ie, brief bouts of 10 mins) but not exclusively (ie, can include structured PA), using standard cognitive-behavioural techniques; including goal setting, and self-monitoring (daily diary and pedometer). After a baseline period of pedometer wearing for 2 weeks, smokers will be encouraged to increase pedometer step counts by 10% from one week to the next (or at a self-determined rate) until achieving 10,000 steps per day or the participant's target. At the same time they will be encouraged to monitor mood/affect and smoking patterns. Counselling sessions will seek to reinforce the smoker's beliefs in the value of PA as an effective self-control strategy for reducing cigarette cravings and withdrawal. Up to £100 vouchers per smoker will be offered to support involvement in PA and minimise barriers to access. MP3 players (c. £15) will be provided to those interested, with a recording of a guided seated isometric exercise programme. Research suggests that such a programme can reduce momentary urges to smoke.

Financial subsidy will be available to support involvement in structured, supervised moderate-vigorous intensity exercise in gyms/leisure centres for example. This intensity of exercise may well reduce cigarette smoking and lead to increases in quit attempts for several reasons, such as: it may raise awareness of symptoms of breathlessness associated with smoking which may trigger a stronger motivation to quit; it places smokers in environments with fewer smokers, which reinforces reduced smoking and a non-smoking identity; and there may be a greater sense of achievement from doing more strenuous exercise. However, heavier smokers are more likely to do less moderate-vigorous physical activity and our experiences suggest that most smokers prefer walking. In contrast, moderate intensity exercise is more pleasurable[62], creates fewer perceived barriers (eg, cost, convenience and time, and social) and hence is likely to be more sustainable, and has similar effects in reducing cigarette cravings and withdrawal symptoms to more vigorous exercise[63, 64]. It is also used by about 35% of quitters as a smoking cessation aid[45] and promoted by over half of NHS SSS advisors[37].

14. WITHDRAWAL FROM THE STUDY

Participation in the study is entirely voluntary and participants will be free to withdraw at any time.

15. ETHICAL CONSIDERATIONS

15.1 RISKS TO SUBJECTS

Moderate intensity physical activity is safe and is recommended for most adults. It is anticipated that most smokers will increase walking and walking has no contraindications for most. Other physical activities will also be offered in the community and participants will be advised on the suitability of these (see below).

15.2 ADEQUACY OF PROTECTIONS AGAINST RISKS

During the screening process those smokers who are contraindicated for moderate intensity physical activity or who have injury or illness which might be aggravated by exercise, will be required to gain approval from their GP before engaging in the study. Vigorous intensity activity can acutely and transiently increase the risk of sudden cardiac death and acute myocardial infarction in susceptible persons,96 so the focus of all recommendations for increasing PA will be on moderate intensity PA. Participants will be given clear guidance on exercising at this intensity (ie, something that increases the heart and breathing rate but not to the point of breathlessness or unable to maintain a conversation). Participants will be advised to seek approval from their GP prior to engaging in any vigorous intensity PA, regardless of age and gender. The smokers will be monitored for contraindications to exercise, for adverse events (see section (v) 'Data and safety monitoring plan' below) including physical symptoms (e.g. chest pain, extreme breathlessness), or change in health status at each counselling session and follow-up appointment. If there is any further doubt about the involvement of a participant in the study the Trial Manager will liaise with the participant's GP.

15.3 POTENTIAL BENEFITS OF THE PROPOSED RESEARCH TO THE PARTICIPANTS AND OTHERS

The smokers participating in the study may have a greater chance of stopping smoking and remaining abstinent, relative to those who try to stop without behavioural support. Though we do not plan to test the hypothesis in this pilot study, we may expect that those in the exercise condition will have an enhanced opportunity of stopping smoking. Those who increase and maintain regular physical activity during and following the study will receive many general health benefits, including a reduced risk of developing cardiovascular disease, stroke, hypertension, obesity and some cancers, even if they continue smoking[65].

15.4 IMPORTANCE OF THE KNOWLEDGE TO BE GAINED

Little is known about if and how behavioural support can help smokers to cut down, and if cutting down then leads to more quit attempts and continuous abstinence. The planned study seeks to inform the feasibility and acceptability of a behavioural intervention to be tested against brief advice (usual care) in a future large scale trial. This pilot trial will allow us to estimate if a full trial is justified, from both an effectiveness and cost-effectiveness perspective. If such a physical activity intervention was shown in a full trial to be effective and cost-effective for increasing quit attempts and smoking cessation it would offer important evidence for the design of behavioural interventions which are not currently available in the NHS. Smokers are typically less active than the general

population[66] and evidence from interventions that help change multiple health behaviours are urgently required. Weight gain is common among quitters [67, 68], but nothing is known about the effects of smoking reduction on weight gain or weight concern. The proposed study may provide unique information on changes in a variety of psychological variables (eg, cravings and withdrawal symptoms) and weight gain and weight concerns among those who cut down and quit.

16. ADVERSE EVENTS

It is anticipated that there will be few, if any, adverse events in response to the behavioural intervention. Any adverse events (AEs) will be monitored by the researchers and practitioners. If necessary these events will be discussed with one of the GPs (Dr Jones, Dr Ayres, Dr Aveyard, Dr Byng or Prof Campbell) on the research team. Where necessary AE Reports will be produced and will be forwarded to the Data Monitoring and Ethics Committee (DMEC) or to the TSC if a DMEC is not considered necessary for the trial. This will include, reviews of the research protocol and any recommendations for changes to the safety monitoring procedures. In addition, any AEs which could possibly be related to the study will be followed up.

17. DATA MANAGEMENT

17.1 DATA SECURITY AND CONFIDENTIALITY

Data management will follow study specific data management standard operating procedures, and will operate in accordance with the Data Protection Act (1998).

All computers holding study data will be password protected. Files containing study data and information will be accessible to only the study team, and all files containing personally identifiable data will also be password protected. Backup copies of the study data will be kept in a locked filing cabinet.

The data will be entered on to an Access database by the research staff, and will be later transferred to SPSS for analysis. The ACCESS database will be held on a secure internet server. The participants will be assigned a study number and will be identified on the database only by this number and will not be identified by name. Access to the database will be password protected and will be permitted only by the researchers, the PI and the trial statistician (Prof Rod Taylor). Only these individuals will have the information linking the study numbers to the participants' names. The clinical record forms and a copy of the database on CD will be stored in a locked filing cabinet in the Department of Primary Care, PCMD, Plymouth. Only the researchers, the PI and the trial statistician will have access to these records.

17.2 LONG TERM STORAGE OF DATA

Data will be stored in the Principal Investigator's office in the School of Sport and Health Sciences at the University of Exeter, St Lukes Campus, Magdalen Road, Exeter.

17.2 DATA ANALYSIS

Analysis will be undertaken to provide an estimate of the intervention (vs control) effect size and its precision based on continuous abstinence at 4 weeks post quit. Given the pilot nature of the trial, it is anticipated that hypothesis testing will not be undertaken on the primary outcome of interest. We will however, explore differences in other measures at the respective follow-up assessment, after determining if groups were comparable at baseline. For example, we will compare the groups on the number of quit attempts and readiness to quit 8 weeks post-baseline, number achieving at least a 50% reduction in cigarettes, and importance of, and confidence for, quitting. We will explore if FTND, perceived stress and strength of cravings and withdrawal symptoms at baseline predict outcomes, and whether amount of physical activity is associated with changes in outcomes.

The data analysis will be completed by the Principal Investigator (Prof Adrian Taylor) in the School of Sport and Health Sciences in The University of Exeter and by the Trial Statistician (Prof Rod Taylor) in the Clinical Trials Unit, PCMD, at The University of Exeter.

18. COST EFFECTIVENESS

The research will identify the key areas of resource use and costs (e.g. Health Trainer time, subsidised access to exercise, recruitment of those 'hard to reach') associated with the delivery of the intervention (and control, where appropriate), and will test/develop methods for the collection of data in a future trial (e.g. through use of 'work-sampling' methods, person-level recording of resource use via either routinely collected data, and/or self report methods). Identification of resource use, and methods for measurement of resource use, will include areas covered by NHS stop smoking services.

Any future economic evaluation alongside a RCT is expected to involve presentation of costs and benefits (e.g. in the form of a cost-consequences analysis), and will also involve modelling of longer term policy-relevant outcomes (i.e. impact on life-expectancy), from trial outcomes, to estimate cost per life-year and cost per QALY gained, and these requirements will set the context for pilot research proposed here. Research proposed here will include a general literature review of the data required for cost-effectiveness analyses, and evidence synthesis will be used to inform exploratory modelling of cost-effectiveness analyses (e.g. building on the work of Wang[2]), with simulation modelling and the related approach of 'value of information analysis'[69] used where possible to investigate areas of uncertainty. It is anticipated that the pilot research will offer a good indication of the expected costs of delivering the intervention, but we acknowledge that any economic modelling will involve assumptions, and 'what if' analyses, in a number of areas (including measure of effectiveness). Therefore, research will assess both the issue of potential value in terms of commissioning future research (e.g. RCT)[70], and the issues of design (framework for CEA) for future research.

Current estimates are that it costs approximately £250 per smoker (for recruitment, and behavioural and pharmacological NHS support) who is still abstinent 4 weeks after quitting. Our cost effectiveness work will provide estimates of whether the intervention would cost more than this, and lead to discussion about the merits of proceeding to a full trial. Also, data from the SF36 may allow us to estimate the cost of improvements in quality of life.

19. QUALITATIVE ASPECTS

In the Table below we identify a framework for conducting the proposed qualitative work. After training, semi-structured interviews (focus groups and individual) led by the PM will be digitally recorded, transcribed and anonymised (with the consent of participants). Interview schedules (topic guides) will be developed with reference to existing literature on assessing the feasibility and acceptability of trial methods and /or behavioural interventions[71] and on developing behavioural interventions[72, 73].

Phase	Key issues	Who	Content/focus
1 Pre-trial	Recruitment	Focus groups with professionals, community workers (and volunteers) and smokers. Individual interviews with HTs working outside Plymouth.	Defining 'hard to reach'; how to identify and recruit them (in primary care and the community); snowball sampling (who, where, when).
	Study design & methods	Focus groups with professionals, community workers (and volunteers) and smokers.	Assessments (adapting to sample); How best to conduct assessments in PA and control group (where, when, who), including self-report, accelerometers and CO monitoring.
	Intervention development	Focus groups with professionals, community workers (and volunteers) and smokers from different 'hard to reach' groups.	General behavioural strategies used by smokers for smoking reduction. Selecting core behavioural change components (initial and progressive support), implicit (focus on just increasing PA) v explicit (focus on increasing PA as a coping behaviour) PA promotion, PA opportunities and support in community, links to NHS SSS, integrated post-quit support. Training HTs and treatment fidelity.
	Intervention pre-pilot trial.	Recipients of the intervention and HTs.	Smokers: Acceptability of intervention. What worked and didn't? Perceived value of intervention for cutting down (and quitting). Suggestions for additional support. HTs: Discussion of sample of video replays of sessions with smokers with PM and PI, with focus on fidelity (counselling style, content, motivational strategies).
2 Pilot trial	Recruitment	During and after pilot RCT. HTs and others in a position to recruit (eg, practice nurses, Stop Smoking Services). Decliners from different 'hard to reach' groups.	Feasibility and engagement: Which groups were harder to reach and why? What worked and didn't to recruit the most resistant? How did primary care v community recruitment compare?

	Intervention	HTs and smokers from different 'hard to reach' groups. Also, sample smokers who: were able to cut down but not quit; cut down then quit; didn't cut down or quit; didn't cut down but attempted to quit.	Acceptability of intervention. What worked and didn't. Perceived value of intervention for cutting down (and quitting). Suggestions for additional support.

For most qualitative issues, the data will be subject to thematic analysis using constant comparison techniques to extract concepts and themes[74] (and using NVivo to manage the data). The transcripts relating to smoker experiences of the intervention will also be analysed to produce individual narratives, allowing an increased insight into the processes of recruitment /engagement and the processes of supporting behaviour change[75]. These will inform modification of the recruitment techniques and the intervention /behaviour change process model to tailor the intervention better to the needs of hard-to-reach participants [76]. Second coding of a sample of the transcripts and discussion of the emerging coding framework, as well as techniques such as negative case-finding and hypothesis testing will be used to increase the depth of analysis and enhance the likely objectivity of interpretation[77]. Interviews will be conducted in community locations acceptable to those involved.

20. QUALITY CONTROL

A quality control plan will be implemented as follows:

20.1 PHASE 1

Interviews will be digitally recorded and transcripts produced and stored securely as below. Any samples of quotes will be linked to the securely stored transcripts, using a securely stored coding system. Transcripts will be subject to thematic analysis and verified by the PI.

20.2 PHASE 2

20.2.1 Sampling and Recruitment

20% of screening forms will be checked by the project manager. If it is found that a smoker has failed to meet the inclusion criteria and has still been recruited, the smoker will be immediately withdrawn from the study, but will continue to be offered smoking reduction support. If more than a 1% error rate is detected all the screening forms will be checked.

20.2.2 Intervention and Delivery

Audio recordings will be made of a sample of intervention sessions to check for treatment fidelity.

20.2.3 Data Collection

10% of all clinical record forms (CRFs) will be checked by the project manager. If any baseline data on demographics or smoking characteristics are missing the smokers will be contacted and the data will be entered.

20.2.4 Data Entry

10% of all data entered will be checked against the hard data (in the CRFs) by a second researcher. If the error rate is greater than 1% all the data will be checked against the hard data. 100% of the data for self-reports of continuous smoking abstinence at 4 weeks post-quit (or 16 weeks post-baseline) will be checked against the hard data.

20.2.5 Expired CO

Using the manufacturers' recommendations, the performance of the CO measure for expired air will be regularly checked and calibrated accordingly.

21. TRIAL MANAGEMENT AND SUPERVISION

21.1 TRIAL STEERING COMMITTEE (TSC)

A TSC will be established to provide overall supervision of the trial. This committee will include key personal and independent members who are experts on exercise or smoking cessation, as well as at least one smoker or ex-smoker who would fall into our categories of 'hard to reach' smokers. The steering committee will convene during preparation for the trial to contribute to and approve the final study protocol and every six months during the first year of the study and yearly thereafter, or as deemed necessary. The committee's responsibilities will include monitoring: recruitment rates, adherence to the interventions and retention in the study, as well as monitoring research developments which may impact on the merit of the scientific output from the study.

21.2 DATA MONITORING AND ETHICS COMMITTEE

Given the lack of safety concerns and the lack of stopping rules for the trial, we do not anticipate a DMEC will be necessary but this will be to the discretion of the TSC.

21.3 PROJECT MANAGEMENT

Bi-weekly progress meetings will be held involving AT (PI), the PM, the 2 HT/researchers, and RA, in Plymouth. Quarterly meetings will be held, in addition to Phase 1 interviews/focus groups, involving the above plus RT, CG, & AR, as appropriate, plus representatives from Public Health network in Plymouth and local community groups (eg, Devonport Regeneration Community Partnership). The expertise of other co applicants (see below) will be drawn upon at appropriate times during the project.

21.4 PROJECT MANAGER (PM)

The PM will work in collaboration with the PI to finalise the protocol and assessments, manage ethical approval processes, approval to manage the day to day running of Phase 1 and 2, manage the HT/researchers, maintain the central database and coordinate management meetings. RA will provide local support for the PM and HT/researcher staff, and RB will also serve as a conduit for working with primary care in Plymouth. The PM, HTs/researchers, and will be housed in a PCMD office in Plymouth, but it is envisaged that the HTs will spend a considerable amount of time

engaging with participants and other relevant personnel in and about the Devonport, Stonehouse and adjacent neighbourhoods.

22. EXPERTISE

AT will lead the study as PI (0.2 FTE). He has been PI for 3 trials (including 'Walk to Quit', an RCT of a GP exercise referral scheme, and HEALTH – a COPD and exercise RCT), and co-applicant on 3 other funded RCTs involving PA promotion. He also has experience in conducting collaborative action research, and qualitative studies. Design and data analysis support will be provided by RT, in the PCMD's Clinical Trials Unit (CTU), and has extensive experience in trial methodology and statistics, and works with AT & JC on 2 RCTs. CG is a Senior Lecturer in Health Economics and has expertise in cost-effectiveness analysis. JC has experience with both exercise and primary care trials, including TREAD (HTA 03/45/07), GETuP (RDA 02/06), HEALTH (IPCRG funded) all with AT. RJ has experience of conducting trials and is clinical lead for Plymouth Respiratory Care services. MU has experience as PI for 3 trials on exercise and smoking cessation, including an HTA trial, LEAP, currently underway with pregnant smokers. PNA & RW have experience with smoking cessation trials, and have worked with MU and AT on previous trials. PNA has co-authored a recent HTA review on Cut Down Then Quit trials. AR has extensive expertise in measuring PA with accelerometers. SM has extensive expertise in designing and evaluating complex behavioural interventions, particularly among the 'hard to reach.' On-going trials include the evaluation of promoting walking in primary care, and the effects of a bespoke smoking cessation intervention for people with severe mental illness. She is on Department of Health committees for developing and evaluation of the Health Trainer professional, and advising on complex behavioural interventions. We do not envisage any difficulty in recruiting suitable personnel for the roles of project manager and Health Trainer/researcher. RA has worked closely in and with the neighbourhoods where the study will take place in his capacity as part-time GP, Medical Advisor for Devonport Community Regeneration Project and as lead for Plymouth Teaching PCT for Health Inequalities. RB is a clinical academic with a specialism in mental health and is based in Primary Care, PCMD, Plymouth.

23. DISSEMINATION

The results will be published in peer review journals and presented to at relevant conferences, nationally and internationally. The production of a manual for the physical activity intervention will enable us to provide specific guidance on the training that would be needed and the nature of the intervention for a larger scale trial. Findings on acceptability and feasibility of the trial procedures will inform the design of a future larger scale trial. The findings will also be disseminated locally (via workshops and conferences) among health professionals and those working for community agencies, in a professional and voluntary capacity. An HTA report will also be produced, and published within the HTA series of peer review publications.

24. COSTING

	TOTAL (£)
STAFF COSTS	231,559
NON-STAFF COSTS	
Travel/Subsistence	14,540
Equipment	5,660
Consumables	13,100
Consultancy	4,000
Indirect Costs	251,257
RESEARCH GRANT TOTAL (80%)	416,093
NHS Costs	19,443
RESEARCH GRANT INC. NHS COSTS	£435,536

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26. LIST OF APPENDICES

I EARS Consort Diagram

II Measures to be Taken and Schedule of Assessments

III GANTT Chart

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V Draft Recruitment Poster

VI Phase 1: Letter of Invitation to Participant

VII Phase 1: Participant Information Sheet

VIII Phase 1: Informed Consent

IX Phase 2: Letter of Invitation to Participant from GP

X Phase 2: Participant Information Sheet

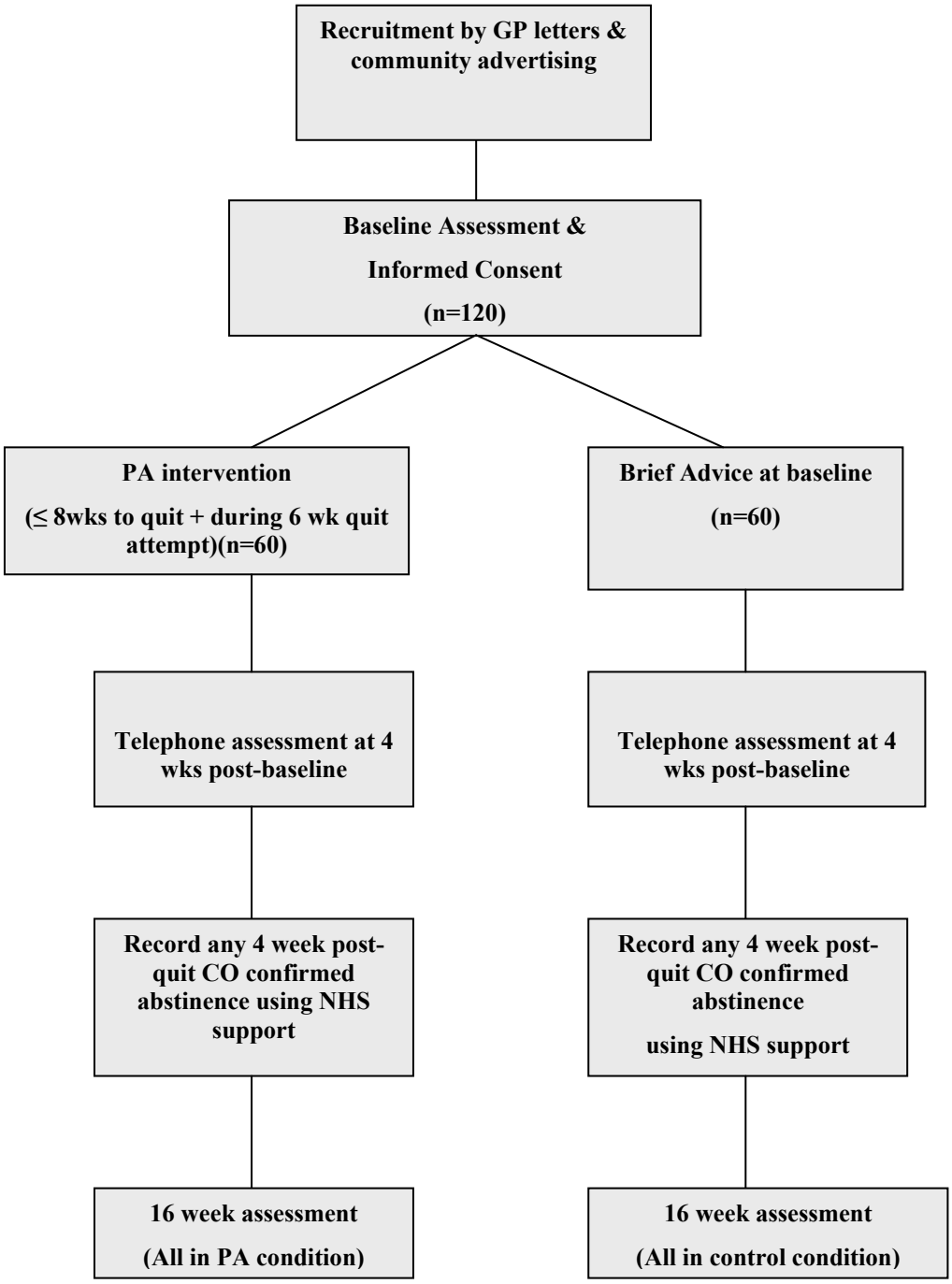
XI Phase 2: Informed Consent

XII Questionnaires:

A. Demographics
B. Smoking history, quitting and cessation aids used
C. Smoking dependence and status
D. Alcohol consumption
E. Self-reported cravings and withdrawal symptoms
F. mCEQ (smoking satisfaction)
G. Perceived Stress Scale (PSS)
H. Physical Activity Readiness Questionnaire (PAR-Q)
I. Self-reported PA
J. EQ-5D
K. SF12

APPENDIX I

EARS CONSORT DIAGRAM



APPENDIX II

MEASURES TO BE TAKEN AND SCHEDULE OF ASSESSMENTS

Measure	Week 1	Week 2-3 in PA arm	Phone call measures at 4 weeks post-baseline	Week 5-7 in PA arm	At start of quit attempt or 8 wks post-baseline	Weekly, 6 weeks during quit attempt (with NHS support)	Week 16 post-baseline (or at 4 wks post-quit if same)
Demographics	X						
Smoking history	X						
Self-reported quit attempts in past 8 months lasting ≥ 24 hrs	X						
Self-reported cigarettes (pipes, cigars) smoked	X	X	X	X	X		X
Prolonged abstinence	X	X	X	X	X	X	X
Readiness to quit smoking	X		X		X		X
Expired CO	X				X	X	X (primary)
FTND	X				X		X
Urge to smoke (2 items) + other MPSS items	X	X	X	X	X	X	X
PSS	X	X	X	X	X	X	X
Confidence to quit, cut down & importance of quitting	X	X	X	X	X		
mCEQ	X	X	X	X	X		
Self-reported physical activity (PA).	X	X	X	X	X	X	X
Pedometer step counts (diary)		X		X		X	
Accelerometer (1 week)	X				X		X
Weight & height (BMI)	X				X		X
Alcohol consumption	X				X		X
SF36/EQ5-D	X				X		X
Self-reported use of NRT products or smoking-related aids	X	X	X	X	X	X	X
Adverse or serious adverse events		X	X	X	X	X	X

Measures to be taken from participants in both arms of the trial shown in shaded columns.

CO=Carbon Monoxide; MPSS = Mood and Physical Symptoms Scale; FTND = Fagerstrom Test for Nicotine Dependence; SF36 = quality of life measures; FTND = Fagerstrom Test for Nicotine Dependence. mCEQ =Modified Cigarette Evaluation Questionnaire. PSS = Perceived Stress Scale. Demographics = gender, age, SES, co-habiting smokers

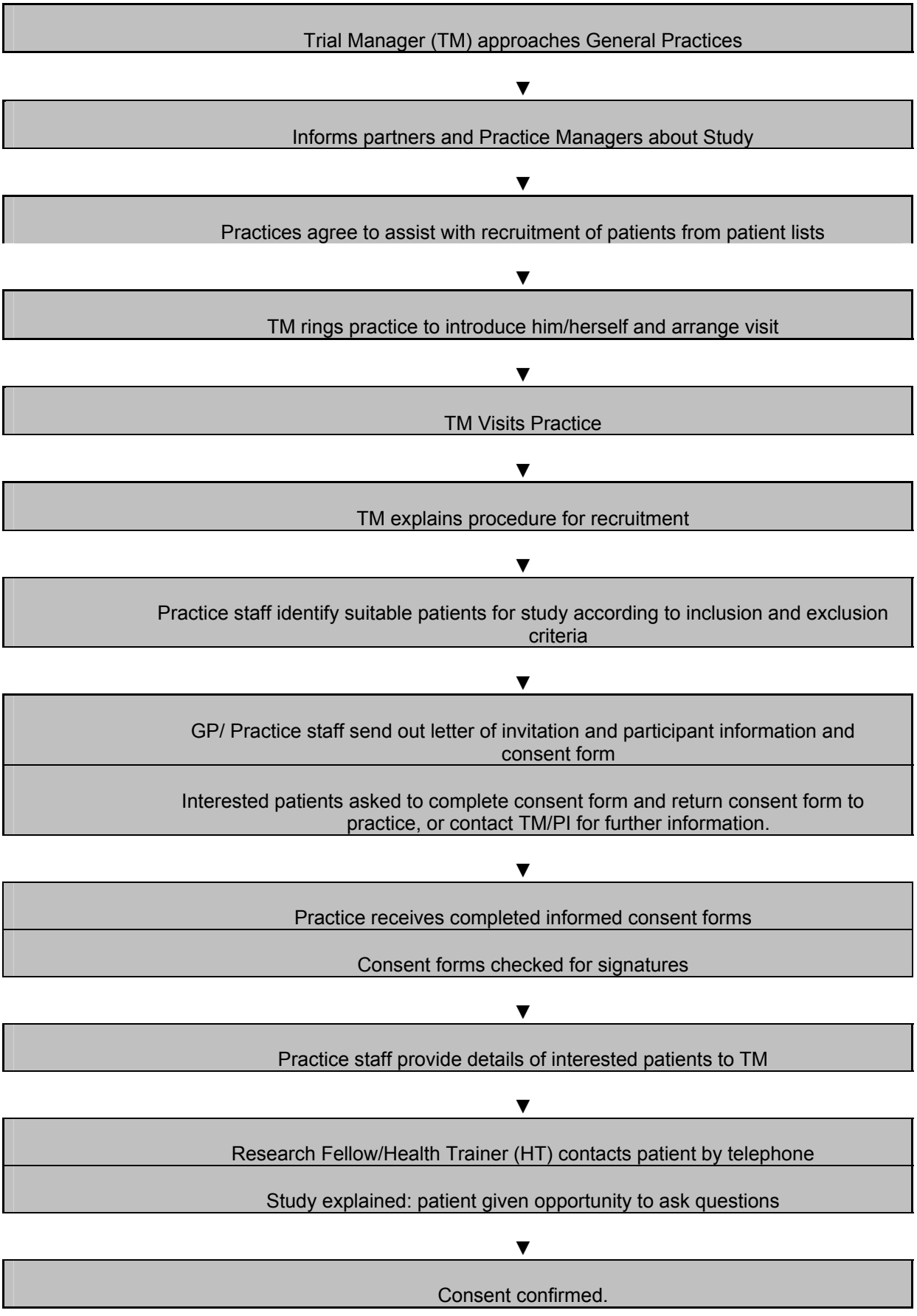
APPENDIX III

GANTT CHART – PROJECT MILESTONES AND TIMETABLE

YEAR	2010	2010	2010	2010	2010	2010	2010	2011	2011	2011	2011	2011	2011	2011	2011	2011	2011	2011	2011	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012	2012
Week beginning	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	March	April	May	June	July	Aug	Sept	Oct	Nov
RF, ethics Develop intervention (Collab Action Res)	Confirm 2 GP practices. Submit Ethics.	Interview for Trial Manager. Local work	Local work																											
Appt Health Trainer/RA and Pilot intervention																														
Recruit for Exploratory trial																														
16 week FU assessment																														
Data analysis & report																														
Health economist RF																														

APPENDIX IV

RECRUITMENT FLOWCHART



Eligibility confirmed (inclusion/exclusion criteria)

Date made for attendance at baseline assessment

▼

Patient attends and completes baseline assessment

Patient randomly assigned

Control participants receive simple information on cutting down and quitting

▼

Support for reduction participants return for first contact session

APPENDIX V

DRAFT RECRUITMENT POSTER

A study of the effects of local support for smokers who wish to cut down but not quit.

Are you a moderate or heavy smoker?
Do you wish to cut down but not make an abrupt quit attempt?

Many smokers want to cut down the number of cigarettes they smoke but few are ready to make an abrupt quit attempt. Little is known about the best way to cut down, but those who do try often don't succeed. Some smokers have given us some ideas and we want to see if they work.

So who are we?
We are researchers at the Peninsula College of Medicine and Dentistry and funded by the government.

Is this a genuine study?
We have NHS ethical approval and will follow the strictest guidelines on conducting research with the general public.

What's in it for you?
Cutting down (and quitting) can really help your health.
We may be able to help you cut down by increasing physical activity with free pedometers and access to exercise facilities if you want.

Where can I found out more about taking part?
Please read the enclosed Participant Information Sheet before you decide whether or not you are interested in taking part. If you would like more information, please contact the study team on one of the following telephone numbers or by e-mail:

APPENDIX VI

Phase 1: INVITATION TO PARTICIPANT

Date

Ref: A study of the effects of local support for smokers who wish to cut down but not quit.

I am writing to ask if you would be interested in taking part in a research study run by researchers in the Peninsula College of Medicine and Dentistry and the University of Exeter, here in Plymouth. This study is funded by the National Institute of Health Research.

The overall study involves two parts:
Phase 1, preliminary work to establish how best to conduct the research.
Phase 2, a larger trial to determine the effects of local support for smokers who wish to cut down but not quit

In this Phase 1, we are interested in your views concerning how moderate to heavy smokers who wish to cut down but not make an abrupt quit attempt (in the next 4 weeks) can be recruited into a study and would engage in a local intervention to provide support to cut down.

It is important that we capture the views of a range of people, including smokers, professionals who help people to quit and others who work alongside smokers. The best way to do this is to conduct individual and group-based interviews.

Many smokers want to cut down the number of cigarettes they smoke but few are ready to make an abrupt quit attempt. However, little is known about the best way to cut down, but those who do try often don't succeed. Some smokers and people who help people to quit have already given us some ideas and we want to explore them a bit more before finally offering this as part of a larger randomised trial involving 120 smokers, 60 of whom will be offered the support.

Participation in the study is entirely voluntary, and if you decide not to participate this will not affect your treatment in any way. Any information that you provide will be treated with confidentiality and will not be disclosed to anyone without your prior permission. Any published information will be fully anonymised.

Please read the enclosed Participant Information Sheet before you decide whether or not you are interested in taking part. If you would like more information, please contact the study team on one of the following telephone numbers or by e-mail.

Project Manager:
Tom Thompson
Peninsula College of Medicine and Dentistry:
Telephone number: 01752 437 300
E-mail: T.P.Thompson@exeter.ac.uk
Or:
The Principal Investigator:
Professor: Adrian Taylor:
School of Sports and Health Sciences (University of Exeter):
Telephone number: 01392-264747.
E-mail: A.H.Taylor@ex.ac.uk

Thank you,

Yours faithfully <GP Name>

APPENDIX VII

Phase 1: PARTICIPANT INFORMATION SHEET

A study of the effects of local support for smokers who wish to cut down but not quit.

Before you decide whether or not to take part it is important for you to understand why the research is being done and what it involves. Please read the following information carefully, and take time to decide. Please ask if you would like more information.

What is the purpose of this study?

In this Phase 1, we are interested in your views concerning how moderate to heavy smokers who wish to cut down but not make an abrupt quit attempt (in the next 4 weeks) can be recruited into a study and would engage in a local intervention to provide support to cut down. It is important that we capture the views of a range of people, including smokers, professionals who help people to quit and others who work alongside smokers. The best way to do this is to conduct individual and group-based interviews.

What will happen if I want to take part?

You will be invited to attend 30-60 min individual or group-based interviews/discussion about how to recruit smokers into such as study, and about how best to design the intervention or support package to help smokers cut down, and possibly quit. This will take place in a convenient location. Any reasonable expenses incurred will be reimbursed.

What are the possible benefits of taking part?

As a smoker you may gain an insight into how best to cut down or quit smoking, as one of the best ways to improve your health. As a non-smoker you can help us to improve the services offered to smokers in helping them to reduce and/or quit.

Do I have to take part in this research?

No, it is entirely voluntary. If you do not, you will still be entitled to the same NHS support and treatment.

Will any information I provide be confidential?

Yes. Information relating to your participation will be kept confidential and will not be disclosed without your prior permission. Confidential information will be stored safely in a locked cabinet. The study will be written up in scientific journals in such a way that none of the people taking part can be identified.

Where can I get more information about this study?

By contacting:

Project Manager: Tom Thompson
Peninsula College of Medicine and Dentistry:
Telephone number: 01752 437 300
E-mail: T.P.Thompson@exeter.ac.uk
Or:
The Principal Investigator: Professor: Adrian Taylor:
School of Sports and Health Sciences (University of Exeter):
Telephone number: 01392-264747.
E-mail: A.H.Taylor@ex.ac.uk

APPENDIX VIII

Phase 1: PARTICIPANT INFORMED CONSENT FORM

A study of the effects of local support for smokers who wish to cut down but not quit.

LREC Study Number: **Patient Study Number:** ……

Name of Researcher: ……

Please read carefully and initial the box if you are in agreement with the statement.

1. I confirm that I have read and understand the Participant Information Sheet dated xx/xx/xx for the above study and have had an opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected. ☐

3. I understand that to take part in this study it is necessary for me to be able to increase the amount of moderate intensity physical activity (typically up to a level where I can just still hold a conversation). ☐

4. I agree to take part in the above study. ☐

Signatures

Name of person taking consent (Print)	Date	Signature
Name of researcher (Researcher to Print)	Date	Signature

APPENDIX IX

Phase 2: LETTER OF INVITATION TO PARTICIPANT FROM GP

<GP address>
Date
Dear <Patient Name>

Ref: A study of the effects of local support for smokers who wish to cut down but not quit.

I am writing to ask if you would be interested in taking part in a research study run by the Peninsula College of Medicine and Dentistry and the School of Sports and Health Sciences at the University of Exeter. This study is funded by the National Institute of Health Research.

You are being invited to take part in this study because you are a moderate or heavy smoker according to our records held in your GP practice. We wish to recruit smokers who wish to cut down but not make an abrupt quit attempt (in the next 4 weeks). Please read on before deciding whether this is something you are interested in or not.

Many smokers want to cut down the number of cigarettes they smoke but few are ready to make an abrupt quit attempt. However, little is known about the best way to cut down, but those who do try often don't succeed. Some smokers have given us some ideas and we want to try them out to see if they work.
We are interested in whether providing some simple support in your local community can make a difference to successfully helping smokers, who want to cut down but not quit, to reduce their smoking. That support will be for setting plans to reduce smoking and also increase physical activity which may help with withdrawal symptoms. We plan to remove as many barriers to becoming more physical activity as possible, as part of the support you may receive.

Participation in the study is entirely voluntary, and if you decide not to participate this will not affect your treatment in any way. Any information that you provide will be treated with confidentiality and will not be disclosed to anyone without your prior permission. Any published information will be fully anonymised.

Please read the enclosed Participant Information Sheet before you decide whether or not you are interested in taking part. If you would like more information, please contact the study team on one of the following telephone numbers or by e-mail.

Project Manager:
Tom Thompson
Peninsula College of Medicine and Dentistry:
Telephone number: 01752 437 300
E-mail: T.P.Thompson@exeter.ac.uk

Or:
The Principal Investigator:
Professor: Adrian Taylor:
Sports and Health Sciences (University of Exeter):
Telephone number: 01392-264747.
E-mail: A.H.Taylor@ex.ac.uk

Thank you,

Yours faithfully <GP Name>

APPENDIX X

Phase 2: PARTICIPANT INFORMATION SHEET

A study of the effects of local support for smokers who wish to cut down but not quit.

You are being invited to take part in a research study which is being funded by the National Institute of Health Research. Before you decide whether or not to take part it is important for you to understand why the research is being done and what it involves. Please read the following information carefully, and take time to decide. Please ask if you would like more information.

What is the purpose of this study?

Many smokers want to cut down the number of cigarettes they smoke but few are ready to make an abrupt quit attempt. Those that do, with NHS Stop Smoking Service support, are four times more likely to successfully quit. However, little is known about the best way to cut down, but those who do try often don't succeed.

The purpose of this study is to investigate whether providing some simple support in your local community can make a difference to successfully helping smokers, who want to cut down but not quit in the next 4 weeks, to reduce their smoking. The effects of different approaches, supported by a local Health Trainer, will be compared with normal guidance. One hundred and twenty moderate to heavy smokers will take part, half will be allocated to receive support from a community health trainer and half will continue with normal care. You have been asked to take part because you are currently a moderate to heavy smoker, and you may wish to reduce your smoking but not quit just now.

What will happen if I want to take part?

You will be invited to attend an assessment to check your suitability to join the study, and complete some simple questions about your smoking and other behaviours that have been linked to health, including alcohol consumption and physical activity. A computer will be used to randomly (by chance) allocate various study numbers to receive either the support for reduction programme or normal care.

If you are allocated to the support for reduction programme, you will be able to receive three face to face sessions with a Health Trainer for up to 45 mins, in week 1, 4 and 8, plus 15 min phone calls in weeks 2, 3, 5, 6 and 7. The phone support will be extended for a further 6 weeks if you choose to quit. If you do choose to quit you will be given information on how to seek support to quit from the National Health Service (NHS) Stop Smoking Services.

The support from a Health Trainer will include help with deciding how best to reduce your smoking, from several alternatives from which you can choose, plus support to increase your physical activity or exercise. The latter may include setting targets, using a free pedometer, and having subsidised access to exercise facilities and opportunities.

If you are allocated to the normal care condition you will be offered advice on the benefits of cutting down and quitting and information on how to seek support to quit from the NHS Stop Smoking Services. At the end of the study (after 4 months) you will be given further material that may help you cut down or quit if you wish.

All participants will attend assessments at a convenient local place in weeks 8 and 16 weeks, and be asked similar questions on the phone in week 4, after the initial assessment. Each assessment session will last about 20-25 mins,

What are the possible benefits of taking part?

Reducing smoking and increasing physical activity are two of the most important things that you can do

to improve your health and quality of life. The support you may receive could help you to do both. Less heavy smokers are more likely to have the confidence to quit smoking, and give up for good. The information you provide may help to design better support to help you and others to cut down in the future and possibly quitting. Cutting down does not offer the same protection for your future health as quitting.

Will taking part in this research affect my treatment?

No, you will be entitled to the same NHS support and treatment whether you take part in this study or not.

Are there any side effects?

As you may well have experienced, reducing or stopping smoking may cause some moderate or intense withdrawal symptoms. Failure to cope with these often leads to a return to previous smoking levels. The study aims to provide support with strategies to deal with these withdrawal symptoms. One approach is to use physical activity to reduce withdrawal symptoms, such as low mood and irritability. Moderate intensity physical activity will be recommended, which has few if any side effects. You will be given guidance on how best to avoid stiffness after exercise. You will be advised to check with your doctor if you wish to engage in vigorous exercise which may be associated with greater risk of health problems, particularly if you have existing poor health and have been inactive for some time.

What will happen if I do not want to take part in the study?

Taking part is entirely voluntary. If you do not wish to take part, this decision will not affect your medical care in any way. Even if you are recruited into the study you are free to withdraw at any time without explanation. However it would be helpful for the study team to know why you do not wish to continue. Your withdrawal will not affect the progress of the study.

Under what circumstances will the study be stopped?

If the Principal Investigator considers it necessary he will stop the study in the interest of the safety and well being of the participants.

Will any information I provide be confidential?

Yes. Information relating to your participation will be kept confidential and will not be disclosed without your prior permission. Confidential information will be stored safely in a locked cabinet. The study will be written up in scientific journals in such a way that none of the people taking part can be identified.

What should I do if something goes wrong during the study?

If you feel unusually unwell you should contact your GP in the first instance. If you have a medical emergency at any time you should ring 999 and request an ambulance.

Problems relating to your participation in the study should be reported to the person who conducts your initial assessment as part of the study. Details of how they can be contacted will be provided at the beginning of the study.

If you have received an invitation to join the study from your GP, does your GP receive any financial reward for your participation in the study?

A small payment will be paid to the practice in respect of the administrative costs involved in assisting

with the study. This is the normal procedure for research with NHS patients.

Where can I get more information about this study?

By contacting:

Project Manager:
Tom Thompson
Peninsula College of Medicine and Dentistry:
Telephone number: 01752 437 300
E-mail: T.P.Thompson@exeter.ac.uk

Or:
The Principal Investigator:
Professor: Adrian Taylor:
School of Sports and Health Sciences (University of Exeter):
Telephone number: 01392-264747.
E-mail: A.H.Taylor@ex.ac.uk

APPENDIX XI

Phase 2: PARTICIPANT INFORMED CONSENT FORM

A study of the effects of local support for smokers who wish to cut down but not quit.

LREC Study Number: **Patient Study Number:** ……

Name of Researcher: ……

Please read carefully and initial the box if you are in agreement with the statement.

1. I confirm that I have read and understand the Participant Information Sheet dated xx/xx/xx for the above study and have had an opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without my medical care or legal rights being affected. ☐

3. I understand that to take part in this study it is necessary for me to be able to increase the amount of moderate intensity physical activity (typically up to a level where I can just still hold a conversation). ☐

4. I agree to take part in the above study. ☐

Signatures

Name of patient (Patient to Print)	Date	Signature
Name of person taking consent (Print)	Date	Signature
Name of researcher (Researcher to Print)	Date	Signature

APPENDIX XII

Questionnaires

A. Demographics
B. Smoking history, quitting and cessation aids used
C. Smoking dependence and status
D. Alcohol consumption
E. Self-reported cravings and withdrawal symptoms
F. mCEQ (smoking satisfaction)
G. Perceived Stress Scale (PSS)
H. Physical Activity Readiness Questionnaire (PAR-Q)
I. Self-reported PA
J. EQ-5D
K. SF12

XII. A. DEMOGRAPHICS

1. Researcher:	.....				
2. Date of birth of participant:	...../...../.....				
3. Initials	. .				
4. How old are you?	.....years				
5. Are you...	Married or living with a partner	Single/divorced/ widowed/separated			
	☐	☐			
6. Are you...	Employed	Seeking Work	Home Keeper	Retired	Student
	☐	☐	☐	☐	☐
7. What is your usual job?	.....				
8. How old were you when you left full time education?	.....years				
9. Does your partner or other co-habitant smoke tobacco?	Yes	No	N/A		
	☐	☐	☐		
10. How would you describe your ethnic group? (please tick one box only)	British	Other Ethnic Group			
	☐	☐			
Please describe:	.....				
11. Weight (Kg)	.....kg				
12. Height (M)	.....m				
13. Exhaled Carbon Monoxide (CO) reading	.....ppm				

XII. B. SMOKING HISTORY, QUITTING AND CESSATION AIDS USED

1. Are you seriously thinking of quitting smoking?	YES, within the next **30 days** ☐	YES, within the next **6 months** ☐	NO, not thinking of quitting ☐
2. For how many years have you smoked?	…….years		
3. About how many cigarettes have you smoked each day (during those years)? (use to calculate 'pack yrs')	……..cigarettes		
4. What smoking cessation aids did you use?	_____ (record all applicable) (show list of NRT products, medications, and other strategies, including physical activity).		
2. In the last year, how many times have you quit smoking for at least 24 HOURS?	.....times		
3. How important is it for you to stop smoking permanently and completely in the next 6 months? *(please circle)*	**1 2 3 4 5 6 7** *Not at all important* ◄····► *Extremely important*		
4. How confident are you that you can stop smoking permanently and completely in the next six months? *(please circle)*	**1 2 3 4 5 6 7** *Not at all confident* ◄····► *Extremely confident*		
5. How easy would it be for you to stop smoking permanently and completely in the next six months? *(please circle)*	**1 2 3 4 5 6 7** *Not at all easy* ◄····► *Extremely easy*		
6. An important person in your life thinks you should quit smoking. *(please circle)*	**1 2 3 4 5 6 7** *Strongly disagree* ◄····► *Strongly agree*		

XII. C. SMOKING DEPENDENCE AND STATUS

1. How many cigarettes do you usually smoke each day now?	.....cigarettes a day			
2. How soon after you wake up do you smoke your first cigarette?	Within 5 minutes	6-30 minutes	31-60 minutes	After 60 minutes
	☐	☐	☐	☐
3. Do you smoke more frequently in the first hours after waking than during the rest of the day?	Yes		No	
	☐		☐	
4. Do you find it difficult to refrain from smoking in areas where it is forbidden?	Yes		No	
	☐		☐	
5. Which cigarette would you hate to give up most?	The first one in the morning		Any other	
	☐		☐	
6. Do you smoke if you are so ill that you are in bed most of the day?	Yes		No	
	☐		☐	

At follow-up assessments only after a quit attempt has been recorded:

Have smoked, even a puff, since we last met? _____

Expired CO measure _____

XII. D Alcohol consumption

1. How often do you have a drink containing alcohol?

never	☐ 1
once a month or less	☐ 2
two to four times a month	☐ 3
two to three times a week	☐ 4
four or more times a week	☐ 5

2. How many drinks containing alcohol do you have on a typical day when you are drinking?

one or two	☐ 1
three or four	☐ 2
five or six	☐ 3
seven to nine	☐ 4
ten or more	☐ 5

3. How many drinks containing alcohol have you had in the past week?

one or two	☐ 1
three or four	☐ 2
five or six	☐ 3
seven to nine	☐ 4
ten or more	☐ 5

XII. E. SELF-REPORTED CRAVINGS AND WITHDRAWAL SYMPTOMS

1. How much of the time have you felt the urge to smoke today? *(please circle)*					
Not at all	A little of the time	Some of the time	A lot of the time	Almost all the time	All the time
0	**1**	**2**	**3**	**4**	**5**

2. How strong have the urges been today? *(please circle)*					
No urges	Slight	Moderate	Strong	Very Strong	Extremely strong
0	**1**	**2**	**3**	**4**	**5**

3. Please show for each of the items below how you have been feeling over the past WEEK *(please circle one number for each item):*					
Item	Not at all	Slightly	Somewhat	Very	Extremely
a) Restless	**1**	**2**	**3**	**4**	**5**
b) Irritable	**1**	**2**	**3**	**4**	**5**
c) Depressed	**1**	**2**	**3**	**4**	**5**
d) Hungry	**1**	**2**	**3**	**4**	**5**
e) Poor Concentration	**1**	**2**	**3**	**4**	**5**
f) Poor sleep at night	**1**	**2**	**3**	**4**	**5**
g) Stressed out	**1**	**2**	**3**	**4**	**5**
h) Tired	**1**	**2**	**3**	**4**	**5**
i) Tense	**1**	**2**	**3**	**4**	**5**

XII. F. mCEQ

Circle a number between 1 (not at all) and 7 (extremely), that best describes how smoking has made you feel in the past week:							
Question	Not at all	Very little	A little	Moderately	A lot	Quite a lot	Extremely
1. Was smoking satisfying?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
2. Did the cigarettes taste good?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
3. Did you enjoy the sensations in your throat and chest?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
4. Did smoking calm you down?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
5. Did smoking make you feel more awake?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
6. Did smoking make you feel less irritable?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
7. Did smoking help you concentrate?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
8. Did smoking reduce your hunger for food?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
9. Did smoking immediately reduce your craving for a cigarette?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
10. Did you enjoy smoking?	**1**	**2**	**3**	**4**	**5**	**6**	**7**

XII. G. PSS

These questions ask about how stressed you have been feeling.

For each statement below, circle the number that comes closest to how you have been feeling over the past WEEK *(please circle one number for each statement):*

Question	Never	Almost never	Sometimes	Fairly often	Very often
1. I have been unable to control the important things in my life	**0**	**1**	**2**	**3**	**4**
2. I have felt confident about my ability to handle personal problems	**0**	**1**	**2**	**3**	**4**
3. I have felt that things are going my way	**0**	**1**	**2**	**3**	**4**
4. Difficulties are piling up so high that I cannot overcome them	**0**	**1**	**2**	**3**	**4**

XII. H. PHYSICAL ACTIVITY READINESS QUESTIONNAIRE (PAR-Q)

Could you please answer YES or NO to the following questions:		
	Yes	**No**
1. Has a doctor ever said you have a heart condition and recommended only medically supervised physical activity?	☐	☐
2. Do you have chest pain brought on by physical activity?	☐	☐
3. Have you developed chest pain in the last month?	☐	☐
4. Do you tend to lose consciousness or fall over as a result of dizziness?	☐	☐
5. Do you have any bone or joint problems that become aggravated when you are more active?	☐	☐
6. Has a doctor ever recommended medication for your blood pressure or a heart condition?	☐	☐
7. Are you aware, through your own experience or a doctor's advice, of any other medical reason why you shouldn't be physically active without medical supervision?	☐	☐

XII. I. SELF REPORTED PHYSICAL ACTIVITY

Which of the statements below most accurately describes how you feel at present about being physically active?

We are only interested in physical activity which is hard enough to make you breathe slightly harder than normal, makes you warmer, makes you aware that your heart is beating faster, and that you do continuously for at least 10 minutes. Include activities such as brisk walking, gardening and heavy housework, as well as organised exercise and sport. To consider yourself *physically active*, you must be doing a *total* of 30 minutes or more of activity per day and on at least 5 days per week. For example, this might be a 30-minute walk or three 10-minute walks. (*Please tick one box only*)

Statement	*Please tick ONE*
1. I am not physically active and I do not intend to become physically active in the next six months	☐
2. I am not physically active and I am planning to become physically active in the next six months, but not in the next month	☐
3. I am not physically active and am planning to become active in the next month	☐
4. I am physically active, but have been for less than six months	☐
5. I have been physically active for at least six months	☐

Instructions for carrying out the 7 day physical activity recall interview:

1. Label the days on the recall table (day one is yesterday).
2. Introduce interview: Explain that you will be asking about their physical activity, starting with yesterday and working backwards through the previous seven days.
3. Define segments of day: Say that you will be asking separately about activities for the morning, afternoon and evening.
4. Describe the type of activity which you are interested in:
   Explain that you are interested in any work, household or leisure activities lasting at least 10 minutes that are, at least, at a level of intensity which makes them breathe slightly harder than normal, makes them warmer, and makes them aware that their heart is beating faster. Say that you are not interested in light activities such as desk work, strolling or light housework.
5. Ask about activities: For each segment of the day, ask the interviewee to recall activity episodes lasting at least ten minutes and record the information in the table (round to the nearest 5 minutes). For each activity record the type of activity (using type codes) and duration of activity in minutes (e.g. “W 10” denotes a 10 minute walk). For each day begin by asking “What did you do and where did you go on that morning”.
6. Record the number of minutes of activity for each day and whether 30 minutes was achieved.
7.

DAY	Morning	Afternoon	Evening	Daily Total (mins)	30 mins achieved?
1. *Yesterday*					☐
2.					☐
3.					☐
4.					☐
5.					☐
6.					☐
7.					☐
			Weekly Totals:		

W: Walk, **ExH**: Sructured home exercise, **ExF**: Structured exercise facility, **H**: Housework, **Sw**: Swimming, **DIY**: Do it yourself, **Cyc**: Cycling, **G**: Gardening, **D**: Dancing, **SpI**: Sport/individual, **SpT**: Sport Team, **Occ**: Occupational, **O**: Other *(please state).*

Record the number of hours of physical activity (minutes/60):	.....hours
Record the number of day with 30 mins or more of activity:	.....days

Indicate the main mode of activity (i.e. that in which the interviewee spends most time):

W	ExH	ExF	H	Sw	DIY	Cyc	G	D	SpI	SpT	Occ	O
1	2	3	4	5	6	7	8	9	10	11	12	13

XII. J. EQ-5D

These next questions ask for your opinion on your state of health TODAY. Please indicate which statement best describes various aspects of your own health TODAY, by placing a tick in ONE box for each question below.

1. Mobility	
I have no problems in walking about	☐1
I have some problems in walking about	☐2
I am confined to bed	☐3
2. Self-care	
I have no problems with self-care	☐1
I have some problems washing or dressing myself	☐2
I am unable to wash or dress myself	☐3
3. Usual activities e.g. work, study, housework, family or leisure activities	
I have no problems with performing my usual activities	☐1
I have some problems with performing my usual activities	☐2
I am unable to perform my usual activities	☐3
4. Pain / discomfort	
I have no pain or discomfort	☐1
I have moderate pain or discomfort	☐2
I have extreme pain or discomfort	☐3
5. Anxiety / depression	
I am not anxious or depressed	☐1
I am moderately anxious or depressed	☐2
I am extremely anxious or depressed	☐3

XII. K. SF12

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.
Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

	Excellent	Very good	Good	Fair	Poor
1. In general would you say your health is:	☐	☐	☐	☐	☐

The following questions are about activities you might do during a typical day. Does your health *now* limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. **Moderate Activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐	☐	☐
3. Climbing **several** flights of stairs	☐	☐	☐

During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. **Accomplished less** than you would like	☐	☐
5. Were limited in the **kind** of work or kind of activities	☐	☐

During the *past 4 weeks*, have you had any of the following problems with your work or other regular daily activities *as a result of any emotional problems* (such as feeling depressed or anxious)?

	Yes	No
6. **Accomplished less** than you would like	☐	☐

7. Didn't do work or activities as **carefully** as usual	☐	☐

8. During the past *4 weeks*, how much did pain interfere with your normal work (including both work outside the home and housework)?	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
	☐	☐	☐	☐	☐

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the *past 4 weeks*...

	All of the time	**Most of the time**	**A good bit of the time**	**Some of the time**	**A little of the time**	**None of the time**
9. Have you felt calm and peaceful?	☐	☐	☐	☐	☐	☐
10. Did you have a lot of energy?	☐	☐	☐	☐	☐	☐
11. Have you felt downhearted and blue?	☐	☐	☐	☐	☐	☐

12. During the past *4 weeks*, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc)?	**All of the time**	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
	☐	☐	☐	☐	☐