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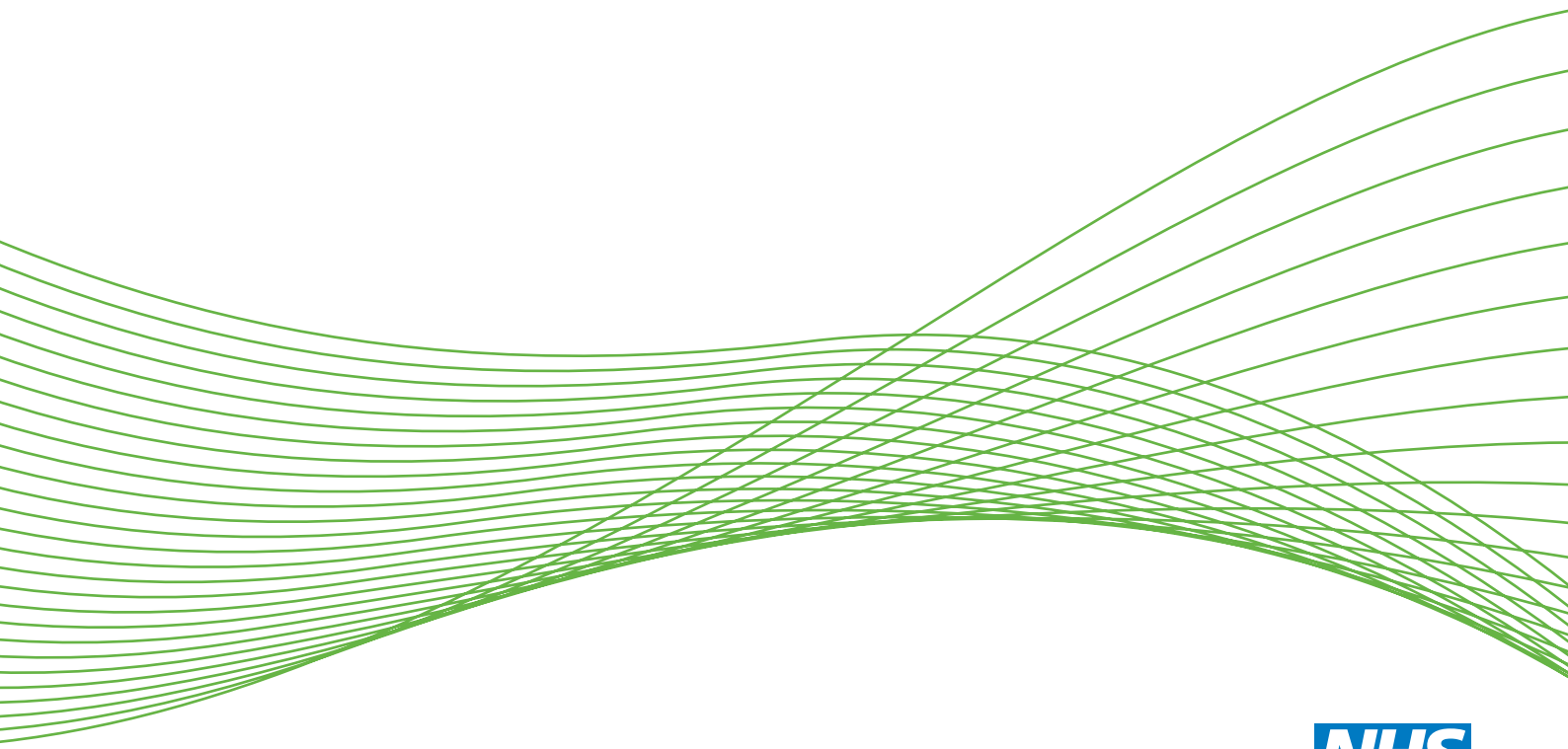

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[1]Department of Health Sciences, University of York, York, UK
[2]Leeds Addiction Unit, Leeds, UK
[3]Institute of Health and Society, Newcastle University, Newcastle, UK
[4]National Addiction Centre, Institute of Psychiatry, King's College London, London, UK
[5]Centre for Health Service Studies, University of Kent, Canterbury, UK

*Corresponding author

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Abstract

AESOPS: a randomised controlled trial of the clinical effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care

JM Watson,[1] H Crosby,[2] VM Dale,[1] G Tober,[2] Q Wu,[1] J Lang,[2] R McGovern,[3] D Newbury-Birch,[3] S Parrott,[1] JM Bland,[1] C Drummond,[4] C Godfrey,[1] E Kaner[3] and S Coulton[5]* on behalf of the AESOPS trial team

[1]Department of Health Sciences, University of York, York, UK
[2]Leeds Addiction Unit, Leeds, UK
[3]Institute of Health and Society, Newcastle University, Newcastle, UK
[4]National Addiction Centre, Institute of Psychiatry, King's College London, London, UK
[5]Centre for Health Service Studies, University of Kent, Canterbury, UK

*Corresponding author S.Coulton@kent.ac.uk

Background: There is clear evidence of the detrimental impact of hazardous alcohol consumption on the physical and mental health of the population. Estimates suggest that hazardous alcohol consumption annually accounts for 150,000 hospital admissions and between 15,000 and 22,000 deaths in the UK. In the older population, hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems. There is evidence of an association between increased alcohol consumption and increased risk of coronary heart disease, hypertension and haemorrhagic and ischaemic stroke, increased rates of alcohol-related liver disease and increased risk of a range of cancers. Alcohol is identified as one of the three main risk factors for falls. Excessive alcohol consumption in older age can also contribute to the onset of dementia and other age-related cognitive deficits and is implicated in one-third of all suicides in the older population.

Objective: To compare the clinical effectiveness and cost-effectiveness of a stepped care intervention against a minimal intervention in the treatment of older hazardous alcohol users in primary care.

Design: A multicentre, pragmatic, two-armed randomised controlled trial with an economic evaluation.

Setting: General practices in primary care in England and Scotland between April 2008 and October 2010.

Participants: Adults aged ≥55 years scoring ≥8 on the Alcohol Use Disorders Identification Test (10-item) (AUDIT) were eligible. In total, 529 patients were randomised in the study.

Interventions: The minimal intervention group received a 5-minute brief advice intervention with the practice or research nurse involving feedback of the screening results and discussion regarding the health consequences of continued hazardous alcohol consumption. Those in the stepped care arm initially received a 20-minute session of behavioural change counselling, with referral to step 2 (motivational

enhancement therapy) and step 3 (local specialist alcohol services) if indicated. Sessions were recorded and rated to ensure treatment fidelity.

Main outcome measures: The primary outcome was average drinks per day (ADD) derived from extended AUDIT – Consumption (3-item) (AUDIT-C) at 12 months. Secondary outcomes were AUDIT-C score at 6 and 12 months; alcohol-related problems assessed using the Drinking Problems Index (DPI) at 6 and 12 months; health-related quality of life assessed using the Short Form Questionnaire-12 items (SF-12) at 6 and 12 months; ADD at 6 months; quality-adjusted life-years (QALYs) (for cost–utility analysis derived from European Quality of Life-5 Dimensions); and health and social care resource use associated with the two groups.

Results: Both groups reduced alcohol consumption between baseline and 12 months. The difference between groups in log-transformed ADD at 12 months was very small, at 0.025 [95% confidence interval (CI) –0.060 to 0.119], and not statistically significant. At month 6 the stepped care group had a lower ADD, but again the difference was not statistically significant. At months 6 and 12, the stepped care group had a lower DPI score, but this difference was not statistically significant at the 5% level. The stepped care group had a lower SF-12 mental component score and lower physical component score at month 6 and month 12, but these differences were not statistically significant at the 5% level.

The overall average cost per patient, taking into account health and social care resource use, was £488 [standard deviation (SD) £826] in the stepped care group and £482 (SD £826) in the minimal intervention group at month 6. The mean QALY gains were slightly greater in the stepped care group than in the minimal intervention group, with a mean difference of 0.0058 (95% CI –0.0018 to 0.0133), generating an incremental cost-effectiveness ratio (ICER) of £1100 per QALY gained. At month 12, participants in the stepped care group incurred fewer costs, with a mean difference of –£194 (95% CI –£585 to £198), and had gained 0.0117 more QALYs (95% CI –0.0084 to 0.0318) than the control group. Therefore, from an economic perspective the minimal intervention was dominated by stepped care but, as would be expected given the effectiveness results, the difference was small and not statistically significant.

Conclusions: Stepped care does not confer an advantage over minimal intervention in terms of reduction in alcohol consumption at 12 months post intervention when compared with a 5-minute brief (minimal) intervention.

Trial registration: This trial is registered as ISRCTN52557360.

Funding: This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 17, No. 25. See the HTA programme website for further project information.

Contents

List of abbreviations

ADD	average drinks per day
AESOPS	Alcohol: Evaluating Stepped care in Older Populations Study
AUDIT	Alcohol Use Disorders Identification Test (10-item)
AUDIT-C	Alcohol Use Disorders Identification Test – Consumption (3-item)
BCC	behavioural change counselling
CEAC	cost-effectiveness acceptability curve
CEP	cost-effectiveness plane
CI	confidence interval
CONSORT	Consolidated Standards of Reporting Trials
DPI	Drinking Problems Index
EQ-5D	European Quality of Life-5 Dimensions
GP	general practitioner
HRQoL	health-related quality of life
ICC	intraclass correlation coefficient
ICER	incremental cost-effectiveness ratio
ISRCTN	International Standard Randomised Controlled Trial Number
ITT	intention to treat
MCS	mental component score
MET	motivational enhancement therapy
NICE	National Institute for Health and Care Excellence
PCS	physical component score
PRS	Process Rating Scale
QALY	quality-adjusted life-year
RCT	randomised controlled trial
SD	standard deviation
SF-12	Short Form Questionnaire-12 items
UKATT	UK Alcohol Treatment Trial
WTP	willingness to pay

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

Scientific summary

Background

There is clear evidence of the detrimental impact of hazardous alcohol consumption on the physical and mental health of the population. Estimates suggest that hazardous alcohol consumption annually accounts for 150,000 hospital admissions and between 15,000 and 22,000 deaths in the UK. In the older population, hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems. There is evidence of an association between increased alcohol consumption and increased risk of coronary heart disease, hypertension, haemorrhagic and ischaemic stroke, increased rates of alcohol-related liver disease and increased risk of a range of cancers. Alcohol has been identified as one of the three main risk factors for falls. Excessive alcohol consumption in older age can also contribute to the onset of dementia and other age-related cognitive deficits and is implicated in one-third of all suicides in the older population.

Objectives

To compare the clinical effectiveness and cost-effectiveness of a stepped care intervention against a minimal intervention in the treatment of older hazardous alcohol users in primary care.

Design

A multicentre, pragmatic, two-armed randomised controlled trial with an economic evaluation. Randomisation was performed by a remote service. Treating nurses, therapists and participants were aware of allocation result, and outcome assessment was average drinks per day (ADD) derived from the extended Alcohol Use Disorders Identification Test – Consumption (3-item) (AUDIT-C).

Setting

General practices in primary care in England and Scotland.

Participants

Participants were eligible to participate in the study if they were aged ≥55 years and scored ≥8 on the Alcohol Use Disorders Identification Test (AUDIT). Following screening, a total of 529 participants were randomised in the study.

Interventions

Participants in the minimal intervention group received a 5-minute brief advice intervention with the practice nurse or research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption. Those in the stepped care arm initially received a 20-minute session of behavioural change counselling (step 1), with referral to step 2 (motivational enhancement therapy) and step 3 (local specialist alcohol services) if indicated. Sessions were recorded to ensure treatment fidelity.

Main outcome measures

The primary outcome was ADD derived from the extended AUDIT-C at 12 months. Secondary outcomes were alcohol-related problems assessed using the Drinking Problems Index (DPI) at 6 and 12 months; ADD (derived from the extended AUDIT-C) at 6 months; extended AUDIT-C score at 6 and 12 months; health-related quality of life (HRQoL) at 6 and 12 months; quality-adjusted life-years (QALYs) (for cost–utility analysis derived from European Quality of Life-5 Dimensions); and health and social care resource use associated with the two groups.

Results

Both groups reduced alcohol consumption between baseline and 12 months. There were no significant differences in ADD between the treatment groups at 12 months. Stepped care had a marginally higher ADD [1.129; standard deviation (SD) 0.037] than minimal intervention (1.104; SD 0.037), but not significantly so. At months 6 and 12, the stepped care group had a lower DPI score than the minimal intervention group, but the difference was not statistically significant at the 5% level. At month 6, the stepped care group had a lower ADD than the minimal intervention group, but this difference was not statistically significant. The stepped care group had a lower mental component score [measured using the Short Form Questionnaire-12 items (SF-12)] than the minimal intervention group at month 6 and month 12. The stepped care group also had a lower physical component score at month 6 and month 12. These differences were not significant at the 5% level.

The cost-effectiveness results indicated that the overall average cost per patient, taking into account health and social care resource use, was £488 (SD £826) in the stepped care group and £482 (SD £826) in the minimal intervention group at month 6. The mean QALY gains were slightly greater in the stepped care group than in the minimal intervention group, with a mean difference of 0.0058 [95% confidence interval (CI) –0.0018 to 0.0133], generating an incremental cost-effectiveness ratio (ICER) of £1100 per QALY gained. At month 12, participants in the stepped care group incurred fewer costs, with a mean difference of –£194 (95% CI –£585 to £198), and had gained 0.0117 more QALYs (95% CI –0.0084 to 0.0318) than the control group. From an economic perspective the minimal intervention, therefore, was dominated by stepped care. Given thresholds of £20,000–30,000 per additional QALY gained, the probability that stepped care is more cost-effective is 81–86% at the 6-month follow-up and 93.5–93.8% at 12 months.

A sensitivity analysis that excluded extreme cases altered the average costs of interventions; the ICERs were £8496 per QALY at 6 months and £4224 per QALY at 12 months. The probability that stepped care is more cost-effective ranges between 80% and 88% at 6 months, and between 87% and 90% at 12 months, using the £20,000–30,000 per QALY gained threshold.

The prevalence of hazardous alcohol consumption in those aged ≥55 years had been estimated at 15% in the general population. Screening results from this study found this to be only 7.5%. Fidelity process rating identified significant differences between the minimal and step 1 interventions, indicating that the two types of intervention were distinct. There were no significant differences in the rating scores between practice or research nurses with different levels of experience (specialist vs non-specialist practitioners).

Conclusions

Stepped care does not confer an advantage over minimal intervention in terms of reduction in alcohol consumption at 12 months post intervention when compared with a 5-minute brief (minimal) intervention. Our cost-effectiveness analysis examining QALY gains suggested that the stepped care intervention is more likely to generate greater health benefits and achieves better value for money compared with minimal

intervention, but caution is required given the uncertainty surrounding the estimates and the absence of a statistically significant difference in effectiveness outcomes.

Implications for health care

There is no evidence that a stepped care approach reduces alcohol consumption in terms of ADD among older hazardous alcohol users after 12 months, or improves AUDIT score, alcohol-related problems or quality of life after 6 or 12 months.

Recommendations for future research

The experience of conducting this study alongside the results obtained has prompted a number of suggestions for future research:

- What factors facilitate or hinder the conduct of research in primary care settings?
- What is the clinical effectiveness and cost-effectiveness of community-based screening and self-directed ultra-brief interventions for hazardous alcohol users compared with screening alone?
- What is the clinical effectiveness and cost-effectiveness of motivational enhancement therapy for opportunistically identified, non-treatment-seeking harmful alcohol users delivered in primary care?
- What are the longer-term clinical and economic impacts of stepped care interventions?

Study registration

This trial is registered as ISRCTN52557360.

Funding

This project was funded by the NIHR Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 17, No. 25. See the HTA programme website for further project information.

Chapter 1 Background

There exists a wealth of evidence regarding the detrimental impact of hazardous alcohol consumption on the physical and mental health of the population [hazardous alcohol consumption is defined as the consumption of more than 21 standard alcohol units in any week for males and 14 for females; or half of the recommended number of standard alcohol units in any one day (10 for males, 7 for females)]. It is estimated that hazardous alcohol consumption accounts for 150,000 hospital admissions and between 15,000 and 22,000 deaths per annum in the UK.[1] In the older population (those aged ≥55 years), hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems.[2] There is evidence of an association between increased alcohol consumption and increased risk of coronary heart disease, hypertension and haemorrhagic and ischaemic stroke, increased rates of alcohol-related liver disease and increased risk of a range of cancers.[3] Alcohol consumption is identified as one of the three main risk factors for falls,[4] a major cause of morbidity and mortality in this population. The Royal College of Physicians estimates that 60% of older people admitted to hospital because of repeated falls, confusion, chest infections and heart failure have undiagnosed alcohol problems.[5] Increased alcohol consumption in older age can also contribute to the onset of dementia and other age-related cognitive deficits, Parkinson's disease and a range of psychological problems including depression and anxiety.[6] Alcohol use is implicated in one-third of all suicides in the older population.[7] It is estimated that 80% of those aged ≥65 years regularly take prescribed medication and that polypharmacy is common, with one-third taking at least four prescribed medications per day.[8] Alcohol is a major contraindication for many of the drugs prescribed for older people, and alcohol and medication interactions are a common phenomenon.[9] Increased alcohol consumption in older age is also associated with a range of social problems including self-neglect, poor nutrition, social isolation and hypothermia.[10]

The prevalence of hazardous alcohol consumption (inclusive of harmful consumption) in those aged ≥55 years is generally considered to be lower than in the wider adult population. The most recent estimate derived from the Alcohol Needs Assessment Research Project[11] indicates a general population prevalence of between 15% and 25% and concurs with other estimates derived from the General Household Survey.[12] There is evidence that these prevalence rates are underestimates of the true prevalence rate.[11] There is also evidence that the prevalence rate in primary care attendees is higher than in the general population.[13] Furthermore, the current Home Office Alcohol Strategy recommends that available research be used in order to understand 'how we can best communicate the risks from alcohol, improving the public's understanding of both personal risks and societal harms. This will include whether separate advice is desirable for the maximum amount of alcohol to be drunk in one occasion and for people over 65'.[14]

Recent research using data derived from the General Practice Research Database indicates that only 5% of people aged ≥55 years with an alcohol use disorder are identified in primary care settings.[15] Older people are less likely to seek treatment for alcohol use disorders[16] and alcohol-related presentations are often atypical or masked by comorbid physical or psychiatric illness that makes alcohol-related diagnosis more difficult.[17] In 2000, 16% of the UK population was ≥65 years old and this is expected to increase to 21% by 2026.[8] As the average age of the population increases, the absolute number of older people consuming alcohol at hazardous levels will increase even if the prevalence rate remains stable. Opportunistic screening is a proactive screening technique that has been used with some success in a variety of health-care areas including type II diabetes[18] and chlamydia infections,[19] and is particularly useful in identifying conditions in populations who would not usually seek treatment.

A number of paper-based screening methods have been developed to identify hazardous alcohol consumption; these include instruments such as the Michigan Alcohol Screening Test,[20] Paddington Alcohol Test,[21] Fast Alcohol Screening Test,[22] Single Alcohol Screening Question[23] and the Alcohol Use Disorders Identification Test (AUDIT).[24] All have acceptable levels of sensitivity and specificity. The AUDIT was specifically developed for use in a primary care population and has 92% sensitivity and 92% specificity

for identifying hazardous alcohol use in a UK primary care setting.[13] More specifically, in older populations (≥65 years) AUDIT has been demonstrated to have higher sensitivity and specificity compared with other screening tests.[25] AUDIT is a short, 10-item questionnaire that addresses frequency of alcohol consumption, alcohol-related problems and alcohol dependence symptoms. Because of the evidence of underdetection and misdiagnosis of hazardous alcohol use in older populations,[16,17] the proactive application of a short universal screening method is likely to be more appropriate. There is evidence that patients are more compliant with screening protocols for alcohol use in health-care settings and that the environment provides an opportunity for a 'teachable moment', increasing the patient's likelihood of engaging in any intervention.[26]

There is a substantial evidence base for the efficacy of brief motivational interventions, aimed at reducing alcohol consumption in primary care. Studies have demonstrated the effectiveness of brief interventions in reducing alcohol consumption in primary care populations in the UK;[27] in particular, six systematic reviews focus specifically on this[28–33] and all conclude that brief interventions in primary care populations are effective in reducing alcohol consumption. However, many of the studies included in these reviews exclude older patients. There are no systematic reviews or subgroup analyses specifically focusing on older patient groups. There is contradictory evidence from primary research of the efficacy of brief interventions specifically targeted at older hazardous alcohol consumers. Moore *et al*.[34] compared a minimal, brief advice intervention with a multifaceted intervention including physician advice and behavioural counselling in adults attending primary care centres in the USA. While reductions were observed in both groups in terms of consumption at 12 months, no significant differences were observed between the groups. Yet in a trial of brief interventions for older alcohol users in primary care in the USA, Fleming *et al*.[35] reported a 34% reduction in alcohol consumption and 64% reduction in those drinking at hazardous levels at 12 months, significantly better than those who received no intervention. Blow and Barry[36] also reported significantly greater reduction in alcohol use in older people treated with brief interventions in primary care than in control subjects. There is also evidence from subgroup analyses of existing studies that older patients are at least as likely to benefit from brief interventions as younger patients[37] and that older adults are more likely to adhere to and comply with brief intervention treatment regimes.[38]

Brief interventions have been proven to be both clinically effective and cost-effective in the management of individuals with hazardous and harmful drinking in primary care settings.[27–29,39] Existing studies, however, have included few older drinkers, and this population may have different alcohol problems and, consequently, different health and social costs. The evidence of brief interventions has been criticised for failing to address a wider range of alcohol use disorders including harmful alcohol consumption[40] and for failing to address more entrenched drinking behaviours.

Screening for alcohol use disorders identifies a range of needs that are likely to require a range of types and intensities of interventions. One of the primary reasons why many general practitioners (GPs) are reluctant to implement screening into routine care is because they lack the appropriate skills for dealing with the more severe cases identified.[41]

Older alcohol consumers are often typified as either 'early-onset' drinkers, whose consumption pattern is a continuation of lifetime hazardous consumption, or 'late-onset' drinkers, whose excessive alcohol consumption begins in later life. 'Late-onset' drinkers are more likely to benefit from brief interventions than 'early-onset' drinkers, who often require a more intensive intervention approach.[42] One such intensive approach that has been used is motivational enhancement therapy (MET). It is relatively short (usually three 40-minute sessions delivered by a trained therapist) but is more intensive than a brief motivational intervention. Primary research has shown it to be as effective as other even more intensive interventions such as Cognitive Behavioural Therapy, Twelve-Step Facilitation Therapy and Social Behavioural Network Therapy [Matching Alcohol Treatments to Client Heterogeneity (Project MATCH)[43]; UK Alcohol Treatment Trial (UKATT)[44]].

Physiological changes that occur as part of the ageing process mean that older people are more vulnerable to the effects of alcohol and experience alcohol-related problems at lower consumption levels than younger people. Stepped care interventions offer a potentially resource-efficient means of meeting the needs of this population. Stepped care interventions provide a means of delivering more intensive interventions only to those who fail to respond to less intensive interventions, and are more in keeping with rational clinical decision-making than the blanket use of any one intervention strategy. This stepped approach has been advocated in a variety of clinical areas including depression,[45,46] smoking,[47] back pain[48] and alcohol use.[49,50] A recent pilot study of stepped care interventions for male alcohol users in primary care indicated a potential effect size difference between stepped care and minimal intervention of 0.25 in favour of stepped care and an indication that stepped care approaches for alcohol users may be more cost-effective than minimal interventions.[51]

Research objectives

- To evaluate the clinical effectiveness and cost effectiveness of stepped care interventions for older hazardous alcohol users in primary care.
- To screen 4170 primary care attendees aged ≥55 years for hazardous alcohol use using the AUDIT questionnaire.
- To evaluate the acceptability and validity of opportunistically screening for hazardous alcohol use in older primary care attendees.
- To estimate the prevalence of alcohol use disorders in an older primary care population.
- To study the process of therapy as delivered by both practice nurses and trained therapists.
- To randomise 500 hazardous alcohol users, with equal probability, to either a minimal intervention or stepped care.
- To conduct 6- and 12-month follow-up on at least 70% of those randomised to assess alcohol consumption, alcohol-related problems, quality of life and service utilisation.

Primary hypothesis (stated as a null hypothesis)

- Stepped care interventions for older hazardous alcohol users are no more effective at reducing alcohol consumption than a minimal intervention 12 months after randomisation.

Secondary hypotheses (stated as a null hypothesis)

- Stepped care is no more cost-effective than minimal intervention 12 months after randomisation.
- Stepped care will not reduce alcohol-related problems in comparison with minimal intervention 12 months after randomisation.
- Stepped care will not increase health-related quality of life (HRQoL) compared with minimal intervention 12 months after randomisation.

Chapter 2 Methods

Trial design

The Alcohol: Evaluating Stepped care in Older Populations Study (AESOPS) was a pragmatic, multicentre, two-armed, randomised controlled, open trial with equal randomisation. Participants aged ≥55 years who scored ≥8 using the AUDIT and consented to participate were randomised (1 : 1) to receive either:

- minimal intervention consisting of a 5-minute brief advice intervention with the practice nurse or research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption; or
- stepped care intervention consisting of three consecutive steps, in which progression between steps is dependent upon the outcome of each previous step.

The study protocol can be seen in *Appendix 1*.

Sample size

At the time of development, there were no previous studies of stepped care interventions for older alcohol-using adults. The closest UK pragmatic randomised controlled trials (RCTs) include that by Wallace *et al*.[27] and STEPWICE,[52] which reported effect size differences between stepped care and minimal interventions of 0.36 and 0.27 respectively. Similar effect size differences were reported in studies from the USA.[35,53,54] There is evidence that older populations respond to brief psychosocial interventions for alcohol use as well as, or even better than, general populations.[38,55] Assuming a conservative effect size difference between stepped care and minimal intervention of the order of 0.3 would require a sample size of 175 participants in each of the two randomised groups, using power at 80% and a 5% significance level.

Our previous experience in conducting RCTs in the fields of substance use, alcohol-using populations[44,52] and elderly populations indicated that, with assiduous follow-up regimes, loss to follow-up at 12 months would be in the order of 20%. Evidence also exists that older populations are more compliant with treatment regimes and follow-up protocols than younger populations.[56] Taking these factors into account, we erred on the side of caution and allowed a loss to follow-up of 30%, requiring 500 participants to be randomised (250 in each group). Previous alcohol use screening and intervention studies conducted in UK health-care settings[57] suggest that 80% of those screened positive tend to be eligible and 75% of those eligible tend to consent to randomisation. This meant that the study required 834 screen-positives, of whom we predicted 500 would be eligible and consent to randomisation.

Approvals obtained

North West Research Ethics Committee approved the study on 11 April 2007.

The details of multicentre research ethics committee, local research ethics committee and Research and Development Department approvals are provided in *Appendix 2*.

The trial was assigned the International Standard Randomised Controlled Trial Number (ISRCTN) of ISRCTN52557360; National Research Register number N0484190633 and United Kingdom Clinical Research Network ID 3796.

Trial sites

The study was conducted in eight UK sites with 55 general practices set up to participate. These sites and practices were recruited throughout the study and represent a range of small and large practices, and urban and rural settings. The sites included were North Yorkshire and York; Hull and East Riding; Norfolk; Leeds; Fife; Kent; Tyneside; and County Durham. Details of the study sites and practices are provided in *Appendix 3*.

Participant eligibility

Inclusion and exclusion criteria were chosen to maintain a balance between ensuring the sample was representative of the primary care population and ensuring that the trial population was able to engage with both the interventions and follow-up.

Inclusion criteria

Patients were considered potentially eligible if they met *all* of the following criteria:

1. They were aged ≥55 years at time of screening.
2. They screened positive for hazardous alcohol use (this is inclusive of harmful and dependent alcohol use) using AUDIT criteria (i.e. scored ≥8).
3. They provided their contact details on the screening form.
4. They were residing in a stable place of residence.
5. They lived within commutable distance of the primary care centre.
6. They were willing to provide informed consent for randomisation, treatment and follow-up.

Exclusion criteria

Potential participants were excluded if they met *any* of the following criteria:

1. They had received treatment for substance use, excluding nicotine, in the previous 90 days.
2. They were already seeking help for alcohol use.
3. They had any outstanding legal issues likely to lead to imprisonment.
4. They suffered from severe mental or physical illness likely to preclude active participation in treatment or follow-up.

Recruitment into the trial

All primary care attendees aged ≥55 years were given the opportunity to pick up a 'screening pack' from the practice waiting room or from the receptionist. The screening pack contained an information sheet (*Appendix 4*), a copy of the AUDIT questionnaire (*Appendix 5*) and a freepost return envelope. The AUDIT questionnaire contained a section asking for contact details to be provided if the patient was willing to help with the research; thereby, patients had the opportunity to complete the form anonymously. This envelope could either be posted back to the University of York (allowing for completion at home if preferred) or left in a postal box within the GP practice. Returned questionnaires were entered into a secure online database that collated the responses to all 10 questions on the AUDIT questionnaire. Patients who scored ≥8 on the AUDIT questionnaire, and had provided their contact details, were contacted by telephone and invited to attend an appointment with the practice/research nurse, ideally within the following 7 days. At that point they had the opportunity to ask any questions. At the appointment, the study was fully explained to the patients, their eligibility to participate was ascertained and they were given an opportunity to ask any further questions. If interested and willing, they were then asked to give written informed consent.

During the study recruitment phase, a change in screening method was brought in (detailed in *Chapter 3*). In addition to the opportunistic screening method, all potentially eligible participants received screening packs by mail from their general practice. This revised method was implemented in some of those practices already screening opportunistically and in all new practices brought on board after the change was implemented.

Baseline assessment

After written informed consent had been obtained, the following data were collected in the baseline questionnaire (*Appendix 6*) prior to randomisation.

Alcohol Use Disorders Identification Test – Consumption (3-item)

This consists of the first three alcohol consumption questions from the AUDIT 10-item scale.[24]

Drinking Problem Index

Alcohol-related problems were assessed using the 17-item participant-completed Drinking Problems Index (DPI). The DPI has been specifically designed and validated for use in older populations.[58]

Health-related quality of life

Participants were given a baseline questionnaire to complete, comprising the Short Form Questionnaire-12 items (SF-12)[59] and European Quality of Life-5 Dimensions (EQ-5D).[60]

Health and social resource used

Details regarding hospital and primary health-care services use, social and care services use and contact with the police and criminal justice system were collected. The service use questionnaire covered a retrospective 6-month period.

Demographics

Details on age, sex, smoking status, main activity, living arrangements, current accommodation and education were collected.

Randomisation

Participants were randomised equally between the two trial arms: minimal intervention and stepped care intervention. Randomisation was carried out using random permuted blocks, stratified by site (North Yorkshire and York; Hull and East Riding; Norfolk; Leeds; Fife; Kent; Tyneside; or County Durham). To maintain allocation concealment, the generation of the randomisation sequence and subsequent treatment allocation were performed by an independent, secure, remote, telephone randomisation service based at the University of York. The computerised randomisation system was checked periodically during the trial following standard operating procedures. Owing to the nature of the intervention and the pragmatic aim of the evaluation, treatment allocation, once determined, was not concealed from the participant or the professional delivering the intervention.

Trial interventions

Participants were randomised to receive either:

- minimal intervention: a 5-minute brief advice intervention with the practice nurse or research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption; or
- stepped care intervention: consisting of three consecutive steps, in which progression between steps is dependent upon the outcome of each previous step.

Intervention delivery

Originally, in some practices, the practice nurse delivered the minimal intervention and step 1 of the stepped care intervention. In other practices, a research nurse or research practitioner took on this role. Following a change to the protocol (as detailed in *Chapter 3*), two new sites used an alcohol health worker. For the purpose of this report, those delivering the minimal intervention and step 1 of the stepped care intervention will be referred to as the 'practice/research nurses'.

In the majority of sites, step 2 was delivered by a different person than step 1. In four sites, the same people delivered the minimal intervention and steps 1 and 2 of the stepped care interventions. For the purpose of this report, those delivering step 2 of the stepped care intervention will be referred to as the 'therapists'.

The set-up of the intervention delivery in each site is detailed in *Appendix 7*.

Training in the delivery of the minimal intervention and step 1 (behavioural change counselling)

The training was delivered by the training centre at Leeds Addiction Unit and lasted either 1 or 2 days, depending on previous experience of the staff being trained. Training for the minimal intervention involved understanding the AUDIT instrument and interpreting the score, and practice in feeding this back to participants and making recommendations for reducing consumption. It was delivered before training for the step 1 (20-minute) intervention that encompassed motivational interviewing skills, feeding back AUDIT scores in a manner that is designed to elicit concerns, and negotiating a behaviour change goal. In both cases training was supported by a written protocol. The training took the form of simulated consultation, followed by a seminar and then another simulated consultation. Each attendee had the opportunity to engage in a simulated consultation and this was recorded. As a group the practice/research nurses discussed the simulated consultations to examine and review the techniques. Prior to the staff seeing any study participants, an assessment of their competency was made using a recorded session that was rated by an independent expert. Ongoing supervision was provided throughout the study by an expert trainer from Leeds Addiction Unit.

A further training session was provided covering protocol issues and use of the study database. This session included the rationale for the study; patient eligibility; use of the online database (making and recording outcomes of appointments); recruitment procedures (including informed consent and randomisation); completion of trial documentation; conducting post-step 1 and post-step 2 assessment telephone calls; and handling of participant withdrawal.

Training in the delivery of step 2 (motivational enhancement therapy)

Motivational enhancement therapy therapists had attended specialist training at the Leeds Addiction Unit. Training was supported by a MET protocol, and follow-up supervision of video-recorded supervision was offered. Particular attention was given to understanding of the evidence base, the theoretical basis of treatment, demonstration of practice and role-play opportunities. Supervision was given in the delivery of a number of therapy sessions, and two recorded sessions were to be completed and reviewed in conjunction with a trained supervisor prior to the therapist seeing study participants. The supervision provided the main opportunity for practising skills and delivering the structure and content of the treatment. Assessment of competence was considered according to the therapist's ability to deliver MET in accordance with the designation of treatment prescribed in the treatment protocol.

A further training session was provided covering protocol issues and use of the study database. This session included the rationale for the study; patient eligibility; use of the online database (making and recording outcome of appointments); and handling of participant withdrawal.

Minimal intervention arm

The minimal intervention consisted of a 5-minute brief advice intervention with the practice/research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption. The participant also received a brief self-help booklet, *Safer drinking – a self help guide* (*Appendix 8*), outlining the consequences of excessive alcohol consumption and providing information on sources of help for drinking problems locally and nationally.

Stepped care intervention arm

The stepped care intervention consisted of three consecutive steps in which progression between steps was dependent upon the outcome of each previous step.

Step 1 consisted of a 20-minute session of behavioural change counselling (BCC) delivered by the practice/research nurse. This intervention, based upon an existing evidence base of brief interventions, utilises the technique of motivational interviewing[40] and aims to address the individual's motivation to change his or her drinking behaviour. The counselling was protocol guided and the practice/research nurses were trained in the delivery. Four weeks after randomisation the participant was contacted by the nurse and a short telephone assessment was made regarding the participant's alcohol consumption in the previous 4 weeks using the extended AUDIT–Consumption (3-item) (AUDIT–C). If the participant was still consuming alcohol at hazardous levels a referral was made to step 2 of the intervention.

Step 2 involved an intervention by a trained therapist in the primary care environment. The intervention, MET, was provided through three 40-minute sessions on, preferably, a weekly basis if possible. The intervention was protocol guided and addressed six basic principles of increasing motivation for change. Feedback about individual alcohol consumption included emphasis on the individual as being the agent responsible to change, advice on how to accomplish change, provision of alternative vehicles for change, maintenance of an empathetic therapeutic style and emphasis on enhancing the individual's self-efficacy. Four weeks after the final MET session, the nurse contacted the participant and a short telephone assessment was made regarding the participant's alcohol consumption in the previous 4 weeks using the extended AUDIT-C. If the participant was still consuming alcohol at hazardous levels a referral was to be made to step 3 of the intervention.

These interventions were guided by treatment protocols to specify the purpose and principles of each intervention and the structure and content of each particular treatment session.

Step 3 consisted of a referral to the local specialist alcohol services to receive specialist intervention, including, as necessary, detoxification, inpatient care, outpatient counselling, group therapy, relapse prevention treatment or medication. There was no limit on the intensity or duration of the step 3 intervention.

Participant follow-up

Appendix 9 shows a summary of the AESOPS trial.

Trial completion

Participants were deemed to have completed the trial when they had been in the trial for 12 months.

Participants were deemed to have fully withdrawn from the trial when:

- they wished to exit the trial fully
- their doctor or nurse withdrew them from the trial or
- they died.

Instead of withdrawing fully from the trial, participants had the option of (1) withdrawing only from receiving trial treatment; or (2) withdrawing only from postal questionnaires.

Participants who elected to withdraw from both the trial treatment and the follow-up postal questionnaires were deemed to be full withdrawals. This ensured appropriate follow-up from the Trials Unit.

Measurement and verification of primary measure

The primary outcome measure was average drinks per day (ADD) at 12 months post randomisation, where a standard drink equates to 8 g of ethanol.

Determination of average drinks per day

This was ascertained using the self completed extended AUDIT-C. The outcome was measured at baseline and then at 6 and 12 months post randomisation.

Measurement and verification of secondary outcomes

Alcohol-related problems

Alcohol-related problems were measured at baseline, 6 and 12 months post randomisation using the 17-item DPI.

Health-related quality of life

Participants were asked to answer questions relating to their HRQoL throughout the study by completing two generic instruments (EQ-5D and SF-12). These instruments are particularly useful for comparing groups of participants while also having a broad capacity for use in economic evaluation. Their generic nature also makes them potentially responsive to side effects or unforeseen effects of treatment.

Each participant's perception of his or her general health was assessed using the acute version of the SF-12[61] and the EQ-5D.[60] The SF-12 is a reliable and well-validated questionnaire,[62] and has been used in UK populations, including with older people.[63] We used a layout of the SF-12 shown in previous work to yield improved response rates and quality.[64] The EQ-5D is a generic measure of health status, where health is characterised on five dimensions (mobility, self-care, ability to undertake usual activities, pain and anxiety/depression).[60] Participants were asked to describe their level of health on each dimension using one of three levels: no problems, moderate problems and severe problems. Each response locates a person in one of 245 mutually exclusive health states (the 243 states arising from the EQ-5D, plus unconscious and dead), each of which has previously been valued on the 0 (equivalent to dead) to 1 (equivalent to perfect health) 'utility' scale based on interviews with a sample of 3395 members of the UK public.[65] The EQ-5D has been validated in the UK and questionnaires containing both instruments were administered to participants in person at baseline and by postal questionnaire at 6 and 12 months.

Collection of resource-use data

At recruitment (baseline) and 6 and 12 months after randomisation, participants were asked to complete a questionnaire on health and social care resource use during the previous 6 months (*Appendix 6*). The questionnaire was designed for participant completion and was returned to the trial office using a prepaid reply envelope. Participants indicated how many times in the previous 6 months they had used health services, for example if they had seen a GP or nurse or received hospital care. In addition, they were asked about contact with the police and criminal justice system. The collection of self-reported resource-use data was continued until the patient had been in the study for 12 months or until the patient withdrew from follow-up, or fully withdrew from the study.

Quality assurance of treatment delivery

Participants were asked to provide consent to have all treatment sessions recorded. A 30% sample was randomly selected, stratified by therapist, site and treatment (minimal and stepped care). Recordings were rated by an independent rater and assessed for quality of delivery and compliance with treatment protocols. A proportion of the recordings were double rated for quality assurances and calibration.

Adverse events

There were no anticipated risks in relation to either treatment arm and there is no documented evidence of adverse events arising as a result of either minimal intervention or stepped care intervention, but a mechanism for recording these was in place in case any arose.

Non-trial participants

Patients who had returned their screening forms and entered their contact details indicating willingness to be approached, but were subsequently found not to be eligible based on their AUDIT score (i.e. they scored <8), were sent a letter informing them of the outcome of the screening. In addition, a 'non-participant' questionnaire identical to the study baseline questionnaire was included and patients were asked to complete this if they so wished and return it anonymously (*Appendix 6*).

Clinical analyses methods

The objective of the clinical analyses was to compare the clinical effectiveness and cost-effectiveness of stepped care interventions for older hazardous alcohol users in primary care.

Outcomes

Primary

- Average drinks per day – derived from extended AUDIT-C at 12 months. The number of times per week alcohol was consumed was calculated from question 1 of the AUDIT-C. This was multiplied by the number of standard drinks reported in question 2 and then divided by 7 to give the ADD. For example, drinking four or five times per week would give a mean number of 4.5 days. If the number of standard drinks stated was 7–9, the number of standard drinks would be taken as the midpoint, 8. The calculation would then be $4.5 \times 8/7 = 5.1$ drinks per day.

Secondary

- Alcohol-related problems (DPI) at 6 and 12 months.
- Quality of life (SF-12) at 6 and 12 months.
- ADD (derived from extended AUDIT-C) at 6 months.
- Extended AUDIT-C score at 6 and 12 months.
- AUDIT-C status at 6 and 12 months (score of ≥ 5 = AUDIT-C positive).

Primary analysis

All analyses were performed on an intention-to-treat (ITT) basis using a two-sided 5% significance level. Analyses were performed in SAS version 9.2 (SAS Institute Inc., Cary, NC, USA).

The primary analysis compared minimal intervention with stepped care on the primary outcome measure, ADD, at 12 months post randomisation using a hierarchical linear model (mixed model). The mixed model

was used to account for any variation due to GP practice and the allocated therapist/nurse delivering the intervention. The analysis was adjusted for baseline ADD.

The model was developed starting from the simplest model, participants nested within GP practice, treating GP as a random effect. Where the data allowed, the therapist/nurse identification was added as random effect to make a three-level hierarchical model: participant within therapist within practice. Model checking was performed by assessing residual plots to ensure all models fit the data; where necessary transformations were employed to make the model a better fit.

The effects of missing data were examined using the commands Proc Mi and Mi Analyse in SAS v9.2. The same covariates that were used in the primary analysis were included. Any baseline characteristics that predicted missingness were also included. These analyses were used as a sensitivity analysis; the reported results will be those obtained from the primary analysis.

Secondary outcomes

Average drinks per day: month 6

Average drinks per day at month 6 was analysed in the same way as the primary outcome: using a mixed model, adjusting for baseline ADD and including GP as a random effect. Model checking was performed by assessing residual plots to ensure the model fit the data; where necessary, transformations or other analysis methods were used.

Alcohol-related problems

Alcohol-related problems measured at baseline, month 6 and month 12 were assessed using the 17-item DPI. The score ranges from 0 to 17, with 17 as the most severe. This was analysed in the same way as the primary outcome: using a mixed model, adjusting for baseline DPI and including GP as a random effect.

Alcohol Use Disorders Identification Test – Consumption (3-item) score

AUDIT-C score was measured at baseline, month 6 and month 12. The score ranges from 0 to 12, with 12 as the most severe. This was analysed in the same way as the primary outcome: using a mixed model, adjusting for baseline AUDIT-C score and including GP as a random effect.

Alcohol Use Disorders Identification Test status – Consumption (3-item)

AUDIT-C status was calculated from the AUDIT-C score at baseline, month 6 and month 12. A score of ≥ 5 is classed as AUDIT-C positive and a score of <5 as AUDIT-C negative. A positive AUDIT-C status is indicative of hazardous alcohol consumption and inclusive of both harmful and dependent consumption. This was analysed using a mixed logistic regression model, adjusting for baseline AUDIT-C score and including GP as a random effect.

Quality of life

Quality of life was measured using the SF-12 questionnaire (measured at baseline and 6 and 12 months). The scores for the physical and mental health components were analysed using a mixed model.

Process Rating Scale

The Process Rating Scale (PRS) was adapted from the validated UKATT PRS[66] and contains items that were used to rate structure, content and style of the delivery of the minimal and the step 1 interventions (*Appendix 10*).

Hypotheses

- Are the mean frequency and quality scores for the specific task items and practice/research nurse style items substantively different for the minimal intervention compared with the 20-minute behaviour change counselling?

- Is the 5-minute intervention characterised by different mean frequency ratings of MET consistent practice/research nurses style items (reflective listening, empathy and open questions) and different MET inconsistent style items (closed questions and giving unsolicited advice) from the 20-minute intervention?
- Is the session content for the two treatment groups different? Should both interventions have covered the same session content?
- Do specialist practice/research nurses receive different mean frequency and quality scores for specific task items and style items from non-specialist practice/research nurses?
- What level of consistency is there between the ratings of the primary and secondary raters (inter-rater reliability)?

Analysis

The mean frequency score and the mean quality score for specific task items and practice/research nurse style items for each session were calculated. Linear regression models were used to compare the scores for the 5-minute and the 20-minute interventions. The dependent variable was mean score (frequency or quality) and the independent variable was session type (5- or 20-minute session). To take account of the clustered nature of the data, a mixed model was used with practice/research nurse fitted as a random effect.

The mean frequency score of MET style items and MET inconsistent items was calculated for each session. Linear regression models were used to compare the scores for the 5-minute (minimal) and the 20-minute (step 1) interventions. The dependent variable was mean frequency score and the independent variable was session type (5- or 20-minute session). To take account of the clustered nature of the data, a mixed model was used with practice or research nurse fitted as a random effect.

Session content was assessed using a series of yes/no answers to five questions. Logistic regression models were used for each of the five questions to test for differences between the session types. Again, a hierarchical model was used, with practice/research nurse fitted as a random effect.

In order to examine differences between types of practice/research nurses, the analysis for specific task items was repeated and the type of practice/research nurse (specialist/non-specialist) was also included in addition to session type.

Inter-rater reliability of the individual frequency items of the scale was examined using the intraclass correlation coefficient (ICC) two-way mixed-effects model (case 3[67]) to estimate the reliability of a mean of several ratings.[68] For four summary measures, the average of the two raters' summary scores was plotted against difference in their summary score[69] to make pairwise comparisons between raters. This illustrates graphically whether or not the summary scores are rated consistently, how well the raters agree on average and what the limits of agreement are.

Economic analysis

Economic evaluation of health interventions is a tool used to assist decision-makers in prioritising and allocating resources in the health-care sector, by assessing the value for money (cost-effectiveness) of alternative interventions.[70]

The aim of the economic evaluation was to assess the cost-effectiveness of a stepped care intervention compared with minimal intervention in the treatment of older hazardous alcohol users in primary care.

The first stage of the economic analysis was to calculate the cost of delivering the trial treatments. Opportunistic screening costs were estimated using the actual costs of screening associated with the study. The costs of delivering the minimal intervention and the first two tiers of stepped care were based on

actual patient contact time from timesheets maintained by practice or research nurses and therapists. The costs of the minimal intervention and the first two tiers of the stepped care programme were based on information gathered on patient contact with the primary care and specialist services during the trial.

The costs of the trial interventions were calculated using local costs of specialist services and included an allowance for the training and supervision costs, using methods developed for the UKATT trial.[71] Utilisation of more specialist services was recorded, including the type of intervention, and costs were applied from previous research trials and a recent Department of Health-funded research project based on a range of specialist providers and intervention types.[72] The incremental cost-effectiveness of stepped care compared with the minimal intervention was assessed from both a health and a personal social services perspective following National Institute for Health and Care Excellence (NICE) guidance[73] and a wider public sector resource perspective.[73] Utilisation of alcohol services outside the trial protocol, along with all other public sector services, including health, social welfare and contact with criminal justice agencies, was assessed from questionnaires administered at baseline and 6 and 12 months. Units of resource use recorded were multiplied by national sources of unit costs[71,74] in order to provide generalisable results.

The economic analysis tested the hypothesis that stepped care is more cost-effective than the minimal intervention, using a cost–utility framework. Utility values were derived from the EQ-5D[60] and were then used with population values and the quality-adjusted life-year (QALY) change calculated using the area under the curve method.[75] Incremental cost-effectiveness analysis combined the costs of the interventions, as detailed above, with the QALY changes, using the cost in the intervention group over and above the control, divided by the incremental QALYs in the intervention group over and above the control. The non-parametric bootstrap resampling technique was used to test the sensitivity of the calculated incremental cost-effectiveness ratios (ICERs) and cost-acceptability curves estimated to demonstrate different threshold values for a QALY.[76] This would show the probability that stepped care was the preferred treatment option at different values for the decision-maker's willingness to pay for a QALY.

The effects of the GP practice were analysed using a multilevel model programmed in MLwiN (MLwiN, Centre for Multilevel Modelling, Bristol, UK). A net benefit framework was used, estimating the benefit of treatment by multiplying QALY changes by a £30,000-per-QALY value net of treatment cost. This estimated a net benefit of treatment for each patient in the trial. The multilevel model tested the proportion of the variation in the net benefit of treatment attributable to the practice to investigate the effect of the treatment location.

Chapter 3 Protocol changes

Outcome measures

In the original protocol the intention was to ascertain a diagnosis of alcohol use disorder using the Short Form-Composite International Diagnostic Interview (SF-CIDI). It was decided to replace this instrument with the AUDIT, with a score of ≥16 indicative of higher-risk alcohol use and possible alcohol dependence. The AUDIT has established sensitivity and specificity for the identification of at-risk alcohol use, inclusive of higher risk and possibly dependent alcohol use, and using this instrument reduced the response burden on participants. In addition, the primary outcome measure (ADD) was to be measured using a timeline follow-back method. This method would have involved a 20- to 30-minute interview with a trained researcher at each of the outcome assessment points. We replaced this with a validated, reliable self-complete instrument: the extended AUDIT-C. Evidence exists that the timeline follow-back method acts as a brief intervention and as such may act to reduce the observed differences between allocated groups.[77] Using the extended AUDIT-C reduced this measurement effect, as well as the response burden on participants. The original protocol had outlined our plan to conduct follow-ups face to face at 6 and 12 months post randomisation. As the primary outcome measure was replaced with a self-completed instrument it was decided to replace this follow-up method with postal follow-ups at 6 and 12 months post randomisation, meaning that the participants did not have to return to the practice for any follow-up assessments.

Recruitment period

The original protocol planned to recruit 500 participants over an 18-month period with all participants being followed up for 12 months. As the study progressed, delays to practice initiations meant that the study had fallen behind schedule, with the first patient not recruited until April 2008. The original end date for recruitment was 31 April 2009. In addition, the recruitment rate was found to be under target as a result of prevalence and uptake rates being lower than anticipated. This led us to apply to the funder in November 2008 for an 18-month extension to the recruitment period. The original sample size remained unchanged. The funders elected instead to track recruitment through monthly reports until the end of January 2010, during which time it would become clearer whether or not the target was achievable within an acceptable timescale. New sites and practices were brought on board (*Appendix 3* details start dates of trial sites) and, following a successful increase in recruitment, in February 2010 an extension was approved allowing recruitment to continue until the end of October 2010, with the 12-month follow-up ceasing by the end of November 2011.

Mail-out

Owing to this lower than expected recruitment in the study, a decision was made to change the screening process in only one centre in order to pilot the new method. As it stood, potentially eligible patients were identified by opportunistic screening in their GP's practice. That is, all patients aged ≥55 years who attended their GP's practice was able to pick up a pack containing a screening form (AUDIT) that they could choose to complete (either with contact details or anonymously) regarding how much alcohol they consume. As the reduced recruitment rate was thought to be due to a lower prevalence rate than first expected, the number of patients requiring to be screened needed to be far greater than anticipated in order to hit the study target of 500. It was felt that the number of patients screened could be increased within this one new site by mailing out forms to all patients aged ≥55 years in the participating GP practice, asking them to complete the AUDIT (entirely voluntarily, and it could still be completed anonymously if preferred), as opposed to distributing forms only to those screened opportunistically at the practice.

Therefore, a new site, Tyneside, was brought on board to pilot this method. In addition, two local (Tyneside) Alcohol Health Workers conducted the study in the practices and the screening form itself was redesigned to fit onto one side of A4 paper. The cover letter and screening form were accompanied by a new, coloured, z-folded patient information leaflet (*Appendix 11*) and a prepaid envelope allowing all completed questionnaires to be returned directly to the co-ordinating centre rather than handed in to the GP's practice.

Following the success of this method all new practices brought on board used this mail-out method. Practices already taking part were given the option to switch to the mail-out method or continue with the current opportunistic screening process.

Chapter 4 Clinical results

This chapter presents the statistical analysis of the AESOPS trial. In the first section of the chapter the clinical data are described, including tables and figures of data summaries. In the second section the statistical models fitted to the data are presented.

Trial recruitment

Eight sites participated in the study from across the UK. These were North Yorkshire and York; Hull and East Riding; Norfolk; Leeds; Fife; Kent; Tyneside; and County Durham. The number of participants recruited per site ranged from 3 to 209. Within these sites, 55 GP practices were set up, but only 53 commenced screening patients. Participants were recruited from 51 of the 53 practices and the number of participants recruited per practice ranged from 1 to 54.

Screening commenced in January 2008 and continued through to October 2010. Approximately 78,000 screening questionnaires were distributed, with over 60,000 of these by mail-out. Twenty-five practices used opportunistic screening only, 28 used mail-out only and six switched from opportunistic screening to mail-out (as detailed in *Appendix 3*). The majority of screening questionnaires returned were from the Tyneside and Leeds sites. The first participant was recruited in April 2008 and recruitment ceased at the end of October 2010. The participant follow-up period ended in November 2011 after which point the study ended.

In total, 21,545 completed screening forms were returned. Sixteen had insufficient information to score the AUDIT. Of the remainder, 1625 were AUDIT positive (scored ≥8 on the AUDIT) (1625/21,529 = 7.5%). This indicates that 7.5% of the population screened were considered hazardous or harmful drinkers, a rate much lower than anticipated (15% to 25%). The proportion of hazardous or harmful drinkers ranged from 6.6% to 10.4% across the sites (*Table 1*).

In total, there were 949 patients who were AUDIT positive and provided contact details; they had an average AUDIT score of 12.10 [standard deviation (SD) 5.65], which was higher than for those who were AUDIT positive but did not provide contact details (*Table 2*).

The percentage of eligible patients (i.e. AUDIT positive with contact details provided) who were deemed fully eligible [928/1626 = 57% (i.e. 949 AUDIT positive, but 21 failed one or more of the other eligibility criteria)] and went on to be randomised was only 57% (529/928 = 57%).

Figure 1, the Consolidated Standards of Reporting Trials (CONSORT) flowchart, shows the progress of participants through the trial.

Clinical data

In total, 529 participants were randomised: 266 to stepped care and 263 to minimal intervention. A baseline questionnaire was not received from seven participants following completion: three from the stepped care group and four from the minimal group.

The majority of participants were male ($n = 425$; 80%) and the average age was 63 years (range 55–85 years) (*Table 3*). A score of ≥ 20 on the AUDIT indicates possible alcohol dependence. Overall, 7.9% of those randomised obtained a score of ≥ 20 at screening. This was higher in the minimal group (9.5%) than in the stepped care group (6.4%). This is summarised in *Table 4*. The average AUDIT-C score

TABLE 1 Proportion of hazardous or harmful drinkers across study sites

Site	*N*; number audit positive, *n* (%)
York	2360; 195 (8.3)
Hull	691; 72 (10.4)
Norfolk	2522; 166 (6.6)
Leeds	6629; 466 (7.0)
Kent	237; 20 (8.4)
Fife	790; 63 (8.0)
Tyneside	5877; 483 (8.2)
County Durham	2423; 160 (6.6)
Total	21,529; 1625 (7.5)

TABLE 2 The AUDIT score at screening

	Positive audit				
	No		Yes		
Statistic	Identifiable	Anonymous	Identifiable	Anonymous	Total
n	11,210	8694	949	676	21,529
Mean (SD)	2.21 (1.90)	2.26 (1.88)	12.10 (5.65)	11.11 (4.45)	2.95 (3.40)
Median (min., max.)	2 (0, 7)	2 (0, 7)	10 (8, 40)	10 (8, 40)	2 (0, 40)

max., maximum; min., minimum.

was 8.3 (SD 2.2) and ADD was 3.39 (SD 2.2). The baseline characteristics are summarised by treatment group (*Tables 5* and *6*).

Comparing the trial participants with those screened, there were more males (80% compared with 45% in the screened population) and participants were slightly younger: 63 years compared with 68 years (*Table 3*).

Baseline data were collected on those who were willing to participate but were not eligible for the trial (non-participants) because they were AUDIT negative at screening. In order to compare the baseline characteristics of participants and non-participants, the AUDIT-C was also calculated for the screening sample. Comparing non-participants with trial participants, trial participants were younger and more likely to be male.

Analysis of clinical results

This portion of the report presents the results of the statistical models fitted to the data. It is arranged into three main sections. The first section presents the results of the modelling of the primary outcome: ADD at 12 months. The second section presents the results of the modelling of the secondary outcomes: ADD (derived from the extended AUDIT-C) at 6 months; alcohol-related problems assessed using the DPI at 6 and 12 months; extended AUDIT-C score at 6 and 12 months; and HRQoL at 6 and 12 months. The third section summarises the conclusions of the statistical analysis of the clinical outcomes.

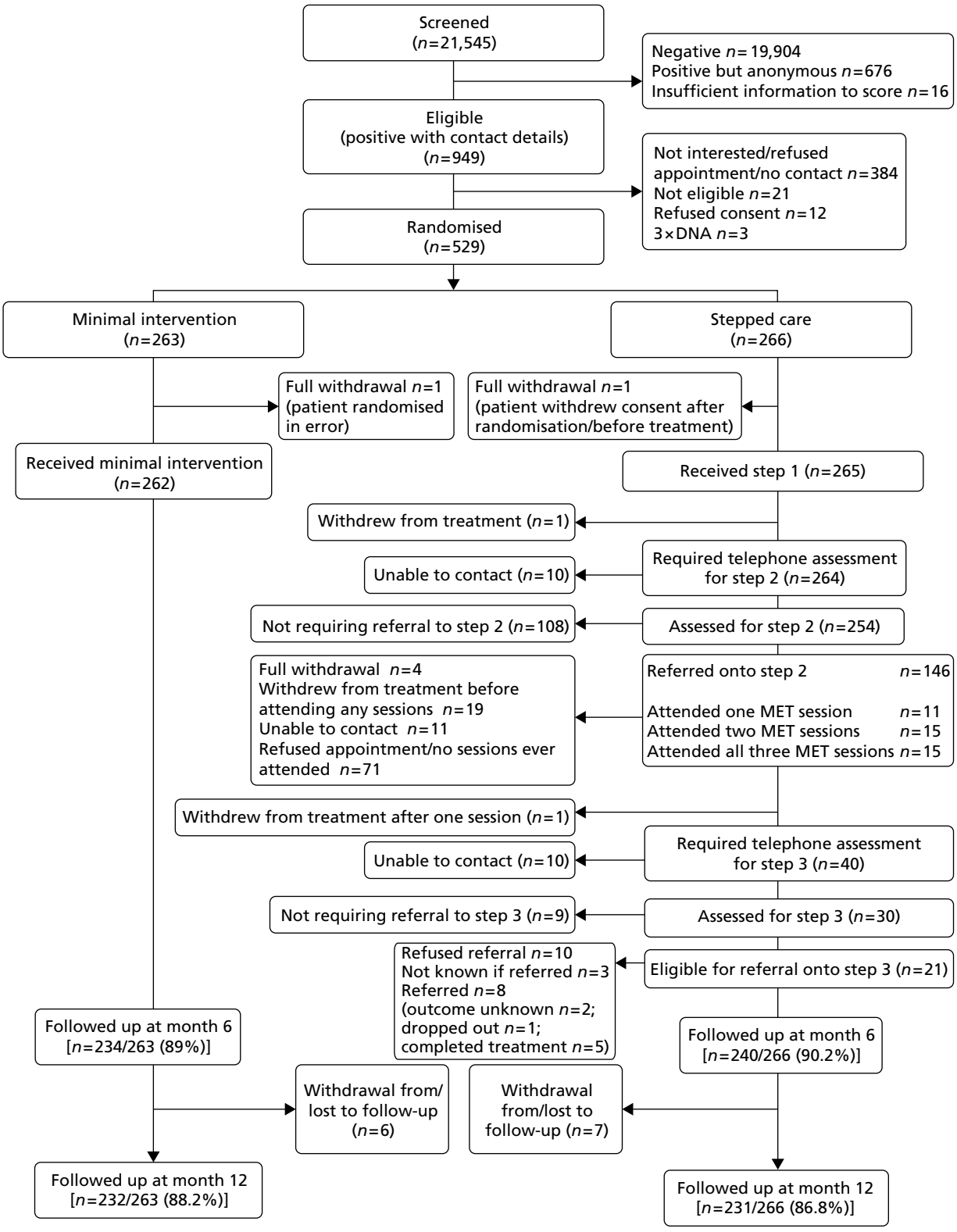

FIGURE 1 The AESOPS CONSORT diagram.

TABLE 3 Characteristics of participants and non-participants

Characteristics	Screened (*n* = 21,545)	Non-participants (*n* = 4231)	Trial participants (*n* = 529)
Sex			
Male (%)	45.3	44.7	80.3
Age (years)			
Mean (SD)	68 (8.6)	67 (7.9)	63 (5.8)
Median (min., max.)	66 (55, 105)	66 (55, 105)	62 (55, 85)
AUDIT-C score			
Mean (SD)	2.6 (2.4)	2.5 (2.0)	8.3 (2.2)
Median (min., max.)	2 (0, 12)	2 (0, 12)	8 (0, 12)
ADD			
Mean (SD)	NA	0.51 (0.76)	3.39 (2.21)
Median (min., max.)	NA	0.15 (0, 8.57)	3 (0, 8.57)

max., maximum; min., minimum; NA, not applicable.

TABLE 4 Numbers randomised in each treatment arm with AUDIT score ≥20 at screening

	Screening AUDIT score ≥20		
Treatment arm	No	Yes	Total
Stepped care, *n* (%)	249 (93.6)	17 (6.4)	266 (100)
Minimal, *n* (%)	238 (90.5)	25 (9.5)	263 (100)
Overall, *n* (%)	487 (92.1)	42 (7.9)	529 (100)

TABLE 5 Baseline patient characteristics

Characteristics	Stepped care (*N* = 266)	Minimal (*N* = 263)	Total (*N* = 529)
Sex, *N*	266	263	529
Male, *n* (%)	220 (82.7)	205 (77.9)	425 (80.3)
Female, *n* (%)	46 (17.3)	58 (22.1)	104 (19.7)
Age (years), *n*	266	263	529
Mean (SD)	62.92 (5.82)	62.74 (5.86)	62.83 (5.83)
Median (min., max.)	62 (55, 83)	62 (55, 85)	62.00 (55, 85)
Smoking status, *N*	256	251	507
Never smoked, *n* (%)	71 (27.7)	80 (31.9)	151 (29.8)
Ex-smoker, *n* (%)	141 (55.1)	125 (49.8)	266 (52.5)
Current smoker, *n* (%)	44 (17.2)	46 (18.3)	90 (17.7)
Employment, *N*	258	258	516
In employment or self-employment, *n* (%)	89 (34.5)	93 (36.0)	182 (35.3)
Retired, *n* (%)	138 (53.5)	132 (51.2)	270 (52.3)
Housework, *n* (%)	4 (1.5)	3 (1.2)	7 (1.4)

TABLE 5 Baseline patient characteristics (*continued*)

Characteristics	Stepped care (*N* = 266)	Minimal (*N* = 263)	Total (*N* = 529)
Student, *n* (%)	1 (0.4)	0 (0.0)	1 (0.2)
Seeking work, *n* (%)	9 (3.5)	5 (1.9)	14 (2.7)
Other, *n* (%)	17 (6.6)	25 (9.7)	42 (8.1)
Living arrangements, *N*	263	257	520
Single, *n* (%)	61 (23.2)	59 (23.0)	120 (23.1)
Married, *n* (%)	166 (63.1)	155 (60.3)	321 (61.7)
Cohabiting, *n* (%)	22 (8.4)	17 (6.6)	39 (7.5)
Widowed, *n* (%)	14 (5.3)	26 (10.1)	40 (7.7)
Accommodation, *N*	263	257	520
Owner occupied, *n* (%)	211 (80.2)	202 (78.6)	413 (79.4)
Private rented, *n* (%)	14 (5.3)	14 (5.4)	28 (5.4)
Local authority/housing association, *n* (%)	37 (14.1)	40 (15.6)	77 (14.8)
Temporary, *n* (%)	1 (0.4)	1 (0.4)	2 (0.4)
Education continued after school, *N*	262	258	520
Yes, *n* (%)	171 (65.3)	158 (61.2)	329 (63.3)
No, *n* (%)	91 (34.7)	100 (38.8)	191 (36.7)
Degree or equivalent professional qualification, *N*	261	256	517
Yes, *n* (%)	116 (44.4)	100 (39.1)	216 (41.8)
No, *n* (%)	145 (55.6)	156 (60.9)	301 (58.2)

max., maximum; min., minimum.

TABLE 6 Baseline outcome measures

Outcome measure	Stepped care (*N* = 266)	Minimal (*N* = 263)	Total (*N* = 529)
ADD, *n*	263	255	518
Mean (SD)	3.38 (2.24)	3.41 (2.19)	3.39 (2.21)
Median (min., max.)	3 (0, 8.57)	3 (0, 8.57)	3 (0, 8.57)
DPI, *n*	262	257	519
Mean (SD)	2.64 (2.90)	3.08 (3.33)	2.86 (3.12)
Median (min., max.)	2 (0, 15)	2 (0, 15.87)	2 (0, 15.87)
SF-12 PCS, *n*	260	256	516
Mean (SD)	47.67 (11.21)	47.33 (10.99)	47.50 (11.09)
Median (min., max.)	52.00 (10.04, 70.37)	49.81 (7.87, 67.17)	51.02 (7.87, 70.37)
SF-12 MCS, *n*	260	256	516
Mean (SD)	51.85 (9.51)	50.18 (10.71)	51.02 (10.15)
Median (min., max.)	55.06 (9.13, 66.33)	52.79 (6.98, 71.21)	54.37 (6.98, 71.21)

continued

TABLE 6 Baseline outcome measures (*continued*)

Outcome measure	Stepped care (*N* = 266)	Minimal (*N* = 263)	Total (*N* = 529)
AUDIT-C score, *n*	263	259	522
Mean (SD)	8.26 (2.19)	8.25 (2.26)	8.26 (2.22)
Median (min., max.)	8 (3, 12)	8 (0, 12)	8 (0, 12)
AUDIT-C status, *N*	263	259	522
Negative, *n* (%)	13 (4.9)	15 (5.8)	28 (5.4)
Positive, *n* (%)	250 (95.1)	244 (94.2)	494 (94.6)

max., maximum; MCS, mental component score; min., minimum; PCS, physical component score.

Primary outcome

Overall, the mean ADD score in both groups decreased from baseline at both month 6 and month 12. At month 6 the stepped care group had a lower ADD but at month 12 the minimal intervention group had the lower ADD. This is summarised in *Table 7*. *Figure 2* shows the mean ADD scores for the complete cases.

A mixed model was used to compare ADD between the two randomised groups. The baseline value of ADD was included as a covariate and a variable was also included for treatment group; these were included as fixed effects. To account for the variation due to GP practice, this was included as a random effect in the model. Expanding the model to a three-level model to include nurse/therapist resulted in a model that failed to converge, and so the final model used was a two-level mixed model with participants nested within GP practice.

The ADD had a skewed distribution; a transformation improved the model fit. A log-transformation was used in the final model so the dependent variable was Ln(ADD_M12 +1) (M12 = month 12).

In total, 456 participants had a response at month 12; however, in seven, ADD value at baseline was missing, and so these participants were not included in the primary analysis. The GP random effect was not significant, indicating that transformed ADD did not vary significantly between centres. There were no significant differences in ADD between the treatment groups at month 12. The stepped care group had a marginally higher ADD than the minimal intervention group but not significantly so. The results of the analysis are seen in *Table 8*.

Transforming the data for the analysis was necessary because of the skewed distribution. As the transformation included the addition of 1, this meant that a back-transformation was more problematic; however, it was anticipated that this would not have a great influence on the back-transformed estimate. To verify this, an additional analysis, excluding those with an ADD of zero, was used to confirm the result. In order to summarise the results in a more meaningful way, the estimate of the difference was anti-logged. It was found that ADD at month 12 for the stepped care group was 1.025 [95% confidence interval (CI) 0.94 to 1.12] times that of the minimal group. The analysis excluding those with ADD of zero, carried out to check that the log(ADD + 1) produced a good approximation, produced very similar results, and so we concluded that these estimates were acceptable.

Missing data

The overall follow-up rate at month 12 was 87.5%, with 86.8% followed up in the stepped care group and 88.2% in the minimal intervention group. Those followed up were slightly older, more likely to be male and had a slightly lower ADD at baseline. The results are summarised in *Table 9*.

TABLE 7 Summary of ADD

	Treatment arm		
Follow-up	Stepped care	Minimal	Total
Baseline			
Valid *n*	263	255	518
Mean (SD)	3.38 (2.24)	3.41 (2.19)	3.39 (2.21)
Median (min., max.)	3.00 (0, 8.57)	3.00 (0, 8.57)	3.00 (0, 8.57)
Month 6			
Valid *n*	236	229	465
Mean (SD)	2.45 (1.85)	2.81 (2.03)	2.63 (1.95)
Median (min., max.)	1.96 (0, 8.57)	2.25 (0, 8.57)	2.25 (0, 8.57)
Month 12			
Valid *n*	228	228	456
Mean (SD)	2.56 (2.09)	2.49 (1.93)	2.53 (2.01)
Median (min., max.)	1.96 (0, 8.57)	2.25 (0, 8.57)	2.11 (0, 8.57)

max., maximum; min., minimum.

TABLE 8 Estimates of ADD (Ln-transformed)

Follow-up	Stepped care estimate (SD) ($n = 226$)	Minimal estimate (SD) ($n = 223$)	Difference (95% CI)	*p*-value
Month 12	1.129 (0.037)	1.104 (0.037)	0.025 (–0.062 to 0.112)	0.575
Covariance parameter estimates			**Estimate (SE)**	***p*-value**
Random GP effect			0.013 (0.009)	0.059
Measurement error			0.215 (0.015)	<0.001

SE, standard error.

The multiple imputation commands in SAS, SAS Proc MI and MI Analyse were used to perform multiple imputations in order to take into account the missing data in the analysis. Multiple imputation[78] replaces each missing value with a range of possible values. Proc MI produces these imputed data sets and MI Analyse allows the results from these datasets to be combined and analysed using standard procedures. The results can be seen in *Table 10*. The estimates from the multiple imputation are similar to the results from the primary analysis.

Analysis of secondary outcomes

In this section, the results of the secondary analysis are presented.

Average drinks per day at month 6

The ADD at month 6 was analysed in the same way as the primary outcomes: using a mixed model, adjusting for baseline ADD and including GP as a random effect. The ADD had a skewed distribution;

TABLE 9 Characteristics of those followed up

Characteristics	Month 12 follow-up?		
	No	Yes	Total
Stepped care, *n* (%)	35 (13.2)	231 (86.8)	263 (100)
Minimal, *n* (%)	31 (11.8)	232 (88.2)	266 (100)
Overall, *n* (%)	66 (12.5)	463 (87.5)	529 (100)
Age (years), *n*	66	463	529
Mean (SD)	61.50 (5.01)	63.02 (5.92)	62.83 (5.83)
Median (min., max.)	61.5 (55, 75)	62 (55, 85)	62 (55, 85)
ADD, *n*	62	456	518
Mean (SD)	3.82 (2.62)	3.34 (2.15)	3.39 (2.21)
Median (min., max.)	3.27 (0.35, 8.57)	3 (0, 8.57)	3 (0, 8.57)
Sex, *N*	66	463	529
Male, *n* (%)	50 (11.8)	375 (88.2)	425 (100)
Female, *n* (%)	16 (15.4)	88 (84.6)	104 (100)

max., maximum; min., minimum.

TABLE 10 Missing data analysis

Follow-up	Primary analysis		Multiple imputation	
	Difference (95% CI) (*n* = 449)	*p*-value	Difference (95% CI) (*n* = 525)	*p*-value
Month 12	0.025 (–0.062 to 0.112)	0.575	0.033 (–0.065 to 0.131)	0.470

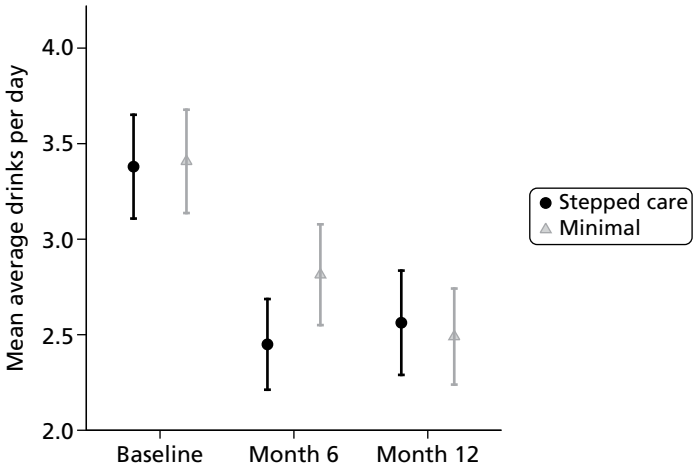

FIGURE 2 Average drinks per day (complete cases).

a transformation improved the model fit. A log transformation was used in the final model so the dependent variable was Ln(ADD_M6 + 1) (*Table 11*).

At month 6, the stepped care group had a lower ADD then the minimal intervention group. This was not significant at the 5% level.

The AUDIT-C score was analysed in a similar way to the primary outcomes: using a mixed model, adjusting for baseline AUDIT-C score and including GP as a random effect. There were no significant differences in AUDIT-C score between the treatment groups at month 6 or month 12. The minimal intervention had a marginally higher AUDIT-C score at month 6, but a lower score at month 12; however, neither difference was significant (*Tables 12* and *13*).

The AUDIT-C status was analysed using a hierarchical logistic regression model, adjusting from baseline status with GP practice treated as a random effect. The outcome was AUDIT-C positive. At month 6, the adjusted analysis found no significant difference in AUDIT-C status between the two treatment groups. At month 6, the stepped care group had a larger proportion of AUDIT-C positives but a smaller proportion at month 12 compared with the minimal intervention. The results can be seen in *Tables 14* and *15*.

Drinking Problems Index

The DPI at month 6 and month 12 was analysed using a mixed model, adjusting for baseline DPI and including GP as a random effect. DPI scores had skewed distributions, so a log transformation was used

TABLE 11 Estimates of ADD (transformed): month 6

Follow-up	Stepped care estimate (SD) (*n* = 234)	Minimal estimate (SD) (n = 230)	Difference (95% CI)	*p*-value
Month 6	1.119 (0.034)	1.192 (0.034)	–0.073 (–0.156 to 0.011)	0.088

TABLE 12 The AUDIT-C scores

	Intervention arm		
Follow-up	Stepped care	Minimal	Total
Baseline			
n	263	259	522
Mean (SD)	8.26 (2.19)	8.25 (2.26)	8.26 (2.22)
Median (min., max.)	8 (3, 12)	8.00 (0, 12)	8 (0, 12)
Month 6			
n	238	231	469
Mean (SD)	7.02 (2.48)	7.38 (2.55)	7.20 (2.52)
Median (min., max.)	7 (0, 12)	8.00 (0, 12)	7.00 (0, 12)
Month 12			
n	229	229	458
Mean (SD)	7.07 (2.48)	6.96 (2.66)	7.02 (2.57)
Median (min., max.)	7 (0,12)	7 (0, 12)	7 (0, 12)

max., maximum; min., minimum.

TABLE 13 The AUDIT-C estimates

Follow-up	Stepped care estimates (SD)	Minimal estimates (SD)	Difference (95% CI)	*p*-value
Month 6	7.085 (0.159) ($n = 236$)	7.373 (0.160) ($n = 228$)	–0.288 (–0.687 to 0.111)	0.156
Month 12	7.116 (0.166) ($n = 227$)	6.957 (0.166) ($n = 226$)	0.160 (–0.250 to 0.569)	0.445

TABLE 14 The AUDIT-C status

Follow-up	Stepped care	Minimal	Total
Baseline, *N*	263	259	522
AUDIT-C negative, *n* (%)	13 (4.9)	15 (5.8)	28 (5.4)
AUDIT-C positive, *n* (%)	250 (95.1)	244 (94.2)	494 (94.6)
Month 6, *N*	238	231	469
AUDIT-C negative, *n* (%)	35 (14.7)	26 (11.3)	61 (13.0)
AUDIT-C positive, *n* (%)	203 (85.3)	205 (88.7)	408 (87.0)
Month 12, *N*	229	229	458
AUDIT-C negative, *n* (%)	35 (15.3)	41 (17.9)	76 (16.6)
AUDIT-C positive, *n* (%)	194 (84.7)	188 (82.1)	382 (83.4)

TABLE 15 The AUDIT–C status: number AUDIT positive

Follow-up	Stepped care	Minimal	Odds ratio (95% CI)	*p*-value
Month 6			0.81 (0.48 to 1.37)	0.427
N	236	228		
n (%)	193 (82)	186 (82)		
Month 12			1.37 (0.76 to 2.47)	0.289
N	227	226		
n (%)	202 (89)	202 (89)		

which improved the model fit. As the DPI range included zero, one (1) was added to the total DPI score to enable logs to be calculated (*Tables 16* and *17*).

At month 6 and month 12, the stepped care group had a lower DPI score than the minimal intervention group. This was not significant at the 5% level.

Quality of life using the Short Form Questionnaire-12 items

The hierarchical model failed to converge so results from a simple linear regression model are presented (*Tables 18* and *19*).

At month 6 and month 12, the stepped care group had a lower mental component score (MCS) than the minimal intervention group. The stepped care group also had lower physical component score (PCS) at month 6 and month 12. These differences were not significant at the 5% level.

TABLE 16 The DPI scores

Follow-up	Stepped care	Minimal	Total
Baseline			
n	262	257	519
Mean (SD)	2.64 (2.90)	3.08 (3.33)	2.86 (3.12)
Median (min., max.)	2.00 (0, 15)	2.00 (0, 15.87)	2.00 (0, 15.87)
Month 6			
n	238	233	471
Mean (SD)	1.79 (2.60)	2.41 (3.22)	2.10 (2.93)
Median (min., max.)	1.00 (0, 16)	1.00 (0, 17)	1.00 (0, 17)
Month 12			
n	229	230	459
Mean (SD)	1.90 (3.03)	2.25 (3.04)	2.07 (3.04)
Median (min., max.)	1.00 (0, 17)	1.00 (0, 16)	1.00 (0, 17)

max., maximum; min., minimum.

TABLE 17 Estimates of DPI scores (transformed)

Follow-up	Stepped care estimate (SD)	Minimal estimate (SD)	Difference (95% CI)	*p*-value
Month 6	*n* = 236 0.799 (0.040)	*n* = 229 0.864 (0.040)	–0.064 (–0.173 to 0.045)	0.247
Month 12	*n* = 227 0.783 (0.038)	n = 225 0.802 (0.038)	–0.018 (–0.125 to 0.088)	0.735

Treatment uptake by the stepped care group

In total, 146 participants were referred to step 2; of these, 41 (28%) went on to receive step 2. The other 105 participants (72%) either declined or could not be contacted. Although those who attended step 2 had a higher average ADD than those who did not attend, it was not significantly higher (*Table 20*).

TABLE 18 The SF-12 quality-of-life scores

Component score	Stepped care	Minimal	Total
PCS			
Baseline			
n	260	256	516
Mean (SD)	47.67 (11.21)	47.33 (10.99)	47.50 (11.09)
Median (min., max.)	52 (10.04, 70.37)	49.81 (7.87, 67.17)	51.02 (7.87, 70.37)
Month 6			
n	237	233	470
Mean (SD)	47.35 (11.33)	47.74 (11.16)	47.54 (11.24)
Median (min., max.)	51.46 (7.02, 66.45)	50.66 (11.38, 68.68)	51.22 (7.02, 68.68)
Month 12			
n	228	228	456
Mean (SD)	47.24 (11.87)	47.48 (10.99)	47.36 (11.42)
Median (min., max.)	51.59 (12.69, 65.02)	51.02 (14.37, 68.20)	51.28 (12.69, 68.20)
MCS			
Baseline			
n	260	256	516
Mean (SD)	51.85 (9.51)	50.18 (10.71)	51.02 (10.15)
Median (min., max.)	55.06 (9.13, 66.33)	52.79 (6.98, 71.21)	54.37 (6.98, 71.21)
Month 6			
n	237	233	470
Mean (SD)	51.77 (9.80)	50.48 (10.61)	51.13 (10.22)
Median (min., max.)	54.96 (11.20, 64.40)	54.34 (12.55, 67.52)	54.66 (11.20, 67.52)
Month 12			
n	228	228	456
Mean (SD)	51.95 (9.72)	51.53 (9.85)	51.74 (9.78)
Median (min., max.)	55.21 (3.58, 64.74)	54.37 (12.50, 73.02)	54.77 (3.58, 73.02)

max., maximum; MCS, mental component score; min., minimum; PCS, physical component score.

TABLE 19 The SF-12 quality-of-life estimates

Component score	Stepped care estimate (SD)	Minimal estimate (SD)	Difference (95% CI)	*p*-value
MCS				
Month 6	51.214 (0.443) ($n = 234$)	51.302 (0.448) ($n = 228$)	–0.088 (–1.329 to 1.153)	0.889
Month 12	51.630 (0.462) ($n = 224$)	52.108 (0.463) ($n = 22$)	–0.478 (–0.809 to 1.766)	0.466
PCS				
Month 6	47.152 (0.423) ($n = 234$)	47.873 (0.429) ($n = 228$)	–0.722 (–1.905 to 0.462)	0.232
Month 12	47.069 (0.489) ($n = 224$)	47.707 (0.490) ($n = 223$)	–0.637 (–1.998 to 0.723)	0.692

MCS, mental component score; PCS, physical component score.

TABLE 20 Average ADD scores: step 2 non-attendees vs attendees

Outcome	Non-attendees ($n = 105$)	Attendees ($n = 41$)	Difference (95% CI)	p-value
ADD score	3.91 (2.13)	4.24 (2.18)	0.33 (–0.45 to 1.12)	0.401

Summary

There was no evidence of a difference in ADD when comparing the stepped care group with the minimal intervention group at month 12.

There was no evidence of a difference in any of the secondary outcome measures (AUDIT score, alcohol-related problems and quality of life) at either month 6 or month 12.

Chapter 5 Economic analysis

Brief interventions have been proven to be both clinically effective and cost-effective in the management of individuals with hazardous and harmful drinking in primary care settings.[27–29,79] Cost-effectiveness for all adult drinkers for such interventions has partly been driven by reductions in health service costs of alcohol harm. The estimated wider costs of alcohol-use disorders, in terms of health care, crime, family problems and loss of productivity, was up to £258 per year in 2008.[80] Existing studies, however, have included few older drinkers, and this population may have different alcohol problems and consequently different health and social costs.

The economic analysis tests the hypothesis that a stepped care intervention is more cost-effective for older hazardous alcohol users in primary care when compared with a 5-minute brief intervention (minimal intervention).

The objectives of the economic analysis are to:

1. compare costs associated with the stepped care and minimal interventions at 6 and 12 months post randomisation
2. estimate the health benefits, measured using QALYs, from the interventions
3. assess the cost-effectiveness of the stepped care intervention compared with the minimal intervention.

Data were analysed according to the ITT principle, whereby all participants were analysed as members of their allocated group irrespective of the intervention received. Following technology appraisal guidelines used by NICE, the analysis was performed from the NHS/Personal Social Services perspective. All costs were estimated for the year 2009–10 in UK pounds (£). Follow-up was at 6 and 12 months from randomisation.

Assessment of costs

A micro-costing approach was used to compute the costs of trial interventions. The estimation of costs involved three distinct phases: identifying the relevant resource-items; measuring the use of the identified resource-items; and assigning unit costs or prices to them.

Attendees at primary care aged ≥55 years were screened to determine if they were eligible for the trial interventions. Opportunistic screening costs were estimated from the actual resource use associated with the screening process, which consisted of an information letter, a copy of the AUDIT questionnaire and the time input of the practice/research nurse or practitioner who contacted screen-positive patients.

The costs of the minimal intervention and the first two tiers of the stepped care programme (step 1 and step 2) were based on information gathered on patient contact with the primary care and specialist services during the trial.

Participants in the control arm received a 5-minute discussion with a practice/research nurse about the health consequences of continued hazardous alcohol consumption, and a brief self-help leaflet. Therefore, the cost of minimal intervention included practice/research nurse time and material costs of the self-help leaflet.

The costs of stepped interventions were calculated using local costs of specialist services and included an allowance for training and supervision costs. For steps 1 and 2 of the intervention, therapists were invited to participate in training sessions to provide them with skills for delivering BCC (step 1) and MET (step 2). The cost component for training included the time that trainers and therapists spent in training and

supervision, plus use of space and materials. The total cost for training in each stage was allocated to the number of sessions delivered for the trial.

Step 1 of the intervention included a 20-minute session of BCC by a practice/research nurse. Step 2 consisted of three 40-minute sessions of MET on a weekly basis delivered by a therapist such as an alcohol health worker, clinical nurse manager or drug and alcohol counsellor. The actual time therapists spent delivering each intervention session was recorded and used to compute actual intervention costs by multiplying by their individual salaries.

Four weeks after each step, participants were contacted by telephone by a practice/research nurse for a reassessment of their alcohol consumption. These costs were calculated based on an average 5 minutes of practice/research nurse time and the costs of the line rental.

Step 3 of the stepped care intervention was a referral to local specialist alcohol services to receive specialist intervention. The resource use of this step was not specified in the trial and could encompass a variety of intervention approaches; interventions in this step could expand beyond the time horizon of the trial and a standard cost of £811 per patient was assumed according to the literature.[81]

Data on additional utilisation of health and social care and criminal justice services outside the trial protocol were collected from questionnaires administered at baseline, 6 months and 12 months. At each time point, participants were asked about their resource use over the previous 6 months. Units of resource use recorded were then multiplied by national sources of unit costs[81] in order to provide generalisable results. *Table 21* presents a summary of the categories of resource use together with their unit costs.

Assessment of outcome

The economic evaluation used QALYs as recommended by NICE as a measure of health benefit for their reference case.[73] QALYs were derived from utility scores measured by EQ-5D questionnaires at baseline and at 6-month and 12-month follow-up. The EQ-5D is a standardised instrument for use as a measure of health outcomes developed by the EuroQol Group.[60] The EQ-5D results were scored using the UK York time trade-off tariff obtained from a sample of around 3000 members of the general UK population.[83,84] Given the assumption that health status changes between measurements are smooth and gradual over time, utility scores were converted into QALYs using the area under the curve method.[85]

To appropriately adjust potential imbalances and ensure comparability with the clinical analysis, multiple regression methods were applied to give the differential mean QALYs and the prediction of adjusted QALYs by controlling for baseline EQ-5D scores.[86,87]

Assessment of cost-effectiveness

Incremental cost-effectiveness analysis was performed to combine the costs of the interventions with health outcomes. The mean difference in costs between the two trial groups was compared with mean difference in effectiveness to generate ICERs.[70]

$$\text{ICER} = \frac{\Delta C}{\Delta E} = \frac{C_{SC} - C_{MI}}{E_{SC} - E_{MI}} \quad (1)$$

Here, E represents the change in effects (in this case measured QALYs), and C represents the costs of intervention, measured in monetary units, while subscripts 'SC' and 'MI' refer to stepped care and minimal intervention, respectively.

TABLE 21 Summary of main resources and unit costs in 2009–10 prices

Resource item	Unit cost (£)	Source
A&E visit	37	Curtis[81]
Inpatient night	240	Curtis[81]
Outpatient attendance	152	Curtis[81]
Day case	637	Curtis[81]
Emergency ambulance	277.80	Curtis[81]
Patient transport service	57.02	Curtis[81]
GP (surgery)	32	Curtis[81]
GP (home)	106	Curtis[81]
Practice nurse (surgery)	10	Curtis[81]
Practice nurse (home)	13	Curtis[81]
Prescription	8.8	Curtis[81]
Day centres	36 per day	Curtis[81]
Meals on wheels	2.86 per meal	Oddie[82]
Social services home care services	92 per day	Curtis[81]
Social worker (office) (30 minutes)	26.50	Curtis[81]
Social worker (home) (60 minutes)	53	Curtis[81]
Care worker (office) (30 minutes)	25	Curtis[81]
Care worker (home) (60 minutes)	50	Curtis[81]

A&E, accident and emergency.

Handling uncertainty

Cost and QALY data are typically not normally distributed. Cost data are often highly right skewed because of a few cases that incur extremely high costs, while QALY data are normally left skewed because of the ceiling effect.[88–90] In this study, the non-parametric bootstrap technique was employed to explore the sensitivity of calculated ICERs. Bootstrapping is a resampling method that generates multiple replications of the statistic of interest (ICER) by sampling with replacement from the original data.[91] The bootstrap method is preferable for skewed data as it does not rely on parametric assumptions concerning the underlying distribution of data.[92,93]

The results from the bootstrap resampling were used to plot cost-effectiveness planes (CEPs) and cost-effectiveness acceptability curves (CEACs) to show the decision uncertainty surrounding adoption decisions. The CEACs present the probability that stepped care is the preferred treatment option at different values for a decision-maker's willingness to pay (WTP) for a QALY.[94]

Sensitivity analysis

Sensitivity analysis is an appropriate way to check on methodological uncertainty. In this study, sensitivity analysis was planned to vary assumptions about costing methods. It was found that the distributional problem that arose for cost data was mainly attributable to a few 'extreme values' in the distribution.

Therefore, extreme values, defined as those deviating by five times the standard deviation, were excluded and the incremental cost-effectiveness analysis was repeated in the sensitivity analysis.

Results of economic analysis

A total of 21,546 primary care attendees aged ≥55 years were screened using the AUDIT questionnaire. A total of 529 hazardous alcohol drinkers were recruited to the trial and received either minimal or stepped care interventions.

The base-case cost-effectiveness analysis was based on 422 participants (212 in the stepped care group and 210 in the minimal intervention group) with both completed cost and outcome estimates for three different time points, i.e. baseline, 6-month and 12-month follow-up.

Costs

The breakdown of screening costs and intervention costs by allocated treatment is summarised in *Table 22*. The opportunistic screening costs consisted of the costs of materials provided to the 21,546 screened patients and the cost of 5 minutes of practice/research nurse time to contact screen-positive patients. The mean screening cost for every participant recruited into the trial was £5.52; this part of the cost was equal in both intervention and control groups.

The average cost of minimal intervention was £2.34 per participant. This included £2.17 cost of practice/research nurse time and £0.17 cost of the self-help material.

For participants assigned to the stepped care group, a 20-minute BCC session together with a self-help booklet was provided for step 1 of the intervention. The intervention cost for this step was £8.89 per participant.

Step 2 consisted of three sessions of MET. Full data were available for 33 of the participants who received at least one session of therapy, averaging out at a cost of £36.84 per patient, calculated using the actual amount of therapist contact time for each patient. As part of the intervention, a practice/research nurse contacted participants and a short telephone assessment was made to reassess alcohol consumption after each step. The average reassessment cost was £2.42 per patient. The trial data show that attendance at the third stage was actually quite rare. Only five patients completed specialist interventions, with an average cost of £811 per person.

Table 23 presents the quantity of health and social care and criminal justice service utilisations at baseline and 6 months and 12 months after randomisation for both trial groups. No police and criminal justice system contacts were reported by participants.

In addition to the costs of delivering the stepped care interventions, a unit training cost per session was added to the intervention cost to estimate a total cost for stepped care. The training costs for BCC (step 1) and MET (step 2) were £3.69 and £12.71 per session, respectively. The overall average cost of treatment for the intervention group was therefore £46.63 (SD £146) per trial participant (*Table 24*).

Costs of resource use were calculated by multiplying the product of each resource-use category by its associated unit cost listed in *Table 21*. Total costs for each group were reported in the table by adding up resource use costs, screening costs and intervention costs (see *Table 24*). The results showed that resource use costs were the biggest contributor to the overall costs for both groups.

The mean total cost per participant in the stepped care group was £496 (SD £844) compared with £475 (SD £903) in the minimal intervention group at the 6-month follow-up. Using a 12-month time horizon,

TABLE 22 Screening and intervention costs (£ in 2010 prices) by allocated treatment

Source of cost	Intervention group	Control group
Opportunistic screening cost		
Information letter and AUDIT questionnaire	1.63 per participant recruited	1.63 per participant recruited
Five minutes of practice/research nurse contact time with screen-positive patients	3.89 per participant recruited	3.89 per participant recruited
Minimal intervention		
Five minutes of practice/research nurse time	0.00	2.17 per participant
Self-help booklet[a]	0.00	0.17 per participant
Stepped care intervention		
Step 1: BCC		
Training cost for practice/research nurses	3.69 per session	0.00
Twenty-minute BCC	8.72 (SD 0.62) per session	0.00
Self-help booklet[a]	0.17 per participant	0.00
Short telephone assessment 4 weeks after[b]	2.42 per participant	0.00
Step 2: MET		
Training cost for therapists	12.71 per session	0.00
Three 40-minute sessions with trained alcohol therapist	36.84 (SD 52.34) per participant	0.00
Short telephone assessment 4 weeks after	2.42 per participant	0.00
Step 3: specialist alcohol services		
	811 per patient	0.00

a 'Safer drinking – a self help guide'.
b Telephone calls at 5p per minute local calls (includes line rental).[95]

the mean total cost was £906 (SD £1369) and £1077 (SD £2636) in the stepped care and minimal groups, respectively.

The costs of health and social care resource use were higher in the stepped care group at baseline (difference £54; 95% CI –£140 to £248). This indicates some baseline imbalance in cost estimates, so we adjusted total costs by controlling for the imbalance in baseline resource use using the multiple regression method.

The adjusted 6-month cost for the stepped care group was £488 compared with £482 for the minimal intervention group, giving a difference of –£6.38 (95% CI –£164 to £151). At the 12-month follow-up, the adjusted mean cost was £875 in the stepped care group compared with £1089 in the minimal group (difference –£194; 95% CI –£585 to £198). The results indicated that stepped care was, on average, less costly compared with minimal intervention at 12-month follow-up, although the difference is not statistically significant.

Outcomes

Mean EQ-5D scores are reported for both groups at the baseline, 6-month and 12-month post randomisations. *Figure 3* presents the change of mean EQ-5D scores over time.

TABLE 23 Mean health and social care and criminal justice service utilisations

	Baseline		6 months		12 months	
Resource item	Control	Intervention	Control	Intervention	Control	Intervention
A&E visit	0.15 (0.58)	0.13 (0.47)	0.17 (0.49)	0.17 (0.64)	0.14 (0.61)	0.09 (0.36)
Inpatient night	0.21 (1.24)	0.48 (3.59)	0.20 (1.02)	0.19 (1.00)	0.44 (2.74)	0.16 (0.98)
Outpatient attendance	1.01 (1.86)	1.00 (2.56)	1.03 (2.77)	0.97 (2.09)	1.10 (3.47)	0.91 (2.22)
Day case attendance	0.14 (0.68)	0.14 (0.53)	0.17 (0.70)	0.15 (0.58)	0.22 (2.29)	0.16 (0.54)
Use of emergency ambulance	0.05 (0.32)	0.06 (0.27)	0.10 (0.42)	0.04 (0.21)	0.10 (0.57)	0.02 (0.15)
Use of patient transport service	0.02 (0.28)	0.07 (0.38)	0.02 (0.17)	0.07 (0.59)	0.15 (1.75)	0.01 (0.14)
GP visit (surgery)	2.45 (2.68)	2.20 (2.19)	2.03 (2.20)	1.83 (1.90)	2.31 (2.90)	1.80 (1.98)
GP visit (home)	0.01 (0.10)	0.03 (0.26)	0.01 (0.10)	0.08 (0.63)	0.06 (0.44)	0.06 (0.45)
Practice nurse visit (surgery)	1.26 (1.88)	1.46 (2.50)	1.17 (1.93)	1.58 (5.35)	1.26 (2.05)	1.01 (1.42)
Practice nurse visit (home)	0.01 (0.21)	0.57 (8.24)	0.07 (0.54)	0.02 (0.17)	0.10 (1.14)	0.01 (0.15)
Prescriptions	4.12 (5.75)	3.58 (2.86)	3.87 (4.04)	4.09 (4.12)	3.83 (3.25)	3.60 (3.39)
Day centre visit	0.52 (5.77)	0.23 (3.30)	0.02 (0.23)	0.23 (3.30)	0.20 (1.74)	0.24 (3.30)
Meals on wheels	0.03 (0.41)	0.03 (0.41)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)
Social services home care services	0.00 (0.00)	0.08 (0.71)	0.00 (0.00)	0.00 (0.07)	0.03 (0.41)	0.01 (0.15)
Social worker (office) (30 minutes)	0.06 (0.83)	0.00 (0.07)	0.03 (0.41)	0.01 (0.15)	0.02 (0.17)	0.03 (0.30)
Social worker (home) (60 minutes)	0.02 (0.28)	0.00 (0.00)	0.03 (0.41)	0.01 (0.15)	0.06 (0.83)	0.00 (0.00)
Care worker (office) (30 minutes)	0.01 (0.21)	0.00 (0.00)	0.02 (0.21)	0.20 (1.83)	0.20 (1.86)	0.04 (0.44)
Care worker (home) (60 minutes)	0.07 (0.59)	0.01 (0.10)	0.01 (0.14)	0.00 (0.07)	0.06 (0.46)	0.06 (0.46)
Police and criminal justice system contacts	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)	0.00 (0.00)

A&E, accident and emergency.
Note: Units correspond to units of resources consumed.

Figure 3 shows that, in both the intervention and control groups, mean EQ-5D scores at 6 months were lower than at baseline, while at the end of the 12-month follow-up, the scores increased and were higher than the baseline utilities. Changes in EQ-5D scores were transformed to estimate the QALY gains for each patient (*Table 25*). The mean unadjusted difference QALY gain over the 6 months from baseline was 0.4030 (SD 0.1026) in the stepped care group and 0.3843 (SD 0.1164) in the minimal intervention group. The corresponding QALY gains for the 12 months from baseline were 0.8067 (SD 0.2012) and 0.7717 (SD 0.2214), respectively.

TABLE 24 Costs of health-care and social services resources used for each group at baseline, 6-month and 12-month follow-up ($n = 422$)

Costs	Stepped care, £ (SD) ($n = 212$)	Minimal intervention, £ (SD) ($n = 210$)	Difference (£)[a] (95% CI)
Six-month resource use at baseline	522.53 (1233.05)	468.25 (727.41)	54.28 (–139.67 to 248.23)
Six-month resource use at 6-month follow-up	443.78 (832.70)	467.52 (903.42)	–23.74 (–189.96 to 142.49)
Six-month resource use at 12-month follow-up	410.65 (729.81)	602.38 (2263.20)	–191.74 (–512.90 to 129.43)
Opportunistic screening cost	5.52 (0.00)	5.52 (0.00)	0
Intervention cost	46.63 (145.88)	2.34 (0.00)	44.29 (24.50 to 64.08)
Costs at 6 months[b]	495.53 (843.78)	474.98 (903.42)	20.56 (–146.75 to 187.87)
Costs at 6 months[c]	488.48 (826.32)	482.10 (826.32)	6.38 (–164.09 to 151.33)
Costs at 12 months[b]	906.18 (1369.31)	1077.36 (2635.77)	–171.18 (–574.06 to 231.70)
Costs at 12 months[c]	895.04 (2049.45)	1088.61 (2049.47)	–193.57 (–585.06 to 197.93)

a Difference = costs for intervention group – costs for control group.
b No adjustment.
c Adjusted for baseline resource use.

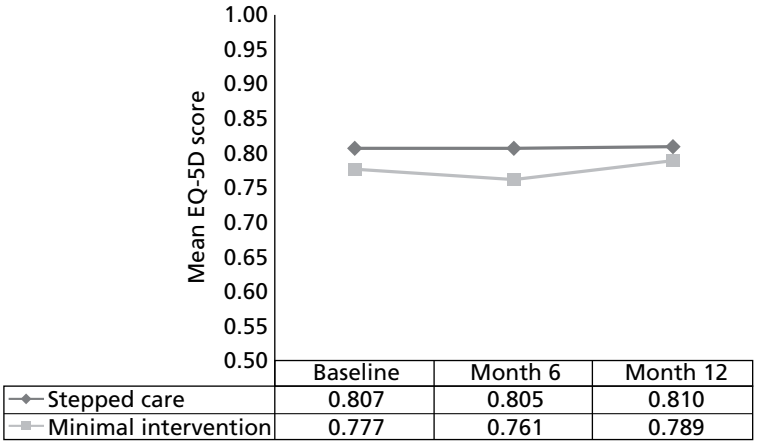

FIGURE 3 Mean EQ-5D scores at baseline, 6 months and 12 months.

Similar to the cost calculation, there is imbalance occurring at the baseline in the mean EQ-5D scores in the two trial groups (*Table 26*). After adjusting QALYs for baseline EQ-5D, the results demonstrate that participants in the stepped care group had, on average, a slightly better quality of life than those in the minimal intervention group [difference in QALYs was 0.0058 (95% CI –0.0018 to 0.0133) at 6 months and 0.0117 (95% CI –0.0084 to 0.0318) at 12 months]. However, this difference was not statistically significant.

TABLE 25 Utility scores (EQ-5D index scores) and QALYs ($n = 422$)

Outcome	Intervention group (SD) ($n = 212$)	Control group (SD) ($n = 210$)	Difference,[a] £ (95% CI)
Baseline EQ-5D scores	0.8066 (0.2204)	0.7767 (0.2507)	0.0299 (–0.0152 to 0.0751)
Six-month follow-up EQ-5D scores	0.8052 (0.2238)	0.7606 (0.2451)	0.0446 (–0.0003 to 0.0895)
Twelve-month follow-up EQ-5D scores	0.8098 (0.2304)	0.7891 (0.2257)	0.0207 (–0.0229 to 0.0644)
QALY (6 months)[b]	0.4030 (0.1026)	0.3843 (0.1164)	0.0186 (–0.0024 to 0.0396)
QALY (6 months)[c]	0.3966 (0.0394)	0.3908 (0.0394)	0.0058 (–0.0018 to 0.0133)
QALY (12 months)[b]	0.8067 (0.2012)	0.7717 (0.2214)	0.0350 (–0.0055 to 0.0755)
QALY (12 months)[c]	0.7951 (0.1054)	0.7834 (0.1054)	0.0117 (–0.0084 to 0.0318)

a Difference = utility for intervention group – utility for control group.
b No adjustment.
c Adjusted for baseline EQ-5D scores.

Results of the cost-effectiveness analysis

Table 26 presents ICERs that combined the costs of interventions with health outcomes.

At the 6-month follow-up, both mean QALY gains and mean cost were greater in the stepped care group than in the minimal intervention group, generating an ICER of £1100 per QALY gained, while at the 12-month follow-up, minimal intervention is dominated by stepped care using the calculated average results. Stepped care participants receive more benefits (greater QALY gains) for less cost; however, none of the differences in costs and benefits between the two interventions was statistically significant. The bootstrap method was therefore employed to evaluate uncertainty surrounding cost-effectiveness estimates. Bootstrapping results were also used to generate incremental CEPs and CEACs to show uncertainty surrounding adoption decisions, shown in *Figures 4* and *5*.

For the 6-month follow-up period, the incremental cost-effectiveness plane (*Figure 4*) showed over half of the plots falling into the south-east quadrant, indicating that stepped care interventions were less costly and more effective. Given WTP thresholds of £20,000–30,000 per additional QALY gained, which is the decision-making threshold used by NICE, the probability that stepped care was more cost-effective is 81.3–86.4%.

Similarly, at the 12-month follow-up (*Figure 5*), the majority of plots in the cost-effectiveness scatter lay in the south-east quadrant and indicated that minimal intervention was dominated by stepped care interventions. The probability of stepped care being cost-effective was between 93.5–93.84% using NICE's threshold range of £20,000–30,000 per QALY gained.

The effects of the GP practice were analysed using a multilevel model programmed in MLwiN. Net monetary benefit was calculated using a WTP threshold of £30,000 per QALY. The analysis indicated that the net monetary benefit did not significantly differ by GP practice.

TABLE 26 Results of incremental cost-effectiveness analysis (completed cases)

Outcome	6 months		12 months	
	Stepped care ($n = 212$)	Minimal intervention ($n = 210$)	Stepped care ($n = 212$)	Minimal intervention ($n = 210$)
Cost (SD)	£488 (£826)	£482 (£826)	£895 (£2049)	£1089 (£2049)
QALY (SD)	0.3966 (0.0394)	0.3908 (0.0394)	0.7951 (0.1054)	0.7834 (0.1054)
ICER (95% CI)	–£1100 per QALY (–£85,991 to £95,546)		–£7997 per QALY (–£238,341 to £172,319)	

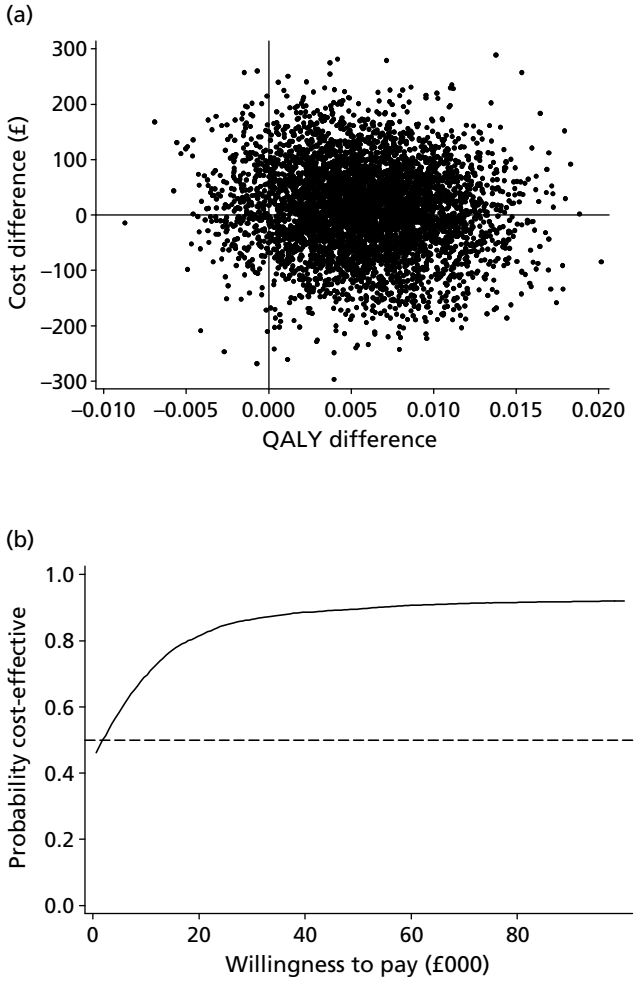

FIGURE 4 Cost-effectiveness plane (a), adjusted for baseline utility and costs, and cost-effectiveness acceptability curve (b), adjusted for baseline utility and costs, at 6 months (completed cases).

Results of the sensitivity analysis

Sensitivity analysis was carried out to check on costing methods in the economic evaluation. In total, 13 participants with extreme costs were excluded in the sensitivity analysis. The changes in costs were noticeable (*Figure 6*). Taking the 12-month resource use as an example, the mean cost for the control group fell from £1162 to £850, and the standard deviation dropped from £2636 to £1125. With the 409 cases left, the incremental cost-effectiveness analysis was repeated. The results are summarised in *Table 27*.

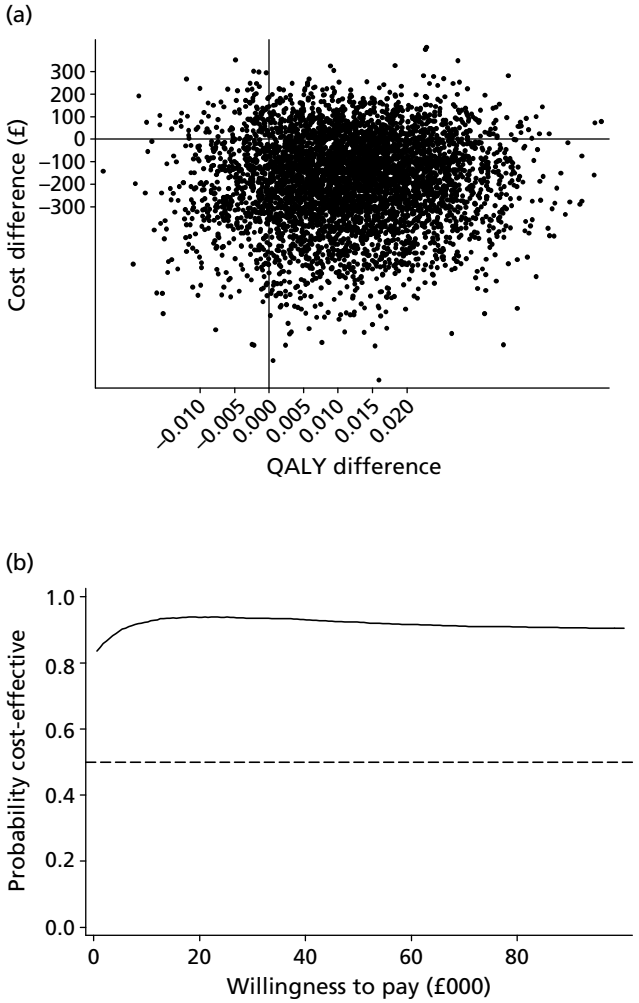

FIGURE 5 Cost-effectiveness plane (a) and cost-effectiveness acceptability curve (b) at 12 months (completed cases).

Taking into account the sensitivity analysis, stepped care continues to demonstrate greater mean QALY gains; however, it is now more costly. The plots on the CEPs move upwards and to the left compared with base-case results. Now the adoption of the intervention relies only on the WTP threshold. Using the NICE threshold range of £20,000–30,000 per QALY, stepped care, with an incremental cost per QALY gained of £8496 at 6 months and £4224 at 12 months, is the more cost-effective option compared with minimal intervention.

Under the new set of ICERs, and using the £20,000–30,000 per QALY gained threshold, the probability that stepped care is more cost-effective ranges between 80% and 88% at 6 months and between 87% and 90% at 12 months (*Figures 7* and *8*).

Summary

The cost-effectiveness results indicated that the costs of delivering stepped care interventions were of the order of 20 times those of the minimal intervention [£46.63 (SD £146) vs £2.34 (SD £0)]. However, the overall cost per patient, taking into account health and social care resource use, was £488 (SD £826) in the stepped care group and £482 (SD £826) in the minimal intervention group at 6 months. The mean QALY gains were slightly greater in the stepped care group than in the minimal intervention group, with a mean difference of 0.0058 (95% CI –0.0018 to 0.0133), generating an ICER of £1100 per QALY gained. At

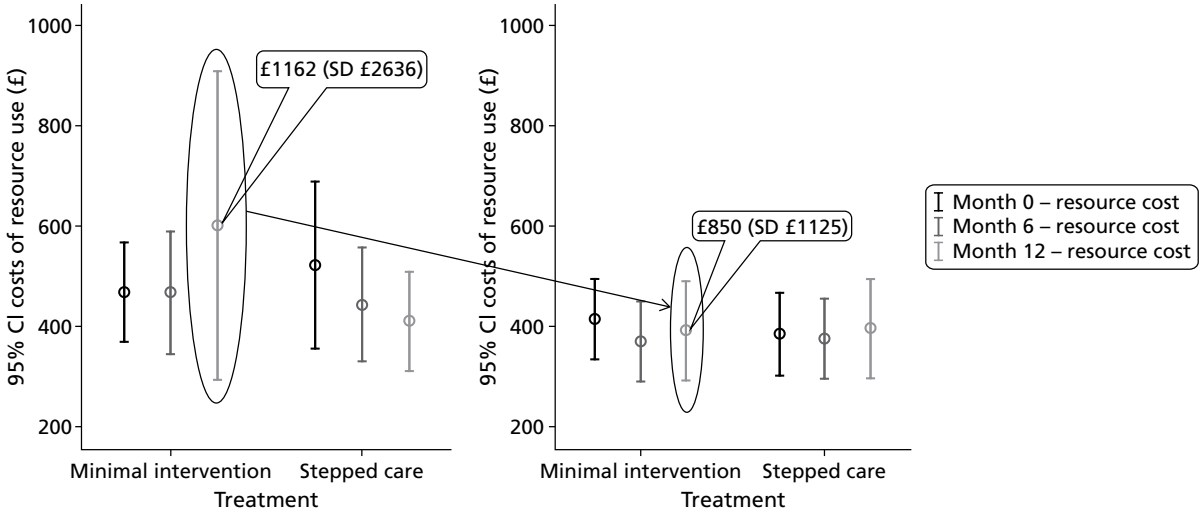

FIGURE 6 Twelve-month health and social care resource use before and after removing extreme cases.

TABLE 27 Results of incremental cost-effectiveness analysis (sensitivity analysis)

Outcome	6 months		12 months	
	Stepped care (*n* = 206)	Minimal intervention (*n* = 203)	Stepped care (*n* = 206)	Minimal intervention (*n* = 203)
Cost (SD)	£430 (£530)	£368 (£530)	£827 (£1029)	£754 (£1029)
QALY (SD)	0.3999 (0.0386)	0.3926 (0.0387)	0.8030 (0.1027)	0.7857 (0.1027)
ICER (95% CI)	£8496 per QALY (–£30,395 to £73,223)		£4224 per QALY (–£37,867 to £57,965)	

month 12, participants in the stepped care group incurred fewer costs, with a mean difference of –£194 (95% CI –£585 to £198), and had gained 0.0117 more QALYs (95% CI –0.0084 to 0.0318) compared with the control group. From an economic perspective, therefore, the minimal intervention was dominated by stepped care.

The results, based on the resampled cost-effectiveness data from the bootstrapping, showed that the probability of stepped care being cost-effective was between 81% and 86% at the 6-month follow-up, and 93.5% and 93.8% at 12 months' follow-up given the NICE decision-making threshold range of £20,000–30,000 per QALY gained. This provides decision-makers with some useful evidence that stepped care interventions are more likely to achieve better value for money than minimal interventions. However, caution is required when interpreting the results given the uncertainty surrounding the estimates.

A sensitivity analysis that excluded extreme cases altered the average costs of interventions; the ICERs were £8496 per QALY at 6 months and £4224 per QALY at 12 months. The probability that stepped care is more cost-effective ranges between 80% and 88% at 6 months and between 87% and 90% at 12 months using the £20,000–30,000 per QALY gained WTP threshold.

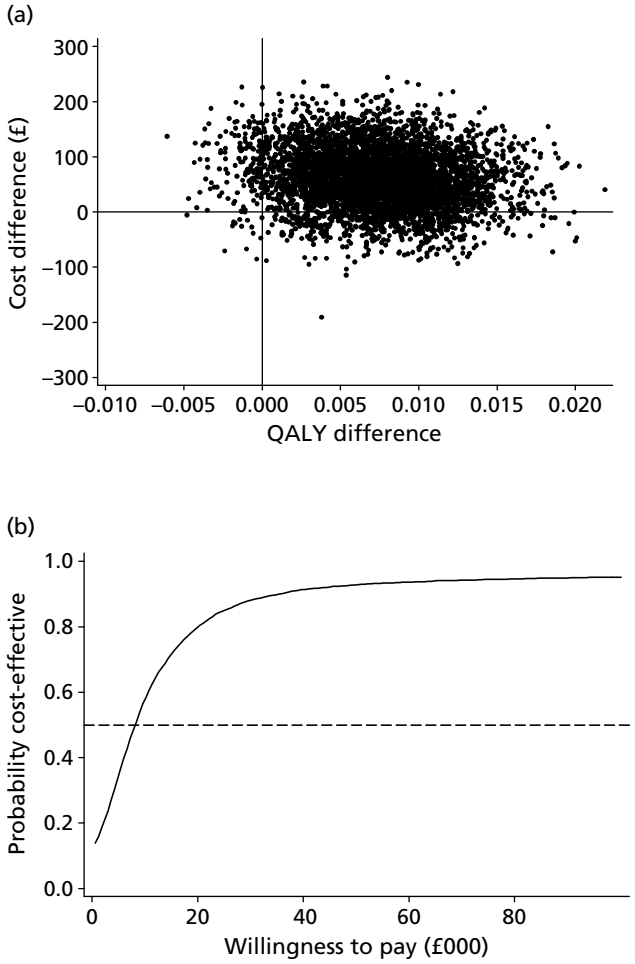

FIGURE 7 Cost-effectiveness plane and cost-effectiveness acceptability curve at 6 months (sensitivity analysis).

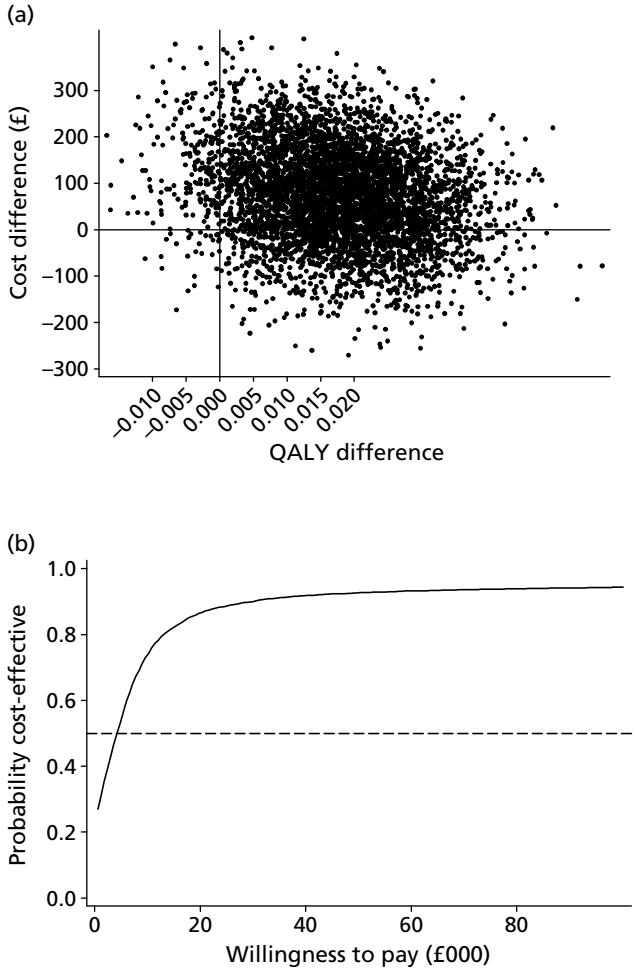

FIGURE 8 Cost-effectiveness plane and cost-effectiveness acceptability curve at 12 months (sensitivity analysis).

Chapter 6 Fidelity process rating

Treatment fidelity plays a crucial role in considering the inferences drawn from effectiveness studies.[66] It provides a means of evaluating whether or not therapists delivered the interventions as described in the session protocols and demonstrates that interventions were distinguishable from one another.[96] In other words, it reports on the internal validity of the study. It also assesses the quality of such delivery, i.e. it measures practitioner skill. This is particularly important as treatment adherence is not always related to therapist competence.[97] A therapist can adhere to a session protocol but deliver the components in a poor or unacceptable manner, such as asking questions at inappropriate times and adopting a cold and judgemental demeanour. Fidelity checks can therefore identify differences in therapist competence and enable potential treatment effects to be accurately attributed.

Methods

Development of the rating scale

The AESOPS PRS (*Appendix 10*) was adapted from the validated UKATT PRS[66] and was designed to rate the delivery of all three trial interventions, namely the minimal intervention, the 20 minutes of BCC (step 1) and MET (step 2). Content and style items from the validated UKATT PRS, including those that rated the delivery of MET, were used as the basis for adapting the scale. These items were examined to ensure that they covered all of the treatment components specified in the session protocols. At this point an item was added to rate the number of open questions asked by the practice/research nurse.

Items described behaviours that were referred to in each of the session protocols and were therefore relevant to each intervention. Style items were largely based on a motivational interviewing approach. In order to distinguish interventions delivered in this style, two items denoting behaviours that were inconsistent with a motivational interviewing approach were included in the pilot phase. These included item 15, the extent to which the practice/research nurse provided unsolicited advice to the patient, and item 17, the number of closed questions asked by the practice/research nurse within the intervention.

The rating scale

The PRS is an 18-item scale, divided into four sections. The first section contains four items relating to overall session management. The middle two sections include eight items measuring specific tasks and five items measuring therapist style. The last section, listed as a single item, contains a session content/activity checklist.

All but three items were rated on two 5-point scales. The first scale provided a frequency rating that showed the extent to which an item was present. The second scale gave a quality rating and showed how well the practice/research nurse performed the behaviour; this scale was rated only if the item received a frequency rating. The frequency ratings ranged from 0 ('not at all'), indicating that the item never explicitly occurred, to 4 ('extensively'), signifying that the item was performed numerous times during the intervention. Intermittent points were labelled 'a little', 'somewhat' and 'considerably'. On the quality scale, a rating of 0 ('very poor') showed that the item was performed in an unacceptable manner, and a rating of 4 ('very well') indicated that the therapist had demonstrated a high level of skill and expertise. Intermittent labels were 'poor', 'good enough' and 'well'.

Global ratings were given for three of the items; two were associated with session management ('session structure' and 'consistency of problem focus') and one with therapist style ('empathy'). The remaining items consisted of frequency counts of specific behaviours with corresponding quality ratings. Each point on the frequency scale related to a predefined number of behaviour counts. For example, a frequency rating of 2 ('somewhat') indicated that the item behaviour occurred either once and in some

detail or three or time times but briefly. Quality scores also had corresponding definitions; for instance, 0 ('very poor') indicated that the practice/research nurse performed the behaviour within each item in an unacceptable manner. Where appropriate, an average quality score was given for each of the item behaviours. For example, if a practice/research nurse attempted to elicit optimism three times within the intervention and received quality scores of 2, 3 and 4, the overall quality rating given for that behaviour would be 3 ('well').

Two items carried a frequency rating only: item 15 ('unsolicited advice') and item 17 ('closed questions'). Given that these behaviours were inconsistent with a motivational interviewing style, it followed that a rating of how well therapists performed these items was not needed. The final item, a session content/activity checklist, asked for a yes/no answer to illustrate whether or not the following content had occurred within the intervention: review AUDIT score, obtain an account of drinking, give correct advice/information, set a target, and make a drinking plan. The checklist also included a tick box question to indicate whether the recording was good or poor.

The rating manual

The rating manual was similarly adapted from that used in the UKATT study.[66] General guidelines were issued for the process of rating, such as rating practice/research nurse behaviours, distinguishing between frequency and quality scores, and avoiding sources of rater bias. Item definitions with guidelines for making higher or lower ratings were provided. These were illustrated with examples of practice/research nurse dialogue and differentiated from closely related items. Explanatory notes were included regarding the rating of session content.

Rater training and supervision

An independent rater was trained to use the adapted scale and rating manual. Supervised practice ratings were held at weekly intervals reviewing a total of 17 recordings split evenly between the trial interventions. Recordings were simultaneously rated and the scores discussed with reference to the manual and rater notes. This ensured rater consistency and prevented rater drift. Familiarity with the manual and rating scale was essential. Independent practice was carried out whereby item definitions were read each time they were scored. Recordings used during rater training were not used in the study. Regular supervision continued after training to discuss independently rated recordings. Selected recordings were rated by the independent rater and the supervisor for the purposes of calibration.

The process of rating

Following guidelines outlined in the rating manual, raters listened to the interventions and scored item behaviours. Where appropriate, frequency counts were given a corresponding quality rating. Item definitions, as specified in the manual, were referred to throughout the process in order to prevent rater drift. Raters had the option to pause the recording or consult the manual without stopping. Brief notes were made during the session to help substantiate assigned scores. These were particularly useful for discussing ratings during supervision. At the end of the session, appropriate global ratings and overall frequency and quality ratings were given. Each session was timed to ascertain duration. All scores were entered into the Statistical Package for Social Sciences (SPSS) version 19 (SPSS Inc., Chicago, IL, USA) for analysis.

Sampling

One hundred and sixty sessions of brief advice (minimal) and BCC (step 1) were selected for independent process rating (*Figure 9*). Only these two treatments were rated, as there were not enough MET sessions (step 2) to enable meaningful results to be obtained. The sample was stratified by site, practice/research nurse and treatment. Replacement sampling was used for eight inaudible recordings. In total, 79 sessions of brief advice and 81 sessions of BCC were rated. Nineteen per cent of these were double rated (i.e. scored by both the independent rater and supervisor): 11 sessions of brief advice and 20 of BCC.

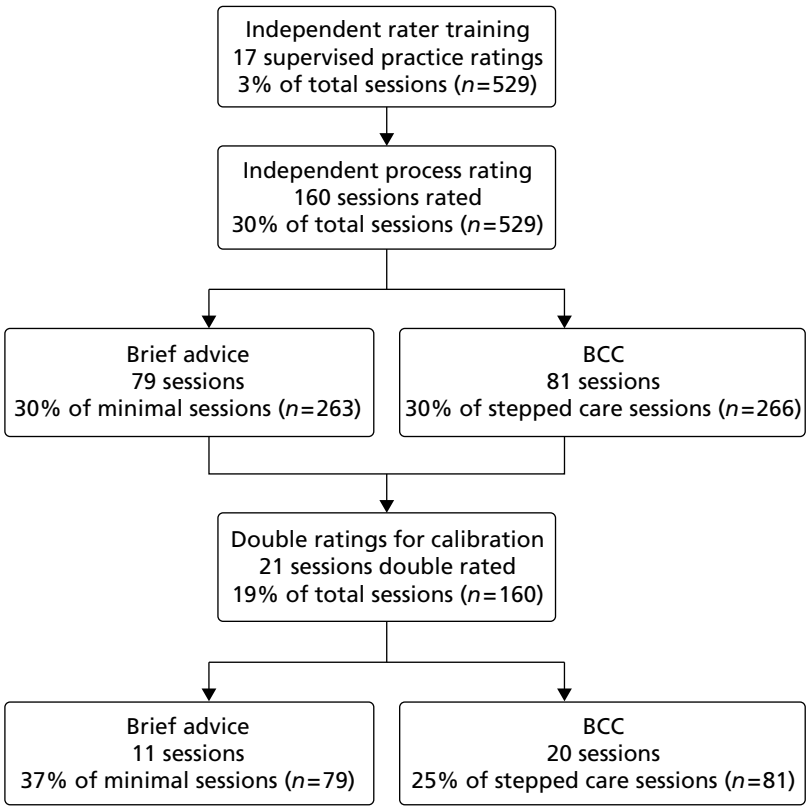

FIGURE 9 Flow diagram of process rating procedure.

Analyses

The PRS consisted of four sections: session management, specific task, practice/research nurse style and session content. The summaries for the scores for each of the treatment sessions are displayed in *Tables 28* to *32*.

Four summary measures were calculated; these were used in the analyses in addition to the time taken to complete the sessions. The summary measures were analysed using mixed models, with practice/research nurse fitted as a random effect. There was a significant difference in time of session between the 5- and 20-minute sessions. The average time for the 5-minute session was 422.57 seconds (7 minutes) and for the 20-minute session 1174.78 seconds (20 minutes).

The 20-minute sessions had significantly higher task frequency and task quality scores. The 20-minute sessions also had significantly higher style frequency and style quality scores. The results can be seen in *Table 33*.

When comparing the session content, there were significant differences between the two sessions on only two measures, 'obtaining a drinking account' and 'setting a target'; both of these were more likely to be performed in the 20-minute sessions. The results of all of the analyses can be seen in *Table 34*.

The analysis of the summary measures was repeated but this time it included a variable to represent specialist practitioners. When comparing the session rating scores for specialist and non-specialist practitioners there were no significant differences found. The full results can be seen in *Table 35*.

Reliability of ratings

A sample of the recordings was rated by two raters. Inter-rater reliability of the individual frequency items of the summary scores was examined using the ICC two-way mixed-effects model (case 3).[67] For the four

TABLE 28 Session management

Management	Intervention		
	Stepped care ($n = 81$)	Minimal ($n = 79$)	Total
Maintaining structure			
Frequency, mean (SD) (min., max.)	1.9 (0.7) (0, 4)	1.8 (0.6) (1, 3)	1.8 (0.6) (0, 4)
Quality, mean (SD) (min., max.)	1.7 (0.8) (0, 4)	1.6 (0.6) (0, 3)	1.7 (0.7) (0, 4)
Agenda setting			
Frequency, mean (SD) (min., max.)	0.9 (0.6) (0, 2)	0.8 (0.4) (0, 2)	0.9 (0.5) (0, 2)
Quality, mean (SD) (min., max.)	1.0 (1.0) (0, 4)	0.8 (0.8) (0, 3)	0.9 (0.9) (0, 4)
Consistency of problem focus			
Frequency, mean (SD) (min., max.)	1.9 (1.1) (0, 4)	2.0 (1.1) (0, 4)	2.0 (1.1) (0, 4)
Quality, mean (SD) (min., max.)	1.9 (1.1) (0, 4)	2.0 (1.1) (0, 4)	2.0 (1.1) (0, 4)
End of session			
Frequency, mean (SD) (min., max.)	0.2 (0.5) (0, 2)	0.1 (0.3) (0, 2)	0.2 (0.4) (0, 2)
Quality, mean (SD) (min., max.)	0.3 (0.8) (0, 3)	0.0 (0.2) (0, 2)	0.2 (0.6) (0, 3)

max., maximum; min., minimum.

TABLE 29 Specific tasks

Tasks	Intervention		
	Stepped care ($n = 81$)	Minimal ($n = 79$)	Total
Drinking: feedback/negative consequences			
Frequency, mean (SD) (min., max.)	0.9 (0.6) (0, 3)	0.9 (0.4) (0, 2)	0.9 (0.5) (0, 3)
Quality, mean (SD) (min., max.)	0.2 (0.5) (0, 2)	0.2 (0.4) (0, 2)	0.2 (0.5) (0, 2)
Eliciting client concerns about drinking			
Frequency, mean (SD) (min., max.)	1.6 (1.1) (0, 4)	0.6 (0.7) (0, 3)	1.1 (1.0) (0, 4)
Quality, mean (SD) (min., max.)	0.7 (0.8) (0, 2)	0.3 (0.6) (0, 2)	0.5 (0.7) (0, 2)
Eliciting self-efficacy for change			
Frequency, mean (SD) (min., max.)	0.7 (0.8) (0, 3)	0.1 (0.3) (0, 1)	0.4 (0.7) (0, 3)
Quality, mean (SD) (min., max.)	0.7 (0.9) (0, 3)	0.1 (0.3) (0, 2)	0.4 (0.8) (0, 3)
Commitment to drinking goal			
Frequency, mean (SD) (min., max.)	1.3 (0.9) (0, 3)	0.7 (0.6) (0, 2)	1.0 (0.8) (0, 3)
Quality, mean (SD) (min., max.)	1.1 (0.8) (0, 3)	0.6 (0.6) (0, 2)	0.9 (0.8) (0, 3)
Ambivalence			
Frequency, mean (SD) (min., max.)	0.3 (0.5) (0, 3)	0.0 (0.0) (0, 0)	0.1 (0.4) (0, 3)
Quality, mean (SD) (min., max.)	0.3 (0.7) (0, 3)	0.0 (0.0) (0, 0)	0.2 (0.5) (0, 3)
Creating conflict			
Frequency, mean (SD) (min., max.)	0.1 (0.4) (0, 2)	0.0 (0.0) (0, 0)	0.1 (0.3) (0, 2)
Quality, mean (SD) (min., max.)	0.1 (0.4) (0, 2)	0.0 (0.0) (0, 0)	0.1 (0.3) (0, 2)

TABLE 29 Specific tasks (*continued*)

Tasks	Intervention		
	Stepped care ($n = 81$)	Minimal ($n = 79$)	Total
Eliciting commitment to change drinking			
Frequency, mean (SD) (min., max.)	1.0 (0.7) (0, 3)	0.2 (0.4) (0, 1)	0.6 (0.7) (0, 3)
Quality, mean (SD) (min., max.)	0.8 (0.8) (0, 3)	0.2 (0.5) (0, 3)	0.5 (0.7) (0, 3)
Eliciting optimism for change			
Frequency, mean (SD) (min., max.)	1.1 (0.8) (0, 3)	0.4 (0.7) (0, 3)	0.7 (0.8) (0, 3)
Quality, mean (SD) (min., max.)	0.8 (0.8) (0, 3)	0.3 (0.6) (0, 2)	0.5 (0.8) (0, 3)

max., maximum; min., minimum.

TABLE 30 Practice/research nurse style

Styles	Intervention		
	Stepped care ($n = 81$)	Minimal ($n = 79$)	Overall
Frequency reflective listening, mean (SD) (min., max.)	2.6 (0.9) (0, 4)	1.1 (0.9) (0, 3)	1.9 (1.2) (0, 4)
Quality reflective listening, mean (SD) (min., max.)	1.7 (0.6) (0, 3)	1.1 (0.8) (0, 3)	1.4 (0.8) (0, 3)
Frequency empathy, mean (SD) (min., max.)	1.9 (0.9) (0, 4)	1.3 (0.9) (0, 4)	1.6 (1.0) (0, 4)
Quality empathy, mean (SD) (min., max.)	1.9 (0.9) (0, 4)	1.4 (1.0) (0, 4)	1.7 (1.0) (0, 4)
Frequency unsolicited advice, mean (SD) (min., max.)	2.9 (1.2) (0, 5)	3.4 (1.0) (0, 4)	3.2 (1.1) (0, 5)
Frequency open questions, mean (SD) (min., max.)	2.7 (0.8) (0, 4)	1.0 (0.9) (0, 3)	1.9 (1.2) (0, 4)
Quality open questions, mean (SD) (min., max.)	1.9 (0.5) (0, 3)	1.4 (0.9) (0, 3)	1.7 (0.8) (0, 3)
Frequency closed questions, mean (SD) (min., max.)	3.1 (1.0) (1, 4)	2.1 (1.1) (1, 4)	2.6 (1.2) (1, 4)

max., maximum; min., minimum.

TABLE 31 Session content

Activity	Intervention		
	Stepped care ($N = 81$)	Minimal ($N = 79$)	Total ($N = 160$)
Review AUDIT score, *n* (%)	63 (79.7)	74 (91.4)	137 (85.6)
Obtain drinking account, *n* (%)	78 (98.7)	40 (49.4)	118 (73.8)
Give correct advice/information, *n* (%)	76 (96.2)	81 (100.0)	157 (98.1)
Set a target, *n* (%)	28 (35.4)	11 (13.6)	39 (24.4)
Make a drinking plan, *n* (%)	11 (13.9)	6 (7.4)	17 (10.6)

TABLE 32 Summary measures

Measures	Intervention		
	Stepped care (20 minutes)	Minimal (5 minutes)	Total
Length of session (minutes and seconds)			
Mean (SD)	19:41 (05:42)	07:10 (01:59)	13:21 (07:34)
Median (min., max.)	19:38 (03:17, 34:30)	06:57 (03:17, 12:57)	11:06 (03:17, 34:30)
Task frequency			
Mean (SD)	0.88 (0.35)	0.36 (0.20)	0.62 (0.39)
Median (min., max.)	0.88 (0.00, 1.88)	0.38 (0.00, 0.88)	0.50 (0.00, 1.88)
Task quality			
Mean (SD)	0.59 (0.41)	0.21 (0.22)	0.40 (0.38)
Median (min., max.)	0.50 (0.00, 1.75)	0.13 (0.00, 1.25)	0.25 (0.00, 1.75)
Style frequency			
Mean (SD)	2.64 (0.47)	1.78 (0.53)	2.20 (0.66)
Median (min., max.)	2.80 (1.20, 3.60)	1.80 (0.40, 3.00)	2.20 (0.40, 3.60)
Style quality			
Mean (SD)	1.87 (0.55)	1.27 (0.66)	1.56 (0.68)
Median (min., max.)	2.00 (0.33, 3.00)	1.33 (0.00, 2.67)	1.67 (0.00, 3.00)

max., maximum; min., minimum.

TABLE 33 Summary measures analyses

Measures	Stepped care intervention (20 minutes), mean (SD)	Minimal intervention (5 minutes), mean (SD)	Difference (95% CI)	*p*-value
Length of session (seconds)	1174.78 (36.53)	422.57 (35.68)	752.22 (674.00 to 830.44)	$p<0.001$
Task frequency	0.92 (0.04)	0.40 (0.04)	0.52 (0.44 to 0.61)	$p<0.001$
Task quality[a]	0.59 (0.04)	0.21 (0.04)	0.38 (0.27 to 0.48)	$p<0.001$
Style frequency[a]	2.64 (0.06)	1.78 (0.06)	0.87 (0.71 to 1.02)	$p<0.001$
Style quality	1.82 (0.10)	1.22 (0.10)	0.60 (0.43 to 0.77)	$p<0.001$

a Mixed model failed to converge so results are from a linear regression model.

TABLE 34 Session content analyses

Activity	Stepped care ($N = 81$)	Minimal ($N = 79$)	Odds ratio (95% CI)	*p*-value
Review AUDIT score, *n* (%)	63 (79.7%)	74 (91.4%)	0.27 (0.05 to 1.42)	0.123
Obtain drinking account, *n* (%)	78 (98.7%)	40 (49.4%)	71.7 (4.00 to 1283.6)	0.004
Give correct advice/information, *n* (%)[a]	76 (96.2%)	79 (100.0%)		0.118
Set a target, *n* (%)	28 (35.4%)	11 (13.6%)	3.41 (1.49 to 7.80)	0.004
Make a drinking plan, *n* (%)	11 (13.9%)	6 (7.4%)	1.88 (0.81 to 4.35)	0.140

a Results from Fisher's exact test.

summary scores, the average of the two raters' summary scores was plotted against the difference in their summary scores[69] to make pairwise comparisons between raters (*Figure 10*).

The ICCs for the summary measures ranged from 0.64 to 0.81 (*Table 36*), which indicates acceptable levels of agreement.[67]

The Bland–Altman plots for each of the summary measures compare the two raters (*Figure 10*). A positive difference indicates that the second rater scores higher than the first rater. A negative difference indicates than the second rater scores lower than the first.

Summary

The scale identified significant differences between the 5- and 20-minute interventions, indicating that the two types of session were distinct. Validation of the rating showed an acceptable level of agreement between the raters. There were no significant differences in the rating scores between practice/research nurses with different levels of experience (specialist vs non-specialist practitioners).

TABLE 35 Comparison of specialist and non-specialist practitioners' rating scores

Rating	Non-specialist, mean (SD)	Specialist, mean (SD)	Difference (95% CI)	*p*-value
Task frequency	0.69 (0.04)	0.61 (0.05)	0.08 (–0.07 to 0.22)	0.260
Task quality[a]	0.42 (0.04)	0.39 (0.04)	0.03 (–0.07 to 0.14)	0.135
Style frequency	2.29 (0.08)	2.18 (0.12)	0.11 (–0.21 to 0.43)	0.459
Style quality	1.46 (0.11)	1.65 (0.17)	–0.18 (–0.62 to 0.26)	0.384

a Mixed model failed to converge so results are from a linear regression model.

TABLE 36 Intraclass correlation coefficient analyses of the individual frequency items of the summary scores

Rating and raters	*n*	Mean rating (SD)	ICC (95% CI)
Task frequency			
Rater 1	33	0.76 (0.45)	0.815 (0.624 to 0.908)
Rater 2	33	0.93 (0.50)	
Task quality			
Rater 1	33	0.51 (0.44)	0.670 (0.332 to 0.837)
Rater 2	33	0.82 (0.64)	
Style frequency			
Rater 1	33	2.30 (0.54)	0.736 (0.465 to 0.869)
Rater 2	33	2.41 (0.81)	
Style quality			
Rater 1	33	1.67 (0.60)	0.640 (0.271 to 0.822)
Rater 2	33	1.95 (0.85)	

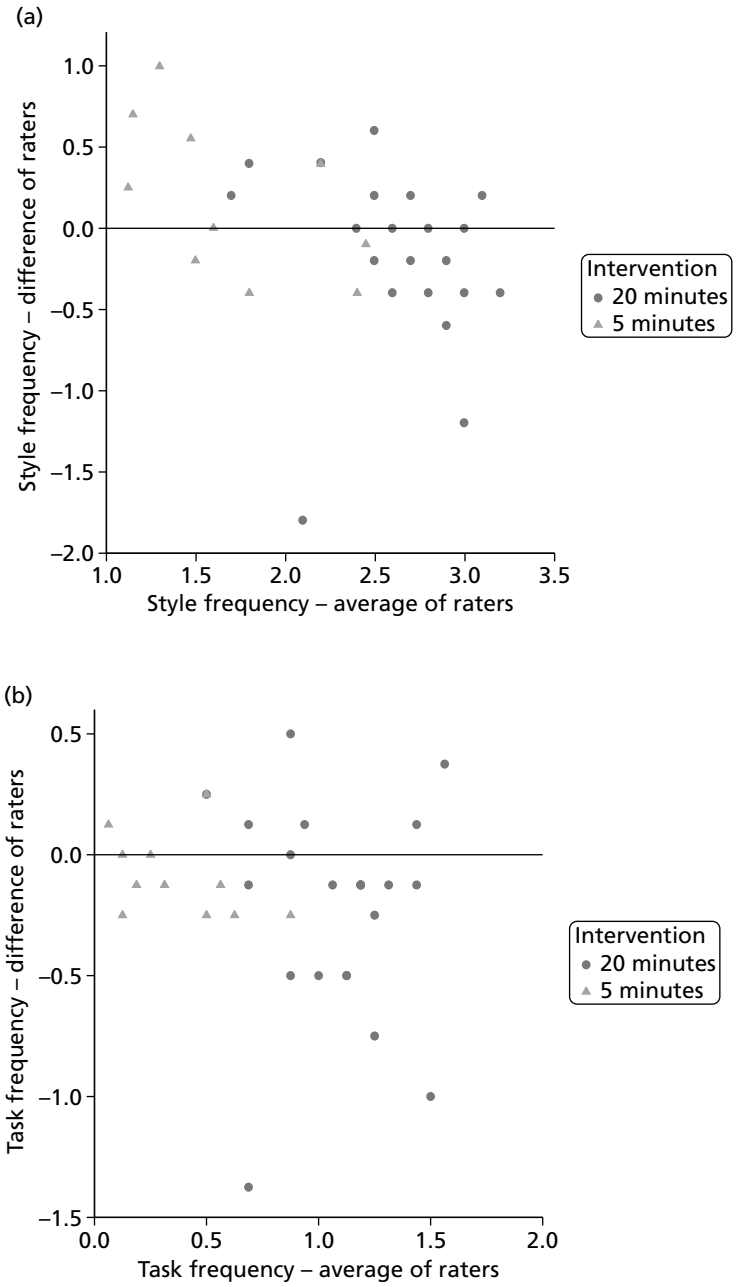

FIGURE 10 Bland–Altman plots.

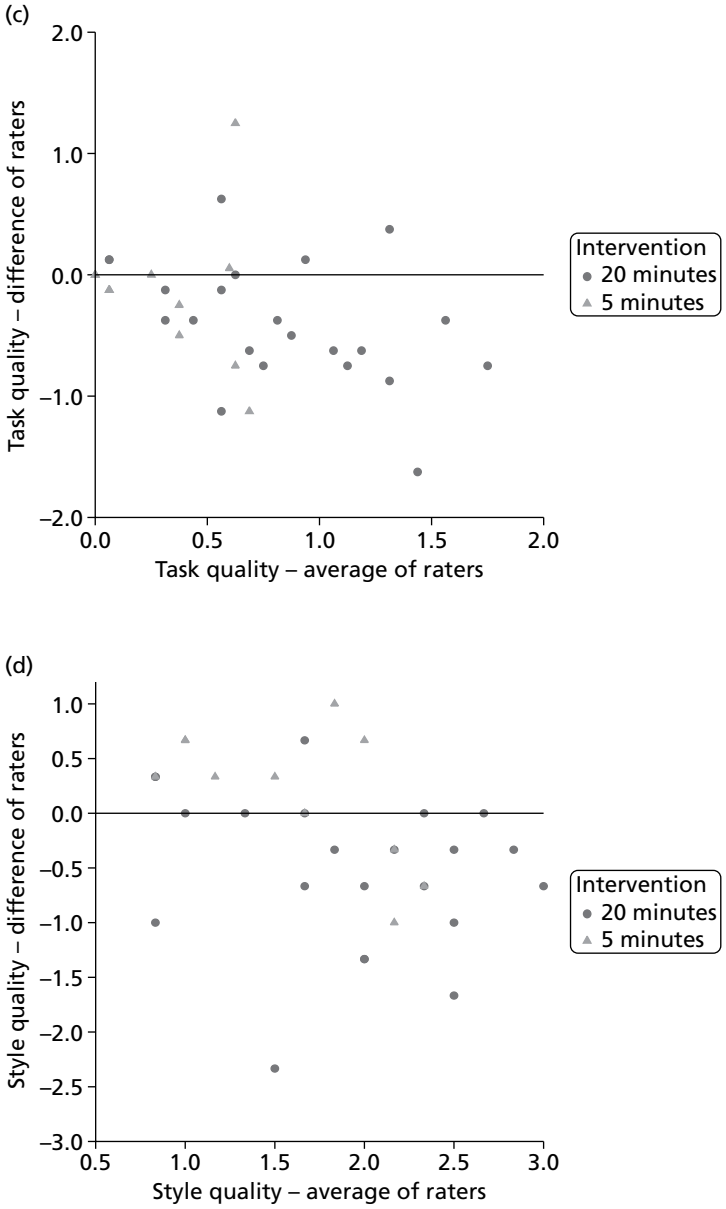

FIGURE 10 Bland–Altman plots. (*continued*)

Chapter 7 Discussion

Here we report the results of a large trial of a stepped care intervention versus a minimal intervention in the management of older hazardous alcohol users in primary care.

Six published systematic reviews focus specifically upon the effectiveness of brief interventions in primary care populations[28–33] although many of the studies excluded older patients. There are no systematic reviews or subgroup analyses specifically focusing on older patient groups. This trial aimed to fill that gap and was conducted and reported in accordance with international guidelines for research excellence.[98–101]

One prompt to conduct this trial was research indicating the underdetection and misdiagnosis of hazardous alcohol use in older populations.[16,17] It is generally considered that the prevalence of hazardous or harmful alcohol consumption in those aged ≥55 years is lower than the general population. Indications are that prevalence is between 15% and 25% of the general population.[11] However, the findings of this study found the prevalence of hazardous drinking in the older population to be less than suggested by previous research. Only 7.5% of those screened were positive on the AUDIT screening questionnaire and the mean AUDIT score of those positive was 12.10 (SD 5.65).

The issues encountered in this trial highlight the fact that research can be difficult to conduct in primary care owing to a number of issues including staff time and workloads. However, the eventual successful recruitment appears to suggest that older populations are as willing and able to engage in research evaluations as the general population and, as demonstrated by the impressive questionnaire return rates, display a greater willingness to be followed up. This concurs with previous research that suggested that older populations are more compliant with follow-up protocols than younger populations.[38,56]

Key findings

This study aimed to compare the effects of a minimal intervention (a 5-minute, brief advice with the practice/research nurse involving feedback of the results of the screening and discussion regarding the health consequences of continued hazardous alcohol consumption) with a stepped care intervention (progression to next step determined by reassessment of alcohol consumption after each previous step). The primary hypothesis was that a stepped care intervention reduced alcohol consumption in older hazardous alcohol users compared with a minimal intervention post randomisation. We found no evidence of a difference in the ADD after 12 months of older hazardous alcohol users when comparing the stepped care group with the minimal intervention group at month 12 [stepped care 1.129 (SD 0.037) vs minimal intervention 1.104 (SD 0.037)]. At month 6, the stepped care group had a lower ADD than the minimal interventions group, but not significantly so.

When adjusting for baseline scores and including GP as a random effect, there was no evidence of any differences in ADD at month 6, or AUDIT-C score or the DPI score at month 6 or month 12.

We investigated changes in HRQoL from baseline using the SF-12.[59] Our results showed that the stepped care group had both lower MCS and lower PCS than the minimal intervention group at months 6 and 12, although the differences were not significant at the 5% level. We cannot conclude that stepped care has any impact on HRQoL.

We evaluated whether or not stepped care was a more cost-effective treatment for the management of older alcohol users in primary care and the results revealed that, with longer follow-ups, stepped care generated greater cost savings (£194 at month 12 vs £6.38 at month 6) and greater QALY gains (0.0117 at month 12 vs 0.0058 at month 6).

The probability that stepped care was cost-effective was higher for the month 12 follow-up period (93.5–93.8%) than the month 6 follow-up (81–86%) under a conventional WTP threshold of £20,000–30,000 per QALY. This indicated that participants may benefit more from stepped care in the longer term with the reduction of alcohol-related health problems in the future. The analysis indicated that the net monetary benefit did not significantly differ by GP practice. A few 'extreme values' were present in the distribution (those deviating by five times the standard deviation) which were excluded, and the incremental cost effectiveness analysis was repeated in a sensitivity analysis. The sensitivity analysis altered the average costs of interventions; however, there was still over 80% certainty that stepped care is more cost-effective than minimal intervention months using the £20,000–30,000 per QALY gained threshold.

The health economic findings raise important issues when contrasted with the null clinical effectiveness findings and some further consideration of the reasons why this may occur is needed.

Firstly, in economic evaluation, an ICER combines the costs of the interventions with health outcomes. The statistic of interest is the ICER, which is estimated on the basis of four statistics from two samples: the costs of the control and intervention groups (C_C and C_I) and the effects of the control and intervention groups (E_C and E_I). This allows us to take advantage of the power to detect a difference in the joint cost-effectiveness outcome. In some cases, the power to detect a difference in this joint outcome exceeds the power to detect differences in either cost or effect alone. It is possible for a study to show no difference in clinical outcomes between interventions, but also to conclude that one intervention is more cost-effective than another, because that intervention costs less when the intervention's costs and subsequent service use are taken into account.

Secondly, the decision rule in an economic evaluation differs from traditional effect analysis. We make decisions to adopt a health technology by comparing the estimated cost-effectiveness ratio with a predefined standard or threshold value; for example, the decision-making threshold used by NICE is £20,000–30,000 per additional QALY gain. Whether or not an intervention is cost-effective varies when the decision threshold changes. Whereas in statistics an intervention is considered to be more effective if the *p*-value of the difference is lower than 0.05, this is not the case in an economic evaluation.

Thirdly, the traditional way of interpreting the CI may sometimes be interpreted in different ways in economic evaluation. For example, a negative ICER can arise as a result of two completely different situations. One scenario is that the intervention is more effective and less expensive. On the other side, the intervention may have a greater cost and a worse effect (cost-ineffective intervention). Therefore, we use CEACs to summarise the evidence in support of the intervention being cost-effective for all potential values of the decision rules. The CEAC presents much more information on uncertainty than it does on CIs in economic analysis, as it presents the probability that the intervention is more effective than the control at different values for a decision-maker's threshold, for example if willing to pay different values to gain one QALY.

It may be the case that the economic analysis indicates that with a far greater sample size a difference in effect of the interventions may become apparent. The sample analysed at the final outcome stage was greater than that estimated in the original sample size calculation and any small effect difference derived from a far larger sample would be unlikely to be a clinically important difference.

Consideration of possible explanations

The importance of the actual screening process itself cannot be excluded as having a possible impact on the alcohol consumption of some trial participants. Previous studies and reviews have reported possible reactivity to such assessments,[77,102–105] although the exact effect is difficult to separate from the study interventions. The fact that the study involved the proactive opportunistic identification of people consuming alcohol at levels that may be detrimental to their health precluded the inclusion of a

no-treatment control. Ethical considerations meant that the study compared two active interventions. The control was a minimally acceptable brief intervention and the provision of an information leaflet. The population identified using opportunistic screening exhibited lower levels of alcohol use and lower levels of alcohol-related problems than treatment-seeking populations and both groups reduced consumption over the 12 months. It may be the case that more intensive interventions in this population are no more effective than minimal interventions and similar results have been found in both systematic reviews and primary research.[28,34,106]

The majority of participants engaged with both the minimal intervention and step 1 of the stepped care intervention and written comments on questionnaires were overwhelmingly positive in describing these. Of note was the fact that two-thirds of those assessed as eligible for referral to step 2 either cancelled or failed to attend. These findings are similar to other studies of stepped care for alcohol use in primary care,[13] extended alcohol interventions for alcohol use in primary care[106] and referrals for interventions in emergency departments.[107] It may be the case that extended multiple session interventions are not considered acceptable to a large proportion of the non-treatment-seeking population, many of whom are consuming alcohol at levels towards the lower end of the severity spectrum.

The use of the same practice/research nurse to deliver both the minimal intervention and step 1 of the stepped care intervention could have resulted in contamination due to the distinction between the interventions blurring and elements from each being found in the other. Verification of intervention fidelity not only ensures that internal validity of a study is maintained but also that external validity is enhanced.[108] This was achieved in AESOPS by each of the treatment sessions being recorded and also the fact that the PRS that was subsequently conducted did indeed identify significant differences between the 5- and 20-minute interventions, indicating that the two types of session were distinct. Therefore, in this study, having the same practice/research nurse deliver the minimal intervention and step 1 of the stepped care intervention is not considered to have affected the outcome.

In the early stages of the study, some problems had been encountered with participating practice nurses finding little time available to see study participants. As the recruitment methods changed, and an increase in potential participants identified was likely, the use of research/specialist practitioners was required (although the task of preparing and sending out the mailings did not involve the practice nurses). The possibility that these two groups (non-specialist and specialist) would be delivering the interventions differently was not proven by the PRS, where no significant differences in the rating scores between practice/research nurses with different levels of experience were found. We therefore do not consider this to have influenced the result in any way.

In the original study design we envisaged opportunistically screening patients as they attended the primary care centre and this being conducted by practice staff. In reality, difficulties in recruiting practices willing to engage in this process meant that the methods of recruitment had to be amended to include mail-out screening and the use of specialist study staff to intervene with the eligible population. This is an indication that opportunistic screening and the delivery of brief interventions embedded within primary care are not currently acceptable to primary care staff.

Comparison with previous research

Previous screening and intervention studies looking at alcohol use conducted in UK health-care settings[52,57] suggested that 80% of those screened positive tend to be eligible and 75% of those eligible tend to consent to randomisation. In this study we found that only 57% of eligible patients consented to randomisation. Although still to be explored, it did not go unnoticed that a number of patients, either by written comment or by telephone, expressed the feeling that the time of the researchers would be better spent tackling binge-drinking and the perceived alcohol problems in the younger ages groups often highlighted in the media.

In addition, the prevalence of hazardous alcohol consumption, inclusive of harmful consumption and possible dependence, in those aged ≥55 years was estimated at 15% in the general population[11] and greater, at 25%, in those attending primary care.[13] Screening results from this study found this to be only 7.5%.

The results of the clinical effectiveness aspects of the study appear to concur with recent research in the area. The population in question was an opportunistically identified population at the lower end of the alcohol use disorder spectrum. A recent systematic review of brief interventions in primary care[28] found no additional benefit of more intensive versus briefer interventions. Primary research in the UK found no additional benefit of extensive brief lifestyle counselling over and above brief advice and the provision of an information leaflet for a general population identified opportunistically using AUDIT in primary care;[106] in addition, a recent US study comparing minimal intervention with more intensive intervention for older alcohol users found that although alcohol use reduced in both groups there were no significant differences between the groups.[34] General population studies in primary care have established the benefits of brief interventions over and above no treatment controls[28] and similar results have been reported for older people in primary care.[35,36]

MEDLINE, EconLit, and NHS Economic Evaluation Database were searched for economic evaluations of alcohol treatments. Fewer than 30 full economic evaluations that compare both the costs and health consequences were found in literature. Only one trial (STEPWICE) was available that compared cost-effectiveness between stepped care and a 5-minute advice session.[51] The result of the cost-effectiveness analysis of the STEPWICE trial was very similar to AESOPS, but with a much smaller sample size ($n = 112$). Both studies found that stepped care was more likely to be cost-effective compared with minimal intervention using the NICE threshold range of £20,000–30,000 per QALY gained.

There are several difficulties when making direct comparisons between existing economic evaluations of alcohol treatments. Firstly, the definition of the interventions varies between studies. For example, 'brief intervention' was used as a common comparator in clinical trials[109–112] but studies define brief intervention differently in terms of contact length, content and style.[113] Secondly, the evaluation of health consequences differs among studies. For instance, the most widely used outcome measurements were drinks per drinking day, binge-drinking episodes or heavy drinking, and percentage of days abstinent. Although some economic evaluations used QALYs as a health outcome measure following NICE's guidance[71,114] none focuses on a similar population or interventions to the AESOPS study.

Strength and limitations of the study

Although we had originally estimated that we would recruit 500 participants from 15 GP practices in three sites over an 18-month period, it took twice this time and many more GP practices: 53 across eight sites. However, we did successfully recruit our target number of older hazardous alcohol users. Our finding of no evidence of a difference is not likely to be due to a lack of power.

As a result of the initial slow recruitment rate, a change in recruitment method was required, moving away from the original design of opportunistic screening in GP practice waiting rooms to the adoption of the more extensive method of mailing out forms to all patients aged ≥55 years on a participating GP practice register. This change, however, not only provided evidence of the limitations of using opportunistic screening at practice attendance as a recruitment method, but also allowed us to estimate a much more robust prevalence rate of hazardous alcohol consumption in this patient group, while also resulting in our recruitment target being met.

The lower than expected prevalence rate may be due to response bias, whereby those who are consuming alcohol at higher levels are less likely to respond to the AUDIT questionnaire and participate in the study. Yet participants were given an option to respond anonymously and those who did so had lower mean

AUDIT scores than those who provided contact details, which may add further weight to the idea that the prevalence figure identified in the study is indicative of the true population prevalence rate. In addition, the study population was generalisable to the population of older alcohol users who were willing to be screened and to engage in an intervention to address their alcohol use.

In addition, there was a reluctance on the part of the primary care nurses to undertake these interventions, and reluctance on the part of the GPs to support their practice nurses in doing this. These issues individually, and together, made it difficult to pursue the protocol as designed without having to adapt in some way. This does, however, have important implications regarding the question of whether or not these sorts of interventions can be implemented in the primary care setting and it does not seem to be the case that practice nurses are enthusiastic about their delivery.

One limitation of this study was the low take-up by those referred to step 2 of the stepped care intervention. The precise reasons for this are unknown but a number of factors could be involved. These include possible unwillingness of participants to accept that their alcohol consumption was having a detrimental impact on their health, particularly if they consumed alcohol at lower levels of severity; unwillingness to reduce consumption any more than agreed in the initial session; or unwillingness or unavailability to attend more than one session. There may also be an issue with the time lag between identification of the problem and the intervention taking place, resulting in attendance being less likely.

Our previous experience in conducting RCTs in the fields of substance use (UKCBTMM), alcohol-using general adult populations (UKATT, STEPWICE) and elderly populations (RESPECT) indicate that, with rigorous follow-up regimes, loss to follow-up at 12 months would usually be in of the order of 20%. Taking these factors into account we had erred on the side of caution and allowed an attrition rate of 30%. In fact, in AESOPS the overall follow-up rate at month 12 was 87.5%, with 86.8% followed up in the stepped care group and 88.2% in the minimal intervention group.

In the cost-effectiveness analysis we made very conservative assumptions to ensure that the costs of the stepped care intervention were not underestimated. We did not take into account the possibility that interventions may prevent and reduce alcohol-related disease and injury, which may result in considerable cost savings, especially if these costs and expected impacts on health status were modelled over a longer time period.[115] The absence of any criminal justice events within this study does suggest that the economic consequences of hazardous and harmful alcohol consumption could be different for older people, but this would need further investigation. It should also be noted that the training costs for practice nurses to deliver minimal intervention were not included in the control group. We assumed that they had already received training to deliver brief advice during their student nurse or early career training. If this part of the training cost was added into the control group, the minimal intervention would turn out to be even more costly compared with stepped care.

Generalisability of the results

The AESOPS recruited from eight sites and 53 GP practices across England and Scotland, including both urban and rural locations, in GP practices of varying sizes. With the population group within AESOPS, we are confident that these results are broadly generalisable to the population who would engage in screening and intervention for alcohol use problems in general practice.

Implications for health care

The evidence from this trial shows that there is no clinical advantage of opportunistic screening in addition to stepped care over opportunistic screening and minimal intervention in terms of the reduction in alcohol

consumption at 12 months post intervention in hazardous alcohol users aged ≥55 years who score ≥8 on the AUDIT, but there is some evidence that it may be cost-effective.

Implications for research

The experience of conducting this research in primary care settings, the implication that extended interventions are not acceptable to participants or practice staff in the management of hazardous alcohol use and have no additional benefit over screening and minimal interventions, the potential to target those with more entrenched harmful or possible dependent alcohol use who are not seeking treatment and the finding that stepped care interventions appear to produce economic benefits have the following implications for future research:

- What factors facilitate or hinder the conduct of research in primary care settings?
- What is the effectiveness and cost-effectiveness of community-based screening and self-directed ultra-brief interventions for hazardous alcohol users compared with screening alone?
- What is the effectiveness and cost-effectiveness of MET for non-treatment-seeking harmful and possibly dependent alcohol users delivered in primary care?
- What are the longer-term clinical and economic impacts of stepped care interventions?

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Collaborations and contributions of the authors

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Simon Coulton was the chief investigator, chaired the Trial Management Group, edited and approved the final draft of the report.

Judith Watson was the trial manager.

Veronica Dale and **Martin Bland** designed the clinical analysis.

Veronica Dale conducted the clinical analyses and oversaw the process ratings analyses.

Qi Wu conducted the economic analyses.

Helen Crosby conducted the process ratings and analyses.

Gillian Tober developed the training, supervised the practice/research nurses and therapists and oversaw the process ratings.

Jenny Lang contributed to and co-ordinated recruitment to the trial in Leeds.

Dorothy Newbury-Birch and **Ruth McGovern** contributed to the study design and co-ordination and managed the Tyneside and County Durham recruitment to the trial.

Steve Parrott oversaw the conduct of the economic analyses.

Martin Bland oversaw the conduct of the analysis.

Colin Drummond, **Christine Godfrey** and **Eileen Kaner** contributed to the study design, conduct of the trial and the Trial Management Group.

Independent Steering Committee Members

Professor Oliver James – chairperson of Independent Steering Committee from August 2007 to end.

Professor Graham Dunn – member of Independent Steering Committee from August 2007 to end.

Professor Helen Smith – member of Independent Steering Committee from June 2009 to end.

Mrs Valerie Lipman – consumer representative and member of Independent Steering Committee from August 2007 to March 2008.

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Appendix 1 Study protocol

REC Ref: Short Title: HTAPRO5

Document Name: Full protocol

Version: 5.0 Date: 17/09/09

Project title

The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care (06/304/142).

Planned investigation

Research objectives

- To evaluate the effectiveness of stepped care interventions for older hazardous alcohol users in primary care.
- To evaluate the cost-effectiveness of stepped care interventions for older hazardous alcohol users in primary care.
- To screen 4170 primary care attendees aged 55 years or more for hazardous alcohol use using the AUDIT questionnaire.
- To evaluate the acceptability and validity of opportunistically screening for hazardous alcohol use in older primary care attendees.
- To estimate the prevalence of alcohol use disorders in an older primary care population.
- To train 15 practice nurses in the delivery of behavioural change counselling.
- To conduct a pragmatic randomised controlled trial comparing stepped care interventions with a minimal intervention for older hazardous alcohol users in primary care.
- To randomise 500 hazardous alcohol users, with equal probability, to either a minimal intervention or stepped care.
- To conduct 6 and 12 month follow ups on at least 70% of those randomised to assess alcohol consumption, alcohol related problems, quality of life and service utilisation.
- To study the process of therapy as delivered by both practice nurses and trained therapists.

Existing research

There exists a wealth of evidence regarding the detrimental impact of hazardous alcohol consumption, consuming more than the weekly recommended number of standard alcohol units in any week (21 for males, 14 for females) or half of the recommended number of standard alcohol units in any one day (10 for males, 7 for females), on the physical and mental health of the population. It is estimated that hazardous alcohol consumption accounts for 150000 hospital admissions and between 15000 and 22000 deaths per annum in the United Kingdom (Academy of Medical Sciences 2004). In the older population, those aged 55 years or more, hazardous alcohol consumption is associated with a wide range of physical, psychological and social problems. There is evidence of an association between increased alcohol consumption and increased risk of coronary heart disease, hypertension, haemorrhagic and ischaemic stroke (Department of Health 1995), increased rates of alcohol-related liver disease and increased risk of a range of cancers (Prime Ministers Strategy Unit 2004). Alcohol consumption is identified as one of the three main risk factors for falls (Wright & Whiley 1994), a major cause of morbidity and mortality in this population. The Royal College of Physicians estimates that 60% of older people admitted to hospital because of repeated falls, confusion, chest infections and heart failure have undiagnosed alcohol problems

(Royal College of Physicians 2002). Increased alcohol consumption in older age can also contribute to the onset of dementia and other age related cognitive deficits (Thomas & Rockwood 2001), Parkinson's disease (Feuerlein *et al* 1986) and a range of psychological problems including depression and anxiety. Alcohol use is implicated in one third of all suicides in the older population (Crome *et al* 1991). It is estimated that 80% of those aged 65 and over regularly take prescribed medication and polypharmacy is common with a third taking at least four prescribed medications per day (Falaschetti *et al* 2002). Alcohol is a major contraindication for many of the drugs prescribed for older people and alcohol and medication interactions are a common phenomenon (Dunne 1994). Increased alcohol consumption in older age is also associated with a range of social problems including self-neglect, poor nutrition, social isolation and hypothermia (Woodhouse 1987).

The prevalence of hazardous alcohol consumption, this is inclusive of harmful consumption, in those aged 55 years and over is generally lower than the general population. The most recent estimate derived from the Alcohol Needs Assessment research Project (Drummond *et al* 2005) indicates a prevalence of between 15% and 25% and concurs with other estimates derived from the General Household Survey. There is also evidence that the prevalence rate in primary care attendees is higher than the general population (Coulton *et al* 2006). There is evidence that these prevalence rates are under-estimates of the true prevalence rate. Older people are less likely to seek treatment for alcohol use disorders (Callahan *et al* 1995) and alcohol related presentations are often atypical or masked by comorbid physical or psychiatric illness that makes alcohol related diagnosis more difficult (Reid *et al* 1997). In 2000 16% of the UK population was over the age of 65 and this is expected to increase to 21% by 2026 (Falaschetti 2000). As the average age of the population increases the absolute number of older people consuming alcohol at hazardous levels will increase even if the prevalence rate remains stable. Recent research using data derived from the General Practice Research Database indicates that only 5% of people aged 55 years or older with an alcohol use disorder are identified in primary care settings (Cheeta *et al* 2006). Opportunistic screening is a proactive screening technique that has been used with some success in a variety of health-care areas including type II diabetes (Johnson *et al* 2005) and *Chlamydia* (Tobin *et al* 2001) and is particularly useful in identifying conditions in populations who would not usually seek treatment.

A number of paper based screening methods have been developed to identify hazardous alcohol consumption, these include instruments such as the Michigan Alcohol Screening Test (Selzer 1971), Paddington Alcohol Test (Patton *et al* 2004), Fast Alcohol Screening Test (Hodgson *et al* 2002) and the Alcohol Use Disorders Identification Test (Saunders *et al* 1993). All have acceptable levels of sensitivity and specificity. The Alcohol Use Disorders Identification Test (AUDIT) was specifically developed for use in a primary care population and has 92% sensitivity and 92% specificity for identifying hazardous alcohol use in a UK primary care setting (Coulton *et al* 2006); more specifically in older populations AUDIT has been demonstrated to have higher sensitivity, 75%, and higher specificity, 97.2% than other screening tests when used in older populations (Philpot *et al* 2003). AUDIT is a short 10-item questionnaire that addresses frequency of alcohol consumption, alcohol related problems and alcohol dependence symptoms. Because of the evidence of under detection and misdiagnosis of hazardous alcohol use in older populations (Callahan 1995, Reid 1997) the proactive application of a short universal screening method is likely to be more appropriate. There is evidence that patients are more compliant with screening protocols for alcohol use in health-care settings and that the environment provides an opportunity for a 'teachable moment' increasing the patient's likelihood to engage in an intervention (Crawford *et al* 2004).

There is a substantial evidence base for the efficacy of brief motivational interventions, aimed at reducing alcohol consumption in primary care. Studies have demonstrated the effectiveness of brief interventions in reducing alcohol consumption in primary care populations in the United Kingdom (Wallace *et al* 1998, Anderson *et al* 1992). Further, there are five systematic reviews focusing specifically upon the effectiveness of brief interventions in primary care populations (Bertholet *et al* 2005, Ballesteros *et al* 2004, Whitlock *et al* 2004, Poikolainen 1999, Kahan *et al* 1995) all conclude that brief interventions in primary care populations are effective in reducing alcohol consumption. But many of the studies included in these reviews exclude older patients. There are no systematic reviews or subgroup analyses specifically focussing

on older patient groups. There is some evidence from primary research of the efficacy of brief interventions specifically for older hazardous alcohol consumers. In a trial of brief interventions for older alcohol users in primary care in the United States, Fleming *et al* (1999) reported a 34% reduction in alcohol consumption and 64% reduction in those drinking at hazardous levels at 12 months, significantly better than those who received no intervention. Blow and Barry (2000) also report significantly greater reduction in alcohol use in older populations treated with brief interventions in primary care than controls. There is also evidence from subgroup analyses of existing studies that older patients are at least as likely to benefit from brief interventions than younger patients (Curtis 1989) and older adults are more likely to adhere and comply with brief intervention treatment regimes (Oslin *et al* 2002). While a number of brief intervention studies have addressed the issue of cost-effectiveness, few have addressed the issue from a pragmatic NHS perspective. The evidence of brief interventions has been criticised for failing to address a wider range of alcohol use disorders including harmful alcohol consumption (Rollnick 1999) and for failing to address more entrenched drinking behaviours.

Motivational enhancement therapy is a relatively short, usually three 40 min sessions delivered by a trained therapist, but more intensive intervention than a brief motivational intervention. Primary research has shown it to be as effective as other more intensive interventions such as cognitive behavioural therapy, twelve steps facilitation therapy and social behavioural network therapy (Project MATCH 1997; UKATT 2005).

Screening for alcohol use disorders identifies a range of needs that are likely to require a range of types and intensities of intervention. One of the primary reasons why many general practitioners are reluctant to implement screening into routine care is because they lack the skills of how to deal with the more severe cases identified (Deehan 1998). Older alcohol consumers are often typified as either 'early-onset' drinkers, whose consumption pattern is a continuation of lifetime hazardous consumption or 'late-onset' drinkers whose alcohol consumption is a reaction to life events occurring in later life. 'Late-onset' drinkers' are more likely to benefit from brief interventions than 'early-onset' drinkers who often require a more intensive intervention approach (Menninger 2002). Physiological changes that occur as part of the ageing process mean that older people are more vulnerable to alcohol and experience alcohol related problems at lower consumption levels than younger people. Stepped care interventions offer a potentially resource efficient means of meeting the needs of this population. Stepped care interventions provide a means of delivering more intensive interventions only to those who fail to respond to less intensive interventions and are more in keeping with rational clinical decision making than the blanket use of any one intervention strategy.

Hypotheses

Primary hypothesis

Stepped care interventions for older hazardous alcohol users reduce alcohol consumption compared with a minimal intervention.

Secondary hypotheses

1. Stepped care is more cost-effective than minimal intervention. 2. Stepped care will reduce alcohol related problems in comparison to minimal intervention. 3. Stepped care will increase health-related quality of life compared with minimal intervention. 4. Opportunistic screening will identify more hazardous alcohol users than usual practice.

Reference methods

The proposed study is a pragmatic randomised controlled trial evaluating the effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users

in primary care. Primary care attendees aged 55 years or over who fulfil the eligibility criteria and provide informed consent will be individually randomised with equal probability to receive either stepped care or a minimal intervention. Baseline assessments will be conducted by the practice nurse and follow up assessments will be conducted by post, at 6 and 12 months after randomisation. Allocation to treatment group will be conducted by a remote randomisation service using random permuted blocks stratified by cluster. A full CONSORT statement indicating trial progress is attached in section 9 of this document.

Planned interventions

Screening

All primary care attendees, aged 55 years or older, will be provided with an information sheet, a copy of the AUDIT questionnaire and a return envelope addressed to the practice nurse on arrival at the practice by the practice receptionist. Returned questionnaires, enclosed in a sealed envelope, will be scored by the practice nurse by summing the responses to all 10 questions on the AUDIT questionnaire. Patients who score 8 or more on the AUDIT questionnaire will be invited to a research assessment with the practice nurse within 7 days. At the research assessment the research nurse will explain the study, provide an opportunity to ask any questions and ask the potential participant for informed consent. The research assessment will include a check on eligibility including an assessment of alcohol consumption using the extended AUDIT-C. If hazardous alcohol use is identified the patient will complete the rest of the baseline assessment and will be randomised using a remote randomisation service. Participants will be randomised with equal probability to either minimal intervention or stepped care.

Minimal Intervention

The minimal intervention consists of a short, 5 min, discussion with the practice nurse about the health consequences of continued hazardous alcohol consumption. The participant will also receive a brief self-help booklet 'Safer drinking – a self help guide' outlining the consequences of excessive alcohol consumption and providing information on sources of help for drinking problems locally and nationally.

Stepped Care Intervention

The stepped care intervention consists of three consecutive steps in which progression between steps are dependent upon the outcome of each previous step.

Step 1 will consist of a 20 min session of behavioural change counselling delivered by the practice nurse. This intervention, based upon an existing evidence base of brief interventions, utilises the technique of motivational interviewing (Rollnick *et al* 1999) and aims to address the individual's motivation to change their drinking behaviour. The counselling is manual guided and practice nurses will be trained in the delivery. Four weeks after randomisation the participant will be contacted by the practice nurse and a short telephone assessment will be made about the participant's alcohol consumption in the past 4 weeks using the extended AUDIT-C. If the participant is still consuming alcohol at hazardous levels a referral will be made to step 2 of the intervention.

Step 2 involves an intervention by a trained alcohol therapist in the primary care environment. The intervention, motivational enhancement therapy, is provided through 3, 40 min sessions on a weekly basis. The intervention is manual guided and addresses six basic principles of increasing motivation for change. Feedback about individual alcohol consumption, emphasis on the individual as being the agent responsible to change, advice on how to accomplish change, provision of alternative vehicles for change, maintenance of an empathetic therapeutic style and emphasis on enhancing the individuals self-efficacy. Four weeks after the last MET session the participant will be contacted by the practice nurse and a short telephone assessment will be made about the participant's alcohol consumption in the past 4 weeks using the extended AUDIT-C. If the participant is still consuming alcohol at hazardous levels a referral will be made to step 3 of the intervention.

Step 3 will consist of a referral to the local specialist alcohol services to receive specialist intervention, including as necessary detoxification, inpatient care, outpatient counselling, group therapy, relapse prevention treatment or medication. There is no limit on the intensity or duration of the step 3 intervention.

Particular emphasis is being paid to ensure that the interventions are pragmatic in nature. The interventions will be delivered by staff routinely employed in primary care, in the case of practice nurses, and specialist alcohol services in the case of motivational enhancement therapists. All of the interventions will be manual guided to specify the purpose and principles of each intervention and the structure and content of each particular treatment session.

Training of practice nurses to deliver behavioural change intervention

It is proposed to train 15 practice nurses in the techniques and delivery of a brief motivational behavioural change intervention. Each practice nurse will spend 3 non-consecutive days at the training centre at Leeds Addiction Unit. Training will be provided by expert trainers in motivational interviewing. The training will take the form of simulated consultation/seminar/simulated consultation. Each nurse will have the opportunity to engage in a simulated consultation which is recorded. As a group the nurses will discuss the simulated consultations to examine and review application of motivational interviewing techniques. The process of simulation/seminar/simulation is repeated on a number occasions with actors who pose as a variety of potential patients. Prior to embarking on the study assessment of competency will be made using a recorded session rated by an independent expert. Practice nurses will be provided with ongoing supervision throughout the study provided by an expert trainer from Leeds Addiction Unit.

Training of therapists to deliver Motivational Enhancement therapy

It is proposed to train three alcohol therapists from local alcohol agencies. Therapists will have at least two years post-qualifying experience. Initial training will involve a three day intensive group training course provide by motivational enhancement trainers at Leeds Addiction Unit. Particular attention will be given to understanding the evidence base, understanding the theoretical basis of treatment, demonstration of practice and role-play opportunities. Therapists will be supervised in the delivery of a number of therapy sessions. Therapists will be expected to complete two taped sessions both reviewed in conjunction with a trained supervisor. Supervision will provide the main opportunity for practising skills and delivering the structure and content of treatment. Assessment of competence will depend upon the therapist's ability to deliver motivational enhancement therapy according to the designation of treatment prescribed in the treatment manual.

Planned inclusion/exclusion criteria

Inclusion and exclusion criteria have been chosen to maintain a balance between ensuring the sample is representative of the primary care population whilst ensuring that the trial population are able to engage both with the interventions and follow up.

Inclusion criteria

1. Age 55 years or over at time of screening. 2. Diagnosis of an alcohol use disorder using AUDIT criteria. 3. Residing in a stable place of residence. 4. Living within commutable distance of the primary care practice. 5. Providing informed consent for randomisation, treatment and follow up.

Exclusion criteria

1. Treatment for substance use in the past 90 days, excluding nicotine. 2. Already seeking help for an alcohol use disorder. 3. Received treatment for primary drug dependence, excluding nicotine in the past 90 days. 4. Outstanding legal issues likely to lead to imprisonment. 5. Severe mental or physical illness likely to preclude active participation in treatment or follow up.

Ethical arrangements

The study will only start once full MREC approval has been granted. There are no anticipated risks in relation to either treatment. There is no documented evidence of adverse events arising due to either the minimal intervention or the stepped care intervention.

Screening

In accordance with guidance on best practice, all attendees at primary care who are aged 55 years or older, will be informed by the practice receptionist that a study is taking place. They will be provided with an information sheet and a copy of the AUDIT questionnaire. The information sheet will provide details of the study taking place and make clear that completion of the screening questionnaire is not compulsory. Participants will have the option to not complete the questionnaire, to complete the questionnaire anonymously or complete the questionnaire with full contact details. Completed questionnaires will be returned to the receptionist in sealed envelopes.

Invitation to attend practice nurse assessment

All AUDIT positives who complete their contact details will be contacted by the practice nurse. Contained within the invitation will be a detailed information sheet providing information on the purpose of the study, the eligibility criteria, the proposed interventions and follow up assessments. Potential participants will be informed that participation is not compulsory.

Baseline assessments

At the baseline assessment the practice nurse will discuss the study and the process of assessment and provide the potential participant an opportunity to ask any questions about participation in the study. A standard baseline assessment will be conducted and all information recorded on forms that contain only an identification number. Eligible participants will be invited to provide written informed consent. For those who do consent, randomisation will be conducted using the secure remote randomisation service at York Trials Unit. At this point the patients contact details and identification number will be associated and held on a secure server located at the University of York. This master register will be held separate from the outcome data and accessible only to those who need to know for purposes of conducting the study. Randomisation will be conducted using block randomisation stratified by cluster with an equal probability of receiving stepped care or minimal intervention.

Follow up assessments

Follow up assessments will be conducted by post from the trials unit at the University of York.

Retention of trial data

All trial data will be identified using a unique trial identification number. No personally identifiable information will be held beyond the final 12 month follow up. Analytical datasets will not contain any patient identifiable information. Anonymised data will be retained for a period of 42 months.

Proposed sample size

There are no previous studies of stepped care interventions, a brief opportunistic intervention followed by successively more intensive interventions for those who fail to respond to treatment, for older alcohol using adults. The closest UK pragmatic randomised controlled trials include Wallace *et al* 1998 and STEPWICE 2003, both of these reported effect size differences between stepped care and minimal intervention of 0.36 and 0.27 respectively. Similar effect size differences are reported in studies from the United States (Fleming 1999; Moyer *et al* 2003; Gordon *et al* 2003). There is evidence that older populations respond as well, or even better, to brief psychosocial interventions for alcohol use than general populations (Oslin *et al* 2002; Lemke *et al* 2003). Assuming a conservative effect size difference between

stepped care and minimal intervention of the order of 0.3 would require a sample size of 175 participants in each of the two randomised groups, using power at 80% and a 5% significance level.

Our previous experience in conducting randomised controlled trials in the fields of substance use (UKCBTMM), alcohol using populations (UKATT, STEPWICE) and elderly populations (RESPECT) indicate that with assiduous follow up regimes loss to follow up at 12 months is of the order of 20%. There also exists evidence that older populations are more compliant with treatment regimes and follow up protocols than younger populations (Atkinson 1995; Oslin *et al* 2002). Taking these factors into account we have erred on the side of caution and allowed a loss to follow up of 30%, requiring 500 participants to be randomised, 250 in each group. Previous alcohol use screening and intervention studies conducted in UK health-care settings (Heather *et al* 1996; STEPWICE 2003) suggest that 80% of those screened positive tend to be eligible and 75% of those eligible tend to consent to randomisation. This means the study requires 834 screen positives of whom we predict 500 will be eligible and consent to randomisation.

The prevalence of hazardous alcohol consumption, inclusive of harmful consumption, in those aged 55 years or older is estimated at 15% in the general population (Drummond *et al* 2005) and greater, at 25%, in those attending primary care (Coulton *et al* 2006). If we conservatively estimate the prevalence at 20% we would need to screen 4170 primary care attendees in an 18 month period. Assuming 15 practices, in three geographic regions consent to take part in the study, each practice would be expected to screen 278 primary care attendees over 18 months, a total of 18 per practice per month.

Statistical analysis

Opportunistic screening

We will use a comprehensive cohort approach to the analysis of the acceptability and validity of opportunistic screening. Practice receptionists will keep records of the age and sex of all attendees offered an AUDIT questionnaire. Participants will have a choice of not completing the questionnaire, completing the questionnaire with basic age/sex demographics or completing the questionnaire with full contact details.

Effectiveness analysis

The primary analysis will be intention to treat comparing minimal intervention with stepped care on the primary outcome measure, average drinks per day, at 12 months post-randomisation. Participants will be analysed as part of the group allocated irrespective of treatment received. The primary outcome will be analysed using analysis of covariance controlling for baseline values. Multi-level modelling analysis will be undertaken to account for any variation due to centre, cluster and therapist. Primary analysis will be conducted after all 12 month follow ups have been completed. Analysis of secondary outcomes will be conducted using analysis of covariance and adjusted using multi-level modelling. Regression analysis will be undertaken to explore any baseline predictors of outcome, any baseline predictors of referral to step 2 for the stepped care group and any potential baseline x treatment interaction effects.

Economic analysis

The incremental cost-effectiveness of stepped care compared to the minimal intervention will be assessed both from a health and personal social services perspective following NICE guidance (NICE, 2004) and a wider public sector resource perspective (NICE, 2006). While the opportunistic screening costs will be common to both intervention arms, its cost will be estimated from the trial data as this would form part of a wider implementation cost of the stepped care programme. The costs of the minimal intervention and the first two tiers of the stepped care programme will be based on information gathered on patient

contact with the primary care and specialist services during the trial. The units of service used will be based on the local costs of specialist services and include an allowance for the training and supervision costs, using methods developed for the UKATT trial (UKATT Research team, 2005b). Any use of more specialist services will be collected, including the type of intervention, and costs will be applied from previous research trials and a current Department of Health funded research project based on a range of specialist providers and intervention types (Raistrick *et al*, 2004). The use of alcohol services outside the trial protocol, along with all other public sector services, including health, social welfare and contact with criminal justice agencies will be assessed from questionnaires administered at baseline, 6 and 12 months. This service use questionnaire developed over a number of alcohol and illicit drug trials will be adapted for the specific needs of this project, for example, by additional questions on falls. Units recorded will be combined with national sources of unit costs (Netten *et al*, 2005; UKATT Research Team, 2005b). The EQ-5D will be used with population values and the QALY change calculated using the area under the curve method. Bootstrapping methods will be used to test to explore the sensitivity of the calculated incremental cost-effectiveness ratios and cost-acceptability curves presented.

Proposed outcome measures

Screening

Screening for alcohol use disorders will be conducted using the Alcohol Use Disorders Identification Test (AUDIT) (Saunders *et al* 1993). The instrument addresses alcohol consumption frequency and quantity, alcohol related problems and elements of alcohol dependence. The 10-item patient completed questionnaire takes approximately 3 min to complete and 2 min to score. A score of 8 or more indicates hazardous alcohol use. AUDIT exhibits high levels of sensitivity (92%) and specificity (92%) in UK primary care populations (Coulton *et al* 2006) and high levels of sensitivity (75%) and specificity (93%) in older populations (Philpot *et al* 2003).

Eligibility assessment

To establish eligibility a potential participant should score positive for the AUDIT questionnaire and be classified as a hazardous alcohol user using extended AUDIT-C criteria. Hazardous alcohol consumption is established if the participant has consumed more than 21 standard units for males, or 14 for females, in any one week or 10 standard units for males or 7 standard units for females in any 1 day in the previous 90 days. The extended AUDIT-C is used to derive the primary outcome measure for the study.

Primary outcome measure

The primary outcome measure for the study is average drinks per day. This is ascertained using the time extended AUDIT-C. Three other variables can be derived from the data; percent days abstinent, drinks per drinking day and total alcohol consumed. The extended AUDIT-C is self-completed and takes approximately 2 min to complete. The outcome is measured at baseline, 6 months post randomisation and 12 months post-randomisation.

Secondary outcome measures

1. Alcohol related problems measured at baseline, 6 months and 12 months post randomisation. Alcohol related problems are assessed using the 17-item participant completed Drinking Problems Index (DPI). The DPI has been specifically designed and validated for use in older populations (Finney *et al* 1991). 2. Quality of life is measured at baseline, 6 months and 12 months post randomisation. Quality of life is measured using the SF-12 (ware *et al* 1996). SF-12 is a 12-item self completed questionnaire that established validity and reliability for measuring physical health and mental health components of quality of life. 3. Health utility will be measured at baseline, 6 months and 12 months using the EQ-5D (Euroqol 1990). EQ-5D is a 5-item participant completed questionnaire with established reliability and validity in this population.

Economic outcome measures

Opportunistic screening costs will be estimated from the actual costs of screening using the actual costs of screening associated with the study. Costs of delivering the minimal intervention and the first two tiers of stepped care will be based upon actual patient contact time from time sheets maintained by practice nurses and therapists. The units of services used will be based upon local costs of services and include allowances for managerial and premises overheads and the costs associated with training and supervision using methods utilised in similar intervention studies (UKATT 2005). The costs of any specialist referral will be costed using information on the actual costs associated with specialist service provision based upon Department of Health costs of specialist interventions (Raistrick *et al* 2004).

Participant use of health services, other alcohol services outside the study, public services and criminal justice services will be assessed using a service use questionnaire at baseline, 6 months and 12 months post randomisation. The service use questionnaire has been developed over a number of alcohol intervention studies (STEPWICE 2003; UKATT 2005) will be adapted to capture costs specifically associated with this population.

Quality assurance of treatment delivery

Participants will be asked to provide consent to have all treatment sessions recorded. A 20% sample of each type of treatment session, minimal intervention, behavioural change intervention, motivational enhancement therapy will be randomly selected stratified by treatment type. Tapes will be rated by an independent rater and assessed for quality of delivery and compliance with treatment protocols.

Research governance

The proposed study will be conducted in accordance with the MRC Guidelines on Good Clinical Practice in Clinical Trials. Prior to undertaking the study, full ethical approval will be sought from the Multicentre Research Ethics Committee. All data will be held in a secure environment identified by a unique participant identification number. Master registers containing patient identifiable information and participant identification numbers will be stored in a secure area separate from the majority of data. Data management will be conducted by York Trials Unit, a unit regularly inspected for the purpose of governance procedures.

The study organisation is presented in appendix 2. The study will be managed on a day to day basis by a trial manager in conjunction with the project manager. Regular meetings of the Trial Management Group will take place and twice yearly meetings of the Trial Steering Committee made up of independent members with clinical, methodological and statistical expertise. We will also invite a representative of a consumer group such as Age Concern.

Project timetable and milestones

Timetable

Months 1 – 6: Recruit participating practices, ethics application, develop clinical record forms, practice nurse training, therapist training, recruit research assessors.

Months 7 – 24: Screen 4170 participants in 15 primary care centres. Recruit 500 participants.

Months 12 – 30: Conduct 6 month follow ups

Months 18 – 36: Conduct 12 month follow ups

Months 36 – 42: Collate data, statistical and economic analysis and writing of report.

Changes to protocol

In the North East region the project will be carried out in a different way. Changes to the protocol above refer to the sections looking at planned interventions (pages 4 and 5), training of practice nurses to deliver behavioural change intervention (page five), Screening (page 6), invitation to attend practice nurse assessment (page 7) and baseline assessments (page 7). These sections are shown below with changes made. Any practices in currently participating (as of 17/09/09) centres which have only recently come on board will be offered the opportunity to convert to this method or to remain using the opportunistic screening. New practices brought on board in future will screen using the mail out system.

Planned interventions

Screening

All primary care attendees, aged 55 years or older, will be posted a letter signed by the trial manager and the lead GP of the relevant practice as well as an information leaflet, a copy of the AUDIT questionnaire and a return envelope addressed to the trial manager. Returned questionnaires, enclosed in a sealed envelope, will be scored by staff in York by summing the responses to all 10 questions on the AUDIT questionnaire. Patients who score 8 or more on the AUDIT questionnaire will be invited to a research assessment with the Alcohol Health Worker within 7 days. At the research assessment the Alcohol Health Worker will explain the study, provide an opportunity to ask any questions and ask the potential participant for informed consent. The research assessment will include a check on eligibility including an assessment of alcohol consumption using the extended AUDIT-C. If hazardous alcohol use is identified the patient will complete the rest of the baseline assessment and will be randomised using a remote randomisation service. Participants will be randomised with equal probability to either minimal intervention or stepped care.

Minimal Intervention

The minimal intervention consists of a short, 5 min, discussion with the Alcohol Health Worker about the health consequences of continued hazardous alcohol consumption. The participant will also receive a brief self-help booklet 'Safer drinking – a self help guide' outlining the consequences of excessive alcohol consumption and providing information on sources of help for drinking problems locally and nationally.

Stepped Care Intervention

The stepped care intervention consists of three consecutive steps in which progression between steps are dependent upon the outcome of each previous step.

Step 1 will consist of a 20 min session of behavioural change counselling delivered by the Alcohol Health Worker. This intervention, based upon an existing evidence base of brief interventions, utilises the technique of motivational interviewing (Rollnick *et al* 1999) and aims to address the individual's motivation to change their drinking behaviour. The counselling is manual guided and practice nurses will be trained in the delivery. Four weeks after randomisation the participant will be contacted by the Alcohol Health Worker and a short telephone assessment will be made about the participant's alcohol consumption in the past 4 weeks using the extended AUDIT-C. If the participant is still consuming alcohol at hazardous levels a referral will be made to step 2 of the intervention.

Training of practice nurses to deliver behavioural change intervention

It is proposed to train two Alcohol health Workers in the techniques and delivery of a brief motivational behavioural change intervention. Each Alcohol Health Worker will spend 3 non-consecutive days at the training centre at Leeds Addiction Unit. Training will be provided by expert trainers in motivational interviewing. The training will take the form of simulated consultation/seminar/simulated consultation. Each Alcohol Health Worker will have the opportunity to engage in a simulated consultation which is recorded. Together the Alcohol Health Workers will discuss the simulated consultations to examine and review application of motivational interviewing techniques. The process of simulation/seminar/simulation

is repeated on a number occasions with actors who pose as a variety of potential patients. Prior to embarking on the study assessment of competency will be made using a recorded session rated by an independent expert. Alcohol Health Workers will be provided with ongoing supervision throughout the study provided by an expert trainer from Leeds Addiction Unit.

Screening

In accordance with guidance on best practice, all attendees at primary care who are aged 55 years or older, will be sent a letter explaining the study. They will be provided with an information leaflet and a copy of the AUDIT questionnaire. The information leaflet will provide details of the study taking place and make clear that completion of the screening questionnaire is not compulsory. Participants will have the option to not complete the questionnaire, to complete the questionnaire anonymously or complete the questionnaire with full contact details. Completed questionnaires will be returned to York in sealed envelopes.

Invitation to attend practice nurse assessment

All AUDIT positives who complete their contact details will be contacted by the Alcohol Health Worker. Contained within the invitation will be a detailed information leaflet providing information on the purpose of the study, the eligibility criteria, the proposed interventions and follow up assessments. Potential participants will be informed that participation is not compulsory.

Baseline assessments

At the baseline assessment the Alcohol Health Worker will discuss the study and the process of assessment and provide the potential participant an opportunity to ask any questions about participation in the study. A standard baseline assessment will be conducted and all information recorded on forms that contain only an identification number. Eligible participants will be invited to provide written informed consent. For those who do consent, randomisation will be conducted using the secure remote randomisation service at York Trials Unit. At this point the patients contact details and identification number will be associated and held on a secure server located at the University of York. This master register will be held separate from the outcome data and accessible only to those who need to know for purposes of conducting the study. Randomisation will be conducted using block randomisation stratified by cluster with an equal probability of receiving stepped care or minimal intervention.

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Appendix 2 Regulatory approvals

The MREC approval was obtained for the study from the North West Research Ethics Committee on 10 April 2007. LRECs were also approached in each recruitment area prior to recruitment, as were the relevant Research and Development departments. Approval was given at the meetings detailed in the table below.

Site	PCT/trust	LREC	Approved	Research and development approval
North Yorkshire	North Yorkshire & York PCT	York REC	18 May 2007	16 May 2007
Hull & East Riding	Hull PCT and East Riding PCT	Hull & East Riding REC	18 May 2007	18 July 2007
Norfolk	Norfolk PCT and Great Yarmouth and Waveney PCT	Norfolk REC	8 June 2007	4 July 2007
Norfolk	Norfolk and Waveney Mental Health Partnership NHS Trust	Norfolk REC	12 July 2007	4 July 2007
Hull & East Riding	Humber Mental Health Teaching NHS Trust	Hull & East Riding REC	28 September 2007	5 November 2007
Leeds	Leeds PCT	Leeds (East) REC	28 November 2007	12 June 2008
Leeds	Leeds Mental Health Teaching NHS Trust	Leeds (East) REC	28 November 2007	12 June 2008
Fife	NHS Fife	Process changed		12 June 2009
Kent	Eastern and Coastal Kent PCT, West Kent PCT	Process changed		2 August 2009
Kent	Kent and Medway NHS and SC Partnership Trust	Process changed		3 August 2009
Tyneside	NHS South of Tyne and Wear	Process changed		26 August 2009
County Durham	Country Durham & Tees Valley PCTs	Process changed		11 June 2010

Approval was gained at one additional site, but the study did not commence.

Appendix 3 Details of study sites and practices

Centre	Practice ID number	Practice list size (approximate)	Start date in study	Used in-practice packs? (yes/no)	Used mail-out? (yes/no)	If mail-out used, number sent
Leeds[a]	20	9883	September 2008	Yes	No	NA
	26	11,598	June 2009	Yes	No	NA
	27	4459	June 2009	Yes	Yes	1170
	28	9173	June 2009	Yes	Yes	2100
	35	4353	August 2009	Yes	No	NA
	36	6552	August 2009	Yes	Yes	2466
	38	10,263	August 2009	Yes	Yes	1610
	52	5009	May 2010	No	Yes	1050
	53	8238	May 2010	No	Yes	2139
	55	9166	June 2010	No	Yes	2945
	59	6778	July 2010	No	Yes	1700
	62	6826	September 2010	No	Yes	2227
	63	6967	September 2010	No	Yes	1432
	64	11,228	September 2010	No	Yes	2401
	65	12,101	September 2010	No	Yes	2860
North Yorkshire	15	13,675	July 2008	Yes	No	NA
	16	11,486	July 2008	Yes	No	NA
	17	5836	July 2008	Yes	Yes	1831
	18	16,911	July 2008	Yes	No	NA
	21	14,387	September 2008	Yes	No	NA
	23	16,315	December 2008	Yes	No	NA
Hull & East Riding[a]	19	12,455	July 2008	Yes	No	NA
	22	7300	September 2008	Yes	No	NA
	25	3300	January 2009	Yes	No	NA
	29	12,096	July 2009	Yes	No	NA
Norfolk	10	3483	January 2008	Yes	No	NA
	12	13,365	January 2008	Yes	No	NA
	13	2790	January 2008	Yes	No	NA
	14	17,827	January 2008	Yes	No	NA
	33	16,409	June 2009	Yes	No	NA
	39		September 2009	Yes	No	NA
	37	9795	August 2009	Yes	No	NA
	41	7104	September 2009	Yes	No	NA

APPENDIX 3

Centre	Practice ID number	Practice list size (approximate)	Start date in study	Used in-practice packs? (yes/no)	Used mail-out? (yes/no)	If mail-out used, number sent
Kent	30	9611	November 2009	Yes	No	NA
Fife	32	7249	June 2009	Yes	No	NA
	34	4656	June 2009	Yes	No	NA
	43	6220	September 2009	Yes	No	NA
	44	4762	December 2009	Yes	No	NA
	57	3799	June 2010	No	Yes	1047
Tyneside	40	4500	October 2009	Yes	Yes	1000
	45	9300	December 2009	No	Yes	2000
	46	10,500	December 2009	No	Yes	3500
	47	4900	December 2009	No	Yes	5000
	48	10,009	January 2010	No	Yes	3300
	49	11,500	February 2010	No	Yes	2600
	50	2393	March 2010	No	Yes	700
	51	3300	March 2010	No	Yes	1800
	54	4171	May 2010	No	Yes	1110
	56	12,167	June 2010	No	Yes	3377
County Durham	58	15,267	July 2010	No	Yes	4800
	60	10,445	August 2010	No	Yes	2665
	66	3122	September 2010	No	Yes	955
	67	2458	September 2010	No	Yes	678
Total	53	447,457				60,463

NA, not applicable.
a One additional practice in both of the Hull and Leeds sites was set up, but no packs were ever sent out.

Appendix 4 Patient information sheet

REC Ref:
Short Title: **PIS v1.2**
Document Name: Patient information Sheet
Version: **1.2**
Date: **25/09/2007**

[Insert Header – University of York & Practice]

Randomised Evaluation of a Stepped Care Treatment Approach for Older Alcohol Users in Primary Care.

Patient Information Sheet

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what taking part in the research will involve. Please find the time to read the following information and discuss it with family, relatives, friends or your GP if you wish.

It is entirely up to you if you take part in the research study. If you do not wish to take part your usual care will not be affected in any way. If you do decide to take part you are free to stop taking part in the study at any time, you do not need to provide a reason.

The research is being conducted by the University of York, in conjunction with your local GP practice. The research is funded by the Department of Health and the study has been checked by [insert ethics committee].

Please read the following information carefully. If you have any questions about this study you can ask the practice nurse, [insert practice nurse name & telephone], or you can contact the study manager, [insert trial manager name and telephone]. The study is taking place in [No of practices] across England. We hope that 500 patients who are eligible will consent to take part in the study.

All patients attending [insert practice details] between [start date] and [end date] are being asked to complete a questionnaire about how much they drink alcohol. You completed this questionnaire and the results indicate that you may be drinking more alcohol than is good for your health. [Practice nurse name] telephoned you and made an appointment for you to discuss the study on [insert appt date time].

At the appointment [practice nurse name] will discuss the study with you. If you are happy to take part in the study you will be asked to sign a consent form, a copy of which is enclosed. [Practice Nurse Name] will ask you some questions about how much and when you drink alcohol, you will then be asked to fill in a short questionnaire about your general health and how often you use healthcare resources. Once this is completed the practice nurse will use a computer to decide what treatment you will receive. The practice nurse has no influence over the treatment you receive. All treatment provided will be tape recorded for quality assurance purposes. If you would prefer not to have your treatment session recorded you can indicate this on the consent form. The two treatment approaches are detailed below.

1. Treatment 1: You will receive a short 5 minute discussion about your drinking with the practice nurse and some written information about alcohol and your health.

2. Treatment 2: You will receive a 20 minute discussion with the practice nurse about your drinking and explore ways in which you could reduce the amount you drink. About 4 weeks later the practice nurse will call and discuss how much alcohol you have drunk in the 4 week period. If at this time the practice nurse feels you are still drinking too much alcohol for your health they will invite you to see a specialist at the general practice for three 40-minute appointments. The specialist is trained in a technique called Motivational Enhancement Therapy. This approach is known to be effective in helping many people reduce the amount of alcohol they drink. Four weeks after the last of these appointments the practice nurse will again contact you to discuss how much alcohol you are drinking. If at this time they feel you are still drinking alcohol at levels that are not good for your health they will ask the general practitioner to make a referral to the local specialist alcohol services.

Irrespective of what treatment you receive, we will send you two questionnaires by post. One will be sent 6 months and the other 12 months after the computer decided which treatment you would be receiving. These questionnaires will be similar to the one you completed just before your treatment was decided.

All information collected in this study is strictly confidential. We will inform your general practitioner that you are taking part in the study, but if you do not want your GP informed you can indicate this on the consent form. At the end of the study we will send you a copy of the brief report outlining the results of the study.

Thank you for taking the time to read this information sheet. If you need any advice or wish to discuss the study please feel free to contact the practice nurse, [practice nurse name & contact] or the trial manager at the address below. If you have any complaint about the study please contact the trial manager below who will deal with your complaint within 7 days.

[Trial Manager contact details]

If you are concerned about any issues related to the questions asked in this study or would like further information on where you can obtain help in relation to your drinking you can contact the National Alcohol Helpline:

Freephone DrinkLine 0800-917-8282 (11am-7pm Mon - Fri).

Drinkline offers the following services:

- Information and self-help materials.
- Help to callers worried about their own drinking.
- Support to the family and friends of people who are drinking.
- Advice to callers on where to go for help.

Drinkline is confidential and no names need be given. Callers to the above number have the option of listening to recorded information about alcohol or talking to an adviser.

Appendix 5 Screening questionnaire

[Insert Header – Practice]

Dear patient

We are asking all patients, aged 55 years or older, to complete a questionnaire about how much alcohol they drink. You should have received a copy of the questionnaire and an envelope from the receptionist when you came for your appointment.

We would be grateful if you would complete both sides of the questionnaire and then place the completed questionnaire in the envelope, seal it and place in the box by the practice reception, or if you prefer to complete the questionnaire at home return it in the stamped addressed envelope provided..

We are conducting a study in the practice looking at how much alcohol people drink and looking at different treatments for those who are drinking more alcohol than is good for their health. If you are happy to help us in this study please enter your name and address on the questionnaire. The practice nurse may contact you within the next week to discuss the study with you or to ask you to complete an additional questionnaire.

If you do wish to be considered for the study please complete the questionnaire and **complete the name and address section**. The practice nurse will contact you in the near future about participation.

All returned questionnaires will be treated in strictest confidence.

Many thanks for reading this letter.

Yours truly,

The following questionnaire asks a few questions about you and about how much alcohol you drink. Please answer the questions on this side of the paper and then turn over the paper and answer the questions on the other side. The questionnaire should only take a few minutes to complete.

If **you are willing to be considered for our research study** please enter your name, address and telephone number in the box below. If you **do not** wish to be considered for our research study leave the box below empty and continue to complete the questionnaire.

Name, Address and Telephone

Please answer the following questions then turn over the page

1. What is your age? ☐

2. Are you male or female? Male ☐ Female ☐

Now please answer the questions overleaf...

For each of the 10 questions please put a cross in the box below the answer that is correct for you.

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

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 or more times a week
☐	☐	☐	☐	☐

2. If you drink alcohol. How many drinks, containing alcohol do you have on a typical day when you are drinking?
A drink is half a pint of normal bitter, lager or cider or a small glass of wine or a small measure of spirits.

1 or 2	3 or 4	5 or 6	7 to 9	10 or more
☐	☐	☐	☐	☐

3. How often do you have 6 or more drinks on a single occasion?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

4. How many times in the past year have you found that you were not able to stop drinking after you had started?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

5. How often during the last year have you failed to do what was normally expected of you because of your drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

6. How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

7. How often during the last year have you had guilt or remorse after drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

8. How often during the last year have you been unable to remember what happened the night before because you have been drinking?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

9. Have you, or someone else been injured as a result of your drinking?

No	Yes, but not in the last year	Yes during the last year
☐	☐	☐

10. Has a relative, friend, doctor or other health worker been concerned about your drinking and suggested you cut down?

No	Yes, but not in the last year	Yes during the last year
☐	☐	☐

Appendix 6 Data collection booklets

In Confidence

Aesops

Baseline Questionnaire

Office use only (for designated person to complete)

Practice ID: ☐☐ - ☐☐☐☐☐

Date AUDIT Completed: ☐☐ / ☐☐ / ☐☐☐☐
day month year

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire.

The responses you give in this questionnaire will help us understand the relationship between drinking and health. Please read each section carefully. Please answer all the questions. Although some questions appear similar, it is still important that you answer every one. If you find it difficult to answer a question, please give the best answer that you can.

Please follow the instructions for each question carefully.

For each question you will be asked to put a cross in the box.

For example in the following question, if your answer to the question was 'Yes', you should place a cross in the box next to 'Yes'.

Do you drive a car ? **Yes** ☒

No ☐

Please use a black or blue pen. Please do not use a pencil or any other coloured pen.

Section 1

This section asks about the alcohol you have drunk in the past **6 months**. The questions ask about how many **standard drinks** you have consumed. A description of a standard drink is given in the box below.

Please answer each question by placing a cross in the box. Please only cross one box for each question.

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

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 to 5 times a week	6 or more times a week
☐	☐	☐	☐	☐	☐

2. How many **standard drinks** containing alcohol do you drink on a typical day you are drinking ?

None	1 to 2	3 to 4	5 to 6	7 to 9	10 or more
☐	☐	☐	☐	☐	☐

3. How often have you had 6 or more **standard drinks** on a single occasion in the past 6 months?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

4. **Compared with six months ago**, how much alcohol do you drink in a typical week?

Much less than 6 months ago	A bit less than 6 months ago	About the same as 6 months ago	A bit more than 6 months ago	A lot more than 6 months ago
☐	☐	☐	☐	☐

Section 2

The following questions ask about any problems you have experienced related to drinking alcohol. Please answer each question by placing a cross in the box. If you do not drink alcohol please cross the 'Never' box for each question.

In the **past 6 months** how often have you....

	Never	Once or twice	Occasionally	Fairly often	Often
Been drunk after drinking	☐	☐	☐	☐	☐
Had a fall or accident after drinking	☐	☐	☐	☐	☐
Felt confused after drinking	☐	☐	☐	☐	☐
Had a friend worry or complain about your drinking	☐	☐	☐	☐	☐
Neglected your appearance because of your drinking	☐	☐	☐	☐	☐
Had problems occur between you and a member of your family because of your drinking	☐	☐	☐	☐	☐
Gone to anyone for help about your drinking	☐	☐	☐	☐	☐
Neglected your work because of your drinking	☐	☐	☐	☐	☐
Lost friends because of your drinking	☐	☐	☐	☐	☐
Become intoxicated or drunk after drinking	☐	☐	☐	☐	☐
Skipped meals because of your drinking	☐	☐	☐	☐	☐
Had a family member worry or complain about your drinking	☐	☐	☐	☐	☐
Felt you were spending too much money on drink	☐	☐	☐	☐	☐
Felt isolated from people because of your drinking	☐	☐	☐	☐	☐
Had a drink to help you forget your worries	☐	☐	☐	☐	☐
Had a craving for a drink the first thing after you woke up	☐	☐	☐	☐	☐
Neglected the appearance of your living quarters because of your drinking	☐	☐	☐	☐	☐

Section 3
This section asks for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the past **4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the past **4 weeks**, how much of the time have you been limited in performing any kind of regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the past **4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the past **4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the past **4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

9. How much during the **last month** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. How much during the **last month** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How much during the **last month** have you felt downhearted and depressed ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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.) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

Section 4

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your health state today.

Place a cross in one box in each group.

1. Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

2. Self-care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

3. Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

4. Pain or discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

5. Anxiety or depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Section 5

This section asks about your use of health and social resources in the past 6 months. Please read each question carefully and remember each question relates to the **past 6 months only**. If your answer is 'none', please enter 'zero' in the box.

Hospital and Primary Health Care Services

1. In the **past 6 months** how many times have you visited an accident and emergency department as a patient? ☐☐☐
2. In the **past 6 months** how many nights have you spent in hospital as an inpatient? ☐☐☐
3. In the **past 6 months** how many times have you attended hospital as an outpatient? ☐☐☐
4. In the **past 6 months** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight) ☐☐☐
5. In the **past 6 months** how many times have you been taken to hospital in an emergency ambulance? ☐☐☐
6. In the **past 6 months** how many times have you been taken to or from hospital using a patient transport service? ☐☐☐
7. In the **past 6 months** how many times have you visited a doctor at your GP practice? ☐☐☐
8. In the **past 6 months** how many times has a doctor visited you at home? ☐☐☐
9. In the **past 6 months** how many times have you visited the nurse at your GP practice? ☐☐☐
10. In the **past 6 months** how many times has a nurse visited you at home? ☐☐☐
11. How many times have you received a prescription in the **past 6 months?** ☐☐☐
12. In the **past 6 months** have you visited any other health care professional other than a doctor or nurse at your GP surgery?

Professional visited	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

13. In the **past 6 months** has any other health care professional other than a doctor or nurse visited you at home?

Professional who has visited you	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

Social and Care Services

1. In the **past 6 months** have you used any of the following services and if so, how many times?

Community/Day Centres	☐☐☐
Meals on Wheels	☐☐☐
Social Services Home Care Services	☐☐☐

2. In the **past 6 months** how many times have you been visited by a social worker at home? ☐☐☐

3. In the **past 6 months** how many times have you visited a social worker at their office? ☐☐☐

4. In the **past 6 months** how many times have you visited a care worker or advisor at their office? ☐☐☐

5. In the **past 6 months** how many times have you been visited at home by a care worker or advisor? ☐☐☐

Police and Criminal Justice System Contacts

1. In the **past 6 months** how many times have you been arrested, cautioned or received an on-the-spot fine? ☐☐☐

2. Have you appeared in court in the **past 6 months**? ☐ Yes ☐ No

   If yes how many times?

Magistrates Court (days)	☐☐☐
Crown Court (times)	☐☐☐

3. Have you been in prison in the **past 6 months**? ☐ Yes ☐ No

   If yes how many days in total?

Number of days	☐☐☐

Section 6

1. What is your age in years? ☐☐

2. Are you? Male ☐ Female ☐

3. Are you?
   - A current smoker ☐
   - An ex-smoker ☐
   - A never smoker ☐

4. Which of the following best describes your main activity?
   - In employment or self employment ☐
   - Retired ☐
   - Housework ☐
   - Student ☐
   - Seeking Work ☐
   - Other ☐

   (If 'Other', please specify below)

5. Which of the following best describes your living arrangements?
   - Single ☐
   - Married ☐
   - Co-habiting ☐
   - Widowed ☐

6. Which of the following best describes your current accommodation?
   - Owner occupied ☐
   - Private rented ☐
   - LA/Housing association ☐
   - Temporary ☐

7. Did your education continue after the minimum school leaving age? Yes ☐ No ☐

8. Do you have a Degree or equivalent professional qualification? Yes ☐ No ☐

9. Are you willing to be contacted regarding participation in this research study? Yes ☐ No ☐

If you have any comments you would like to add, please use the space below.

In Confidence

Aesops

Six Month Questionnaire

Office use only (for designated person to complete)

Practice ID: ☐☐ - ☐☐☐☐☐

Date AUDIT Completed: ☐☐ / ☐☐ / ☐☐☐☐
day month year

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire.

The responses you give in this questionnaire will help us understand the relationship between drinking and health. Please read each section carefully. Please answer all the questions. Although some questions appear similar, it is still important that you answer every one. If you find it difficult to answer a question, please give the best answer that you can.

Please follow the instructions for each question carefully.

For each question you will be asked to put a cross in the box.

For example in the following question, if your answer to the question was 'Yes', you should place a cross in the box next to 'Yes'.

Do you drive a car ? **Yes** ☒

No ☐

Please use a black or blue pen. Please do not use a pencil or any other coloured pen.

Section 1

This section asks about the alcohol you have drunk in the past **6 months**. The questions ask about how many **standard drinks** you have consumed. A description of a standard drink is given in the box below.

Please answer each question by placing a cross in the box. Please only cross one box for each question.

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

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 to 5 times a week	6 or more times a week
☐	☐	☐	☐	☐	☐

2. How many **standard drinks** containing alcohol do you drink on a typical day you are drinking ?

None	1 to 2	3 to 4	5 to 6	7 to 9	10 or more
☐	☐	☐	☐	☐	☐

3. How often have you had 6 or more **standard drinks** on a single occasion in the past 6 months?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

4. **Compared with six months ago**, how much alcohol do you drink in a typical week?

Much less than 6 months ago	A bit less than 6 months ago	About the same as 6 months ago	A bit more than 6 months ago	A lot more than 6 months ago
☐	☐	☐	☐	☐

Section 2

The following questions ask about any problems you have experienced related to drinking alcohol. Please answer each question by placing a cross in the box. If you do not drink alcohol please cross the 'Never' box for each question.

In the **past 6 months** how often have you....

	Never	Once or twice	Occasionally	Fairly often	Often
Been drunk after drinking	☐	☐	☐	☐	☐
Had a fall or accident after drinking	☐	☐	☐	☐	☐
Felt confused after drinking	☐	☐	☐	☐	☐
Had a friend worry or complain about your drinking	☐	☐	☐	☐	☐
Neglected your appearance because of your drinking	☐	☐	☐	☐	☐
Had problems occur between you and a member of your family because of your drinking	☐	☐	☐	☐	☐
Gone to anyone for help about your drinking	☐	☐	☐	☐	☐
Neglected your work because of your drinking	☐	☐	☐	☐	☐
Lost friends because of your drinking	☐	☐	☐	☐	☐
Become intoxicated or drunk after drinking	☐	☐	☐	☐	☐
Skipped meals because of your drinking	☐	☐	☐	☐	☐
Had a family member worry or complain about your drinking	☐	☐	☐	☐	☐
Felt you were spending too much money on drink	☐	☐	☐	☐	☐
Felt isolated from people because of your drinking	☐	☐	☐	☐	☐
Had a drink to help you forget your worries	☐	☐	☐	☐	☐
Had a craving for a drink the first thing after you woke up	☐	☐	☐	☐	☐
Neglected the appearance of your living quarters because of your drinking	☐	☐	☐	☐	☐

Section 3
This section asks for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the past **4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the past **4 weeks**, how much of the time have you been limited in performing any kind of regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the past **4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the past **4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the past **4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

9. How much during the **last month** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. How much during the **last month** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How much during the **last month** have you felt downhearted and depressed ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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.) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

Section 4

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your health state today.

Place a cross in one box in each group.

1. **Mobility**
   - I have no problems in walking about ☐
   - I have some problems in walking about ☐
   - I am confined to bed ☐

2. **Self-care**
   - I have no problems with self-care ☐
   - I have some problems washing or dressing myself ☐
   - I am unable to wash or dress myself ☐

3. **Usual activities** (e.g. work, study, housework, family or leisure activities)
   - I have no problems with performing my usual activities ☐
   - I have some problems with performing my usual activities ☐
   - I am unable to perform my usual activities ☐

4. **Pain or discomfort**
   - I have no pain or discomfort ☐
   - I have moderate pain or discomfort ☐
   - I have extreme pain or discomfort ☐

5. **Anxiety or depression**
   - I am not anxious or depressed ☐
   - I am moderately anxious or depressed ☐
   - I am extremely anxious or depressed ☐

Section 5

This section asks about your use of health and social resources in the past 6 months. Please read each question carefully and remember each question relates to the **past 6 months only**. If your answer is 'none', please enter '0' in the box.

Hospital and Primary Health Care Services

1. In the **past 6 months** how many times have you visited an accident and emergency department as a patient? ☐☐☐
2. In the **past 6 months** how many nights have you spent in hospital as an inpatient? ☐☐☐
3. In the **past 6 months** how many times have you attended hospital as an outpatient? ☐☐☐
4. In the **past 6 months** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight) ☐☐☐
5. In the **past 6 months** how many times have you been taken to hospital in an emergency ambulance? ☐☐☐
6. In the **past 6 months** how many times have you been taken to or from hospital using a patient transport service? ☐☐☐
7. In the **past 6 months** how many times have you visited a doctor at your GP practice? ☐☐☐
8. In the **past 6 months** how many times has a doctor visited you at home? ☐☐☐
9. In the **past 6 months** how many times have you visited the nurse at your GP practice? ☐☐☐
10. In the **past 6 months** how many times has a nurse visited you at home? ☐☐☐
11. How many times have you received a prescription in the **past 6 months?** ☐☐☐
12. In the **past 6 months** have you visited any other health care professional other than a doctor or nurse at your GP surgery?

Professional visited	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

13. In the **past 6 months** has any other health care professional other than a doctor or nurse visited you at home?

Professional who has visited you	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

Social and Care Services

1. In the **past 6 months** have you used any of the following services and if so, how many times?

   Community/Day Centres ☐☐☐

   Meals on Wheels ☐☐☐

   Social Services Home Care Services ☐☐☐

2. In the **past 6 months** how many times have you been visited by a social worker at home? ☐☐☐

3. In the **past 6 months** how many times have you visited a social worker at their office? ☐☐☐

4. In the **past 6 months** how many times have you visited a care worker or advisor at their office? ☐☐☐

5. In the **past 6 months** how many times have you been visited at home by a care worker or advisor? ☐☐☐

Police and Criminal Justice System Contacts

1. In the **past 6 months** how many times have you been arrested, cautioned or received an on-the-spot fine? ☐☐☐

2. Have you appeared in court in the **past 6 months**? ☐ Yes ☐ No

   If yes how many times?

   Magistrates Court (days) ☐☐☐

   Crown Court (times) ☐☐☐

3. Have you been in prison in the **past 6 months**? ☐ Yes ☐ No

   If yes how many days in total?

   Number of days ☐☐☐

If you have any comments you would like to add, please use the space below.

In Confidence

Aesops

Twelve Month Questionnaire

Office use only (for designated person to complete)

Practice ID: ☐☐ - ☐☐☐☐☐

Date: ☐☐ / ☐☐ / ☐☐☐☐
day month year

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire.

The responses you give in this questionnaire will help us understand the relationship between drinking and health. Please read each section carefully. Please answer all the questions. Although some questions appear similar, it is still important that you answer every one. If you find it difficult to answer a question, please give the best answer that you can.

Please follow the instructions for each question carefully.

For each question you will be asked to put a cross in the box.

For example in the following question, if your answer to the question was 'Yes', you should place a cross in the box next to 'Yes'.

Do you drive a car ? **Yes** ☒

No ☐

Please use a black or blue pen. Please do not use a pencil or any other coloured pen.

Section 1

This section asks about the alcohol you have drunk in the past **6 months**. The questions ask about how many **standard drinks** you have consumed. A description of a standard drink is given in the box below.

Please answer each question by placing a cross in the box. Please only cross one box for each question.

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

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 to 5 times a week	6 or more times a week
☐	☐	☐	☐	☐	☐

2. How many **standard drinks** containing alcohol do you drink on a typical day you are drinking ?

None	1 to 2	3 to 4	5 to 6	7 to 9	10 or more
☐	☐	☐	☐	☐	☐

3. How often have you had 6 or more **standard drinks** on a single occasion in the past 6 months?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

4. **Compared with six months ago**, how much alcohol do you drink in a typical week?

Much less than 6 months ago	A bit less than 6 months ago	About the same as 6 months ago	A bit more than 6 months ago	A lot more than 6 months ago
☐	☐	☐	☐	☐

Section 2

The following questions ask about any problems you have experienced related to drinking alcohol. Please answer each question by placing a cross in the box. If you do not drink alcohol please cross the 'Never' box for each question.

In the **past 6 months** how often have you....

	Never	Once or twice	Occasionally	Fairly often	Often
Been drunk after drinking	☐	☐	☐	☐	☐
Had a fall or accident after drinking	☐	☐	☐	☐	☐
Felt confused after drinking	☐	☐	☐	☐	☐
Had a friend worry or complain about your drinking	☐	☐	☐	☐	☐
Neglected your appearance because of your drinking	☐	☐	☐	☐	☐
Had problems occur between you and a member of your family because of your drinking	☐	☐	☐	☐	☐
Gone to anyone for help about your drinking	☐	☐	☐	☐	☐
Neglected your work because of your drinking	☐	☐	☐	☐	☐
Lost friends because of your drinking	☐	☐	☐	☐	☐
Become intoxicated or drunk after drinking	☐	☐	☐	☐	☐
Skipped meals because of your drinking	☐	☐	☐	☐	☐
Had a family member worry or complain about your drinking	☐	☐	☐	☐	☐
Felt you were spending too much money on drink	☐	☐	☐	☐	☐
Felt isolated from people because of your drinking	☐	☐	☐	☐	☐
Had a drink to help you forget your worries	☐	☐	☐	☐	☐
Had a craving for a drink the first thing after you woke up	☐	☐	☐	☐	☐
Neglected the appearance of your living quarters because of your drinking	☐	☐	☐	☐	☐

Section 3
This section asks for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the past **4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the past **4 weeks**, how much of the time have you been limited in performing any kind of regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the past **4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the past **4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the past **4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

9. How much during the **last month** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. How much during the **last month** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How much during the **last month** have you felt downhearted and depressed ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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.) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

Section 4

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your health state today.

Place a cross in one box in each group.

1. Mobility

- I have no problems in walking about ☐
- I have some problems in walking about ☐
- I am confined to bed ☐

2. Self-care

- I have no problems with self-care ☐
- I have some problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

3. Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities ☐
- I have some problems with performing my usual activities ☐
- I am unable to perform my usual activities ☐

4. Pain or discomfort

- I have no pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have extreme pain or discomfort ☐

5. Anxiety or depression

- I am not anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am extremely anxious or depressed ☐

Section 5

This section asks about your use of health and social resources in the past 6 months. Please read each question carefully and remember each question relates to the **past 6 months only**. If your answer is 'none', please enter '0' in the box.

Hospital and Primary Health Care Services

1. In the **past 6 months** how many times have you visited an accident and emergency department as a patient? ☐☐☐
2. In the **past 6 months** how many nights have you spent in hospital as an inpatient? ☐☐☐
3. In the **past 6 months** how many times have you attended hospital as an outpatient? ☐☐☐
4. In the **past 6 months** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight) ☐☐☐
5. In the **past 6 months** how many times have you been taken to hospital in an emergency ambulance? ☐☐☐
6. In the **past 6 months** how many times have you been taken to or from hospital using a patient transport service? ☐☐☐
7. In the **past 6 months** how many times have you visited a doctor at your GP practice? ☐☐☐
8. In the **past 6 months** how many times has a doctor visited you at home? ☐☐☐
9. In the **past 6 months** how many times have you visited the nurse at your GP practice? ☐☐☐
10. In the **past 6 months** how many times has a nurse visited you at home? ☐☐☐
11. How many times have you received a prescription in the **past 6 months?** ☐☐☐
12. In the **past 6 months** have you visited any other health care professional other than a doctor or nurse at your GP surgery?

Professional visited	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

13. In the **past 6 months** has any other health care professional other than a doctor or nurse visited you at home?

Professional who has visited you	Number of visits
_____	☐☐☐
_____	☐☐☐
_____	☐☐☐

Social and Care Services

1. In the **past 6 months** have you used any of the following services and if so, how many times?

Community/Day Centres	☐☐☐
Meals on Wheels	☐☐☐
Social Services Home Care Services	☐☐☐

2. In the **past 6 months** how many times have you been visited by a social worker at home? ☐☐☐

3. In the **past 6 months** how many times have you visited a social worker at their office? ☐☐☐

4. In the **past 6 months** how many times have you visited a care worker or advisor at their office? ☐☐☐

5. In the **past 6 months** how many times have you been visited at home by a care worker or advisor? ☐☐☐

Police and Criminal Justice System Contacts

1. In the **past 6 months** how many times have you been arrested, cautioned or received an on-the-spot fine? ☐☐☐

2. Have you appeared in court in the **past 6 months**? ☐ Yes ☐ No

   If yes how many times?

Magistrates Court (days)	☐☐☐
Crown Court (times)	☐☐☐

3. Have you been in prison in the **past 6 months**? ☐ Yes ☐ No

   If yes how many days in total?

Number of days	☐☐☐

If you have any comments you would like to add, please use the space below.

In Confidence

Aesops

Non Participant Questionnaire

Office use only (for designated person to complete)

Practice ID:	☐☐
A_Score:	☐☐
Date AUDIT Completed:	☐☐ / ☐☐ / ☐☐☐☐ (day / month / year)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to complete this questionnaire. We will only ask you to complete this questionnaire. The questionnaire contains no information that can identify you.

The responses you give in this questionnaire will help us understand the relationship between drinking and health. Please read each section carefully. Please answer all the questions. Although some questions appear similar, it is still important that you answer every one. If you find it difficult to answer a question, please give the best answer that you can.

Please follow the instructions for each question carefully.

For each question you will be asked to put a cross in the box.

For example in the following question, if your answer to the question was 'Yes', you should place a cross in the box next to 'Yes'.

Do you drive a car ? **Yes** ☒

No ☐

Please use a black or blue pen. Please do not use a pencil or any other coloured pen.

Section 1

This section asks about the alcohol you have drunk in the past **6 months**. The questions ask about how many **standard drinks** you have consumed. A description of a standard drink is given in the box below.

Please answer each question by placing a cross in the box. Please only cross one box for each question.

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

Never	Monthly or less	2 to 4 times a month	2 to 3 times a week	4 to 5 times a week	6 or more times a week
☐	☐	☐	☐	☐	☐

2. How many **standard drinks** containing alcohol do you drink on a typical day you are drinking ?

None	1 to 2	3 to 4	5 to 6	7 to 9	10 or more
☐	☐	☐	☐	☐	☐

3. How often have you had 6 or more **standard drinks** on a single occasion in the past 6 months?

Never	Less than monthly	Monthly	Weekly	Daily or almost daily
☐	☐	☐	☐	☐

4. **Compared with six months ago**, how much alcohol do you drink in a typical week?

Much less than 6 months ago	A bit less than 6 months ago	About the same as 6 months ago	A bit more than 6 months ago	A lot more than 6 months ago
☐	☐	☐	☐	☐

Section 2

The following questions ask about any problems you have experienced related to drinking alcohol. Please answer each question by placing a cross in the box. If you do not drink alcohol please cross the 'Never' box for each question.

In the **past 6 months** how often have you....

	Never	Once or twice	Occasionally	Fairly often	Often
Been drunk after drinking	☐	☐	☐	☐	☐
Had a fall or accident after drinking	☐	☐	☐	☐	☐
Felt confused after drinking	☐	☐	☐	☐	☐
Had a friend worry or complain about your drinking	☐	☐	☐	☐	☐
Neglected your appearance because of your drinking	☐	☐	☐	☐	☐
Had problems occur between you and a member of your family because of your drinking	☐	☐	☐	☐	☐
Gone to anyone for help about your drinking	☐	☐	☐	☐	☐
Neglected your work because of your drinking	☐	☐	☐	☐	☐
Lost friends because of your drinking	☐	☐	☐	☐	☐
Become intoxicated or drunk after drinking	☐	☐	☐	☐	☐
Skipped meals because of your drinking	☐	☐	☐	☐	☐
Had a family member worry or complain about your drinking	☐	☐	☐	☐	☐
Felt you were spending too much money on drink	☐	☐	☐	☐	☐
Felt isolated from people because of your drinking	☐	☐	☐	☐	☐
Had a drink to help you forget your worries	☐	☐	☐	☐	☐
Had a craving for a drink the first thing after you woke up	☐	☐	☐	☐	☐
Neglected the appearance of your living quarters because of your drinking	☐	☐	☐	☐	☐

Section 3
This section asks for your views about your health. This section will help us keep track of how you feel and how well you are able to do your usual activities.

Answer every question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
(please cross one box only)

Excellent	Very Good	Good	Fair	Poor
☐	☐	☐	☐	☐

2. During a typical day does **your health** limit you in **moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

3. During a typical day does **your health** limit you in climbing **several** flights of stairs ? If so, how much ?
(please cross one box only)

Yes, limited a lot	Yes, limited a little	No, not limited at all
☐	☐	☐

4. During the past **4 weeks**, how much of the time have you accomplished less than you would like in regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

5. During the past **4 weeks**, how much of the time have you been limited in performing any kind of regular daily activities **as a result of your physical health** ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

6. During the past **4 weeks**, how much of the time have you accomplished less than you would have liked in your work or any other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

7. During the past **4 weeks**, how much of the time have you done work or other activities less carefully than usual **as a result of any emotional problems** (such as feeling depressed or anxious) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

8. During the past **4 weeks**, how much did **pain** interfere with your normal work (both outside the home and housework) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

9. How much during the **last month** have you felt calm and peaceful ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

10. How much during the **last month** did you have a lot of energy ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

11. How much during the **last month** have you felt downhearted and depressed ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

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.) ?
(please cross one box only)

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐	☐	☐	☐	☐

Section 4

This section also asks about your health in general. By placing a cross in one box in each group below, please indicate which statement best describes your health state today.

Place a cross in one box in each group.

1. **Mobility**
   - I have no problems in walking about ☐
   - I have some problems in walking about ☐
   - I am confined to bed ☐

2. **Self-care**
   - I have no problems with self-care ☐
   - I have some problems washing or dressing myself ☐
   - I am unable to wash or dress myself ☐

3. **Usual activities** (e.g. work, study, housework, family or leisure activities)
   - I have no problems with performing my usual activities ☐
   - I have some problems with performing my usual activities ☐
   - I am unable to perform my usual activities ☐

4. **Pain or discomfort**
   - I have no pain or discomfort ☐
   - I have moderate pain or discomfort ☐
   - I have extreme pain or discomfort ☐

5. **Anxiety or depression**
   - I am not anxious or depressed ☐
   - I am moderately anxious or depressed ☐
   - I am extremely anxious or depressed ☐

Section 5

This section asks about your use of health and social resources in the past 6 months. Please read each question carefully and remember each question relates to the **past 6 months only**. If your answer is 'none', please enter 'zero' in the box.

Hospital and Primary Health Care Services

1. In the **past 6 months** how many times have you visited an accident and emergency department as a patient? ☐☐☐
2. In the **past 6 months** how many nights have you spent in hospital as an inpatient? ☐☐☐
3. In the **past 6 months** how many times have you attended hospital as an outpatient? ☐☐☐
4. In the **past 6 months** how many times have you attended a day hospital? (i.e. you have been admitted to hospital but not kept in overnight) ☐☐☐
5. In the **past 6 months** how many times have you been taken to hospital in an emergency ambulance? ☐☐☐
6. In the **past 6 months** how many times have you been taken to or from hospital using a patient transport service? ☐☐☐
7. In the **past 6 months** how many times have you visited a doctor at your GP practice? ☐☐☐
8. In the **past 6 months** how many times has a doctor visited you at home? ☐☐☐
9. In the **past 6 months** how many times have you visited the nurse at your GP practice? ☐☐☐
10. In the **past 6 months** how many times has a nurse visited you at home? ☐☐☐
11. How many times have you received a prescription in the **past 6 months?** ☐☐☐
12. In the **past 6 months** have you visited any other health care professional other than a doctor or nurse at your GP surgery?

Professional visited	Number of visits
	☐☐☐
	☐☐☐
	☐☐☐

13. In the **past 6 months** has any other health care professional other than a doctor or nurse visited you at home?

Professional who has visited you	Number of visits
	☐☐☐
	☐☐☐
	☐☐☐

Social and Care Services

1. In the **past 6 months** have you used any of the following services and if so, how many times?

Community/Day Centres	☐☐☐
Meals on Wheels	☐☐☐
Social Services Home Care Services	☐☐☐

2. In the **past 6 months** how many times have you been visited by a social worker at home? ☐☐☐

3. In the **past 6 months** how many times have you visited a social worker at their office? ☐☐☐

4. In the **past 6 months** how many times have you visited a care worker or advisor at their office? ☐☐☐

5. In the **past 6 months** how many times have you been visited at home by a care worker or advisor? ☐☐☐

Police and Criminal Justice System Contacts

1. In the **past 6 months** how many times have you been arrested, cautioned or received an on-the-spot fine? ☐☐☐

2. Have you appeared in court in the **past 6 months**? ☐ Yes ☐ No

   If yes how many times?

Magistrates Court (days)	☐☐☐
Crown Court (times)	☐☐☐

3. Have you been in prison in the **past 6 months**? ☐ Yes ☐ No

   If yes how many days in total?

Number of days	☐☐☐

Section 6

1. What is your age in years? ☐☐

2. Are you? Male ☐ Female ☐

3. Are you?
   - A current smoker ☐
   - An ex-smoker ☐
   - A never smoker ☐

4. Which of the following best describes your main activity?
   - In employment or self employment ☐
   - Retired ☐
   - Housework ☐
   - Student ☐
   - Seeking Work ☐
   - Other ☐

   (If 'Other', please specify below)

5. Which of the following best describes your living arrangements?
   - Single ☐
   - Married ☐
   - Co-habiting ☐
   - Widowed ☐

6. Which of the following best describes your current accommodation?
   - Owner occupied ☐
   - Private rented ☐
   - LA/Housing association ☐
   - Temporary ☐

7. Did your education continue after the minimum school leaving age? Yes ☐ No ☐

8. Do you have a Degree or equivalent professional qualification? Yes ☐ No ☐

If you have any comments you would like to add, please use the space below.

Appendix 7 Intervention delivery by site

		Minimal intervention and	
Centre	Practice ID number	Step 1 delivered by	Step 2 delivered by
Leeds[a]	20	Practice nurse	Specialist addiction services therapist
	26	Practice nurse	
	27	Alcohol development nurse, then research practitioner A	
	28		
	35	Alcohol development nurse, then research practitioner B	
	36	Alcohol development nurse, then research practitioner A	
	38	Alcohol development nurse, then research practitioner B	
	52	Research practitioner B	
	53		
	55		
	59	Research practitioner A	
	62	Research practitioner B	
	63	Research practitioner A	
	64	Research practitioner B	
	65	Research practitioner A	
North Yorkshire	15	Practice nurse	Drug and alcohol counsellor
	16	Practice nurse	
	17	Research practice nurse	Alcohol service manager
	18		
	21	Practice nurse	
	23	Practice nurse and practice nurse manager	
Hull & East Riding[a]	19	Practice nurses×2	Clinical nurse manager (addiction services)
	22	Practice nurse and nurse practitioner	
	25	Practice nurse	
	29	Practice nurses×2	
Norfolk	10	Practice nurse, then a research nurse	GP liaison nurses×2 (alcohol and drugs service)
	12	Practice nurse, then a research nurse	
	13	Research nurse	
	14		

Centre	Practice ID number	Minimal intervention and	
		Step 1 delivered by	Step 2 delivered by
	33		
	39		
	37		
	41		
Kent	30	Practice nurse	Counsellor for drug and alcohol community services
Fife	32	Research nurses×2	Same research nurses×2
	34		
	43		
	44		
	57		
Tyneside	40	Alcohol health workers×2	Same alcohol health workers
	45		
	46		
	47		
	48		
	49		
	50		
	51		
	54		
	56		
County Durham	58	Alcohol health workers×2	Same alcohol health workers
	60		
	66		
	67		

a The Hull and Leeds sites each had one additional practice set up, but no packs were ever distributed.

Appendix 8 Safer drinking leaflet

Making a plan

Drinking plan for each day

Day	When?	Where?	With whom?	How much?
Monday				
Tuesday				
Wednesday				
Thursday				
Friday				
Saturday				
Sunday				

Safer drinking: a self help guide

How to count your units of alcohol

Are you at risk from drinking alcohol?

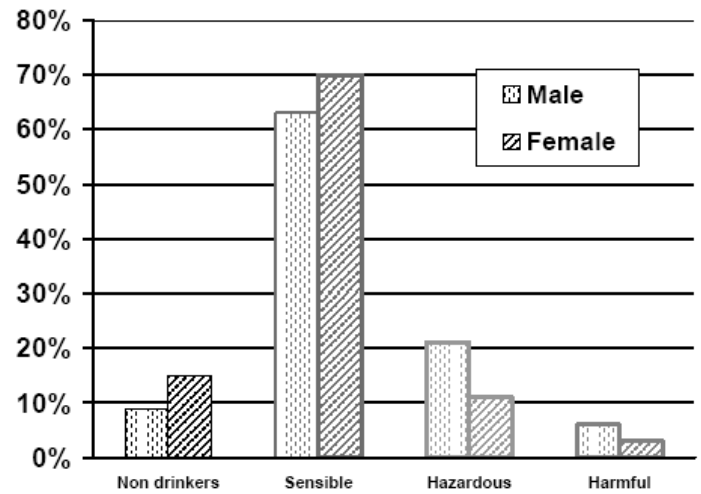
Risk	AUDIT Score	Men	Women	Common Effects
Sensible	0-7	21 units or fewer per week or up to 4 units a day	14 units or fewer per week or up to 3 units a day	• Increased relaxation • Reduced risk of heart disease • Sociability
Hazardous	8-15	22 – 49 units per week or regular drinking of more than 4 units per day	15 – 35 units per week or regular drinking of more than 3 units per day	• Less energy • Depression/ Stress • Insomnia • Impotence • Risk of injury • High blood pressure
Harmful	16-19	50+ units per week	36+ units per week	• All of the above and… • Memory loss • Increased risk of liver disease • Increased risk of cancer • Possible alcohol dependence

- If you scored between 8 and 15:
  Your score suggests you may be at risk of problems in the future.
  What do you think?

- If you scored over 15:
  You appear to be drinking at a rate that increases your risk of harm.
  What do you think?

Jot down some of your own concerns

Percent of population by drinking levels



What targets should you aim for?

Women
3 or fewer units on a drinking day
Maximum of 14 or fewer units weekly

Men
4 or fewer units on a drinking day
Maximum of 21 or fewer units weekly

As well as keeping to weekly limits, it is recommended that you keep at least two days of the week alcohol free.

There are times when you are at risk even after two or three drinks, for example when exercising, operating heavy machinery, driving or are taking certain medicines.

Binge drinking is considered to be drinking twice the daily limit in one sitting (8 units or more for men and 6 units or more for women).

Dependent drinkers should avoid alcohol as no units can be said to be safe: a dependent drinker is someone who feels that they cannot control their drinking, cannot stop once they have started, feels sweaty and shaky on waking and / or feels the need to have a drink to get going.

World Health Organisation 2007

What are the benefits of cutting down?

Physical

- Reduced risk of injury
- Reduced risk of high blood pressure
- Reduced risk of cancer
- Reduced risk of liver disease
- Reduced risk of brain damage
- Sleep better
- More energy
- Lose weight
- No hangovers
- Improved memory
- Better physical shape

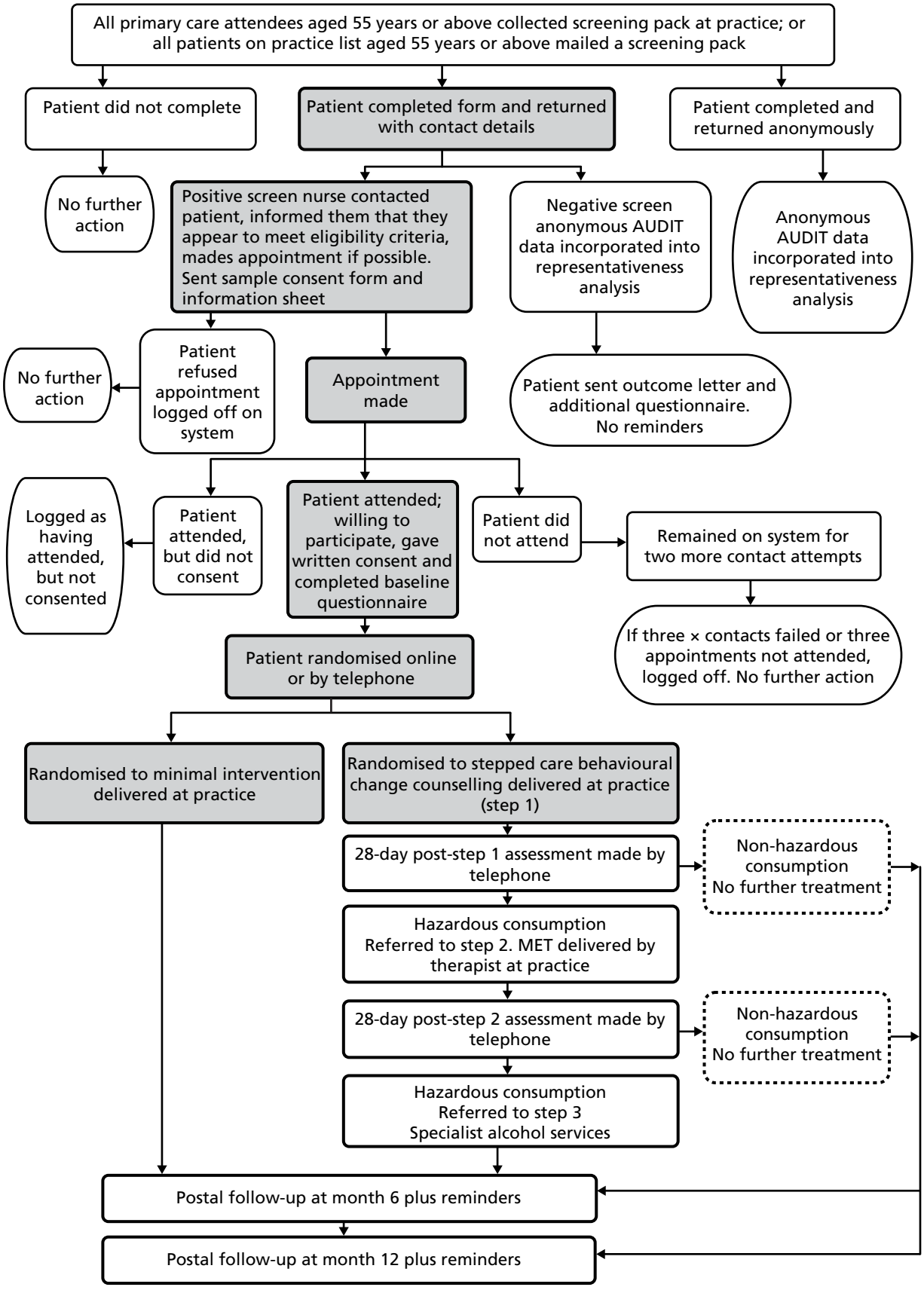
Psychological/ Social/ Financial

- Improved mood
- Improved family relationships
- Reduced risk of drink driving
- Save money

What are the benefits of cutting down *for you*?

DOI: 10.3310/hta17250

Appendix 9 Study summary



Appendix 10 AESOPS Process Rating Scale

AESOPS PRS SHEET

Duration:

Session Management

1) *Maintaining Structure*

Frequency:
Quality:

2) *Agenda Setting*

Frequency:
Quality:

3) *Consistency of Problem Focus*

Frequency:
Quality:

4) *End of Session Summary*

Frequency:
Quality:

Specific Tasks

5) *Drinking – Feedback/Negative Consequences*

Frequency:
Quality:

6) *Eliciting Client Concerns about Drinking*

Frequency:
Quality:

7) *Eliciting Self-efficacy for Change*

Frequency:
Quality:

8) *Commitment to Drinking Goal*

Frequency:
Quality:

9) *Ambivalence*

Frequency:
Quality:

10) *Creating Conflict*

Frequency:
Quality:

11) *Eliciting Commitment to Change Drinking*

Frequency:
Quality:

12) Eliciting Optimism for Change

Frequency: Quality:

Therapist Style

13) Reflective Listening

Frequency: Quality:

14) Empathy

Frequency: Quality:

15) Unsolicited Advice

Frequency:

16) Open Questions

Frequency: Quality:

17) Closed Questions

Frequency:

18) Session content

Please tick appropriate box for the following:

Content/Activity	**Yes**	**No**
Review AUDIT score		
Obtain an account of drinking		
Give correct advice/Information		
Set a target		
Make a drinking plan		

Additional Comments: Please tick appropriate box for the following:

Tape Quality	**Sound**
Poor	……
Good	……

Appendix 11 Mail-out documentation

REC Ref:
Short Title: AUDIT-v2
Document Name: AUDIT Screening Questionnaire
Version: 2 (Newcastle)
Date: 16/06/2009

[Insert Header – Practice]

Dear patient

We are asking all patients, aged 55 years or older, to complete a questionnaire about how much alcohol they drink.

We would be grateful if you would complete both sides of the questionnaire and then place the completed questionnaire in the envelope, seal it and return it in the enclosed prepaid envelope.

We are conducting a study in the practice looking at how much alcohol people drink and looking at different treatments for those who are drinking more alcohol than is good for their health. If you are happy to help us in this study please enter your name and address on the questionnaire. Someone may contact you within the next week to discuss the study with you or to ask you to complete an additional questionnaire.

If you do not wish to be considered for the study please complete the questionnaire and **do not** complete the name and address section.

All returned questionnaires will be treated in strictest confidence.

Many thanks for reading this letter.

Yours truly,

[insert signatories]

AESOPS

16/06/2009 V2

The following questionnaire asks a few questions about you and how much alcohol you drink. Please answer all the questions below. The questionnaire should only take a few minutes to complete.

If you are willing to be considered for our research study please enter your **name, address and telephone number** below. If you **do not** wish to be considered for our research study then please leave the box below empty and continue to complete the rest of the questionnaire.

Name _____

Address _____

_____

Telephone number: Home _____ **Mobile:** _____

What is your age? ☐ **Are you?** **Male** ☐ **Female** ☐

Please circle the relevant answer on each of the 10 questions below.

How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
If you drink alcohol, how many drinks, containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
How often do you have 6 or more drinks on a single occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How many times in the past year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you failed to do what was normally expected of you because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you had guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes during the last year
Has a relative, friend, doctor or health worker been concerned about your drinking and suggested you cut down?	No		Yes, but not in the last year		Yes during the last year

Thank you for completing. Please return in the stamped addressed envelope provided.

REC Ref:
Short Title: v2.1
Document Name: AUDIT Screening Questionnaire
Version: 3 (Mailout)
Date: 17/09/09

[Insert Header – Practice]

Dear patient

We are asking all patients, aged 55 years or older, to complete a questionnaire about how much alcohol they drink.

We would be grateful if you would complete both sides of the questionnaire and then place the completed questionnaire in the envelope, seal it and return it in the enclosed prepaid envelope.

We are conducting a study in the practice looking at how much alcohol people drink and looking at different treatments for those who are drinking more alcohol than is good for their health. If you are happy to help us in this study please enter your name and address on the questionnaire. The practice nurse or research nurse may contact you within the next week to discuss the study with you or to ask you to complete an additional questionnaire.

If you do not wish to be considered for the study please complete the questionnaire and **do not** complete the name and address section.

All returned questionnaires will be treated in strictest confidence.

Many thanks for reading this letter.

Yours truly,

[insert signatory]

AESOPS

17/09/2009 V2.1

The following questionnaire asks a few questions about you and how much alcohol you drink. Please answer all the questions below. The questionnaire should only take a few minutes to complete.

If you are willing to be considered for our research study please enter your **name, address and telephone number** below. If you **do not** wish to be considered for our research study then please leave the box below empty and continue to complete the rest of the questionnaire.

Name _____

Address _____

_____

Telephone number: Home _____ **Mobile:** _____

What is your age? ☐ **Are you?** **Male** ☐ **Female** ☐

Please circle the relevant answer on each of the 10 questions below.

How often do you have a drink containing alcohol?	Never	Monthly or less	2-4 times a month	2-3 times a week	4 or more times a week
If you drink alcohol, how many drinks, containing alcohol do you have on a typical day when you are drinking?	1 or 2	3 or 4	5 or 6	7 to 9	10 or more
How often do you have 6 or more drinks on a single occasion?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How many times in the past year have you found that you were not able to stop drinking once you had started?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you failed to do what was normally expected of you because of your drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you needed a first drink in the morning to get yourself going after a heavy drinking session?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you had guilt or remorse after drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
How often during the last year have you been unable to remember what happened the night before because you had been drinking?	Never	Less than monthly	Monthly	Weekly	Daily or almost daily
Have you or someone else been injured as a result of your drinking?	No		Yes, but not in the last year		Yes during the last year
Has a relative, friend, doctor or health worker been concerned about your drinking and suggested you cut down?	No		Yes, but not in the last year		Yes during the last year

Thank you for completing. Please return in the stamped addressed envelope provided.

If you are concerned about any issues related to the questions asked in this study or would like further information on where you can obtain help in relation to your drinking you can contact the National Alcohol Helpline:

Freephone DrinkLine

0800-917-8282

(11am-7pm Mon - Fri).

Drinkline offers the following services:

- Information and self-help materials.
- Help to callers worried about their own drinking.
- Support to the family and friends of people who are drinking.
- Advice to callers on where to go for help.

Drinkline is confidential and no names need be given.

Callers to the above number have the option of listening to recorded information about alcohol or talking to an adviser.

All information collected in this study is strictly confidential. We will inform your general practitioner that you are taking part in the study, but if you do not want your GP informed you can indicate this on the consent form. At the end of the study we will send you a copy of the brief report outlining the results of the study.

Thank you for taking the time to read this information sheet. If you need any advice or wish to discuss the study please feel free to contact the Alcohol Health Worker or the trial manager at the addresses below.

If you have any complaint about the study please contact the trial manager below who will deal with your complaint within 7 days.

[Trial Manager contact details]

[Alcohol health worker contact details]

PIL v1 (Newcastle) 16/08/09

Randomised Evaluation of a Stepped Care Treatment Approach

Aesops

PARTICIPANT INFORMATION SHEET

DOI: 10.3310/hta17250

You are being invited to take part in a research study. Before you decide whether to take part it is important that you understand why the research is being done and what taking part in the research will involve. Please find the time to read the following information and discuss it with family, relatives, friends or your GP if you wish.

It is entirely up to you if you take part in the research study. If you do not wish to take part your usual care will not be affected in any way. If you do decide to take part you are free to stop taking part in the study at any time, you do not need to provide a reason.

The research is being conducted by the University of York, in conjunction with your GP practice and is funded by the Department of Health and the study has been checked by [insert ethics committee].

Please read the following information carefully. If you have any questions about this study you can ask the Alcohol Health Worker or you can contact the study manager. The study is taking place in [No of practices] across England. We hope that 500 patients who are eligible will consent to take part in the study.

All patients attending this practice who are 55 years or older, between [start date] and [end date] are being asked to complete a questionnaire about how much they drink alcohol and if the results indicate that you may be drinking more alcohol than is good for your health and you have given us your contact details our Alcohol Health Worker will telephone you and make an appointment for you to discuss the study.

If you are happy to take part in the study you will be asked to sign a consent form, a copy of which is enclosed. She will ask you some questions about how much and when you drink alcohol. You will then be asked to fill in a short questionnaire about your general health and how often you use healthcare resources. Once this is completed she will make a telephone call to find out what intervention you will receive. She has no influence over the choice of intervention. All interventions provided will be tape recorded for quality assurance purposes. If you would prefer not to have your session recorded you can indicate this on the consent form. The two approaches are detailed below.

Intervention One: You will receive a short 5 minute discussion about your drinking with the Alcohol Health Worker and some written information about alcohol and your health.

Intervention Two: You will receive a 20 minute discussion with the Alcohol Health Worker about your drinking and explore ways in which you could reduce the amount you drink. About 4 weeks after the Alcohol Health Worker has seen you she will call you and discuss how much alcohol you have drunk in the 4 week period. If at this time she feels you are still drinking too much alcohol for your health they will invite you to see a specialist at the general practice for three 40-minute appointments. The specialist is trained in a technique called Motivational Enhancement Therapy. This approach is known to be effective in helping many people reduce the amount of alcohol they drink. Four weeks after the last of these appointments the Alcohol Health Worker will again contact you to discuss how much alcohol you are drinking. If at this time they feel you are still drinking alcohol at levels that are not good for your health they will ask the general practitioner to make a referral to the local specialist alcohol services.

Irrespective of what intervention you receive, we will send you two questionnaires by post. One will be sent 6 months and the other 12 months after the computer decided which intervention you would be receiving. These questionnaires will be similar to the one you completed just before your intervention was decided.

If you are concerned about any issues related to the questions asked in this study or would like further information on where you can obtain help in relation to your drinking you can contact the National Alcohol Helpline:

Freephone DrinkLine

0800-917-8282

(11am-7pm Mon - Fri).

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All information collected in this study is strictly confidential. We will inform your general practitioner that you are taking part in the study, but if you do not want your GP informed you can indicate this on the consent form. At the end of the study we will send you a copy of the brief report outlining the results of the study.

Thank you for taking the time to read this information sheet. If you need any advice or wish to discuss the study please feel free to contact the Practice nurse/ Research nurse or the trial manager at the addresses below.

If you have any complaint about the study please contact the trial manager below who will deal with your complaint within 7 days.

[Trial Manager contact details]

[Practice nurse/ Research nurse contact details]

PILv1.1_Mailout 17/09/09

Randomised Evaluation of a Stepped Care Treatment Approach

Aesops

PARTICIPANT INFORMATION SHEET

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