



NETSCC, HTA

4 June 2010

REC Ref:

Short Title: ~~HTAPRO4~~ **HTAPRO5**

Document Name: Full protocol

Version: ~~4.0~~ **5.0**

Date: ~~16/06/2009~~ **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 ischemic 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 & Whitley 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 healthcare 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 healthcare 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 minute 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 minute, 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 minute 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 minute 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 a 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 healthcare 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 minutes to complete and 2 minutes 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 minutes 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 (Euroquo1 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 Multi-Centre 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 minute, 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 minute 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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