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The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care

Submission date
16/04/2007

Recruitment status
No longer recruiting

Registration date
16/04/2007

Overall study status
Completed

Last Edited
14/07/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
There is a lot of evidence about the detrimental impact of hazardous alcohol consumption on health. In older people hazardous alcohol consumption is associated with increased risk of heart disease, stroke, cancers, the onset of dementia and is a major risk factor for falls. Alcohol use in older people is considered a hidden problem, in part because of a reticence on the part of people to seek help and treatment and in part because of wide scale misdiagnosis. The prevalence of hazardous alcohol consumption in older people is far higher than initially thought, about 20%, but only a small percentage receive any treatment. The aim of this study is to evaluate whether screening combined with a stepped care treatment approach for older hazardous alcohol users in primary care is more effective at reducing alcohol consumption at 12 months than a minimal treatment intervention.

Who can participate?
Patients aged 55 or over with an alcohol use disorder

What does the study involve?
Participants are screened for alcohol use disorders whilst attending for primary care appointments. Those who do have an alcohol use disorder are randomly allocated to either a treatment as usual approach, involving brief advice, or a stepped care approach. Stepped care is a logical rational approach in which more invasive and intensive treatments are only delivered to those who do not benefit from less intensive and invasive approaches. The steps are a short motivational intervention delivered by a practice nurse followed by a more intensive motivational therapy delivered by a trained therapist. Both of these approaches have shown reductions in alcohol consumption in other studies. If neither of these benefit the patient they are referred to specialist alcohol services. Changes in alcohol consumption, alcohol problems and quality of life are analysed over 12 months. The costs of each treatment and what potential savings can be made to the NHS are also assessed.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Kent (UK)

When is the study starting and how long is it expected to run for?
April 2007 to April 2007

Who is funding the study?
Health Technology Assessment Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 06/304/142

Study information

Scientific Title

The effectiveness and cost-effectiveness of opportunistic screening and stepped care interventions for older hazardous alcohol users in primary care

Acronym
AESOPS

Study objectives
To evaluate whether screening combined with a stepped care treatment approach for older hazardous alcohol users in primary care is more effective at reducing alcohol consumption at 12 months than a minimal treatment intervention.

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/06304142
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0004/51349/PRO-06-304-142.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West Research Ethics Committee, 11/04/2007, ref: 07/MRE08/24

Study design
Pragmatic prospective randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Older hazardous alcohol users

Interventions
1. Minimal intervention:
The minimal intervention consists of a short, five minute, discussion with the practice nurse, immediately after randomisation, 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.

2. 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 immediately after randomisation. This intervention, based upon an existing evidence base of brief interventions, utilises the technique of motivational interviewing and aims to address the individuals 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 participants alcohol consumption in the past four weeks using the 28-item Short Form (SF-28). 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 (MET), is provided through three 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 participants alcohol consumption in the past four weeks using the SF-28. 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.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome measure for the study is average drinks per day. This is ascertained using the time line follow back method and the Form-90 instrument. Three other variables can be derived from the data:
1. Percent days abstinent
2. Drinks per drinking day
3. Total alcohol consumed

The time line follow back interview is conducted by a trained individual and takes approximately 20 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

2. Quality of life is measured at baseline, 6 months and 12 months post randomisation. Quality of life is measured using the 12-item Short Form (SF-12). 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 Euro Quality of Life questionnaire (EQ-5D). 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. 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.

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) and 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.

Overall study start date
01/04/2007

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. Age 55 years or over at time of screening
2. Diagnosis of a hazardous or harmful alcohol use disorder using International Classification of Diseases (ICD-10) criteria or confirmed hazardous alcohol consumption in the past 90 days using time line follow back method
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

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
500

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

Date of first enrolment
01/04/2007

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
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Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	12/06/2008		Yes	No
Results article	results	01/06/2013		Yes	No