ISRCTN89156543 https://doi.org/10.1186/ISRCTN89156543

Brief intervention to improve alcohol consumption and co-morbid outcomes in primary care patients with hypertension or mild to moderate depression

Submission date
23/08/2013

Recruitment status
No longer recruiting

Registration date
21/10/2013

Overall study status
Completed

Last Edited
30/06/2014

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Some people living with high blood pressure or mild to moderate depression also drink alcohol over medically recommended levels. If they change the amount or the way in which they drink their symptoms may improve. Brief advice is known to help people who drink excessively to reduce their alcohol consumption, and may also lead to improvements in associated high blood pressure or mental health problems. A large study of brief advice would show whether this is the case. To find out whether this is feasible, this study aims to find out how many patients could be invited and agree to take part in a study like this, how many would stay involved with the study, and whether they would find it practical and acceptable.

Who can participate?
Patients aged 18 and over and registered with GPs in the North East of England can take part if they are drinking alcohol over the UK recommended levels (21 units per week for men, 14 units per week for women) and are either diagnosed as hypertensive (high blood pressure) or have had mild to moderate depression or low mood.

What does the study involve?
The study involves filling in a questionnaire about alcohol and posting it back to the research team. If you choose to supply contact details on the questionnaire, a researcher will then contact you to arrange a 15-20 minute meeting at your GP surgery. At the meeting, the researcher will either measure your blood pressure using a standard cuff or ask a few questions about your mood. Participants will be randomly allocated to a control or an intervention group. Participants in the control group will receive a leaflet on high blood pressure or depression to take home. Intervention group participants will receive the same leaflets as the control group and the researcher may also briefly offer some advice about alcohol consumption and health. After 6 months you will be asked to meet again with the researcher at your GP surgery for 15 minutes to measure your blood pressure or ask questions about your mood, and to ask a few more questions about your alcohol consumption. This should take no longer than 15 minutes.

What are the possible benefits and risks of participating?
If you take part you will receive confidential advice on whether the amount you are drinking could be a risk to your health, as well as information about links between alcohol consumption and your condition (hypertension or depression) and how to reduce drinking to levels of low risk to health.
There are no anticipated risks involved in taking part. Any information about you which leaves the GP surgery will have your name and address removed.

Where is the study run from?
Study is coordinated by North Tyneside Primary Care Trust. The study will be run from GP surgeries in the North East of England.

When is the study starting and how long is it expected to run for?
The study started in August 2010 and ran until February 2012.

Who is funding the study?
North Tyneside NHS Primary Care Trust, UK.

Who is the main contact?
Dr Graeme Wilson, Project manager, Newcastle University

Contact information

Type(s)
Scientific

Contact name
Prof Eileen Kaner

Contact details
Institute of Health & Society
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
10SUBM001

Study information

Scientific Title
Feasibility trial of brief intervention to improve alcohol consumption and Co-morBId outcomes in primary care patients with hypertension or mild to moderate depression

Acronym
ComBIne

Study objectives
The study aim is to investigate the feasibility of conducting larger future trials exploring brief intervention in primary care for heavy drinkers with co-morbid hypertension or depression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
County Durham and Tees Valley NHS Research Ethics Committee, 23/07/2010, REC Reference Number 10/H0908/35

Study design
Two parallel two-arm cluster randomised controlled pilot trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Excessive alcohol drinking with co-morbid hypertension or mild to moderate depression

Interventions
1. In control arm, patients receive either an advice leaflet produced by the British Heart Foundation (hypertension trial) or a leaflet on depression produced by a regional NHS organisation (depression trial).
2. In intervention arm, participants receive the same leaflets as in the control arm plus a brief intervention involving a single practice-based 10 minute session of structured advice about reducing alcohol consumption levels, delivered by a trained research worker.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Rates of eligibility for the trial
2. Recruitment
Eligibility and recruitment of participants are recorded on the trial database at entry to the study; frequencies for each of these are calculated as a proportion of patients screened to give the outcome measures.
3. Retention
Retention of the participants in the trial is recorded on the database at the six-month follow-up; frequencies are calculated as a proportion of patients recruited to give this outcome measure.

Secondary outcome measures
1. Score on Alcohol Use Disorder Identification Tool (AUDIT)
2. Systolic and diastolic blood pressure (hypertension trial)
3. Score on Patient Health Questionnaire (PHQ-9, depression trial)
4. Acceptability of trial instruments and procedures
Each of these is measured at the baseline appointment, then again at the six month follow up appointment.

Overall study start date
01/08/2010

Completion date
29/02/2012

Eligibility

Key inclusion criteria
1. Male or female primary care patients
2. Aged 18 and over
3. Either diagnosed as hypertensive or with mild to moderate depression (scoring 5-19 inclusive on PHQ-9)
4. Drinking alcohol over the UK recommended levels of 21 units per week for men or 14 units per week for women

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Both

Target number of participants
120

Key exclusion criteria
1. Under the age of 18
2. Cognitive impairment
3. Terminal illness
4. Severe depression or mental health problems
5. Accessing treatment for alcohol misuse

Date of first enrolment
01/08/2010

Date of final enrolment
29/02/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Institute of Health & Society
Newcastle Upon Tyne
United Kingdom
NE2 4AX

Sponsor information

Organisation
North Tyneside Primary Care Trust (UK)

Sponsor details
NHS North of Tyne
Bevan House
1 Esh Plaza
Great Park
Newcastle upon Tyne
England
United Kingdom
NE13 9BA

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
North Tyneside NHS Primary Care Trust (UK)

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?
Results article	results	19/06/2014		Yes	No