ISRCTN85355606 https://doi.org/10.1186/ISRCTN85355606

Bradford Hypertension and Alcohol Intervention Trial

Submission date
17/06/2015

Recruitment status
Stopped

Registration date
01/07/2015

Overall study status
Stopped

Last Edited
13/03/2020

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Although is it well established that alcohol consumption can cause or contribute to the development of high blood pressure, we do not know what kind of assessment is best or sufficient to address this, and what level of treatment or intervention is required in order to show better outcomes.
This is particularly the case for patients above the age of 60, where standard screening tools for problematic alcohol consumption need to be adjusted; however, it is not clear how and what the result of any intervention might be, especially not with regards to cardiovascular risk and high blood pressure readings. The aim of this study is to find out the best way to assess patients and and advise them on how to reduce their alcohol consumption in GP surgeries.

Who can participate?
Any patient registered with a GP surgery that is part of the Bradford Districts Clinical Commissioning Group and who is newly diagnosed with hypertension.

What does the study involve?
GP surgeries are randomly allocated to one of three groups.
1. Control Group: GPs are asked to treat as usual with no additional intervention or change of their usual practice. We will only ask for a repeat blood pressure (BP) reading three months after the initial diagnosis and will conduct a brief telephone interview, which will be conducted by the local alcohol treatment service and ask patients to mention any lifestyle intervention they recall being given at the time of diagnosis as well as whether they have acted on any of these. We will also use a screening tool to assess the level of alcohol consumption in this group called AUDIT-C, consisting of three questions to assess the frequency and amount of alcohol consumed. If AUDIT-C indicates a drinking behaviour that is regarded as hazardous or harmful, a brief intervention will be conducted with signposting to access further treatment if necessary.
2. Treatment Arm 1: At the time of diagnosis of high blood pressure, patients will be asked about their alcohol consumption using an accredited screening tool called AUDIT-C by their GP. This screening tool will produce a numeric result between 0 and 12. All patients who are not abstinent (AUDIT-C > 0) will be enrolled and given a standardised brief intervention by the healthcare professional, explaining that alcohol is a major contributing factor to develop hypertension, and that a reduction in alcohol consumption should lead to a reduction in blood

pressure. The estimated time to see a reduction in blood pressure is between 4-12 weeks, therefore any pharmacotherapy can be delayed whilst patients work towards a reduction or abstinence from alcohol. It is usual practice to repeat blood pressure readings 4 weekly when pharmacotherapy is started, so we would encourage patients to attend for a BP check as usual at week 4 and 8, and require them to attend a repeat BP reading at week 12, with a repeat of the AUDIT-C at this time, reflecting on the last 3 months.
3. Treatment Arm 2: As per treatment arm 1, patients will be asked about their alcohol consumption using an accredited screening tool called AUDIT-C by their GP. If the AUDIT-C > 0, that means the patient is not abstinent, a referral for a health check will be offered for a more detailed assessment by the primary care alcohol team. This assessment should be done within 10 working days and entail the use of other assessment tools, namely AUDIT (a longer, more accurate version of the AUDIT-C, consisting of 10 questions) and a further intervention will be offered if and when appropriate. These additional interventions will take on the format of an extended brief intervention or brief treatment, with face to face counselling over a period of 4-12 weeks, weekly or fortnightly, for 30 minutes, using counselling techniques like cognitive behaviour therapy or motivational interviewing as deemed appropriate by the patient and councillor. If necessary, a referral to more specialist alcohol treatment can be initiated at any time.

What are the possible benefits and risks of participating?
The benefits include positive biofeedback (decrease in blood pressure due to reduction in alcohol intake), which can other areas of health as well, as it might result in avoiding pharmacotherapy and even reverse high blood pressure altogether.
There is a limited risk to patients for a defined period whilst pharmacotherapy is withheld in order to show improvements in blood pressure by lifestyle interventions alone. The timeframe we chose to observe of 3 months is limited and we exclude any patients who need immediate treatment with drugs to reduce blood pressure because their risk of developing a stroke or heart attack is too high to wait.

Where is the study run from?
GP surgeries in Bradford Districts Clinical Commissioning Group

When is the study starting and how long is it expected to run for?
August 2015 to November 2016

Who is funding the study?
Lundbeck Ltd (UK)

Who is the main contact?
Dr Carsten Grimm

Contact information

Type(s)
Scientific

Contact name
Dr Carsten Grimm

Contact details

Douglas Mill
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BD5 7JR

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Version 4

Study information

Scientific Title
Bradford Hypertension and Alcohol Intervention Trial: a randomised cluster trial

Acronym
BHAIT

Study objectives
What level of screening and intervention for alcohol use disorder is best compared to a control group to lower blood pressure in newly diagnosed patients?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitted via IRAS - pending

Study design
Randomised controlled cluster trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

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
Alcohol use disorder in patients with newly diagnosed hypertension

Interventions
3 arms: use of screening tool AUDIT-C with brief intervention without further referral versus further referral for a full alcohol use disorder assessment via the primary care alcohol liaison team vs treatment as usual (control group).

Intervention Type
Mixed

Primary outcome measure
Blood pressure reduction (clinic readings) after 12 weeks

Secondary outcome measures
Reduction in alcohol consumed (AUDIT-C) at 3 months.
We are planning to follow up all patients medium to long term in a separately funded study and want to look at annual changes in biometrics (blood pressure, weight), smoking status, updated AUDIT-C as well as healthcare utilisation. There are at present no further concrete plans.

Overall study start date
01/08/2015

Completion date
01/11/2016

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Any patients registered with a GP surgery that forms Bradford Districts Clinical Commissioning Group who is newly diagnosed with hypertension.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants

2000-4000

Key exclusion criteria
Malignant hypertension which requires immediate treatment or hospital admission.

Date of first enrolment
01/08/2015

Date of final enrolment
01/08/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GP surgeries in Bradford Districts Clinical Commissioning Group
Douglas Mill
Bowling Old Lane
Bradford
United Kingdom
BD5 7JR

Sponsor information

Organisation
Bradford Districts Clinical Commissioning Group

Sponsor details
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Sponsor type
Other

ROR
https://ror.org/05wx2c490

Funder(s)

Funder type
Industry

Funder Name
Lundbeck Ltd

Results and Publications

Publication and dissemination plan
We hope to publish by Autumn 2016. If we get sufficient patient numbers recruited (we aim for 2000), earlier.
We can make the basic dataset available (QRISK2, AUDIT-C score, clinic and average BP, biometrics and sociographics, comorbidities). Further data would be extracted from S1 in a separate study.

Intention to publish date
31/10/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request