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Psychological Intervention Alcohol Misuse Learning Disability

Submission date
17/12/2013

Recruitment status
No longer recruiting

Registration date
17/12/2013

Overall study status
Completed

Last Edited
12/09/2017

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Problems associated with alcohol misuse are becoming increasingly common in people with learning disabilities due to much more ready access to alcohol associated with living in the community. There are no specific treatments for people with mild to moderate learning disabilities that can help with harmful use of alcohol. The aim of this study is to examine whether a psychological intervention that is available to adults with Alcohol Use Disorders (AUD), called Extended Brief Intervention (EBI), can be delivered to people with mild to moderate learning disabilities. The National Institute of Health and Clinical Excellence recommends EBI for people with AUD before they receive any more specialist treatment. It includes three to five sessions with a trained professional and follow up in addition to usual care (medical, nursing and social input). There is one study of EBI in people with learning disabilities. These people were patients in a psychiatric hospital and was not compared with usual care. Therefore, the aim of this study is to explore if and how EBI could be offered in the community.

Who can participate?
People from community learning disabilities services in Hertfordshire and North Essex, aged over 18, who have mild or moderate learning disability and who use alcohol in a harmful way.

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 receive their usual care with an additional half-hour EBI session every week and a final one-hour EBI session at eight weeks. Group 2 receive their usual care. The researchers investigate if the study is acceptable, if service users would like to take part, if they can engage clinicians, and if the research questionnaires perform well. Participants and their carers are assessed at the start of treatment, the end of treatment and at 3 months. At around week 12 service users, carers and clinicians are interviewed to find out what they thought of EBI.

What are the possible benefits and risks of participating?
Participants have the chance to receive a treatment for their alcohol problem. This treatment is modified to meet the needs of people with mild to moderate learning disabilities. No side

effects are expected from this treatment. If the study shows that it is feasible to offer EBI to people with mild to moderate learning disabilities, then a bigger study will be carreied to investigate if the addition of EBI to usual care is a better treatment than usual care alone.

Where is the study run from?
The study is organised by the Hertfordshire Partnership NHS Foundation Trust in collaboration with University College London. It takes place in Hertfordshire and North Essex and recruits from all 10 community learning disabilities teams.

When is the study starting and how long is it expected to run for?
January 2014 to February 2015

Who is funding the study?
National Institute of Health Research (UK)

Who is the main contact?
Dr Christos Kouimtsidis
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Contact information

Type(s)
Scientific

Contact name
Ms Sophie Nicholls

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
15271

Study information

Scientific Title

A feasibility study of a psychological intervention to address alcohol misuse for people with mild to moderate learning disabilities living in the community

Study objectives
Can we design a feasible large scale randomised controlled trial that will address whether Extended Brief Intervention is more effective than usual care in helping persons with mild to moderate learning disabilities to manage hazardous or harmful drinking?

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Berkshire, 03/05/2013, ref: 13/SC/0143

Study design
Randomised interventional treatment 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 the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Addictions, Learning difficulties development disorders; Disease: Addictive Substances alcohol, Learning difficulties

Interventions
Based on the guidelines by the MRC, our feasibility study is in three stages:
1. Adaptation of the intervention from existing literature, feedback from professionals and service users with learning disabilities and the therapist (4 months)
2. Completion of a single-blind randomised controlled trial of EBI and usual care versus usual care to investigate whether the study is acceptable and service users can be recruited, whether we can engage clinicians, and whether the instruments we have chosen perform well (24 months)
3. A qualitative study to examine what service users, carers and service providers thought of EBI (overlaps with phase 2)
The duration is 30 months in total. We will use the data from the study to apply for a large trial.

As this is a feasibility study we have not performed a sample size calculation. However, we aim to recruit up to 50 (minimum 40) participants, which will allow us to analyse the data in terms of descriptive statistics and point and interval estimations.

EBI and usual care versus usual care

Extended Brief Intervention, Extended Brief Intervention (EBI) modified as described in stage 1. It will be provided over five half hour weekly sessions and there will be a final one hour session after eight weeks.; Follow Up Length: 3 month(s); Study Entry : Single Randomisation only

Intervention Type
Drug

Phase
Not Applicable

Primary outcome measure
Reduction in primary outcome scores: the percentage of days of abstinence (PDAS) and percentage of days of heavy drinking

Secondary outcome measures
Secondary outcomes will be willingness to change, health status, service use and mental status
Feasibility outcomes: weekly recruitment rates, loss to follow up, compliance rates (number of sessions attended) and basic costs
Completion rates are also measured to assess acceptability

Overall study start date
06/01/2014

Completion date
28/02/2015

Eligibility

Key inclusion criteria
Adults with mild to moderate learning disabilities aged 18 years who are known to professionals within the learning disabilities services as possibly having an alcohol problem will be eligible to be referred to the study. Once found to be eligible to take part, they will be further assessed with the WASI to assess their level of cognitive functioning (unless results from a previous cognitive assessment are available). Once consented to participate, they will be screened using the Alcohol Use Disorder Identification Test (AUDIT).

Inclusion criteria:
1. AUDIT score >8 and up to 19. We appreciate that the NICE (18) advice is to reduce scores in particular populations in which prevalence of AUD is lower than the general population such as older people, females and younger people. Local data, however, suggests that the prevalence of AUD in the local population with mild to moderate learning disability in contact with treatment services using AUDIT 8 as the cut-off point is 22.5%, which is similar to the prevalence in the general population. Therefore, we have decided to adopt the same cut-off AUDIT score as in the general population and to consider any changes, e.g. lowering the cut-off, following the findings from the study.
2. Residents in the area within the last 12 months.
3. Full Scale IQ<70 (+/5% CI).
4. Target Gender: Male & Female; Upper Age Limit 65 years; Lower Age Limit 18 years

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 40; UK Sample Size: 40

Key exclusion criteria
1. Severe to profound learning disabilities
2. Non-English speaking
3. Receipt of treatment for alcohol-related problems in the last 12 months
4. Severe and enduring mental illness
5. Polysubstance misuse including alcohol where the illicit substance, e.g. cocaine/heroin /cannabis is the main problem

Date of first enrolment
06/01/2014

Date of final enrolment
28/02/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Warren Court, Eric Shepherd Forensic Services
Abbots Langley
United Kingdom
WD5 0HT

Sponsor information

Organisation

Hertfordshire Partnership Foundation NHS Trust (UK)

Sponsor details
Hertfordshire Partnership Foundation NHS Trust
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0128dmh12

Funder(s)

Funder type
Government

Funder Name
NIHR (UK) - Research for Patient Benefit (RfPB); Grant Codes: PB-PG1111-26022

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	25/03/2015		Yes	No
Results article	results	12/05/2017		Yes	No
	study manual				

Other publications	01/12/2017		Yes	No
HRA research summary		28/06/2023	No	No