ISRCTN14621127 https://doi.org/10.1186/ISRCTN14621127

Structured preparation for alcohol detoxification

Submission date	Recruitment status	[X] Prospectively registered
20/02/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/02/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
02/08/2021	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Alcohol-related problems are widespread in England. Those most severely affected are dependent drinkers, who have lost control over drinking and need alcohol in order to function every day. Current research shows that rushed attempts to stop using alcohol (detoxifications) do not help patients to stay off alcohol for the rest of their lives. It may be also harmful going through many detoxes and make future attempts to stop drinking even harder. It is important that patients get treatment before being detoxed that gives them the best chance of achieving long term abstinence. Clinicians have developed a group programme to prepare dependent patients before detox. The aim of the programme is to stabilise drinking, to support patients to prepare for a new life without alcohol and to encourage them to attend support after the detox. Small studies have already been done suggesting that this programme is working and that patients are happy to take part. In the future, a large study will be conducted to assess properly if this group programme is effective and suitable for widespread use. This study aims to test this on a small scale to find out information to ensure the full scale study runs smoothly.

Who can participate?
Alcohol dependent patients who attend NHS alcohol community services.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive usual care alone. This involves planning detoxification, detoxing and aftercare with the alcohol community services. Those in the second group take part in the group programme. This involves attending six hour-long sessions in groups of eight, which are run by two trained facilitators. Each session consists of a combination of education with the aim of reducing risk of withdrawal symptoms and helping participants to maintain concentration. After three, six and 12 months, participants in both groups are interviewed in order to find out if and how they are still using alcohol.

What are the possible benefits and risks of participating?
Participants who receive the programme may benefit as it has the potential to improve the lives

of people with alcohol dependency and their families through stabilising drinking and supporting patients to prepare for a new life without alcohol. There are no anticipated risks involved with participating.

Where is the study run from?
1. iHEAR Partnership (UK)
2. Camden Alcohol Service (UK)

When is the study starting and how long is it expected to run for?
March 2016 to November 2019

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

Who is the main contact?
Dr Benjamin Kelly
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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
33554

Study information

Scientific Title
A feasibility study of an intervention for Structured Preparation before detoxification in Alcohol Dependence: the SPADe trial

Acronym
SPADe

Study objectives
The aim of this study is to assess the feasibility of evaluating a group intervention (Structured Preparation for Alcohol Detoxification: SPADe) for adults with moderate to severe alcohol dependence seeking abstinence and attending public alcohol community services, so that a fully powered randomised controlled trial (RCT) can be properly planned and efficiently carried out.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C Research Ethics Committee, ref: 17/SC/0051

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Psychological & Behavioural

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Alcohol misuse

Interventions
Once consented, participants will be randomised using a third-party web-based randomisation system which will ensure concealed allocation developed by UEA. Participants will be stratified according to number of previous detoxifications (>2 vs ≤2) and site. Randomisation will have a random block size (2-6).

Control group: Participants receive usual care alone. This involves planning for detoxification; detoxification delivery; and aftercare. Clients enter detoxification at the first available opportunity (likely to be within 4 weeks from presentation). Whilst waiting for detoxification,

they meet their key worker (one-to-one) on 2-3 occasions to maintain motivation and plan aftercare. Detoxification is medically assisted in the community as an outpatient, or inpatient, as clinically indicated. The choice depends on health risk factors and availability of social support during detoxification. The type of detoxification has been shown by NICE not to affect treatment outcomes. Aftercare (following detoxification) includes peer support groups such as SMART or Alcoholics Anonymous, a small number of individual key worker sessions, and pharmacological interventions as appropriate.

Intervention group: Participants take part in six group sessions in addition to usual care, with the aim of helping participants regain control over their drinking, prior to detoxification. The six sessions are numbered and offered weekly in a given order but each session can act as an entry point (i.e. an open rolling programme group). Each session has two facilitators, lasts for one hour and is divided into three parts:
1. In the first part (15 minutes) group rules are established (as advised in PPI), new members are introduced, aims of the intervention, in-between sessions practice allocated in previous session, and individual targets set for the previous week are reviewed.
2. The second part (30 minutes, main part) explores the following themes depending on session number: 1 –Understand your drinking; 2 – Control your drinking; 3 – Make lifestyle changes; 4 – Reduce alcohol to safer levels; 5 – Review personal treatment plan; 6 – Relapse Prevention strategies.
3. In the third part (15 minutes), the group summarises the main learning points and agree in-between sessions practice and targets to be achieved before the next session. A group work folder will be provided enabling notes and worksheets to be kept together, as suggested in PPI. The number of participants per group at any point is capped at eight, as this is considered appropriate for theory-based treatment groups, to reach a balance between education, treatment, group interactions and facilitator's attention to each participant. This maximum is unlikely to be reached in the feasibility trial. The duration of 1 hour as suggested in PPI, will reduce risk of withdrawal symptoms and help participants to maintain concentration.

Follow up for all participants involves a face to face interview conducted by a research assistant blinded to group allocation and takes place at 3, 6 and 12 months from randomisation.

Intervention Type
Behavioural

Primary outcome measure
1. Duration of continuous abstinence with no incidents of lapse or relapse is assessed by self-report with the use of Time Line Follow Back method at 3, 6 and 12 months post randomisation.
2. Percentage of Days of Abstinence (PDA) is assessed by self-report with the use of Time Line Follow Back method at 3, 6 and 12 months post randomisation
3. Time to relapse is assessed by self-report from randomisation to first day of alcohol use

Secondary outcome measures
1. Severity of alcohol dependence is measured using the Severity of Alcohol Dependence Questionnaire (SADQ) at baseline, 3, 6 and 12 months post randomisation
2. Severity of cravings and urges are measured using the Alcohol Urge Questionnaire at baseline, 3, 6 and 12 months post randomisation
3. Changes in cognitive performance is measured using the Incentive Conflict Task (ICT) at baseline, 3, 6 and 12 months post randomisation
4. Participation in aftercare is extracted from clinical notes retrospectively at 3,6 and 12 months post randomisation

Overall study start date
24/03/2016

Completion date
30/11/2019

Eligibility

Key inclusion criteria
1. Presentation to alcohol services seeking abstinence from alcohol
2. Alcohol dependence (moderate to severe), scoring 16 and above on Severity of Alcohol Dependence Questionnaire (SADQ)
3. Stated intention to stay in the area within the time period of the intervention
4. Willingness to be part of a group intervention if randomised to receive it
5. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 50; UK Sample Size: 50

Total final enrolment
48

Key exclusion criteria
1. Age less than 18 (as not usually treated by specialist alcohol services).
2. Pregnancy: Pregnant women need urgent intervention to come off alcohol, due to the effect of alcohol on the foetus.
3. Known terminal illness with life expectancy of less than 6 months.
4. Severe medical condition that requires urgent medical admission, which would lead to an un-planned medically assisted withdrawal.
5. Severe cognitive impairment that compromises capacity and /or ability to participate in a group intervention.
6. Acute stage of severe and enduring mental illness (schizophrenia, Bipolar Affective Disorder, recurrent depressive disorder: current episode severe), when acute symptomatology compromises client’s ability to participate in a group intervention.

Date of first enrolment
01/10/2017

Date of final enrolment
31/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
iHEAR Partnership
1 Prince Regent Road
London
United Kingdom
TW3 1NE

Study participating centre
Camden Alcohol Service
7-8 Early Mews
Arlington Road
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NW1 7HG

Sponsor information

Organisation
Surrey and Borders Partnership NHS Foundation Trust

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00f83h470

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
A particular effort will be made to involve key stakeholders who are involved directly or indirectly in delivering services in disseminating the results. The study team has excellent links with stakeholders. A lay summary will be produced with the support of our service user representatives. Dissemination will be undertaken at lay venues attended by service users, at GP surgeries and through newsletters, leaflets, peer mentors, using online forums including twitter and also on electronic screen displays in service waiting rooms as recommended by our PPI representatives. Research findings will be presented to community drug and alcohol service teams, mental health teams, service managers and commissioners, with each of the participating sites, and regionally and nationally with the support of Public Health England and Clinical Commissioning Groups. Dissemination to the wider public will be undertaken using public /academic online interfaces ('The Conversation').
The project is adopted by the Mental Health Clinical Academic Group (CAG) of Surrey Health Partners and it will be widely published and results disseminated by the CAG across partners in all academic and research events. Similar dissemination activities will take place at the University of East Anglia, Sussex University and Imperial, using local events and opportunities. Results of the research will be disseminated via (1) presentations at local, regional and national patient and carer forums, following advice on the most appropriate channels of communication taken from our PPI steering group member. (2) Presentations at relevant national and international

conferences (such as Society for the Study of Addiction annual symposium, the Royal College of Psychiatrists annual conference and the Addiction Faculty Annual Meeting). (3) Publication of research papers in peer reviewed, high impact factor journals (the BMJ, the Lancet, Addiction). The findings will also be widely disseminated through the MHRN/CLRN websites and newsletters.

Intention to publish date
30/09/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Christos Kouimtsidis (drckouimtsidis@hotmail.com). Both quantitative and qualitative data will be available from 01/12/2019 and for a period of 5 years.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	27/04/2019	08/05/2019	Yes	No
Results article		29/07/2021	02/08/2021	Yes	No
HRA research summary			28/06/2023	No	No