ISRCTN27417180 https://doi.org/10.1186/ISRCTN27417180

# Alcohol Brief Interventions for men on remand in prison

| Submission date | Recruitment status | [X] Prospectively registered |
|---|---|---|
| 07/12/2018 | No longer recruiting | [X] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 27/11/2019 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 07/05/2024 | Mental and Behavioural Disorders | |

## Plain English summary of protocol

Background and study aims
Approximately 94,000 people are incarcerated in United Kingdom (UK) prisons (95% males). Many frequently suffer from multiple and complex health issues, including mental and physical health problems, learning difficulties and alcohol and drug misuse. The researchers' previous work identified that 80% of participants surveyed in prison have an alcohol use disorder (males on remand: 19% hazardous; 14% harmful; and 49% probably dependent). Alcohol-related crime costs £11 billion per year and as many as 70% of prisoners have admitted to being under the influence of alcohol when committing the crime which led to their imprisonment. Providing support and advice regarding alcohol consumption (often known as an 'intervention') can be effective in some groups of people. It is not yet known whether an alcohol intervention can be delivered or be effective when delivered to men on being held on remand. The aim of the study is to 'test' an alcohol intervention using a small 'trial'. The overall aim is to find out if it is possible and acceptable to deliver an alcohol brief intervention to men on remand in prison and upon liberation. This small trial is often the best way to find out whether a new intervention will work before it can be tested in a larger trial and provided in the longer term.

Who can participate?
Men will be eligible to take part in the study if they are over the age of 18, are being held on remand in one of our recruitment sites and if they score an 8 or above on a questionnaire which is designed to assess whether an individual consumes alcohol at a potentially harmful level.

What does the study involve?
There are two parts to this study. The first is what is known as a feasibility trial. For this part, eligible participants who consent to take part in the study will be asked to complete a set of questionnaires. All participants who take part in the study will complete the questionnaire at three timepoints (at the start of the study, and 6 and 12 months later). The questionnaires assess alcohol consumption, attitudes towards alcohol, general health and well-being, and use of health and social care services.
After participants complete the first set of questionnaires, they will be allocated to either the intervention or control group. Those allocated to the control group will receive care as usual and those allocated to the intervention group will receive an alcohol brief intervention (the APPRAISE Intervention). The APPRAISE Intervention consists of a 40-minute face-to-face session

where the participant will receive information about the impact of alcohol and will be supported to make a detailed plan for reducing their alcohol consumption. If any of the intervention participants are liberated, they will receive three follow-up phone calls each lasting about 20 minutes. The purpose of the phone calls is to check in with participants and to re-confirm goals and strategies for reducing alcohol consumption.
The second part of the research is known as a process evaluation and will be used to help identify whether the APPRAISE intervention is acceptable to participants, intervention staff, and other stakeholders. Data collection for part two will be collected alongside the intervention delivery and through interviews conducted following intervention delivery. As part of the process evaluation the researchers will interview 32 of the men who agreed to take part in the study, 8 members of the intervention team and 8 additional stakeholders (prison staff, commissioners, policy makers, and third sector partners).

What are the possible benefits and risks of participating?
There are no direct benefits to participants, but the results from this study might help the future healthcare of other prisoners. It is not thought that there are any risks or disadvantages to taking part. However, if any participant is distressed for any reason the researcher will ensure that a suitably trained person is made available to speak with the participant.

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

When is the study starting and how long is it expected to run for?
December 2018 to March 2021

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

Who is the main contact?
Victoria Guthrie
Victoria.guthrie@ed.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Prof Aisha Holloway

### ORCID ID
http://orcid.org/0000-0003-3070-3703

### Contact details
Nursing Studies, School of Health in Social Science, Doorway 6, Old Medical Quad, The University of Edinburgh
Edinburgh
United Kingdom
EH8 9AG
+44 (0)131 651 1525
aisha.holloway@ed.ac.uk

# Additional identifiers

### EudraCT/CTIS number
Nil known

### IRAS number

### ClinicalTrials.gov number
Nil known

### Secondary identifying numbers
PHR 17/44/11; CPMS: 44281

# Study information

### Scientific Title
A two-arm parallel group individually randomised Prison Pilot study of a male Remand Alcohol Intervention for Self-efficacy Enhancement: the APPRAISE study.

### Acronym
APPRAISE

### Study objectives
The APPRAISE study is being conducted as a feasibility study, the overall aim is to determine whether it is possible to conduct a randomised control trial in the UK of an evidence-based alcohol brief intervention to men on remand in prison.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Approved 23/08/2019, East of Scotland Research Ethics Service (Tayside Medical Science Centre (TASC), Residency Block Level 3, George Pirie Way, Ninewells Hospital and Medical School, Dundee, DD1 9SY, UK; Tel: +44 (0)1382 383 878; Email: eosres.tayside@nhs.net), ref: LR/19/ES /0068

### Study design
Two-arm, interventional, parallel group, individually randomised controlled trial, pilot study

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Community, Prison/detention, Telephone

### Study type(s)

Treatment

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

## Health condition(s) or problem(s) studied
Harmful, hazardous or dependent alcohol consumption

## Interventions
Participants will be randomised to the intervention or control condition using pre-determined envelopes. Those in the control group will receive care as usual and those in the intervention condition will receive the APPRAISE alcohol brief intervention which consists of a 40-minute intervention delivered face to face in the prison by trained interventionists who are independent from the study.

The intervention condition will be delivered by CGL staff. The APPRAISE intervention comprises of nine elements (10.2.1) to be delivered in 4 steps: Step 1 will comprise a 1 x 40-minute face-to face session in which the 9 elements will be covered, delivered by a trained staff member from Change Grow Live (CGL) in the prison setting. Steps 2, 3 and 4 are 20-minute sessions conducted by phone, at 3 days, 1 week and 3 weeks post liberation respectively, by the same staff member who delivered Step 1. The post liberation sessions will include elements 1 (preliminary discussion), 5 (situation-appraisal), 6 (goal setting), 7 (relapse), 8 (self-evaluation/self-reinforcement and 9 (culmination).

All participants will be followed up at 6 and 12 months after recruitment.

## Intervention Type
Behavioural

## Primary outcome measure
Total alcohol consumed in a 28-day period will be measured using the 28 day time line follow back questionnaire (TLFB-28) at TP1 and TP2.

## Secondary outcome measures
Secondary outcome measures will be completed at TP0, TP1 and TP2:
1. Alcohol use frequency, quantity (on a typical occasion) and binge drinking will be assessed using the Alcohol Use Disorder Identification Test (AUDIT).
2. Mental wellbeing will be assessed using the Warwick-Edinburgh Mental Well-being scale (WEMWBS).
3. Readiness to change will be measured using the Readiness to Change Ruler which measures readiness to change drinking behaviour.
4. Self-reported alcohol self-efficacy will be measured using the Drinking Refusal Self-efficacy Questionnaire – revised (DRSEQ-R)
5. Alcohol expectancy will be measured using the Negative Alcohol Expectancy Questionnaire (NAEQ).
5. Social costs (including in the domains of health care use, criminal justice involvement, unemployment, and work absences, and motor vehicle accidents) will be measured using Euroqol EQ-5D -5L and the economic form 90.

## Overall study start date

01/12/2018

### Completion date
31/03/2021

# Eligibility

### Key inclusion criteria
Current inclusion criteria as of 13/01/2021:

1. Informed consent given
2. Men aged 18 years or over
3. Have been in prison for three months or less on the current charge
4. Score 8 or more on the AUDIT
5. Detained in either of the study sites within the SPS or HMPS

_____

Previous inclusion criteria:

1. Men aged 18 years and over
2. Have been in the prison setting for three months or less
3. Over or equal to 8 on the AUDIT screening tool
4. Detained in either the Scottish Prison Service (SPS) Scottish study site or Her Majesty's Prison Service (HMPS) North East England study site

### Participant type(s)
Other

### Age group
Adult

### Lower age limit
18 Years

### Sex
Male

### Target number of participants
180

### Key exclusion criteria
Current exclusion criteria as of 13/01/2021:

1. Previously recruited to APPRAISE
2. Unable to give informed consent or deemed incompetent/unable to make an informed decision regarding consent
3. Identified as a risk to self and/ or others by prison staff
4. Judged to be under the influence of an illicit substance by prison or research staff
5. Currently taking Disulfiram (frequently referred to as Antabuse
6. On a segregative rule (under prison rules)

7. Not able to understand the documents (English language) or agree to the researcher aiding their understanding

_____

Previous exclusion criteria:

1. Risk to self and/or others. Including: nature of crime charged with or identified as 'risky' through Suicide Risk Management
2. At risk, due to being using any illicit substances
3. Being placed on a segregative rule under the prison rules
4. Not able to understand the documents, which are in the English language or agree to the Research Assistant (RA) working with them to understand them

### Date of first enrolment
01/12/2019

### Date of final enrolment
01/06/2020

## Locations

### Countries of recruitment
England

Scotland

United Kingdom

### Study participating centre
**HMP Prison Edinburgh**
33 Stenhouse Road
Edinburgh
United Kingdom
EH11 3LN

### Study participating centre
**HMP Prison Durham**
19 Old Elvet
Durham
United Kingdom
DH1 3HU

## Sponsor information

### Organisation
The University of Edinburgh

### Sponsor details
57 George Square
Edinburgh
Scotland
United Kingdom
EH8 9JU

### Sponsor type
University/education

### ROR
https://ror.org/01nrxwf90

## 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
To find out the best way to carry out the trial, the researchers have met with people who have been in prison and others who are involved in providing alcohol support and advice.

The researchers will share the results of the trial with a range of people including, those who take part in the study, prison services (including healthcare), prison staff, through short reports, academic papers, meetings and social media.

The researchers will be submitting the protocol for publication in 2020. Planned publication of the results in a high-impact peer-reviewed journal by 01/04/2022.

## Intention to publish date
01/04/2022

## Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository and are not expected to be made available due to the nature of the study.

## IPD sharing plan summary
Not expected to be made available

## Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 02/04/2021 | 06/04/2021 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Basic results | | | 07/05/2024 | No | No |