ISRCTN10723141 https://doi.org/10.1186/ISRCTN10723141

Assessing the impact and effectiveness of alcohol care teams targeting adults with alcohol dependence admitted to NHS hospitals in England

Submission date
10/10/2023

Recruitment status
Recruiting

Registration date
01/11/2023

Overall study status
Ongoing

Last Edited
28/07/2025

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
The number of alcohol-related hospital admissions in England is increasing each year. Prolonged, high-risk alcohol consumption is linked to over 60 medical diseases and conditions which commonly require inpatient care including cardiovascular disease, cancer, and liver disease as well as harms caused by accidents and injuries. Individuals may also experience common mental health problems such as depression and anxiety, as well as memory problems. Those who develop alcohol disorders, including harmful drinking, alcohol dependence and alcohol-related liver disease, and are frequently admitted to hospital, experience a range of problems requiring treatment. Alcohol care teams (ACTs) provide specialist support and care for people with alcohol-related problems who are admitted to hospital or who attend accident and emergency. These teams aim to improve the quality of care for people admitted to hospital who have alcohol-related problems and reduce admissions and hospital attendance. Hospitals have received additional NHS funding to develop or expand ACTs, however, there is limited evidence as to the effectiveness of ACTs for individuals who experience alcohol problems. The aim of this study is to evaluate the effectiveness of hospitals with an established optimised alcohol care team compared to hospitals with no alcohol care team intervention for people with alcohol dependence, based on the quantity of alcohol consumed 6 months after admission.

Who can participate?
Current hospital inpatients at one of the six study sites can participate if they meet the criteria for alcohol dependence, are aged 18 years or older, are well enough and willing to take part, and are able to take part in a follow-up interview 6 months later.

What does the study involve?
This study will include 545 patients from six participating hospitals across England. Three hospitals will have well-established, optimised alcohol care teams and three sites will have no alcohol care team and minimal or no alcohol care provision. Current inpatients in these hospitals who meet the study criteria will be provided with information about the study and invited to

participate. Participants will meet with a researcher in a private area of the ward or hospital. First, participants will be asked to sign a consent form on a computer. They will then be invited to answer a questionnaire with a researcher to ensure that they meet all the study inclusion criteria. If participants meet the study inclusion criteria, they will be asked to complete a series of questionnaires with the researcher. These will include questions about the participant and their home environment, how much alcohol they have drunk on each day in the last month, problems associated with drinking alcohol, how participants have been feeling recently, and the health and social care services they have recently used. The questions will take around one hour to answer. All participants will then be contacted again 6 months later, and they will be asked the same questions. The follow-up questionnaires can be administered over the telephone, online or in person.

What are the possible benefits and risks of participating?
There may not be any direct benefits of taking part, but it is hoped that this research will help to find out whether alcohol care teams have an impact on the lives of people with alcohol-related problems who are admitted to hospital. As required by the funder, the findings will be shared with policymakers, who will use the information to make decisions about future services. Some people may find talking about their feelings, experiences and past or current drinking upsetting. Participants will not have to answer any questions that they do not want to answer and if they become upset, they will be able to take a break or stop the interview completely. Participants may find answering the questions tiring. They can take as many breaks as they need during the research interviews and, if needed, they will have the option to finish answering the questions at another time.

Where is the study run from?
Institute for Clinical and Applied Health Research at the University of Hull (UK)

When is the study starting and how long is it expected to run for?
May 2021 to May 2027

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

Who is the main contact?
Maddie Wilkinson, ProACTIVE Trial Manager, proactive@hull.ac.uk

Study website
https://www.hull.ac.uk/work-with-us/research/institutes/health-trials/study/proactive

Contact information

Type(s)
Scientific

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Principal Investigator

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Type(s)
Principal Investigator

Contact name
Prof Julia Sinclair

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
330296

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 58437, IRAS 330296

Study information

Scientific Title
Prospective pragmatic quasi-experimental study to assess the impact and effectiveness of alcohol care teams (ACTs) targeting adults with alcohol dependence admitted to NHS Hospitals in England: the ProACTIVE prospective patient study

Study objectives
Primary hypothesis:
Optimised alcohol care teams will be no more effective than no or minimal alcohol care provision in terms of self-reported alcohol consumption, measured using Timeline Follow Back 28 at 6 months.

Secondary hypothesis:
Optimised alcohol care teams will be no more cost-effective than no or minimal alcohol care provision at 6 months.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/10/2023, London - Hampstead Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, UK; +44 (0)207 1048345; hampstead.rec@hra.nhs.uk), ref: 23/LO/0797

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital, Other

Study type(s)
Treatment

Participant information sheet

See study outputs table

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

Interventions
Current interventions as of 11/07/2025:

This is a quasi-experimental study comparing patient outcomes from three hospital sites with optimal alcohol care teams (oACT) (based on the NHS England and NHS Improvement guidance: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/11/ACT-wh at-are-we-proposing-and-why-011119.pdf) to outcomes of patients matched through propensity score matching from three hospital sites with minimal or no specialist alcohol provision (NoACT). Propensity score matching will allow an equivalent control group to be derived in the absence of randomisation to intervention versus control group. A quasi-experimental design has been adopted because Alcohol Care Teams are already in place across England; therefore, a randomised controlled trial study design would not be appropriate for this research.

Sample and sample size:
A total of 545 current inpatients with a diagnosis of alcohol dependence will be recruited to take part in this research. This number will comprise 245 participants from oACT sites and 300 from NoACT sites. The higher number of participants from NoACT sites is to allow for propensity score matching. Over the 6-month recruitment window, we conservatively estimate at least 250 potential participants will be admitted to each of the six hospitals, and we aim to identify and approach 350 across the intervention hospitals and 428 across the controls, of whom we anticipate 70% will consent leading to a target recruitment sample of 545 participants. This recruitment estimate is sufficient to allow for estimation of at least a small, yet clinically important, standardized effect size difference in the quantity of alcohol consumed between the groups of 0.3 with 90% power and a two-sided alpha of 0.05.

Approaching patients:
Clinical staff in the hospitals will identify potentially eligible participants who they consider well enough to participate. Clinical staff will introduce the study and seek verbal agreement from the patient for the researcher to approach them and discuss the study further. The clinician will provide the patient with the summary and/or full participant information sheet (PIS).

Informed consent and initial assessment:
If patients agree to speak with a researcher, the researcher will ensure that they have received the full PIS. Potential participants will be given as long as they need to consider the research. This will be a minimum of 30 minutes. Although a longer minimum time period was considered, 30 minutes was chosen because (1) the average admission for a patient with alcohol dependence is 3 days, meaning that there is likely to be a short window between the individual being well enough to participate and being discharged; (2) the ProACTIVE PPI representative who reviewed the protocol felt that some people would prefer to take part straight away and (3) a similar project set in UK emergency departments successfully implemented a 30 minute period for considering the PIS (IRAS 275280).

If people are interested in taking part, they will meet with the researcher in a confidential area of the ward/hospital. The clinical team will be made aware of where they are in case the patient is needed. The researcher will go through the PIS in full, answering any questions the patient may have and if the patient wishes to proceed they will be asked to sign an electronic consent form.

For consenting patients, all inclusion and exclusion criteria will be reviewed and a diagnosis of alcohol dependence will be confirmed using the Composite International Diagnostic Interview (CIDI)-alcohol.

Baseline data collection:
Baseline data collection can take place immediately after consent or at a later time if requested and will take place in a confidential area of the ward/hospital. Data will be collected on demographic characteristics (age, sex, living situation, family environment, socioeconomic status). Data on comorbid conditions will be collected from patient
records only for those participants who (optionally) consent to this. These data will be used for propensity score matching and characterising the sample. Data on alcohol consumption over the past month (primary outcome) will be collected using the TimeLine Follow Back - 28 day. Data on alcohol use disorders, alcohol dependence severity, alcohol-related problems, quality of life, wellbeing, common mental disorders, any co-occurring drug use and use of health and care services over the past 6 months will be collected via validated measures. This interview will take approximately 1 hour. Participants will be able to take as many breaks as needed.

Follow-up data collection:
Six months following baseline data collection, participants will be contacted to take part in a follow-up interview. Participants will have provided their contact details during the consent process. They will also have had the opportunity to provide (optional) consent for the study team to contact one or more family members and/or friends to support locating the participant should their contact details have changed.

This interview will take place either over the telephone, video call, or face-to-face in a community or healthcare setting. The follow-up interview will repeat all of the measures from the baseline interview, except the demographic data and (optional) the Charlson comorbidity Index. This interview will take approximately 1 hour. Participants will be able to take as many breaks as needed.

The ProACTIVE Public Advisory Group (PAG) is a group of people with lived experience of alcohol-related problems. The PAG have advised on all participant-facing documents and the lay summary included in this application. In advance of recruitment to this study starting, a researcher manual will be developed in conjunction with the ProACTIVE PPI Coordinator and it will be discussed with, and reviewed by, the PAG in order to ensure that all researchers on the project approach participants/potential participants with sensitivity and support participants to complete the questionnaires in a way which maximises participant wellbeing whilst also ensuring data fidelity.

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Previous interventions as of 27/06/2025:

This is a quasi-experimental study comparing patient outcomes from three hospital sites with optimal alcohol care teams (oACT) (based on the NHS England and NHS Improvement guidance: https://www.longtermplan.nhs.uk/wp-content/uploads/2019/11/ACT-wh at-are-we-proposing-and-why-011119.pdf) to outcomes of patients matched through propensity score matching from three hospital sites with minimal or no specialist alcohol provision (NoACT). Propensity score matching will allow an equivalent control group to be derived in the absence of randomisation

to intervention versus control group. A quasi-experimental design has been adopted because Alcohol Care Teams are already in place across England; therefore, a randomised controlled trial study design would not be appropriate for this research.

Sample and sample size:
A total of 735 current inpatients with a diagnosis of alcohol dependence will be recruited to take part in this research. This number will comprise 245 participants from oACT sites and 490 from NoACT sites. The higher number of participants from NoACT sites is to allow for propensity score matching. Over the 6-month recruitment window, we conservatively estimate at least 250 potential participants will be admitted to each of the six hospitals, and we aim to identify and approach 350 across the intervention hospitals and 700 across the controls, of whom we anticipate 70% will consent leading to a target recruitment sample of 735 participants. This recruitment estimate is sufficient to allow for estimation of at least a small, yet clinically important, standardized effect size difference in the quantity of alcohol consumed between the groups of 0.3 with 90% power and a two-sided alpha of 0.05.

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wellbeing, common mental disorders, any co-occurring drug use and use of health and care services over the past 6 months will be collected via validated measures. This interview will take approximately 1 hour. Participants will be able to take as many breaks as needed.

Follow-up data collection:
Six months following baseline data collection, participants will be contacted to take part in a follow-up interview. Participants will have provided their contact details during the consent process. They will also have had the opportunity to provide (optional) consent for the study team to contact one or more family members and/or friends to support locating the participant should their contact details have changed.

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Previous interventions as of 25/06/2025:

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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Quantity of alcohol consumed is measured using the Timeline Follow-Back (TLFB)-28 day for alcohol at baseline and 6 months

Secondary outcome measures
1. Percent days abstinent from alcohol is measured using the Timeline Follow-Back (TLFB)-28 day for alcohol at baseline and 6 months
2. Quantity and type of substance used and percent days abstinent from each substance is measured using the Timeline Follow-Back (TLFB)-28 day for drugs at baseline and 6 months
3. Alcohol misuse is measured using the Alcohol Use Disorders Identification Test (AUDIT) at baseline and 6 months
4. Alcohol-related problems are measured using the Alcohol Problems Questionnaire (APQ) at baseline and 6 months
5. Severity of dependence is measured using the Severity of Dependence Questionnaire (SADQ) at baseline and 6 months
6. Mental health and wellbeing are measured using the Short Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS) at baseline and 6 months
7. Depressive symptoms are measured using the Patient Health Questionnaire (PHQ-9) at baseline and 6 months
8. Symptoms of anxiety are measured using the Generalised Anxiety Disorder scale (GAD-7) at baseline and 6 months
9. Health-related quality of life is measured using the EQ-5D-5L at baseline and 6 months
10. NHS and community resource use is measured using the Client Service Receipt Inventory (CSRI) at baseline and 6 months

Overall study start date
01/05/2021

Completion date
31/05/2027

Eligibility

Key inclusion criteria
1. Adult aged >= 18 years
2. An ICD-10 diagnosis alcohol dependence as measured by CIDI-alcohol
3. Patient admitted to a participating hospital
4. Agrees to be contacted by the research team and participate in a follow-up interview at 6 months
5. Judged by clinical staff to be medically and psychologically fit enough to participate in the study
6. Willing and able to provide informed consent to take part in the trial

Participant type(s)
Patient

Age group
Adult

Lower age limit

18 Years

Sex
Both

Target number of participants
545

Key exclusion criteria
1. Severe physical/mental illness likely to preclude active participation in baseline or follow-up interviews
2. Current participation in another research study
3. Unable to adequately understand verbal English due to the majority of the validated measures being available in English only
4. Currently prescribed opioid substitution therapy

Date of first enrolment
10/01/2024

Date of final enrolment
28/02/2026

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Rotherham General Hospital
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
St Helier Hospital
Wrythe Lane
Carshalton
United Kingdom
SM5 1AA

Study participating centre

Doncaster Royal Infirmary
Armthorpe Road
Doncaster
United Kingdom
DN2 5LT

Study participating centre
St Thomas' Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre
Chelsea and Westminster Hospital NHS Foundation Trust
Chelsea & Westminster Hospital
369 Fulham Road
London
United Kingdom
SW10 9NH

Study participating centre
Hull University Teaching Hospitals NHS Trust
Hull Royal Infirmary
Anlaby Road
Hull
United Kingdom
HU3 2JZ

Study participating centre
Scarborough General Hospital
Woodlands Drive
Scarborough
United Kingdom
YO12 6QL

Sponsor information

Organisation

University of Hull

Sponsor details
Cottingham Road
Hull
England
United Kingdom
HU6 7RX
+44 (0)1482 464454
researchgovernance@hull.ac.uk

Sponsor type
University/education

Website
https://www.hull.ac.uk

ROR
https://ror.org/04nkhwh30

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR152084

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and reports to key stakeholders

Intention to publish date
31/05/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 1.2	02/10/2023	01/11/2023	No	Yes
Protocol file	version 1.0	21/07/2023	01/11/2023	No	No
Participant information sheet	version 3.0	11/10/2024	27/06/2025	No	Yes
Protocol file	version 3.0	11/10/2024	27/06/2025	No	No