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Assertive outreach treatment for alcohol related admissions

Submission date
02/11/2016

Recruitment status
No longer recruiting

Registration date
22/11/2016

Overall study status
Completed

Last Edited
17/03/2020

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Harmful alcohol consumption is a major public health problem, and is the third leading cause of disability in Europe. The Department of Health estimates that alcohol costs the NHS in England £3.5 billion each year, 80% of which through inpatient and emergency care costs. Alcohol-related hospital admissions have doubled in the last eight years to over 1.2m per annum in England, a quarter (304,000) of which were for conditions wholly attributable to alcohol. Reducing alcohol related admissions is therefore a key public health target in England. An intervention called assertive outreach treatment (AOT) has been developed to target the patients who have the most frequent alcohol related hospital admissions. AOT emphasises active engagement over an extended period and has several features, including rapid access to services, a small caseload, a high ratio of community to office-based appointments, assertive engagement (e.g. with multiple attempts) and a shared care approach, with care coordinators working within a multidisciplinary team that meets frequently. The aim of this study is to assess the effectiveness and cost effectiveness of AOT plus care as usual (CAU) compared with CAU alone for patients who have frequent alcohol related admissions.

Who can participate?
Adults with alcohol dependence who have been admitted to hospital at least twice in the last year, with at least one admission attributable to alcohol; has presented to the emergency department at least four or ten times in the last year; and had been admitted at last once for in-patient care due to alcohol and has been to A&E at least four times in the last year.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive care as usual. Those in the second group receive assertive outreach treatment plus care as usual. This involves receiving support from the assertive outreach team, in the form of regular contact with the care co-ordinator over 12 months. The appointments take place in the participant's preferred location (home, local neighbourhood or at the service). Participants in both groups complete a number of questionnaires at the start of the study and then again after 6 and 12 months to assess alcohol consumption.

What are the possible benefits and risks of participating?
Participants may experience health benefits if the treatment helps them to cut down their alcohol consumption. There is a small risk that some participants may feel uncomfortable filling in the study questionnaires.

Where is the study run from?
1. King's College Hospital (UK)
2. South London and Maudsley NHS Trust (UK)
3. Guy's Hospital (UK)
4. St Thomas' Hospital (UK)
5. St George's Hospital (UK)
6. University Hospital Lewisham (UK)

When is the study starting and how long is it expected to run for?
January 2013 to December 2018

Who is funding the study?
1. National Institute for Health Research (UK)
2. Guy's and St Thomas' Charity and National Institute for Health Research (UK)

Who is the main contact?
Professor Colin Drummond
colin.drummond@kcl.ac.uk

Contact information

Type(s)
Scientific

Contact name
Prof Colin Drummond

Contact details
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Additional identifiers

Protocol serial number
20808

Study information

Scientific Title
Development and evaluation of an assertive outreach treatment for patients who have frequent alcohol related admissions to in-patient care in King's Health Partners

Study objectives
The aim of this study is to assess if assertive outreach treatment plus care as usual is effective, in terms of increasing the proportion of days abstinent from alcohol, and cost effective in patients with frequent alcohol related hospital admissions when compared to care as usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee: London – Harrow Research Ethics Committee, 06/04/2016, ref: 16/LO/0411

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

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Mental Health, Primary sub-specialty: Addictions - alcohol; UKCRC code/ Disease: Mental Health/ Unspecified mental disorder

Interventions
Participants are randomised to one of two groups using an electronic allocation system.

Control group: Participants will receive care as usual (CAU). This may include treatment of presenting physical or mental health problems and referral to specialist addiction services for ongoing help with alcohol related problems. Patients receiving CAU have access to medical detoxification, psychological interventions targeting drinking behaviour and aftercare, which is usually provided by specialist addiction services. The emphasis will be on the patient’s own motivation to engage with available services.

Intervention group: Participants will receive assertive outreach treatment (AOT) plus care as usual (CAU) for 12 months. AOT is an established model of care for patients with psychotic disorders, which has proven feasible as an approach with alcohol related frequent attenders. AOT is flexible and adapted to the needs of the individual patients. AOT will incorporate the following elements:
1. A maximum caseload of 15 AOT patients per AOT practitioner
2. Care provided by a multidisciplinary team (including psychiatrists, community addiction nurses, substance misuse specialists, community support workers)
3. Frequent and regular contact between practitioner and patient (at least once a week)

4. Assertive engagement – persistent and repeated attempts by the practitioner to make contact, with the emphasis being on maintaining contact and building relationships and rapport
5. Content of sessions will focus on both health and social care needs – including accommodation, finance (timely payment of household bills), leisure, occupation, and physical and mental health, with an emphasis on a patient-led agenda
6. Flexibility – practitioners should work flexibly with patients' goals even when these are peripheral to the addiction
7. Openness – practitioners are explicit about their goals both in care planning and in visits
8. Practitioners step outside of professional roles and going the extra mile for patients
9. Extended care – AOT will be provided for a prolonged period of 1 year during which patients will be introduced to other existing community services who will ultimately provide them with on-going support in the longer-term

Participants in both groups are followed up after 6 and 12 months.

Intervention Type
Other

Primary outcome(s)
Percent days abstinent in the 90 days prior to 12 months follow up measured using the Time Line Follow Back (TLFB) Form 90 administered at baseline, 6 and 12 months.

Key secondary outcome(s))
1. Drug use will be measured using the Time Line Follow Back (TLFB) Form 90 at baseline, 6 and 12 months
2. Alcohol related problems will be assessed using the Alcohol Problems Questionnaire (APQ) at baseline, 6 and 12 months
3. Severity of dependence will be measured using the Severity of Alcohol Dependence Questionnaire (SADQ) at baseline, 6 and 12 months
4. Health related quality of life will be measured using the EQ-5D-5L and the Short-Form Health Survey at baseline, 6 and 12 months
5. Participants' use of services will be measured using the Alcohol and Drug Adapted Adult Service Use Schedule (AD-SUS) at baseline, 6 and 12 months
6. Potential mechanisms of action of assertive outreach treatment will be measured using the Readiness to Change questionnaire and the Important People and Activities Inventory at baseline, 6 and 12 months
7. The therapeutic relationship between the participants and the care providers will be measured using the STAR rating scale at 12 months

Completion date
30/09/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 05/06/2017:
1. Age 18 years or over
2. Able to understand English sufficiently well to obtain informed consent and complete the assessment questionnaires
3. ICD-10 diagnosis of alcohol dependence
4. Willing to provide informed consent to participate in the trial

5. Has been admitted at least two times to in-patient care in any of the participating NHS trusts with at least one diagnosis wholly attributable to alcohol, within a one year period
or
6. Has at least ten presentations to an Emergency Department in any of the participating NHS trusts, within a one year period
or
7. Has at least four presentations to an Emergency Department in any of the participating NHS trusts, within a month
or
8. Has been admitted at least one time to in-patient care with a diagnosis wholly attributable to alcohol and has at least four presentations to an Emergency Department in any of the participating NHS trusts, within a one year period

Original inclusion criteria:
1. Age 18 years or over
2. Able to understand English sufficiently well to obtain informed consent and complete the assessment questionnaires
3. Has been admitted at least three times to in-patient care in any of the three NHS trusts within King's Health Partners with at least one diagnosis wholly attributable to alcohol, within a one year period
4. ICD-10 diagnosis of alcohol dependence
5. Willing to provide informed consent to participate in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Unable to give informed consent
2. Experiencing severe mental of physical illness likely to preclude active participation in the treatment or research follow up
3. Already in receipt of assertive outreach services or participation in another trial
4. Dependence on opiates or stimulants
5. Has a severe cognitive impairment as determined by Mini Mental State Examination score of ≤ 10
6. Has a history of violence to staff or is registered under MAPPA
7. Street homeless or has no recourse to public funds

Date of first enrolment
02/08/2016

Date of final enrolment
30/11/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
King's College Hospital
Denmark Hill
London
United Kingdom
SE5 9RS

Study participating centre
South London and Maudsley NHS Trust
Michael Rutter Centre
Denmark Hill
London
United Kingdom
SE5 8AZ

Study participating centre
Guy's Hospital
Great Maze Pond
London
United Kingdom
SE1 9RT

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

Study participating centre

St George’s Hospital
Blackshaw Road
London
United Kingdom
SW17 0QT

Study participating centre
University Hospital Lewisham
Lewisham High Street
London
United Kingdom
SE13 6LH

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
South London and Maudsley NHS Foundation Trust

ROR
https://ror.org/015803449

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

Funder Name
Guy's and St Thomas' Charity

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The current 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?
Protocol article	protocol	14/03/2020	17/03/2020	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V1.2	22/03/2016	22/11/2016	No	Yes
Participant information sheet	version V1.2	22/03/2016	22/11/2016	No	Yes
Participant information sheet	version V1.2	22/03/2016	22/11/2016	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes