ISRCTN17083622 https://doi.org/10.1186/ISRCTN17083622

ADAM: Alcohol dependence and adherence to medicine

Submission date	Recruitment status
16/09/2015	No longer recruiting
Registration date	**Overall study status**
16/09/2015	Completed
Last Edited	**Condition category**
06/11/2023	Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Alcohol dependence, also called alcoholism, is a growing problem worldwide. When a person becomes physically or mentally dependent on alcohol, it can be very difficult to stop. Acamprosate is a medication which works by reducing cravings for alcohol. When taken as directed, it can be very effective at making sure people do not start drinking again. Many people who are prescribed it do not take it consistently however, which reduces its effectiveness. Medication management (MM) is a programme designed to help people to following their medication treatment plans. It works by providing support and advice, as well as educating people about their drinking behaviours and the importance of taking their medication. MM has been used to help support people take their medication in clinical trials but not in routine care. Contingency management (CM) uses rewards, such as small financial incentives, to encourage people to stick to their treatment plans. There is evidence that these techniques are effective for treating drug addiction, however there is limited research exploring its effectiveness in alcohol dependency. The aim of this study is to find out if MM and CM are effective in helping alcohol dependent people follow their acamprosate treatment plans.

Who can participate?
Alcohol dependent adults who are currently sober, and are being treated with acamprosate.

What does the study involve?
Participants are randomly allocated into three groups. The first group receives standard care only for the entire study period. Participants in the second group receive standard care in addition to 12 MM sessions over a 6 month period. Participants in the third group receive standard care and the 12 MM sessions, but they are also given incentives in the form of vouchers for attending the MM sessions, as part of a CM programme.

What are the possible benefits and risks of participating?
A potential benefit is that if the interventions are successful in improving acamprosate adherence, then it could decrease the risk of alcohol relapse. This could help will long-term alcohol abstinence, leading to improvements in health and quality of life. Risks of participating are minimal. There is a possibility of psychological discomfort when completing the questionnaires, however the potential benefits are believed to outweigh this risk.

Where is the study run from?
National Addiction Centre (UK)

When is the study starting and how long is it expected to run for?
September 2015 to November 2020 (updated 03/09/2020, previously: May 2020)

Who is funding the study?
National Addiction Centre (UK)

Who is the main contact?
Dr Kim Donoghue
kim.donoghue@ucl.ac.uk

Study website
http://www.kcl.ac.uk/ioppn/depts/addictions/research/alcohol/ADAM-Alcohol-Dependence-and-Adherence-to-Medications.aspx

Contact information

Type(s)
Public

Contact name
Dr Kim Donoghue

ORCID ID
http://orcid.org/0000-0002-7316-1716

Contact details
Department of Clinical, Educational and Health Psychology
University College London
London
United Kingdom
SE5 8BB
+44 (0)20 7679 1897
kim.donoghue@ucl.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 19571

Study information

Scientific Title
A three-arm randomised controlled trial of the effectiveness and cost-effectiveness of adjunctive medication management and contingency management to enhance adherence to medications for relapse prevention in alcohol dependence

Acronym
ADAM

Study objectives
The aim of this study is to improve the adherence to acamprosate in order to maximise the benefits for patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge South, 17/09/2015, 15/EE/0308

Study design
Randomized; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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
Alcohol dependence

Interventions
Contingency Management (CM), Providing small financial or other incentives to change behaviour and/or
engage with treatment. Incentives in the form of vouchers will be provided to reinforce attendance at the Medication Management sessions that are delivered by telephone with the pharmacist.; Medication Management (MM), MM is an intervention to help improve medication and treatment adherence by providing education, support and advice to patients about their drinking behaviours and medication. In this study, it will be delivered by specially trained

pharmacists via a central telephone support service. Participants are randomly allocated into three groups:

Group 1: Standard support only
Group 2: Standard support with Medication Management (MM)
Group 3: Standard support with Medication Management (MM) and Contingency Management (CM)

Participants receiving MM will receive 12 sessions over a 6 month period (weekly for 6 weeks, fortnightly for 6 weeks and monthly for 3 months).

Intervention Type
Other

Primary outcome measure
Proportion of medication taken as prescribed measured using Medication Events Monitoring (MEMS) Cap, pill count and self reporting over 24 weeks.

Secondary outcome measures
1. Alcohol related problems, severity of dependence and cravings measured using the alcohol problems questionnaire (APQ), the severity of alcohol dependence questionnaire (SADQ) and the Alcohol Urge Questionnaire (AUQ) 6 months post randomisation
2. Economic status measured using the Health related Quality of life (EQ-5D-5L) and Adult service use (modified ADSUS) at 6 and 12 months
3. Process outcomes measured using beliefs about medication questionnaire (BMQ) at baseline and 6 months, and scale to assess relationships (STAR) at 6 months
4. Proportion of prescribed medication taken measured using self reporting at 12 months post randomisation
5. Time to first drink, relapse to heavy drinking, relapse to any drinking measured using self reporting at 12 months post randomisation
6. Total alcohol consumed, drinks per drinking day and percentage of abstinence measured over the past 90 days using the timeline follow-back method at 6 and 12 months post randomisation

Overall study start date
01/12/2014

Completion date
30/11/2020

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Diagnosis of alcohol dependence
3. Currently alcohol abstinent
4. Prescribed acamprosate by treating clinician

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 748; UK Sample Size: 748; Description: Participants will be randomised to one of three trail arms in the order of 2:1:1;1. Standard support N = 374,2. Standard support plus medication management N = 1873. Standard support plus medication management with contingency management N = 187

Total final enrolment
739

Key exclusion criteria
1. Severe physical/mental illness likely to preclude active participation in treatment or follow up
2. Current participation in another trial
3. Unable to adequately understand verbal English
4. Currently dependent on an illicit substance

Date of first enrolment
30/09/2015

Date of final enrolment
11/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
National Addiction Centre
4 Windsor Walk
Denmark Hill
London
United Kingdom
SE5 8BB

Sponsor information

Organisation
King's College London

Sponsor details
Room 1.8
Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/0220mzb33

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
Preliminary qualitative work has been completed to inform the trial protocol. This includes four focus groups with service users and four focus groups with pharmacists. It is planned to publish the results of this work in a peer reviewed journal in the later part of 2015. A plain language

summary of the research and it’s results will also be developed and disseminated to those who took part in the research, service user research groups and to the general public via the study webpage.

The primary results of the full trial will be published in a peer reviewed journal, open-access following completion of the 12 month follow-up in approximately December 2018. A plain language summary will be produced and disseminated to those who took part in the research and service user groups. There are also plans for the research to be disseminated via national, international and service user led conferences.

Intention to publish date
30/11/2021

Individual participant data (IPD) sharing plan
Trial data will be stored securely by King's College London. All data requests should be submitted to the Chief Investigator for consideration. Access to anonymised data may be granted following review.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Results article		01/10/2023	06/11/2023	Yes	No