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Randomised controlled feasibility trial of a web-based alcohol treatment programme

Submission date
04/10/2013

Recruitment status
No longer recruiting

Registration date
16/04/2014

Overall study status
Completed

Last Edited
28/06/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
This is an initial investigation before a much larger study. We want to find out if an online alcohol treatment programme called HELP-Drink (Healthy Living for People who Drink), which mirrors a face-to-face alcohol treatment provided at a Community Alcohol Service (CAS), is as effective and acceptable as the face-to-face treatment, for people who drink too much alcohol.

Who can participate?
Adults, referred by a health professional or self-referred, willing and able to use an online treatment, can participate.

What does the study involve?
Participants will be randomly allocated to one of two groups: HELP-Drink or usual face-to-face treatment by specialist alcohol workers. Those allocated to HELP-Drink will receive access to the online programme and those allocated to usual face-to-face treatment will have to make weekly visits to see the specialist. All participants will be asked to complete a questionnaire after completion of the study.

What are the possible benefits and risks of participating?
This online programme provides high quality information on alcohol use with methods to help people cut down or stop drinking. This programme offers additional support of facilitated access to the website. It also provides prompts via email/text/phone call to encourage participants to use the website. Participants need not attend appointments, which incur travel costs. There is the potential risk of patients reading information that they are not expecting. With this particular website, this risk is reduced firstly because users are able to use the website selectively by only accessing information which is of interest to them, and secondly because information on the website is provided with additional support linking the participant to a dedicated alcohol counsellor, who is able to refer to more intensive services if required. Participants do have to meet the costs of internet access either through their existing home Internet arrangements, or at public internet access points such as internet cafes, however participants will be signposted to local facilities which provide free Internet access.

Where is the study run from?
Research Department of Primary Care and Population Health, University College London (UK).

When is the study starting and how long is it expected to run for?
The study starts in May 2014 and runs for 30 months.

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

Who is the main contact?
Dr Fiona Hamilton
f.hamilton@ucl.ac.uk

Study website
http://www.downyourdrink.org.uk/

Contact information

Type(s)
Scientific

Contact name
Prof Elizabeth Murray

Contact details
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London
United Kingdom
NW3 2PF

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Randomised controlled feasibility trial of a web-based intervention to reduce consumption in people with 'hazardous and harmful' alcohol intake compared with a face-to-face intervention

Study objectives
The overall aim of the trial is to determine the most cost-effective and acceptable method of delivering interventions to hazardous or harmful drinkers referred, or self-referred, to Community Alcohol Services (CAS). We intend to compare two methods of delivering interventions of proven effectiveness: (i) facilitated access to a web-based programme (comprising Motivational Interviewing, Behavioural Self Control, Cognitive Behavioural Therapy and Relapse Prevention) or (ii) usual CAS face-to-face treatment.
Our null hypothesis is that both delivery methods will be equally effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London Bloomsbury NRES Committee, 16/06/2014, ref:14/LO/0664, amendment approved 22/09/2014

Study design
Randomised controlled feasibility trial

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Hazardous or harmful alcohol use

Interventions
Potential participants will be patients referred or self-referred to participating community alcohol services. They will attend the CAS for their first assessment appointment with an alcohol counsellor as usual, where the counselor will record baseline measures including previous week's alcohol consumption and current levels of anxiety. If at the end of the assessment appointment the counsellor decides the patient meets the inclusion criteria to enter the trial, they will tell them about the trial and give them a participant information sheet. Interested eligible patients will then be consented by the alcohol counsellor at the end of their assessment appointment, and also asked for consent for the trial manager to contact them by phone or text after a 24-hour 'cooling off' period to see if they still want to participate in the trial (see patient information sheet and consent form).

If they do still want to participate in the trial they will be randomised by computer to HELP-Drink or face-to-face treatment at the CAS, and given a date for the facilitated introduction to the website at a convenient location, or for treatment as usual at the CAS.
1. Participants randomised to HELP-Drink will access one online module a week for six weeks, supported by tailored text messages and/or phone calls.
2. Participants randomised to face-to-face treatment will attend weekly for the standard number of appointments (usually six).

At 90 days after completing their treatment programmes, all participants will be contacted by email to complete online outcome measure questionnaires (including a measure of satisfaction with the intervention and whether they dropped out of the treatment to which they were randomised).

25/05/2018: Amendment made
The RCT was split into two sequential studies due to poor initial recruitment necessitating a change in recruitment strategy.
Study 1
Recruitment was from community drug and alcohol services. Study 1 started 01/10/14 and ran till 01/08/15.
Study 2
Recruitment was from hospital emergency departments and from online adverts on alcohol support websites. Study 2 ran from 01/10/15 to 01/10/16. The inclusion and exclusion criteria were the same as for Study 1. The intervention and control treatment were also the same as for Study 1.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 20/06/2018:
1. Recruitment as a percentage of eligible patients
2. Retention, measured by completeness of online data collection at 3 months as a percentage of patients randomised

Previous primary outcome measures:
The outcomes examined at three months and 12 months will be:
1. Recruitment
2. Study attrition
3. Change in unit consumption of alcohol per week (using TOT-AL, an online beverage-specific measure which requires participants to enter the type and quantity of alcohol drinks consumed on each day of the past week)

Secondary outcome measures
Current secondary outcome measures as of 20/06/2018:
1. Average alcohol intake in units measured using TOT-AL, an online beverage-specific measure, at baseline, 1 and 3 months
2. Problem drinking assessed using AUDIT at baseline and 3 months
3. Psychological distress assessed using CORE-10 at baseline and 3 months
4. Confidence in avoiding alcohol assessed using SCQ-8 at baseline and 3 months
5. Satisfaction with care assessed using CSQ-8 at 3 months
6. Adherence to the intervention (for those randomised to this arm), measured through

automated recording of numbers of log-ins and numbers of pages visited at each log-in, at 3 months
7. Other sources of support accessed during treatment, measured using a drop down menu of options: group therapy; horticulture; acupuncture; art therapy; other therapies (participant to state in free text); at 1 and 3 months

Previous secondary outcome measures:
1. Demographic and clinical characteristics will be recorded at baseline, which will enable us to determine if there are inequalities in access to the online alcohol programme
Secondary outcomes examined at three months and 12 months will be:
2. Change in participant satisfaction with care (measured using the 8-item Client Satisfaction Questionnaire (CSQ-8)
3. Change in Hospital Anxiety and Depression scale
4. Change in well-being scores (using EQ-5D)
5. Health professional time (a proforma will be used to record health professional time in minutes taken in both interventions, including failed encounters)

Overall study start date
28/03/2013

Completion date
01/10/2016

Eligibility

Key inclusion criteria
1. Participants will be hazardous and harmful drinkers in north London, identified using a validated screening tool such as AUDIT, referred from primary care, secondary care, or self-referred, to CAS.
2. Patients aged 18 or over at time of screening
3. Diagnosis of an alcohol use disorder using AUDIT criteria (score 8 or over)
4. Residing in a stable place of residence
5. Providing informed consent for randomisation, treatment and follow-up
6. Patients without prior internet experience, or without home access to the internet will be included, but will be offered additional training as part of their facilitated access to DYD. All participants will be given information about local free or low-cost public internet access points, such as libraries, health centres and cluster rooms.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

At least 200 patients

Key exclusion criteria
1. Patients undergoing treatment for substance use or primary drug dependence (excluding nicotine) in the past 90 days
2. Already receiving help for an alcohol use disorder
3. Outstanding legal issues likely to lead to imprisonment
4. Severe mental or physical illness likely to preclude active participation in treatment or follow-up
5. Severe physical dependency on alcohol (LDQ > 20)
6. Unable to consult in English without an interpreter
7. Pregnancy
8. Patients with severe physical dependency or severe and complex co-existing physical or mental health problems will be referred for Tier 4 services in line with DH guidelines
9. Patients at risk of high risk of self-harm or suicide will not be excluded, but will be referred back to their GP for additional help

Date of first enrolment
03/03/2014

Date of final enrolment
01/10/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
HAGA - Action on Alcohol
171 Park Lane
London
United Kingdom
N17 0HJ

Study participating centre
CASA - CASA Alcohol - Blenheim CDP
332C Goswell Road
London
United Kingdom
EC1V 7LQ

Study participating centre

CGL (Change, grow, live - formerly CRI)
184 Royal College Street
Camden
London
United Kingdom
NW1 9NN

Study participating centre
Primary Care Alcohol & Drug Services (PCADS)
15b Hornsey Street
London
United Kingdom
N7 8GG

Study participating centre
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Study participating centre
University College London Hospital
2bu, 235 Euston Road
London
United Kingdom
NW1 2BU

Study participating centre
Royal Free Hospital
Pond Street
London
United Kingdom
NW3 2QG

Study participating centre
North Middlesex Hospital
Sterling Way
London
United Kingdom
N18 1QX

Study participating centre
Barnet Hospital
Wellhouse Lane
Barnet
United Kingdom
EN5 3DJ

Sponsor information

Organisation
University College London (UCL)/Royal Free London NHS Foundation Trust (UK)

Sponsor details
Joint Research Office
Rowland Hill Street
London
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United Kingdom
NW3 2PF
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Sponsor type
University/education

Website
http://www.ucl.ac.uk/jro/index

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
University College London (UCL) Partners/National Institute for Health Research (NIHR) CLAHRC (UK)

Results and Publications

Publication and dissemination plan
Planned publication of the study results in a high-impact peer reviewed journal.

Intention to publish date
03/02/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from help-alcohol@ucl.ac.uk

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	08/08/2015		Yes	No
Results article	results and process evaluation	21/08/2017		Yes	No
Results article	results	15/06/2018		Yes	No
HRA research summary			28/06/2023	No	No