Self help interventions for alcohol use

Submission date 12/08/2014	Recruitment status No longer recruiting	[X] Prospectively registered
		☐ Protocol
Registration date 22/08/2014	Overall study status Completed	Statistical analysis plan
		☐ Results
Last Edited	Condition category	☐ Individual participant data
18/12/2020	Mental and Behavioural Disorders	[] Record updated in last year

Plain English summary of protocol

Background and study aims

Many people who drink too much (regardless of whether they are experiencing alcohol related problems or not) do not seek treatment services. Due to the costs to the individual and society of heavy drinking, it is necessary to find ways to help those who could benefit from reducing the amount of alcohol they drink. The internet provides the opportunity to provide treatment services (i.e. interventions) to people in their own homes. There are many websites which claim to help people to change their drinking habits, but many have not been assessed for their usefulness and safety. Previous research (in Canadian adults) has demonstrated that the amount of alcohol people drink can be reduced through the use of two web-based self help methods (interventions). Here, we want to find out whether these same interventions also work in the UK, and whether a full large scale study to find out how well they work is practical.

Who can participate?

Adults (aged 18 or over) who are heavy drinkers

What does the study involve?

Participants will be randomly allocated to one of four groups. Group one will receive the Check Your Drinking site which is a basic intervention based on comparing alcohol consumption to others who are similar in age, sex and location. Group two will receive access to the Alcohol Help Center site which has more tools to explore individual alcohol use. Group three will receive access to Check Your Drinking first and Alcohol Help Centre after three months. Group four will be asked about elements they consider important in alcohol self-help programs. Participants will be contacted at the start of the study and followed up at three and six months. They will also be contacted (and separate consent will be given) to take part in qualitative interviews to discuss their experience in more depth.

What are the possible benefits and risks of participating?

Information from this study will be used to develop future alcohol self-help program, to better understand alcohol use and to develop trial methods in online interventions. Participants receive £10 vouchers for each questionnaire returned. There are limited risks to taking part but participants will be informed of sources of help should they have concerns about either their own or others alcohol use. There are both general contact details (Alcohol Concern) and more specific details for each region of the UK.

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

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

The study will start recruitment in August 2014 and follow up will end in March 2015. The study will continue until December 2015.

Who is funding the study?

The HSC research and development division of the Public Health Agency (Northern Ireland) (UK)

Who is the main contact? Dr Gillian W Shorter

Contact information

Type(s)

Scientific

Contact name

Dr Gillian Shorter

Contact details

University of Ulster, Northland Road, Londonderry United Kingdom BT48 7JL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers STL/4971/14

Study information

Scientific Title

Self Help Interventions to Reduce Alcohol Consumption

Acronym

SHIRAC

Study objectives

As this is a feasibility (external) pilot study the aims are:

1. To assess the impact of minimal and full internet based self help interventions for hazardous drinkers in the UK compared with no intervention control

- 2. To determine the rates of recruitment and retention using online methods and evidence the feasibility of the trial methods in the UK context
- 3. To understand the barriers and facilitators of behavior change in hazardous drinkers in the UK context (using qualitative research methods)

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Ulster, Psychology Filter Committee, 05/08/2014

Study design

Randomized allocation to one of four arms; Masking: Double blind (subject and statistician assessing outcomes) Single centre

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Internet/virtual

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

Heavy alcohol use, alcohol dependence

Interventions

Behavioural: Check your drinking (CYD)

Internet based programe of lower intensity compared to the Alcohol Help Centre. Designed to assess drinking patterns, increase awareness of triggers and set/achieve goals related to alcohol use reduction.

Behavioural; Alcohol Help Centre (AHC)

Internet based program of higher intensity as compared to the CYD intervention above. Designed to assess drinking patterns, increase self-awareness of individual triggers and set or achieve alcohol reduction goals. Designed for repeated use.

Arm one receives CYD

Arm two AHC

Arm three CYD then AHC three months later

Arm four receives a no intervention control but are asked to describe what they would consider key components of alcohol self-help interventions to be

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Alcohol consumption as measured by the total score on the Alcohol Use Disorders Identification Test, quantity and frequency of past month alcohol consumption, highest number of drinks on occasion, and standard drinks consumed in the past week. Measured at baseline, three months and six month intervals.

Secondary outcome measures

- 1. Alcohol Use Disorders Identification Test Consumption factor
- 2. Alcohol Use Disorders Identification Test Problem factor
- 3. Drinking refusal self-efficacy
- 4. Rates of recruitment and retention
- 5. Intervention use
- 6. Barriers and facilitators of change

Overall study start date

25/08/2014

Completion date

31/12/2015

Eligibility

Key inclusion criteria

- 1. Resident in the UK
- 2. Aged 18 years or over
- 3. Hazardous drinking indicated by a score of eight or more on the Alcohol Use Disorders Identification Test
- 4. Access to the internet

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Around 400 randomized from 1000 recruited

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

25/08/2014

Date of final enrolment

31/12/2015

Locations

Countries of recruitment

Northern Ireland

United Kingdom

Study participating centre University of Ulster

Londonderry United Kingdom BT48 7JL

Sponsor information

Organisation

HSC Public Health Agency Research & Development Division (UK)

Sponsor details

Public Health Agency 12-22 Linenhall Street Belfast United Kingdom BT2 8BS

Sponsor type

Government

Website

http://www.publichealth.hscni.net

ROR

https://ror.org/03ek62e72

Funder(s)

Funder type

Government

Funder Name

HSC Research & Development Division, Public Health Agency, Northern Ireland (UK): Reference STL/4971/14

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration