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Experimental evaluation of the Swedish National Alcohol Helpline

Submission date
21/11/2015

Recruitment status
No longer recruiting

Registration date
18/01/2016

Overall study status
Completed

Last Edited
15/02/2023

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
Drinking harmful amounts of alcohol can damage a person's health and can lead to both social and economic costs. The Swedish National Alcohol Helpline provides telephone counselling to people that indulge in harmful and hazardous drinking who wish to change their drinking habits. The main aim of this study is to compare the effect of the current telephone counselling provided by the helpline, based on Motivational Interviewing techniques (treatment as usual), with a treatment based on self-help material and proactive follow-up counselling.

Who can participate?
Adults (aged at least 18) calling the Swedish National Alcohol Helpline for the first time in order to receive support to change their alcohol drinking habits

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 receive counselling currently offered by the Swedish National Alcohol Helpline (treatment as usual). The counselling is delivered according to each participants preference and involves Motivational interviewing and Cognitive Behavioural Therapy. Participants in group 2 are given a self-help booklet with information and exercises to help them change their alcohol drinking habits, followed by one session via telephone by a counsellor from the Helpline. All participants are assessed for their alcohol drinking habits and other health related statuses by telephone interview at the beginning of the study, as well as six and twelve months later.

What are the possible benefits and risks of participating?
Changes in alcohol drinking habits is very likely to lead to improvements in health and well-being. There is no risk of direct physical harm to participating in this study.

Where is the study run from?
Department of Public Health Sciences, Karolinska Institutet (Sweden)

When is study starting and how long is it expected to run for?
October 2014 to December 2018

Who is funding the study?
1. Public Health Agency of Sweden
2. Stockholm County Council

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled study comparing the effectiveness of two counselling models at the Swedish National Alcohol Helpline in promoting changes of drinking habits among persons with hazardous or harmful alcohol use.

Acronym
AlC_HL

Study objectives
Current hypothesis as of 10/05/2017:
An alternative, partly proactive counselling model complemented by self-help material is more

effective than the current on-demand counselling model in promoting change in a client's alcohol drinking habits, measured by shift to lower AUDIT risk levels 6 and 12 months after the initial contact.

Previous hypothesis:
An alternative, partly proactive counselling model complemented by self-help material is as effective as the current on-demand model in promoting change in a client's alcohol drinking habits, measured by AUDIT scores 6 and 12 months after the initial contact.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical Review Board of Stockholm Region, 06/11/2014, ref: 2014/1732-31/5

Study design
Current study design as of 10/05/2017:
Single-centre superiority pragmatic randomized trial

Previous study design:
Single-centre non-inferiority pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Available in Swedish at: http://alkohollinjen.se/om-alkohollinjen/studier-pa-alkohollinjen/pagaende-studie/

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

Interventions
Participants are randomly allocated to one of two treatments:
1. The Alcohol Helpline's free-of-charge telephone service (treatment as usual) designed to provide support to persons whose alcohol-related problems are moderate to severe. The current counselling is based on Motivational Interviewing (MI) combined with elements of Cognitive Behaviour Therapy and is adapted to the severity of the problems and to the changes that the client is ready to adopt. In practice, the intervention for a specific individual may consist of a varying number of client-activated (reactive) and/or counsellor-activated (proactive) sessions according to the client's preference.
2. The alternative counselling model which includes the delivery of self-help booklet followed by

a proactive call where the Helpline counsellor monitors the client's progress and use of the material. The material is designed as a guide to the change of alcohol use patterns.

Intervention Type
Behavioural

Primary outcome measure
Change of alcohol drinking habits measured with AUDIT score. The outcome assessment will be done at 6 and 12 month follow-up for each participant in the trial. Since entry in the trial will be at different dates the follow-up will follow a staggered schedule.

Secondary outcome measures
1. Depression or anxiety disorder (GAD) measured through MINI
2. Number of days of sick leave
3. Care seeking from other services for alcohol problems

The outcome assessment will be done at 6 and 12 month follow-up for each participant in the trial. Since entry in the trial will be at different dates the follow-up will follow a staggered schedule.

Overall study start date
01/10/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. First time caller of the National Alcohol Helpline
2. Seeking support to change his/her own alcohol drinking habits
3. At least 18 years of age
4. Provide informed consent

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300

Total final enrolment

261

Key exclusion criteria
1. Very severe alcohol problems requiring clinical treatment
2. Abuse of other drugs
3. Severe mental illness
4. Acute health problems

Date of first enrolment
27/05/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Centre for Epidemtiology and Community Medicine, Stockholm County Council
Tomtebodavägen 18a
Stockholm
Sweden
17177

Sponsor information

Organisation
Karolinska Institute

Sponsor details
Department of Public Health Sciences
Tomtebodavägen 18a
Stockholm
Sweden
17177

Sponsor type
University/education

Website
http://www.ki.se

ROR

https://ror.org/056d84691

Organisation
Centre for Epidemiology and Community Medicine, Stockholm County Council

Sponsor details
Tomtebodavägen 18a
Stockholm
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17177

Sponsor type
Government

Funder(s)

Funder type
Government

Funder Name
Public Health Authority of Sweden

Funder Name
Stockholms Läns Landsting

Alternative Name(s)
Stockholm County Council

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Sweden

Results and Publications

Publication and dissemination plan

Intention to publish date
31/03/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	06/06/2017		Yes	No
Results article	results	08/07/2019	18/03/2020	Yes	No
Results article		27/04/2021	15/02/2023	Yes	No