







Experimental evaluation of the Swedish National Alcohol Helpline

Submission date 21/11/2015	Recruitment status No longer recruiting	 Retrospectively registered
Registration date 18/01/2016	Overall study status Completed	 Protocol added
Last Edited 15/02/2023	Condition category Mental and Behavioural Disorders	 SAP not yet added
		 Results added
		 Raw data not yet added
		 Study completed

Plain English Summary

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?

Prof. Maria Rosaria Galanti
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Contact information

Type(s)

Scientific

Contact name

Prof Maria Rosaria Galanti

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Protocol/serial number

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 hypothesis

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/>

Condition

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

Overall study end date

31/12/2018

Eligibility

Participant 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

Participant exclusion criteria

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

Recruitment start date

27/05/2015

Recruitment end date

31/12/2017

Locations**Countries of recruitment**

Sweden

Study participating centre

Centre for Epidemiology 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
Sweden
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