

Online self help program for concerned significant others of someone with an alcohol problem

Submission date 12/02/2019	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 04/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 18/05/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Alcohol problems are stigmatizing not only for the people drinking themselves but also for their concerned significant others (CSO's). It has become more and more evident over the last decades that the second hand effects of alcohol- or other dependence problems - are huge both at a personal and societal level. Being a CSO of someone with Alcohol Use Disorder is associated with increased levels of both mental health problems and somatic disorders. Despite this many relatives refrain from seeking help due to e.g. feelings of shame and failure.

Web-based interventions have advantages due to possible anonymity and accessibility, facilitating for people who otherwise wouldn't seek help to take part of treatment programs. For this study a web-based self-help program consisting of four modules of Community Reinforcement Approach and Family Training (CRAFT) was developed with the intention of helping CSO's increasing their psychological health and via new strategies increasing the possibility of their loved ones lowering their alcohol consumption and entering treatment. Different parental management training programs (PMT's) have shown a lot of positive results during the last decades. The programs often aim at reinforcing positive parental behaviors and strengthening the parent-child relationship. One such Swedish program called ABC (Alla barn i centrum – All Children in the Center) has been used as an add-on feature for parents with a child between 3-11 y/o to investigate if this enhances the effects of the program, especially on the SDQ-outcome.

Who can participate?

Anyone over 18 years old who has a close relationship with a person with alcohol use disorder.

What does the study involve?

Participants are recruited from the Swedish public via websites and online advertisement. For participation they must first register as a user on one of the online help sites Alkoholhjälpen.se (the Alcohol help) or Anhörigstödet.se (help for relatives). After registration participants fill out questionnaires which works both as inclusion/exclusion and baseline measurement. Participants are divided with regards of having children in the right age or not. Participants who do not share a child with their IP are randomized into one of two groups: either access to the full web-based

self-help CRAFT-program or an educational material (control group). Parents who share a child between 3-11 y/o with their IP are randomized to one of two groups: either access to the full web-based self-help CRAFT-program with the ABC add-on or an educational material. After three months the participants from both the control groups receive access to the full program.

What are the possible benefits and risks of participating?

We have not been able to detect any risks of participation in the study. Answering questions about one's own or a concerned significant other's use of alcohol/drugs and how this might affect shared children can be associated with negative emotions. The possible benefits of participation outweighs this given that it might help organizing the present situation that for many concerned significant others is perceived as rather (or very) chaotic. It might also lead to a higher overall quality of life for the participant and a safer environment for children living with parental alcohol or drug problems.

If this project is successful it will make available an evidence based, easy access, self-help program for CSO's possibly helping many thousands of people who otherwise wouldn't receive any help.

Where is the study run from?

Stockholm Centre for Dependency Disorders, Riddargatan 1, Stockholm, 11435

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

October 2017 to December 2022

Who is funding the study?

Folkhälsomyndigheten (Public Health Agency of Sweden), SE-171 82 Solna, Sweden

Who is the main contact?

Magnus Johansson, magnus.johansson.1@ki.se

Study website

<http://www.anhorigstodet.se>

Contact information

Type(s)

Public

Contact name

Dr Magnus Johansson

Contact details

Mottagningen för e-stöd

Riddargatan 1

Stockholm

Sweden

11435

+46812345783

magnus.johansson.1@ki.se

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Folkhälsomyndigheten 03136-2015

Study information

Scientific Title

Effects on levels of self reported depression, anxiety and stress from a web-based, self help Community Reinforcement Approach and Family Training (CRAFT) program for concerned significant others of someone with alcohol use disorder

Acronym

Web-CRAFT

Study objectives

CRAFT presented as an online self-help intervention is superior in reducing levels of depression, anxiety and stress compared to a brief online psychoeducation-only material.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 10/02/2017, Regional Ethics Review Board in Stockholm, (Stockholm ethical committee, Stockholms tingsrätt, Box 8307, 104 20 Stockholm, Sweden; +46-8-524 800 00; stockholm@rdn.jordbruksverket.se), ref: 2016/2179-31

Study design

Single-centre interventional two-arm randomized controlled superiority trials

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Alcohol use disorder, mental health among concerned significant others

Interventions

Participants who are concerned significant others (CSO) of an identified person (IP) with alcohol use disorder (AUD), but do not present AUD themselves, will be recruited from the general public.

This study involves three subgroups:

- A. Parents who share a child (3-11 years) with a person with AUD
- B. CSOs dealing with severe problems (CSOs mental health, IP illicit drugs or partner violence from IP)
- C. CSOs without severe problems or children (3-11 years)

Included participants in each subgroup are randomized 1:1 to:

Arm 1: Sequential four-module self-help program comprising psychoeducation and exercises from Community Reinforcement Approach And Family Training (CRAFT), with therapist support as needed.

Arm 2: Basic psychoeducation about alcohol use disorder (AUD), being a concerned significant other to someone with AUD and where to look for further help.

Primary outcome will be the participant's mental health. Additional outcomes will cover the IP's drinking and treatment seeking as well as parent self-efficacy, parent-child relationship and child's mental health (for parents). Measures will be collected pre-, mid- and post-treatment, and three times during a two-year follow-up period.

Participants eligible for inclusion will be automatically randomised (allocation tickets drawn from a predetermined block-randomised scheme that is reshuffled prior to each draw; no stratification) on accessing their assigned (blinded) treatment program for the first time.

The therapists providing program-support are located at the Centre for dependency disorders in Stockholm, Sweden

The control group will be given access to a brief psychoeducation program, split into four modules and distributed in the same manner as the intervention program (modules made available as completed, although with a minimum 1-week waiting period).

Intervention Type

Behavioural

Primary outcome measure

Participant's total score on Depression, Anxiety and Stress Scale (DASS-21), measured at screening (baseline), mid-treatment (completion of 2/4 modules or maximum of 4 weeks into treatment), post-treatment (4/4 modules or maximum of 8 weeks into treatment), 3, 12 and 24 months after completing treatment.

Secondary outcome measures

All secondary outcomes are measured at screening (baseline), mid-treatment (completion of 2/4 modules or maximum of 4 weeks into treatment), post-treatment (4/4 modules or maximum of 8 weeks into treatment), 3, 12 and 24 months after completing treatment.

For all participants:

1. Participant's depression subscore on the Depression Anxiety and Stress Scale (DASS)
 2. Participant's anxiety subscore on the Depression Anxiety and Stress Scale (DASS)
 3. Participant's stress subscore on the Depression Anxiety and Stress Scale (DASS)
 4. Number of contacts with support groups, health care professionals for both participant (CSO) and IP.
 5. Participant's alcohol consumption measured using the three-item Alcohol Use Disorder - Identification Test (AUDIT-C)
 6. IP's alcohol consumption measured using the AUDIT-C
 7. IP's number of ICD-10 alcohol dependence criteria met
- For parents:
8. Child's externalizing subscore of the SDQ
 9. Child's internalizing subscore of the SDQ
 10. Participant's parental self-efficacy (custom scale)
 11. Participant-child relationship quality measured using the Adult Child Relationship Scale (ACRS)

Overall study start date

01/04/2016

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. 18+ years old
2. Sufficient grasp of Swedish
3. A close relationship to someone who meets AUD criteria, defined as an AUDIT-C score of >3/4 (women/men) and/or meeting ≥ 2 ICD-10 dependence criteria

For participation in subgroup A the following inclusion criteria must also be fulfilled:

4. Co-parent with AUD: meets AUD criteria, defined as an AUDIT-C score of >3/4 (women/men) and/or meeting ≥ 2 ICD-10 dependence criteria
5. Shared child: aged 3-11
6. Shared child: lives >3 days per month with AUD parent
7. Shared child: scores above the clinical cut-off on any of the five sub-scales of the Strengths and Difficulties Questionnaire (SDQ).

Participant type(s)

Other

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Key exclusion criteria

1. Participant (CSO): Meets AUD criteria, defined as an AUDIT-C score of >3/4 (women/men) and /or meeting ≥2 ICD-10 dependence criteria
2. Participant (CSO): use of illicit drugs at least one per week during last 12 months.

Date of first enrolment

30/10/2017

Date of final enrolment

31/08/2019

Locations**Countries of recruitment**

Sweden

Study participating centre

Stockholm Centre for Dependency Disorders

Riddargatan 1

Stockholm

Sweden

11435

Sponsor information**Organisation**

Karolinska Institutet

Sponsor details

Centre for Psychiatry Research

Norra Stationsgatan 69

Stockholm

Sweden

11364

+46 8 123 457 00

info@psykiatriforskning.se

Sponsor type

University/education

Website

<http://psykiatriforskning.se/>

ROR

<https://ror.org/04hmgwg30>

Funder(s)

Funder type

Government

Funder Name

Folkhälsomyndigheten

Alternative Name(s)

Public Health Agency of Sweden

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Sweden

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/10/2023

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request

IPD sharing plan summary

Available on request