

A trial of a web-based Community Reinforcement and Family Training (CRAFT) program for people with relatives with alcohol use disorders

Submission date 27/01/2016	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2016	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/05/2022	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

Excessive alcohol consumption (drinking too much) is one of largest health risk factors worldwide, contributing to many diseases and early deaths. The severe effects of a person being dependent on excessive drinking (alcohol use disorder or AUD) affect both the person themselves (referred to as identified person (IP)) and those closest to them. It is estimated that that 4-5 other people are heavily affected by every IP. These can include family members, friends, relatives (referred to as concerned significant other (CSO)) and work colleagues. The consequences may vary from emotional or psychiatric problems to psychological or actual physical violence. CSOs have shown to be more likely to develop psychiatric problems such as depression s and anxiety when compared to the general population. Research has shown that CSOs try to change a IPs drinking behaviour in a number of ways, including neglecting the IP, threats and persuasion. CSOs may wish to force the IP to a treatment facility, encourage the IP to stop drinking by their own free will, or to improve the relationship between IP and CSO. There is, at present, no evidence available as regards to how much a CSO can influence a IPs drinking behavior or their own well-being. It is possible that CSOs could play a key role in motivating a IP to seek treatment. This is because a CSO spends a lot of time with a IP, providing them with many opportunities for encouraging behavior change (participate in treatment or cut down on the amount of drinking). Since CSOs often have to cope with stressful situations caused by excessive drinking (for example, marriage difficulties, financial worries) they are often very motivated to improve their situation, by encouraging the IP to change their behavior. The aim of the present project is to see how well a web-based Community Reinforcement Approach and Family Training (CRAFT) program for CSOs works in increasing the number of IPs that seek treatment for their AUD while improving the well-being of the CSOs themselves.

Who can participate?

Adults with a relative, spouse, partner or someone living with them that has a AUD.

What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given access to the CRAFT program for 5 weeks. Those in group 2 are placed on a waiting list for 24 weeks; they are given access to the CRAFT program after this time. The CRAFT program helps participants to change their approach to the IP, in order to best help them take steps to combat their drinking problem. The program is assessed by seeing how many IPs seek help for their drinking problem and the well-being of the CSO.

What are the possible benefits and risks of participating?

Possible benefits include the participant being able to manage their IPs drinking problem more effectively and improve their own well-being. Possible risks include discomfort from sharing information about the IP or a negative response, which may involve threats of violence, when communicating with their IP about their AUD.

Where is the study run from?

Karolinska Institutet (Sweden)

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

January 2016 to December 2017

Who is funding the study?

Research Council of the Swedish Alcohol Retail Monopoly

Who is the main contact?

1. Mrs Karin Romberg (public)

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Study website

<https://craft.rg1.se>

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information**Scientific Title**

An RCT of a web-based Community Reinforcement and Family Training (CRAFT) program to increase treatment engagement for alcohol use disorders and to improve psychiatric health for relatives

Acronym

eCRAFT

Study objectives

Participation in internet administered CRAFT program with minimal support for relatives to alcohol-dependent people will increase participation in addiction treatment compared with a waiting list.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Etikprövningsnämnden (Central Ethical Review Board) in Stockholm, Sweden, ref: 2014/2157-31/4

Study design

Multicentre randomized controlled trial

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 disorders (AUD)

Interventions

A web-based Community Reinforcement and Family Training (CRAFT) program.

CSOs (concerned significant other) who are eligible for inclusion are randomized to either a CRAFT-program for 5 weeks or a waiting list for 24 weeks. The web-based CRAFT-program is modeled after the treatment manual developed by Smith and Meyers and comprises the same basic elements. The program consists of five program-modules administered over five consecutive weeks, which in all comprises key components of CRAFT.

Each module consists of the same basic structure: Participants are

1. Presented with an introduction to the module, describing the rationale for improving coping skills in the specified area. The introduction is presented both in written text, as well as short films containing both auditory and visual information;
2. Presented to exercises designed to improve coping skills. The exercises aim at involving the CSO in altering behaviors in relation to both IP and other significant areas which the CSO specifies during the program. The results of the exercises are presented to the study therapist (Working as a specialist within the field of AUD and who has a special education and training both in the CRAFT-model and in web-based treatment programs) through the interactive service in the program
3. Receiving exercise feed-back from the therapist. The personalized feed-back is aimed to further improve coping skills for the CSO, and is presented in a detailed manner following the principles of motivational interviewing (MI). The therapist follow a pre-specified check-list in order to ensure that core components of the CRAFT-training are completed. When the therapist has provided feed-back, the module is completed, and a new module is presented to the CSO. The frequency of modules is limited to one per week.

The modules are:

1. Introduction to CRAFT.
2. CSO self-reinforcement training
3. Functional analysis of drinking – describe typical situations in which IP consume alcohol and its consequences.
4. Communication training
5. Positive reinforcers for non-drinking behaviors, i.e. incentives for increasing the probability for a behavior to be repeated, which imply non-alcohol related IP behaviors
6. Negative consequences – to:

- 6.1. withdraw something pleasurable for the IP when he or she consume alcohol
- 6.2. the “natural consequences procedure” which imply not to compensate for or to fix the negative consequences of IP alcohol related behavior, e.g. to not clean up bottles and other left-over’s following a messy evening.
7. CSO inviting IP to seek treatment – an ultimate goal for many CSO:s may be that an IP receives or at least take an initiative to engage in AUD treatment. The aim of the last module is to prepare the CSO:s for a conversation with the IP concerning treatment. The module includes the following exercises:
 - 7.1 Identify a promising treatment provider that the IP may accept
 - 7.2. Identification of most appropriate time-point to approach the IP for a conversation regarding treatment, based on knowledge of drinking patterns, motivational factors and relational factors
 - 7.3. Conversation practices based on communication skills acquired in earlier modules
 - 7.4. Preparation for different types of outcomes of the conversation (e.g. a negative reaction)

Intervention Type

Behavioural

Primary outcome measure

Proportion of people identified as having a AUD (IPs) engaging in treatment seeking behavior, as measured by:

1. Identified IPs calling a pre-specified telephone number to a specialized center for telephone-based advice concerning alcohol problems (Alkohollinjen)
2. CSO's self-reports of initiatives from IPs to seek treatment. An initiative is defined as at least one conversation with a specialized treatment provider by telephone or by a regular visit to an addiction treatment clinic.

Both primary measures regard from start of the program until 6, 12 and 24 weeks post start of the program. Comparisons are made between CSOs taking part in the CRAFT-program vs. waiting list.

Secondary outcome measures

1. IPs alcohol consumption (according to CSO estimates)
2. Anxiety and depression symptoms for CSOs
3. Relational satisfaction of CSOs
4. Quality of life for CSOs

Measures regard from start of the program until 3, 6, 12 and 24 weeks post start of the program.

Overall study start date

01/01/2016

Completion date

31/12/2017

Eligibility

Key inclusion criteria

1. Man or woman who is a first-degree relative, spouse, intimate partner, or someone who lives regularly with the IP
2. Age of at least 18 (both the CSO and the IP)

3. Have spent time with the IP in at least 40% of the last 90 days (with no planned change in this respect)
4. Describes the IP in accordance with ICD-10 diagnosis of alcohol dependence or abuse
5. Confirming alcohol consumption for IP during 30 of the last 90 days
6. Having a goal of engaging the IP to treatment if possible
7. Gives consent to participate in the study

Participant type(s)

Mixed

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

140

Total final enrolment

94

Key exclusion criteria

1. Positive response from the CSO that the IP would agree to seek treatment for alcohol problems at the present moment
2. Positive response from the CSO that the IP is currently in treatment for alcohol problems or has sought treatment during the last 6 months
3. Major psychiatric or somatic illness for CSO or IP
4. CSO describes IP in accordance with criteria for dependence or abuse for other substances than alcohol or nicotine according to ICD-10 criteria
5. Not enough skills in the Swedish language
6. Participating in another program aimed at supporting CSO:s (e.g. Al-Anon) during the last 12 months;
7. Risk for domestic violence from IP

Date of first enrolment

01/03/2016

Date of final enrolment

30/06/2017

Locations**Countries of recruitment**

Sweden

Study participating centre
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Study participating centre
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Sponsor information

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Sponsor type
University/education

Website
<http://ki.se/en/startpage>

ROR
<https://ror.org/056d84691>

Funder(s)

Funder type
Research council

Funder Name

Research Council of the Swedish Alcohol Retail Monopoly

Funder Name

Swedish Research Council for Health, Working Life and Welfare

Results and Publications

Publication and dissemination plan

Not provided at registration

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

Not provided at registration

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		19/03/2020	17/05/2022	Yes	No