

An online self-help program for parents whose partners abuse alcohol

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| Submission date 13/11/2017 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 28/11/2017 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 17/02/2023 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Alcohol use disorder (AUD) is a pattern of alcohol use that involves problems controlling your drinking, being preoccupied with alcohol, continuing to use alcohol even when it causes problems, having to drink more to get the same effect, or having withdrawal symptoms when you rapidly decrease or stop drinking. Partners and children of individuals with AUD have impaired quality of life and mental health, but seldom seek or participate in traditional supportive interventions. Engaging the parent/partner without AUD in treatment is a promising way of supporting behavior change in both the child and the parent with AUD. Universal parent training (PT) programs are effective in increasing children's well-being and decreasing problem behaviors, but have yet to be tailored for children with a parent with AUD. Community reinforcement approach and family training (CRAFT) programs are conceptually similar, and aim to promote behavior change in individuals with AUD by having a concerned significant other change environmental contingencies. There have been no studies on whether these two interventions can be combined and tailored for partners of individuals with AUD with common children, and delivered as accessible online self-help. The aim of this study is to find out whether using such an online self-help program leads to reductions in the child's mental health problems, the co-parent's drinking and the participant's own emotional distress.

Who can participate?

People who share a child showing mental health problems with a co-parent with AUD, but who do not present AUD themselves

What does the study involve?

Participants are randomly allocated to either a four-module online combined PT and CRAFT program, or a psychoeducation-only comparison intervention. The child's mental health, the partner's drinking, the participant's own mental health and drinking, the child's social adjustment, treatment-seeking, and parental self-efficacy are all assessed before, during and after treatment, and three times during a two-year follow-up period.

What are the possible benefits and risks of participating?

Benefits include help and support in dealing with having a co-parent with AUD, as well as presumed increased mental health. Presumed indirect benefits include increased mental health

for the child in common, and reduced drinking in the co-parent with AUD. There are no identified risks with participation.

Where is the study run from?

Stockholm Centre for Dependency Disorders (Sweden)

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

October 2016 to December 2020 (updated 04/06/2019, previously: December 2019)

Who is funding the study?

Public Health Agency of Sweden

Who is the main contact?

1. Dr Anders Hammarberg

2. Dr Philip Lindner

Contact information

Type(s)

Scientific

Contact name

Dr Anders Hammarberg

Contact details

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Type(s)

Scientific

Contact name

Dr Philip Lindner

Contact details

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11435

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Folkhälsomyndigheten 03136-2015

Study information

Scientific Title

Combining online community reinforcement and family training with a parent training program for parents with partners suffering from alcohol use disorder: a randomized controlled trial

Acronym

Skydda barnen

Study objectives

A online combined community reinforcement and parent training self-help program for parents who share a child with a co-parent with alcohol use disorder (AUD) will led to greater reductions in the child's mental health problems, the co-parent's drinking and the participant's own emotional distress.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethics Review Board in Stockholm, 10/02/2017, ref: 2016/2179-31

Study design

Single-centre interventional two-arm randomized controlled superiority trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Other

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

Alcohol use disorder; internalizing and externalizing behaviors

Interventions

Participants who share a child showing mental health problems with a person with AUD, but do not present AUD themselves, will be recruited from the general public and randomized 1:1 to:
Arm 1: Sequential four-module self-help program integrating psychoeducation and exercises from behavioral parent training and Community Reinforcement 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 having shared children, but no exercises aimed at promoting behavior change.

Primary outcome will be the child's mental health. Additional outcomes will cover the partner's drinking, the participants own mental health and drinking, the child's social adjustment, and treatment-seeking in all three parties, and parental self-efficacy. Measures will be collected pre-, mid- and post-treatment, and three times during a two-year follow-up period. Data will be analyzed using mixed effects modeling.

Intervention Type

Behavioural

Primary outcome measure

Participant's rating of the child's total score on the Strengths and Difficulties Questionnaire (SDQ) for children, 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 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:

1. Child's externalizing subscore of the SDQ
2. Child's internalizing subscore of the SDQ
3. Participant's depression subscore on the Depression Anxiety and Stress Scale (DASS)
4. Participant's anxiety subscore on the Depression Anxiety and Stress Scale (DASS)
5. Participant's stress subscore on the Depression Anxiety and Stress Scale (DASS)
6. Participant's alcohol consumption measured using the three-item Alcohol Use Disorder - Identification Test (AUDIT-C)
7. Participant's parental self-efficacy (custom scale)
8. AUD parent's alcohol consumption measured using the AUDIT-C
9. AUD parent's number of ICD-10 alcohol dependence criteria met
10. Participant-child relationship quality measured using the the Adult Child Relationship Scale (ACRS)
11. Help-seeking behavior among the participant, AUD parent, and child

Overall study start date

01/10/2016

Completion date

31/12/2020

Eligibility

Key inclusion criteria

1. Participant: 18+ years old
2. Participant: sufficient grasp of Swedish
3. Participant's co-parent with AUD: meets AUD criteria, defined as an AUDIT-C score of >3/4 (women/men) and/or meeting >1 ICD-10 dependence criteria
4. Shared child: aged 3-11
5. Shared child: lives >3 days per month with AUD parent
6. Shared child: scores above the clinical cut-off on any of the five sub-scales of the SDQ

Participant type(s)

Carer

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

300

Key exclusion criteria

1. Participant: Meets AUD criteria (as defined above)
2. Participant: use of illicit drugs at least one per week during last 12 months
3. Participant: score in the severe range on all three sub-scales of the DASS, or in the extremely severe range on two of the sub-scales
4. Participant: already participates in an intervention aimed at CSOs of individuals with AUD
5. Shared child: has participated in an intervention aimed at children of individuals with AUD in the last 12 months
6. Shared child: has been exposed to family violence in the last 3 months
7. Participant's co-parent with AUD: use of illicit drugs at least one per week during last 12 months

Date of first enrolment

01/12/2017

Date of final enrolment

31/12/2020

Locations**Countries of recruitment**

Sweden

Study participating centre

Stockholm Centre for Dependency Disorders
Stockholm

Sweden
11435

Sponsor information

Organisation

Karolinska Institutet

Sponsor details

Centre for Psychiatry Research
Norra Stationsgatan 69
11364
Sweden
11364

Sponsor type

University/education

Website

<http://psykiatriforskning.se/>

ROR

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

Funder(s)

Funder type

Government

Funder Name

Public Health Agency of Sweden

Results and Publications

Publication and dissemination plan

The trial will be described in three planned peer-reviewed publications:

1. Study protocol
2. Trial outcomes, including subgroup analyses
3. Mediation

Preliminary results will be presented at scientific conferences.

Intention to publish date

31/12/2021

Individual participant data (IPD) sharing plan

The de-identified, participant-level data used in the published material will be made available upon request (from date of publication) from the study principal investigator Dr Anders Hammarberg.

IPD sharing plan summary

Available on request

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| Protocol article | protocol | 10/08/2018 | 24/10/2019 | Yes | No |
| Results article | | 05/09/2022 | 06/09/2022 | Yes | No |
| Results article | | 15/02/2023 | 17/02/2023 | Yes | No |