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

Submission date
13/11/2017

Recruitment status
No longer recruiting

Registration date
28/11/2017

Overall study status
Completed

Last Edited
17/02/2023

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
Mottagningen för alkohol och hälsa
Riddargatan 1
Stockholm
Sweden
11435

Type(s)
Scientific

Contact name
Dr Philip Lindner

Contact details
Riddargatan 1
Stockhol
Sweden
11435

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Single-centre interventional two-arm randomized controlled superiority trial

Study type(s)
Treatment

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(s)

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex

All

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

ROR
https://ror.org/04hmgwg30

Funder(s)

Funder type
Government

Funder Name
Public Health Agency of Sweden

Results and Publications

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?
Results article		05/09/2022	06/09/2022	Yes	No
Results article		15/02/2023	17/02/2023	Yes	No
Protocol article	protocol	10/08/2018	24/10/2019	Yes	No