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Evaluation of a support program for caregivers of substance-using adolescents

Submission date
07/11/2018

Recruitment status
No longer recruiting

Registration date
04/03/2019

Overall study status
Completed

Last Edited
10/07/2025

Condition category
Mental and Behavioural Disorders

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Alcohol and drug use among adolescents and young adults are key factors for premature death and disease. Prolonged use of substances leads to negative psychological, physiological and social effects. In addition to the individual risks connected to substance use, the network (for example parents and concerned significant others) are at higher risk of psychological conditions, such as depression and anxiety.
Research shows that help-seeking at a care provider helps people resolve their substance use problem. However, adolescents/young adults with problematic substance use often refrain from seeking treatment.
Support programs for concerned significant others have proven effective in adult populations. However, less is known about support programs aimed at caregivers of substance-using adolescents/young adults. Therefore, support programs that target the likelihood of treatment-seeking among adolescents/young adults, as well as the health of the guardians, need to be evaluated. The aim of the study is to investigate the efficacy of CRAFT for caregivers to adolescents/young adults suffering from substance use disorder (SUD), regarding treatment-seeking behaviour and substance use for adolescents/young adults, as well as mental health for caregivers.

Who can participate?
Formal or informal caregivers of adolescents/young adults with alcohol or drug use.

How is the study designed?
Participants are randomly allocated to one of two groups. Group 1 receive counseling according to an extended program of the currently used model at Mini Maria, and includes five individual counseling sessions and one cannabis group education session.
Group 2 receive counseling based on Community Reinforcement Approach and Family Training (CRAFT), a structured method including different themes, developed for concerned significant others of people with substance problems, and includes eight individual counseling sessions. All participants will answer questions about their health-related status and their adolescent's /young adult's health-related status and substance use at four time points, when they enter the study, six weeks, 12 weeks and 24 weeks later.

What are the potential benefits and risks with participating?
All study participants are offered support in difficult situations. The participants presumably acquire more adequate tools to handle the situation, leading to improvements in the health and wellbeing of both the adolescent and the caregiver.
There are no direct risks of physical harm connected to participation in this study.

Where is the study run from?
Stockholm Centre for Dependency Disorders (Sweden)

When will the study start and how long will it run?
October 2018 to November 2021

Who is funding the study?
The Public Health Agency of Sweden (Sweden)
Region Stockholm research funds (ALF)
The KRICA foundation

Who is responsible for the study?
Anders Hammarberg
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2018/1642-31

Study information

Scientific Title
Community Reinforcement Approach and Family Training (CRAFT) administered to caregivers of substance-using adolescents and young adults: a randomized controlled trial

Acronym
CRAFT

Study objectives
Primary hypothesis:
Participation in a CRAFT program for caregivers increases the probability of treatment seeking in adolescents with substance-related problems compared to treatment as usual

Secondary hypotheses:
1. Participation in a CRAFT program for guardians reduces youth's drug and alcohol consumption compared to treatment as usual
2. Participation in a CRAFT program for guardians leads to improved mental health for the participant and youth compared to usual care
3. Participation in a CRAFT program for guardians provides an increased relational satisfaction for the participant compared to treatment as usual
4. Participation in a CRAFT program for guardians gives an increased quality of life for the participant compared to treatment as usual
5. Participation in a CRAFT program for guardians gives an increased the participant's self-efficacy compared to treatment as usual
6. Participation in a CRAFT program for guardians improves psychological flexibility of the participant compared to treatment as usual

Ethics approval required
Old ethics approval format

Ethics approval(s)
Regionala etikprövningsnämnden i Stockholm (The Regional Ethical Review Board of Stockholm), 26/09/2018, 2018/1642-31

Study design

Interventional two-group block randomized parallel trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Other

Study type(s)
Prevention

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
Substance use

Interventions
Current interventions as of 06/10/2022:
Due to the COVID-19 pandemic, the intervention delivery changed from face-to-face at the clinic to video conference after receiving approval for this amendment from the Swedish Ethical Review Authority.

Participants will be randomly allocated to either the intervention or control group through block randomisation in a 1:1 ratio by a researcher not connected to the study.
The intervention group will receive the Community Reinforcement Approach and Family Training (CRAFT), adapted for caregivers of substance-using adolescents. This contains 8 sessions delivered over a 10-week period by counsellors via video conference.
The control group will receive treatment as usual, which involves 4 counselling sessions together with 1 follow-up session delivered by counsellors via video conference and a group session with the main purpose to enhance participants' knowledge about cannabis.
All participants will answer questions about their health-related status and their adolescents' health-related status and substance use at four-time points, when they enter the study and 6 weeks, 12 weeks and 24 weeks later.

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Previous interventions:
Participants will be randomly allocated to either the intervention or control group through block randomisation in a 1:1 ratio by a researcher not connected to the study.
The intervention group will receive the Community Reinforcement Approach and Family Training (CRAFT), adapted for caregivers of substance-using adolescents. This contains 8 sessions delivered over a 10-week period by counsellors at an adolescent substance care unit (Mini Maria).
The control group will receive treatment as usual, which involves 4 counselling sessions together with 1 follow-up session delivered by counsellors at an adolescent substance care unit (Mini Maria) and a group session with the main purpose to enhance participants' knowledge about cannabis.

All participants will answer questions about their health-related status and their adolescents' health-related status and substance use at four timepoints, when they enter the study and 6 weeks, 12 weeks and 24 weeks later.

Intervention Type
Behavioural

Primary outcome measure
Adolescents help-seeking behavior as reported by caregivers at baseline, 6, 12 and 24 weeks follow-up. At inclusion and at week 24, the information is provided in the form of an interview. At week 6 and 12, the information is provided in the form of a questionnaire.

Secondary outcome measures
The following are self-reported by caregivers of their own and the adolescent's status at the baseline and at 6, 12 and 24 weeks:
1. Adolescent drug and alcohol consumption, assessed using:
1.1. Timeline Followback (TLFB)
1.2. Alcohol Use Disorders Identification Test (AUDIT)
1.3. Drug Use Disorders Identification Test (AUDIT)
2. Adolescent's mental health, assessed using the Child Behavior Checklist (CBCL)
3. Caregiver's mental health, assessed using the Depression Anxiety Stress Scale (DASS-21
4. Caregiver's relational satisfaction, assessed using the Relationship Happiness Scale
5. Caregiver's quality of life, asessed using:
5.1. EQ-5D
5.2. Satisfaction With Life Scale (SWLS)
6. Caregiver's self-efficacy, assessed using the Parental Self-Efficacy Scale
7. Caregiver's psychological flexibility, assessed using the Acceptance and Action Questionnaire - II (AAQ-II)

Overall study start date
01/08/2018

Completion date
30/11/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 06/10/2022:
Guardian/caregiver/previous caregiver:
1. Formal or informal present or previous caregiver to a substance-using adolescent/young adult
2. Living with, or being in close contact with, the adolescent at least 50% of the time per month, with no plan to change this pattern
3. Explicit wish that the adolescent/young adult seek formal treatment

Adolescent/young adult of the participating present/previous caregiver:
1. Aged 15-24 years
2. Existing problems related to alcohol or drug
3. Would deny formal treatment at study entry according to the caregiver

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Previous participant inclusion criteria:
Guardian/caregiver:
1. Formal or informal caregiver to a substance-using adolescent
2. Living with the adolescent at least 50% of the time per month, with no plan to change this pattern
3. Explicit wish that the adolescent seek formal treatment
4. Living in the Stockholm region

Adolescent of the participating caregiver:
1. Aged 15-19 years
2. Existing problems related to alcohol or drug
3. Would deny formal treatment at study entry according to the caregiver

Participant type(s)
Other

Age group
Adult

Sex
Both

Target number of participants
160

Total final enrolment
113

Key exclusion criteria
Guardian/caregiver:
1. Fulfill criteria for substance related diagnosis according to DSM-5 (excluding nicotine)
2. Reporting drug use more frequent than one time per month during the last 12 months
3. Prevailing psychological or cognitive problems considered as a barrier in using the program materials, e.g. psychotic conditions
4. Participation in other support programs for significant others to people with drug or alcohol problems currently or during the last three months

Adolescent (according to the caregiver):
1. Prevailing psychological or cognitive problems e.g. psychotic conditions, neuropsychiatric disorders
2. Treatment contact for substance problems during the last 30 days
3. Violent behavior against the guardian during the past year

Date of first enrolment
22/10/2018

Date of final enrolment
31/05/2021

Locations

Countries of recruitment
Sweden

Study participating centre
Stockholm Centre for Dependency Disorders, Stockholm County Council
Friskvårdsvägen 4
Stockholm
Sweden
11281

Study participating centre
Mini Maria Stockholm
Rosenlundsgatan 44B
Stockholm
Sweden
112 19

Study participating centre
Livsstilsmottagningen, Maria Ungdom
Riddargatan 1
Stockholm
Sweden
11435

Sponsor information

Organisation
Stockholm County Council

Sponsor details
Friskvårdsvägen 4
Stockholm
Sweden
SE-112 81

Sponsor type
Hospital/treatment centre

Website
http://beroendecentrum.se/

ROR
https://ror.org/02zrae794

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

Funder Name
Region Stockholm Research Funds (ALF)

Funder Name
The KRICA Foundation

Results and Publications

Publication and dissemination plan
The study protocol will be published. The results of the primary outcome will be published as soon as possible after data collection and aggregation.

Intention to publish date
01/03/2023

Individual participant data (IPD) sharing plan
Current IPD sharing statement as of 06/10/2022:
The datasets generated and analyzed during the current study will be available upon reasonable

request from Ola Siljeholm, ola.siljeholm@regionstockholm.se Data will be available once the results from the primary evaluation of the trial are published in a scientific journal. Scientists interested will contact Siljeholm and make a case for their planned use of the data. Consent from participants to share data with other researchers has not been obtained, but since no identification of participants can occur from the raw data sets we have assessed that the advantages of open data sharing outweigh the potential risks. Requests for using these data will be assessed for any ethical or legal restrictions that may hinder the sharing of data. Requests will have to provide information on such aspects and will be the responsibility of the requesting party.

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Previous IPD sharing statement:
The datasets generated during and/or analysed during the current study are not expected to be made available because of GDPR.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.0	22/08/2018	07/10/2022	No	No
Results article			30/01/2024	Yes	No
Other publications	Qualitative results investigating the experiences of CRAFT	25/06/2024	25/06/2024	Yes	No
Other publications	Secondary analysis	10/07/2025	10/07/2025	Yes	No