

## **Background**

Drug and alcohol use (in the following, substance use is used as an umbrella term) accounts for a large part of the disease burden among young people in the industrialized part of the world (Patel et al., 2007; Lim et al., 2013). There is a great need for effective prevention efforts to reduce substance use among young people, not least to avoid substance use following the individuals into adulthood. Effective prevention methods have great potential from a public health perspective by reducing substance use and its consequences in the short and long term both for the young people themselves but also for relatives and others who are affected. The following project aims to evaluate whether the Community Reinforcement Approach and Family Training (CRAFT) method motivates more young people to seek care for their problems.

Adolescence is a common period for drinking alcohol and, in some cases, also try illicit substances. The prevalence of substance use is highest among young adults and then gradually decreases (e.g. Chen et al., 1995; Hibell, 2010). For some young people, however, use does not decrease, which in many cases leads to poorer mental and physical health, social complications and poorer school performance (Patel et al., 2007; Brown et al., 2018). Substance use during adolescence is associated with several physiological negative effects, for example brain development, physical growth, the endocrine system and liver function (NIAAA, 2006). Research has also drawn attention to negative secondary effects of substance use, for example violence, mental illness among relatives, costs for reduced productivity in working life and insurance costs (for an overview, see Andréasson et al., 2016).

International and Swedish studies have shown that problematic substance use during adolescence is associated with an increased risk of negative effects later in life, for example premature mortality, hospitalizations for physical and mental health problems, criminality, and deteriorating socio-economic status. (Rohde et al., 2001; Hallfors et al., 2002; Hodgins et al., 2009; 2013; Larm et al., 2008).

For many years, Sweden has kept statistics on the alcohol and drug habits of young people. Current figures show that 16% of young people in the second year of high school (age 16-17) report having used a drug on one or more occasions (Hibell, 2010). In addition to this, about 10% of young people up to 18 report a risky alcohol intake (Englund, 2014). Although much suggests that substance use among young people is historically relatively low, other figures suggest that the severity level among those who remain in active substance use is increasing. For example, it can be mentioned that approximately 3,000 patients between the ages of 10 and 19 were treated for a substance-related diagnosis in Swedish care in 2009, which means an increase of 30% compared to 1999 levels (Larsson, 2011 (Missbrukstredningen, The Substance abuse investigation). International studies also indicate that substance-related problems are an underdiagnosed category in youth psychiatric care (Lauth et al., 2010; Hawkins et al., 2009).

As harmful substance use and addiction often begin at a young age, prevention efforts should focus on young people (Toumbourou et al., 2007; Belcher et al., 1998). We know today that the proportion who come to terms with their substance-related problems increases among those who have a care contact (Godley et al., 2006; Robbins et al., 2011; for

an overview, see NIDA, 2014). Relatively small efforts are often required to reduce substance use, even if the efforts sometimes require long-term contacts and involve the network around the young person. A major challenge, however, is that young people with substance-related problems are disinclined to seek addiction treatment (e.g. Duncan et al., 1997; Zucker, Chermack, & Curran, 2000). A significant proportion of those who would benefit from a healthcare contact do not have one, and in many cases adherence to treatment is low. As an example, an American study can be cited that showed that of the estimated 1.4 million young people who met the criteria for alcohol-related problems (abuse or dependence according to the then current criteria), only 227,000 participated in some form of treatment, i.e. approximately 16% of youth (NIAAA, 2006). This treatment gap regarding young people with substance-related problems has been established in several international and Swedish studies (e.g. Cunningham et al., 2004; Kohn et al., 2004; Wigzell, 2005; Larsson, 2011; Lövenhag, 2015; NIDA, 2014; McLellan & Myers, 2004; Griswold et al., 2008; Knight & Sherritt, 2003; Grant et al., 2015). If youth enter treatment, this often occurs as a result of external pressure from family, school, employer, or the justice system (Battjes et al., 1999; Waldron et al., 2004).

### *Relatives' situation*

Relatives of people with substance-related problems show increased risk of psychiatric illness such as depression and anxiety symptoms compared to the general population (Connors et al., 2001; Meyers & Smith, 1997). The relative's situation can be understood theoretically from a stress-strain and coping perspective (Carretero et al., 2009; Orford, 2005). The relative is often exposed to repeated stressors linked to worry about, or the consequences of, the alcohol or drug use, for example that a lot of time is spent with the person concerned, which leads to other parts of life being prioritized away, or feelings of stigma and vulnerability to spend a lot of time with the person concerned (e.g. Orford et al., 2005; Pearlin, Mullan, Semple & Skaff, 1990). These stressors affect relatives differently, depending, among other things, on the degree of social support or the ability to adapt or alternatively change the situation (Carratero, et al., 2009).

The effect of substance-related problems in a family situation has historically received little attention in addiction research. Interventions to support relatives have been a neglected area of research and within regular care, relative support is rarely an established part of the treatment range (Copello & Orford 2002; National Board of Health and Welfare, 2015). Even within specialized addiction care, the situation of relatives has received little attention (Velleman & Orford 1999; Copello et al. 2000a; Howells & Orford 2005) and for guardians of young people with alcohol or drug problems who do not want to seek help for their problems, services are currently offered no help before a treatment contact for the young person is possibly initiated.

### *Methods to motivate care seekers*

There is a great need to develop support programs for guardians of adolescents and young adults with drug or alcohol problems, with the aim of both increasing the proportion who seek care and reducing the psychological suffering of the guardians.

A number of studies with adults have shown the potential of relatives to engage individuals with substance-related problems in treatment (Kirby et al., 1999; Marlowe et al., 2001; Meyers et al., 1999; Miller et al., 1999). A promising alternative is the Community

Reinforcement Approach and Family Training (CRAFT). CRAFT aims to support the relative (Concerned Significant Other - CSO)\* in actively changing their own behavior in relation to the person with substance-related problems (Identified Patient - IP) in order to achieve three aims:

1. to increase the likelihood of getting IP to seek care.
2. to reduce IP's substance use.
3. to improve the CSO's mental and physical health.

The theoretical basis for the model consists of learning psychology principles for behavior change, where substance use is seen as a consequence of the interaction between the individual and environmental factors. From this perspective, a relative (CSO) has a great opportunity to influence the person concerned (IP). On the one hand, a CSO has a significant role for their IP, and on the other hand, in many cases, they spend a large part of the time together, which means that a CSO has many opportunities to influence their IP. How the CSO behaves is therefore important for how the IP in turn behaves. Finally, a CSO often has strong motivation to work for a change for emotional, relational and practical reasons (Velleman et al., 1993; Orford et al., 2001; Orford et al., 2005).

Briefly (detailed description follows in method), the following parts are included in the CRAFT program: development of motivational skills, strategies to improve the mental health of CSOs, learning methods of analysis of substance use, development of positive communication and use of positive reinforcers of "sober" behaviours, information about negative consequences of substance use, exercises and preparations for talking to the IP about seeking care and skills in dealing with violent situations. By changing the environmental factors around IP, CSO also increases the possibility that IP will change their substance use and related behaviors (Sisson & Azrin, 1989; Meyers et al., 1999; Smith & Meyers, 2004). A number of studies have evaluated the effect of CRAFT (for meta-analysis, see Roozen et al., 2011). Overall, the CRAFT method has shown a significant increase in the proportion of individuals with substance-related problems who sought care, compared to other control groups (Kirby et al., 1999; Meyers et al., 1999; Miller et al., 1999; Brigham et al., 2014; Bischof et al., 2016; Osilla et al., 2016). Existing studies have shown that treatment seeking for substance dependent individuals who were initially reluctant to seek care has increased by between 59-74% as an effect of the CRAFT program.

Our research group has recently completed data collection from the first CRAFT study in Sweden (Eek & Romberg et al. 2018). A total of 94 CSOs who reported that a relative (IP) met the criteria for alcohol dependence according to DSM-IV were included in the study. These were randomized to either a 6-week Internet-based CRAFT program or waiting list. The CRAFT program included e-support from certified treatment personnel. Preliminary results from the study show that the participants in the CRAFT program reported that IP reduced their alcohol use and sought care in a higher proportion compared to the participants in the control group. The CRAFT group further reported improved mental health and increased relationship satisfaction for CSOs compared to the control group.

Currently, there is a lack of knowledge about the effect of CRAFT for guardians of young people with substance-related problems. Only one pilot study has been published regarding

CRAFT where all CSOs were guardians of youth with substance-related problems (Waldron et al., 2007). In this non-controlled study, CSOs offered 42 youth to undergo 12 sessions of CRAFT, with the goal of motivating the youth to seek care, to reduce drug use, and to increase the CSO's mental health and level of family functioning. At follow-up at 3 and 6 months, respectively, CRAFT participants showed a reduction in negative health symptoms and 71% of youth had sought care.

Prior to the planned study, the clinic in question has tried the CRAFT program in group activities for guardians (CSO) to 10 young people (IP). The young people's primary problem substance was cannabis and 50% had contact with reception/care in the past. The purpose was to evaluate how the manual for the eight sessions worked in the business, as well as to investigate how the target group responded to the content. The course was completed in May 2018 and the development project shows, among other things, that participating guardians experience significantly improved communication with the youth, have gained a greater understanding of their substance use, a greater opportunity to influence the youth through positive reinforcement and an improved relationship. In previous studies, these measures have shown a connection with the IP having to accompany/take their own initiative for treatment. Since half of the young people already had contact with care, increased participation in care was not possible to investigate.

### *Purpose*

The purpose of the study is to evaluate the effect of CRAFT for guardians (CSO) of youth with substance-related problems (IP), primarily regarding the propensity of IP to seek care. In addition, the project aims to study the effect of CRAFT on important factors such as IP's substance use, mental health (for CSO and IP), relationship satisfaction of CSO, quality of life of CSO and other relevant indicators (see headings Outcome measures and Instruments for detailed description).

### *Hypotheses*

Primary hypothesis:

- Participation in a CRAFT program for guardians increases the propensity of youth with substance-related problems to seek care.

Secondary hypotheses:

- Participation in a CRAFT program for guardians results in a reduction in youth drug and alcohol use.
- Participation in a CRAFT program for guardians leads to improved mental health for the participant and youth.
- Participation in a CRAFT program for guardians results in increased relationship satisfaction for the participant.
- Participation in a CRAFT program for guardians provides an increased quality of life for the participant.
- Participation in a CRAFT program for guardians gives an increased belief in the participant's own ability as a guardian (self-efficacy)
- Participation in a CRAFT program for guardians improves the psychological flexibility of the participant.

## **Method**

### *Design*

The study is designed as a randomized controlled trial (RCT) with two parallel groups, followed up on three occasions. Participants are randomized to the CRAFT program (intervention) or to Counselling sessions (control intervention).

### *Participants*

CSO to 160 young people with substance-related problems. CSO means parent or other guardian, grandparent, or other with a similar relationship to the young person (e.g. stepparent, aunt/uncle, foster parent, etc.).

### *Other inclusion criteria*

Regarding CSOs who wish to participate in the study:

1. Has a formal or informal relationship as a guardian to the IP.
2. Live together with IP 50% or more and do not plan to reduce the share in the next six months.
3. Has a stated desire for IP to seek treatment for substance-related problems.
4. Be a resident of the Stockholm area.

Regarding IP (according to data from CSO):

1. Between 15-19 years.
2. Assessed to have drug or alcohol related problems.
3. Lives at home with the CSO at least 50% or more and does not plan to reduce the share in the next six months.
4. According to the CSO's assessment, would currently answer no to the question of starting a healthcare contact for their substance-related problems.

### *Exclusion criteria*

Regarding CSOs who wish to participate in the study:

1. Meets the criteria for some form of substance-related diagnosis according to DSM-5
2. Drug use more frequent than once per month during the last 12 months.
3. Significant psychological or cognitive problems that are assessed as an obstacle to absorbing the material in the program, for example psychotic conditions or cognitive impairment.
4. Already participates in support efforts or has in the last three months participated in support programs for relatives of people with drug or alcohol problems.

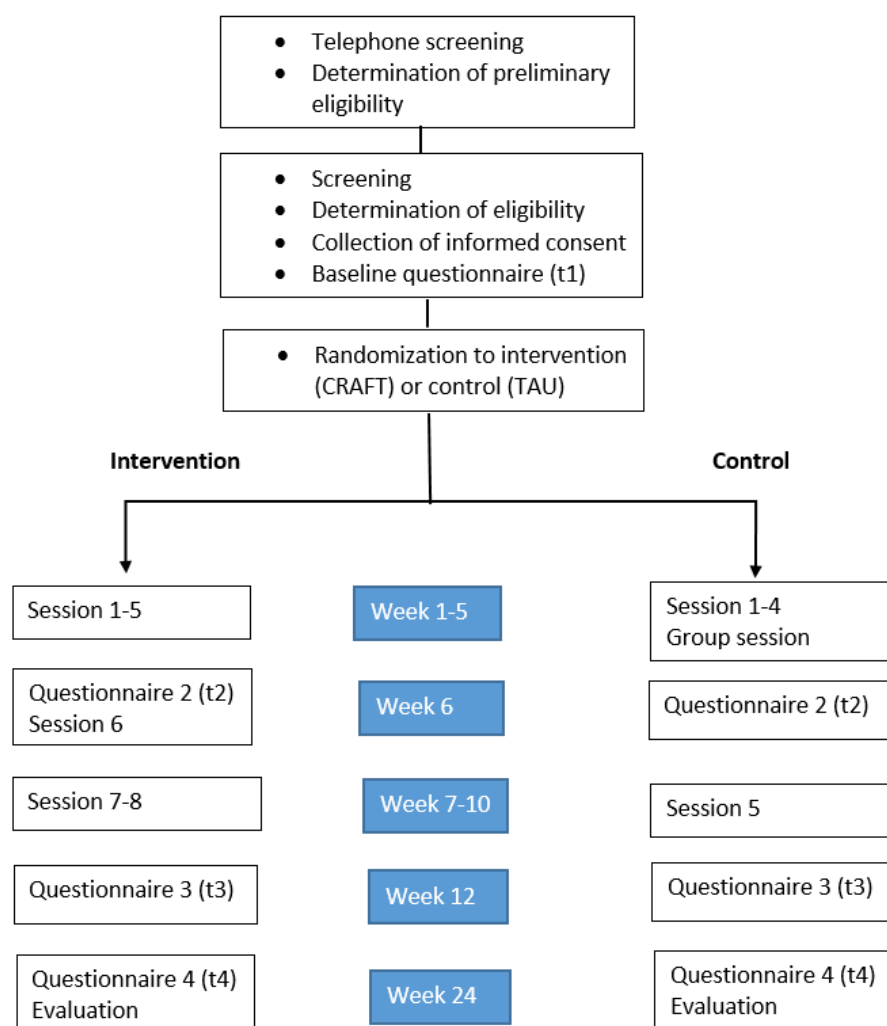
Regarding IP (according to data from CSO):

1. Serious psychiatric problems, for example psychotic conditions, cognitive impairment or severe neuropsychiatric impairment.
2. Care contact regarding substance-related problems during the last 30 days.
3. The IP has used violence against the guardian in the past year.

### *Procedure*

For the full study flow chart, see figure 1. Recruitment takes place primarily via advertising in social media and via pages suitable for the target group within the organization Stockholm Health Care Services. Keyword optimization and Google ads can also be used if study participants do not arrive at the expected rate. Furthermore, staff within the organization

will be informed that the study is ongoing and refer guardians to the study coordinator for further information about the study.



**Figure 1. Study flow chart**

Interested participants who click on the advertisement will be taken to a landing page where they can read information about the study and are then asked to contact the study coordinator via e-form or e-mail if they are interested. Persons who register an interest are contacted by phone by the study coordinator/project manager to receive more information about the study and to undergo a short screening aimed at investigating whether the guardian (and the young person) are current for the study (i.e. meet the criteria for inclusion). For IP, the following is screened: age, substance-related problems, ongoing or recently ended care contact for substance-related problems, if the IP would answer no to the question of initiating care contact at the present time, days/month that the IP lives with the CSO. For CSOs, the following is screened: type of relationship to IP, possible own ongoing drug use and ongoing or recently completed support programs as a relative of someone with addiction problems.

If no exclusion criteria are discovered during the interview, a screening visit is booked.

At the screening visit, the CSO initially receives oral and written information about the study. In case of continued interest, a screening interview is conducted to determine that all selection criteria are met, after which written consent to participation is obtained. The participant then fills in the baseline questionnaire before finally being randomized to CRAFT or usual treatment. The visit is estimated to take approximately 1 hour 30 minutes in total. The screening visit takes place primarily at Maria Ungdom Mini Maria Stockholm in the center of the city of Stockholm. For a schematic overview of the process, see Figure 1 (page 19).

### *Study centre*

The study will be carried out in collaboration with Maria Youth, Mini Maria Stockholm. Maria Youth constitutes an entire care chain for adolescents and young adults who have or are at risk of developing a harmful use/addiction to cannabis, alcohol or other drugs and medicines. The operation is conducted under the auspices of Region Stockholm and is part of a section within the Stockholm Centre for Dependence Disorders, Stockholm Health Care Services. The section consists of a unit for emergency with 6-7 care places for round-the-clock care such as investigation, detoxification and places for sobering up, and a specialized outpatient care unit for adolescents with complex care needs, psychiatric comorbidity and a reception for sex and cohabitation, which is staffed by a midwife. In Stockholm's neighborhoods and surrounding municipalities there are local outpatient clinics - Mini Marias. In the central parts of Stockholm there are two receptions for young adults located and another reception located in Järva, Kista centrum.

Caregivers who contact the reception whose child does not want to accompany them to care are currently offered three advisory calls. Furthermore, group training in drug knowledge (mainly cannabis) is offered via open lecture sessions at the reception in central Stockholm. The treatments within the framework of the study are carried out in close collaboration with the relevant care providers and with existing treatment staff at the treatment centers.

The sponsor for the study is the public care provider Stockholm centre for dependence disorders, Region Stockholm.

## **Interventions**

### *The CRAFT program*

The CRAFT program begins between 0-2 weeks after randomization and is carried out once per week for 8 weeks. Each session is estimated to take about 1 hour. The CRAFT program is carried out by treatment staff at Mini Maria Stockholm (Stockholm centre for dependence disorders) who have undergone adequate training in the CRAFT method.

Participants undergo sessions with the following specific components: (1) Raise awareness of the negative consequences of substance use as well as the potential gains of participating in the program; (2) Focus on improving the participant's mental health by identifying areas where the CSO can implement changes to feel better themselves. The participant sets goals in various areas, for example physical health, relationships, physical activity. The goal is followed up continuously during the duration of the program; (3) So-called functional analysis of substance use situations. This means carefully going through what precedes instances of substance use, how the use is carried out, as well as short-term effects (for

example, reduced stress or anxiety) and long-term effects (missed schooling or social activities) of the use; (4) Communication Training – Participants develop skills in using constructive and helpful communication, which involves a) being concise; b) to express oneself in positive terms; c) to refer to specific behaviors of the young person; d) using "I-messages"; e) to convey understanding and commitment; f) to mediate shared responsibility; g) to offer assistance; (5) Increasing the availability of positive reinforcers for behaviors unrelated to substance use. This may mean conveying which behaviors are desirable (drug-free) through altered response. For example, this could be about bringing up things that the IP wishes or is interested in, alternatively rewarding drug freedom through activities that the IP is interested in. The positive reinforcers should be something that the IP appreciates, that competes with the substance use, that occurs relatively frequently and finally is something that the CSO also appreciates; (6) Negative consequences of substance use. This mainly concerns withholding positive behaviors in connection with substance use. It can also be about letting natural consequences take their course, for example not cleaning up after a party; (7) Conversations about seeking care. A goal for many CSOs is for their IP to take the initiative to seek care. The goal of this session is to prepare the participant as well as possible for such a conversation. This means identifying a suitable reception to seek care at, identifying the most suitable time for the call, using communication skills and being prepared for different possible outcomes of the call; (8) Dealing with the risk of violence. In rare cases, behavioral changes in a CSO who has attended CRAFT have led to increased aggressive behavior by the IP. A mapping of the risk of being affected by violence for each participant is thus carried out and, if necessary, a session will be devoted to how the CSO can act if the IP shows violent tendencies. This module is central to CRAFT aimed at relatives of adults with substance-related problems, and is also relevant for relatives of young people. Each session contains a short theoretical background. Afterwards, the participants get to work on developing skills through modeling the therapist and role-playing. Role playing is a central part of the program, where participants get to practice their new skills and take on the IP's perspective. Between each session, the participants work on homework in order to practice the skills in everyday life.

Each session has a checklist of content that the therapists start from and check off to ensure adherence to the program.

### *Control intervention*

Participants who are randomized to the control condition will be offered five individual counselling sessions as well as an educational opportunity in a group mainly regarding cannabis and negative effects of substance use. The counselling sessions begin between 0-2 weeks after randomization and are carried out on one occasion per week for four weeks. The fifth session is a follow-up session 4-6 weeks after the fourth session.

Counselling sessions follow the guidelines for guardians whose adolescent do not want to come to the treatment centre. As part of the CRAFT study, therapists who carry out counseling sessions have been interviewed by the research team about the topics covered in the sessions. The answers from the interviews have then formed the basis of a simpler manual for homogenizing the counselling sessions carried out in the study's control condition. Thus, the support for the control condition is very close to what can be described as treatment as usual (TAU). It has, however, been formalized and expanded somewhat so



that the control condition will also receive an effort that, in terms of number of occasions, is closer to that of the intervention group (CRAFT).

The manual for the counselling sessions in the control conditions contains several different themes and the therapist chooses the order in which these are presented based on the needs of each participant. The themes included in the conversations are: description of the situation and the CSO's concerns, relationship patterns in the family, creating an understanding of IP's substance use (mentalization-based work) and mapping of networks around IP. Questions before the talks can be, what do the relationship patterns in the family look like and how can the CSO possibly develop and strengthen its relationships with the IP? What can they do to get IP to the treatment centre? Which positive people are there in IP's network to try to encourage contact with?

All participating guardians are asked to take part in a group information session containing information about various drugs (primarily cannabis) and signs of current intoxication in order to better identify when the young person has used. The group courses are given on two occasions per semester.

The counselling sessions are offered by treatment staff not involved in the CRAFT program, to avoid contamination. No active CRAFT components will be offered.

Session	Intervention program (CRAFT)	Session	Control condition
1	<b>Introduction and motivational enhancement:</b> <ul style="list-style-type: none"> <li>* Problem description and analysis of CSOs previous strategies to deal with IPs substance use</li> <li>* General information about CRAFT and rational for involving CSOs in the treatment</li> <li>* Positive expectations of CRAFT</li> <li>* Identify CSOs reinforcers and motivations for change</li> <li>* Investigate risk of violence and strategies for preventing and coping with possible violence</li> </ul>	1	<b>Problem description, CSOs concern and understanding IPs substance use:</b> <ul style="list-style-type: none"> <li>* Validate CSOs concerns about IPs substance use</li> <li>* Analyze IPs substance use and reasons for using</li> <li>* Mapping of CSOs social network (support network?)</li> </ul>
2	<b>Functional analysis and mapping of IPs substance use</b> <ul style="list-style-type: none"> <li>* Functional analysis of IPs substance use</li> <li>* Analysis of behaviors and situations related to IPs substance use</li> <li>* Identify triggers and consequences of IPs substance use</li> </ul>	2	<b>CSOs actions in response to IPs substance use:</b> <ul style="list-style-type: none"> <li>* CSOs previous actions and reactions to IPs substance use</li> <li>* Analysis of previously successful and unsuccessful strategies to guide future behaviors</li> </ul>
3	<b>Communication skills:</b> <ul style="list-style-type: none"> <li>* Components of positive communication</li> <li>* Role-playing exercise in positive communication</li> </ul>	3	<b>Mapping IPs social networks:</b> <ul style="list-style-type: none"> <li>* Identify social networks and influential individuals around IP</li> <li>* Identify individuals or networks associated with IPs substance use</li> <li>* Identify positive influences that encourage IPs sobriety</li> </ul>
4	<b>Encouraging sobriety and positive reinforcement:</b> <ul style="list-style-type: none"> <li>* Identify signs of IPs substance use</li> </ul>	4	<b>Relational patterns in the family:</b> <ul style="list-style-type: none"> <li>* Identify relational patterns in the family</li> <li>* Encourage joint activities for CSO(s) and IP to strengthen IPs sense of cohesion and belonging</li> </ul>

	<ul style="list-style-type: none"> <li>* Identify rewards to use as positive reinforcement of IPs sobriety</li> <li>* Home-exercise to create a plan for positive reinforcement of healthy behaviors</li> </ul>		<ul style="list-style-type: none"> <li>* Encourage CSOs to focus on IPs positive qualities and communicate positive and loving messages</li> </ul>
5	<b>CSOs well-being:</b> <ul style="list-style-type: none"> <li>* Rational for emphasis on CSOs own well-being in CRAFT</li> <li>* Set up goals to enhance CSOs well-being</li> <li>* Home exercise to follow through on a goal to enhance CSOs well-being</li> </ul>	5	<b>Follow-up:</b> <ul style="list-style-type: none"> <li>* Follow up the current situation for IP and CSO</li> <li>* Identify which of CSOs strategies have been successful or unsuccessful</li> <li>* Alternative strategies for the future</li> </ul>
6	<b>Managing IPs substance use:</b> <ul style="list-style-type: none"> <li>* Analysis of current responses to IPs substance use</li> <li>* Identify intentional or unintentional encouragement of IPs substance use</li> <li>* Time-out from positive reinforcement and retraction of rewards</li> <li>* Allowing for natural negative consequences of substance use</li> <li>* Home-exercise in handling IPs substance use</li> </ul>	6	<b>Group session for parents of substance using youths:</b> <ul style="list-style-type: none"> <li>* Information about alcohol, cannabis, other drugs and the teenage brain</li> <li>* Group discussion with other parents</li> </ul>
7	<b>Problem-solving and treatment engagement:</b> <ul style="list-style-type: none"> <li>* Introduce a model for problem-solving</li> <li>* Investigate possible windows of time to invite IP to treatment and identify potential motivators to seek treatment</li> <li>* Identify suitable treatment options</li> <li>* Role-playing exercise in treatment encouragement</li> <li>* Home-exercise to invite IP to treatment</li> </ul>		
8	<b>Summary, treatment-retention and ending the program:</b> <ul style="list-style-type: none"> <li>* Summarize program content</li> <li>* Identify progress made during the program</li> <li>* Maintenance of positive changes made</li> </ul>		

**Table 1, summary of content in CRAFT and Counselling sessions**

### *Method fidelity*

To ensure that treatment manuals are followed in both support programs, all sessions will be recorded and 10% randomly selected for comparison with the checklist in the treatment manual (CRAFT) and for content assurance in the counselling sessions. On two occasions per semester, group supervision is provided for the therapists by project managers (OS or AH). The tutorial takes place in two separate groups: one with CRAFT therapists and one with therapists for the control group.

### *Power measurement*

The effect will be evaluated by monitoring the outcome measures on four occasions during the study. The measurement occasions occur at baseline and 6, 12 and 24 weeks after inclusion in the study.

### *Outcome measure*

All outcome measures (even those for the youth) are based on self-reporting from participating guardians.

## Primary

The primary outcome is defined as treatment-seeking behavior for IP between baseline and the time of the follow-ups.

## Secondary outcomes

- Change in drug and alcohol use for IP in the last 30 days before follow-up compared to the last 30 days before baseline.
- Change in severity of IP's drug- or alcohol-related problems at baseline compared to follow-up.
- Change in IP's mental health between baseline and follow-up.
- Change in mental health of CSOs between baseline and follow-up.
- Change in relationship satisfaction to IP estimated by CSO between baseline and follow-up.
- Change in the CSO's own quality of life between the baseline and the follow-up occasions.
- Change in the CSO's belief in his own ability as a guardian (self-efficacy) between the baseline and the follow-up occasions.
- Change in the CSO's degree of psychological flexibility between baseline and follow-up.

## Procedure for data collection

At baseline and the last follow-up visit (24 weeks after the baseline), data collection is carried out by the study coordinator at the treatment centre, at other follow-up times (6 and 12 weeks after the baseline), a questionnaire is answered and sent to the participant by mail. All forms for each participant are kept in a Case Record Form (CRF) which is kept in a locked record archive.

## Instruments

The following instruments are used during the telephone screening:

1. For questions about previous/ongoing support efforts as a relative of the CSO and treatment-seeking behavior of the IP, a tailored form is used.
2. Car, Relax, Alone, Forget, Friends, Trouble (CRAFT) (Knight, et al 1999) is used to assess whether IP is in the risk zone for drug/alcohol use. CRAFT is a screening form that measures substance problems for alcohol, cannabis and other drugs and has been tested on children and young people aged 12-26. Pre-screening consisting of 3 items and the CRAFT questions consisting of 6 items. Depending on the answers in the pre-screening, 1 or 6 CRAFT questions are then asked. The form is well evaluated internationally and a Swedish validation study has been submitted for publication (Källmén, et al. 2018). Recommended cut-off differs in the literature but is recommended between 1-3 points out of 9 possible.

The following instruments are used during the screening interview at the reception:

1. For demographic questions about the CSO (gender, gender identity, age and country of birth, level of education, employment, marital status, living situation and relationship with the young person) and IP (age, gender, gender identity, country of birth, employment and living situation), a separate form is used.
2. For the assessment of psychiatric conditions in CSOs, selected parts of the M.I.N.I are used. (Sheehan, et al. (1998)), and for the assessment of psychiatric conditions in IP, the M.I.N.I.-KID (Sheehan, et al, 2010) is used.
3. For assessing the risk of violent behavior by IPs, a form with questions about threats of violence is used.

The following instruments are used during the baseline measurement and at all follow-up occasions:

1. For the measurement of treatment-seeking behavior (primary outcome measure), forms are used in which previous/ongoing care contacts are requested.
2. To assess the IP's drug and alcohol consumption in the last 30 days, a structured interview is conducted according to the Timeline follow back (TLFB) methodology (Sobell & Sobell, 1996).
3. The Drug Use Disorder Identification Test (DUDIT), which consists of 11 items (0-44 points), is used to assess the severity of the IP's use of non-prescribed drugs. (Berman et al. 2012).
4. The Alcohol Use Disorders Identification Test (AUDIT) is used to assess the severity of IP's alcohol problems (Babor et al., 2001; Bush, Kivlahan et al. 1998). The instrument is used to measure risky alcohol consumption and related problems. The AUDIT contains 3 questions examining frequency, amount and intensity of alcohol consumption (called AUDIT-C (Berman et al, 2012)) which are used in a separate analysis. The instrument has not been validated in a youth population, but a validation study has been submitted for publication (Källmén, et al., 2018).
5. For assessment of IP's mental health, the Child Behavior Checklist (Achenbach and Rescorla 2001) is used, an instrument for guardians to assess various aspects of mental illness in young people. The instrument examines acting out behaviors and emotional problems, school performance and other factors in adolescents (12-18 years) during the past 6 months. The form is validated for Swedish conditions and is widely used in psychiatric youth research.
6. For assessment of the CSO's mental health, the Depression Anxiety Stress Scale - DASS-21 (Lovibond & Lovibond, 1995 (1)) is used. The DASS-21 is used to measure levels of depression, anxiety and stress and consists of 21 statements about symptoms experienced in the past week. DASS 21 has shown good reliability and has shown high correlation with other instruments that measure similar constructs, including the Beck Depression and Anxiety Inventories (Lovibond, P.F. & Lovibond, S.H. (1995 (2))).
7. To assess the CSO's satisfaction with the relationship with the IP, the Relationship Happiness Scale (Sisson & Azrin, 1973; 1986) is used. The RHS measures the degree of satisfaction with the relationship on 9 different dimensions (can include child/guardian, couples and other types of relationships).
8. For assessment of the CSO's quality of life, the scales EuroQoL (EQ-5D) (EuroQoL, 2011) and Satisfaction With Life-Scale (SWLS) (Pavot et al., 2008; Pavot et al., 1991) are used. EQ-5D is an instrument for describing and measuring health and health-related quality of life. It consists of a questionnaire as well as a form for self-rated health EQ VAS. In the questionnaire, the individual classifies their health in five dimensions (mobility, hygiene, main activities, pain/discomfort, anxiety/depression).  
The Satisfaction With Life Scale (SWLS) is a form intended to measure the individual's own perception of their general satisfaction with life. It consists of five short statements that are answered based on how well the person recognizes themselves in what is described. The scores are summed and give an indication of satisfaction with life.
9. Parental self-efficacy - PSE (Lindberg et al., 2014) is used to assess the CSO's belief in his own ability as a guardian. The questions examine self-efficacy and the guardians' belief that the parenting strategies they use are good for the young people.

10. For assessment of psychological flexibility of the participant, the Acceptance and Action Questionnaire - II (Bond et al, 2011) is used. The AAQ-II is a nine-item self-report instrument that measures emotional avoidance and emotion-focused passivity, constructs often related to anxiety and distinctive in individuals with anxiety disorders. The results from the AAQ-II show a significant correlation with anxiety and phobic avoidance in both clinical and non-clinical groups.

### **Statistical analysis**

The analysis is based on the intention-to-treat (ITT) principle. Secondary, a per protocol (PPT) analysis is performed for participants with outcomes at 24 weeks who completed 5 of 8 sessions.

The primary outcome measure (proportion of participants whose IP participates in care in CRAFT vs Counselling sessions during the time from baseline to 24 weeks) is estimated by conditional logistic regression utilizing multiple imputation by chained equations based on a distribution given other available variables. As a test for overall significance considering proportion of treatment seekers in CRAFT vs Counselling sessions, chi-square statistics will be calculated.

In the data analyses, two types of so-called mixed regression models (Mixed models) are used (Hesser, 2015). Secondary outcomes will be analyzed using generalized linear models (GLM) (continuous outcomes) or logistic regression (binary outcomes), for the same time period as for the primary outcome measure.

Moderating factors in the analysis include, among other things, frequency of contact, IP's gender and IP's age, and implemented components of the treatment.

Data will be analyzed to control for type of missing data. No explicit methods will be used to account for missing data if it is missing at random. Since the mixed model approach uses all the available information, it handles the intra-subject correlation and is robust to data missing at random.

### *Selection size*

The sample size is calculated on the primary outcome, help-seeking between baseline and 24-week follow-up, yes/no. The calculation assumes: the percentage of young people who sought help during the follow-up is 30% in the intervention group (CRAFT) and 10% in the control group (usual treatment). Previous CRAFT studies on adults have shown a significant increase in help-seeking for relative support with CRAFT (Bischof et al., 2016). However, we want to be more conservative in the assumption of effect size in the current adolescent population based on clinical experience at the current study clinic. Preliminary calculations show that approximately 40% of booked visits for young people at MiniMaria Stockholm result in no-shows (unpublished data). This indicates that young people in the current population may be more unwilling to participate in care, compared to adult individuals with addiction problems.

With a two-sided test where the significance level is set at 0.05, outcomes for 62 participants per group are needed to achieve 80% statistical power. With the additional assumption of

20% dropout in each group at the 24-week follow-up, at least 156 participants must be recruited (78 participants per group). In the randomization procedure (see below) blocks of 10 are used, which is why the number of participants is rounded up to the nearest ten. Thus, 80 participants are recruited per group, a total of 160 individuals.

#### *Randomization procedure*

The computer-generated randomization sequence for up to 160 participants is generated and paired with a random series of allocation numbers (1 for CRAFT and 2 for Counselling sessions) in blocks of ten. The allocation sequence is kept hidden from the study coordinator and the participant until the completion of the baseline measurement. A researcher unrelated to the study prepares numbered envelopes (1-160) containing the allocation assigned to participants by the study coordinator as they are included in the study. The code key for the randomization is kept separately from other study material.

#### *Blinding*

It is not realistic that the nature of support programs can be hidden from participants or treatment staff. However, the description of the interventions in the participant information is formulated in as neutral a way as possible to avoid possible expectation effects. The study coordinator also has information about the experimental conditions. However, it is unlikely that the study coordinator will remember each participant's allocation so the risk of bias is minimal. To the extent possible, the study coordinator (ES) and project manager (OS) will take one measurement session per participant each (i.e. one performs the baseline measurement, the other performs the follow-up measurement after 24 weeks) to minimize the risk of bias. The participants' randomization will not be visible to the study coordinator at the follow-up sessions. Responsible project investigator (Anders Hammarberg) and statistician will only have access to information about the trial conditions when the analysis of the primary efficacy measure has been completed. In this way, the risk of bias in the interpretation of the study's results is minimized.

#### *Ethical considerations*

It is difficult to foresee any serious risks of adverse health effects or other adverse consequences that participants would not experience if they refrained from participating in the study.

Filling in questionnaires and answering oral questions about personal relationships can be experienced as unpleasant and as a threat to one's privacy. In order to minimize negative consequences for the participants, the study is conducted in accordance with GCP (Good Clinical Practice). All personnel involved in the implementation of the study must have undergone such training. Participation in the study is voluntary and participants are free to withdraw from the study at any time without having to state any reason for this. All information obtained during the study is stored securely, written material is stored in locked medical records. Only aggregated data will be published impossible to derive to any specific person.

Previous studies of CRAFT have in rare cases been shown to increase the risk of violent behavior by IPs towards CSOs. At each treatment occasion, structured questions about tendencies towards violent behavior or threats of violence will be asked by the therapist

according to a checklist. The participants are also informed that at any time during the study they can contact the therapist and/or responsible researcher if the participant feels that there is a risk of violence or the threat of violent behavior. A careful assessment of the risk of violence is made in these cases, and is followed up by appropriate measures in the form of another support program or similar.

The potential risks should be set against the potential gains that can be achieved at different levels (personal, relational and societal) if a greater proportion of young people with substance-related problems come to care. From a preventive perspective, the study has great potential to contribute to reduced substance-related problems in society in the long term. This brings benefits both for the youth themselves, but also for the guardians for whom the psychological and physical burden is reduced.

### **Schedule**

The application to the regional ethics review board in Stockholm is planned for autumn 2018.

Other preparations for the study, which will be carried out in the autumn, include preparing Case Record Forms (CRFs) for the study, drawing up the randomization list and designing information materials. All therapists in the study must have undergone adequate training in the CRAFT method before the start of the study. A conservative estimate of the inclusion rate in the study, based on the addiction center's statistics for the youth section, is about 100 guardians per year. The estimate considers logistics around screening, inclusion and stays during summer and longer holidays. Recruitment for the study is therefore estimated to last until and including March 2020. A follow-up period of 24 weeks, together with time for data processing, data analysis and report writing, results in a study completion at the end of 2020. Total project time is estimated at three years.

### **The project group**

The project group includes researchers and clinicians with long experience of working with both young people and adults with substance-related problems, as well as their relatives. Doctor of Medicine, Licensed. Psychotherapist Anders Hammarberg, Department of Clinical Neuroscience, Center for Psychiatry Research at Karolinska Institutet. Hammarberg is the primary investigator and is responsible for study design, execution in accordance with GCP, data collection, data analysis, interpretation of results, and report writing. Hammarberg is responsible for the first CRAFT study for relatives of people with substance-related problems in Sweden. The study evaluated the effect of Internet-based CRAFT for relatives of adults with alcohol dependence. The study has been completed and the results are currently being compiled. Hammarberg has worked clinically in specialized addiction care since 1997. He has conducted research into the treatment of alcohol and drug addiction since 1999.

Doctor of Medicine, licensed psychologist Nitya Jayaram-Lindström, Department of Clinical Neuroscience, Center for Psychiatry Research at Karolinska Institutet. Jayaram-Lindström is director of operations for the Center for Psychiatry Research. Jayaram-Lindström oversees that the study is carried out in accordance with the research plan, in accordance with GCP, data collection, data analysis, interpretation of results, and report writing.

Licensed psychologist Ola Siljeholm at Riddargatan 1- Reception for alcohol and health, Stockholm Centre for Dependence Disorders, and doctoral student at the Department of Clinical Neuroscience, Karolinska Institutet. Siljeholm has previously conducted a pilot study on CRAFT in Sweden and has participated in the development of, and been a therapist in, the web-based version of CRAFT which is currently being evaluated in another project. Siljeholm has previous experience in child and youth psychiatry, including with child and parent groups.

Licensed Nurse Hanna Brännström, Head of Unit for Maria Youth, Mini Marias in Stockholm. In the project, Brännström has overall responsibility for the organization around therapists and relatives. Brännström has extensive experience in medical and psychosocial treatment work for adolescents and young adults within specialized addiction care.

Medicine Licentiate Eleonor Säfsten, Department of Public Health Sciences at Karolinska Institutet will participate in the project as study coordinator. In this role, she will have the main responsibility for screening interviews, marketing, follow-up of participants and other project-related tasks.

Maria Norling, licensed psychologist (including basic psychotherapist training) at Maria Youth Mini Maria Stockholm (BCS) participates in the project as a therapist in the CRAFT program. Norling has extensive experience of working with children and young people with various types of psychiatric and substance-related problems within BUP, the pediatric neurologist at the Karolinska University Hospital, the National Center for Obesity, Children and Adolescent Medicine (BUMM). Norling will soon complete her specialist training in clinical child and adolescent psychology. Norling is trained in the CRAFT method.

Catrin Eriksson, social secretary at the Social Service at Mini Maria Stockholm. Eriksson has extensive experience in working with relatives of people with addiction problems and was involved in the implementation of CRAFT in Botkyrka district administration and led several CRAFT groups there. Eriksson is trained in the CRAFT method.

Malin Bergström, Docent at the Department of Medicine, Solna, Clinical Epidemiology (KEP) and researcher at the Center for Health Equity Studies (CHESS), Stockholm University & Karolinska Institutet. Licensed psychologist specializing in child health care at Region Stockholm. Bergström assists through discussions and proposals about study design and outcome measures as well as through supervision and interpretation of results, data analysis and report writing.

Professor Sven Andréasson, Department of Public Health Sciences at Karolinska Institutet and chief physician at Riddargatan 1 Reception for alcohol and health, Stockholm Centre for Dependence Disorders. Andréasson assists by ensuring that the scientific questions are answered in accordance with the research plan, data analysis, interpretation of results, and report writing.



### *Previous experience with the methods and access to relevant personnel*

Within the project group, there is extensive experience in prevention and treatment work with young people with substance-related problems, as well as with adult relatives of such people. The project group is responsible for development and evaluation of support programs for relatives of individuals with substance-related problems within the Addiction Center Stockholm.

The researchers and therapists participating in the project have extensive expertise in the field of addiction, and work to develop and evaluate treatments for alcohol addiction as well as support programs for relatives. Together, the researchers contribute to an infrastructure for very good scientific and clinical expertise to carry out research projects.

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