

# BMJ Open Combining online Community Reinforcement and Family Training (CRAFT) with a parent-training programme for parents with partners suffering from alcohol use disorder: study protocol for a randomised controlled trial

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## ABSTRACT

**Introduction** Partners and children of individuals with alcohol use disorder (AUD) present with impaired quality of life and mental health, yet seldom seek or participate in traditional supportive interventions. Engaging the parent/partner without AUD in treatment is a promising way of supporting behavioural change in both the child and the parent with AUD. Universal parent-training (PT) programmes are effective in increasing children's well-being and decreasing problem behaviours, but have yet to be tailored for children with a parent with AUD. Community Reinforcement Approach And Family Training (CRAFT) programmes are conceptually similar, and aim to promote behavioural change in individuals with AUD by having a concerned significant other change environmental contingencies. There has been no study 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.

**Methods and analysis** n=300 participants with a child showing mental health problems and partner (co-parent) with AUD, but who do not themselves present with AUD, will be recruited from the general public and randomised 1:1 to either a four-module, online combined PT and CRAFT programme or a psychoeducation-only comparison intervention. 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, treatment seeking in all three parties and parental self-efficacy. Measures will be collected preintervention, mid-intervention and postintervention, and three times during a 2-year follow-up period. Data will be analysed using mixed-effects modelling.

**Ethics and dissemination** This study has been approved by the Stockholm Regional Ethical Review Board (2016/2179-31). The results will be presented at conferences and published as peer-reviewed publications.  
**Trial registration number** ISRCTN38702517; Pre-results.

## Strengths and limitations of this study

- The first study on combined Community Reinforcement Approach and Family Training and a parent-training programme for parents with partners with alcohol use disorder and shared children.
- Programme delivered online and is compared with an active control group receiving only basic psychoeducation.
- Large (n=300), community sample will be recruited and assessed preprogramme, mid- programme and postprogramme participation, and three times during a 2-year follow-up period.
- Long-term effects of intervention can only be studied within group since the active control group will receive the full intervention after the first phase.
- Study not designed to disentangle effects of each component, although mediating effects will be explored.

## INTRODUCTION

In Sweden, as many as 15% of men and 12% of women report a hazardous alcohol consumption<sup>1</sup> and 11% are estimated to meet criteria for alcohol use disorder (AUD).<sup>2</sup> The majority of these present with low to moderate severity and remain established in their social context.<sup>3</sup> As many as 20%–30% of community-dwelling children and adolescents perceive their parents to have alcohol problems.<sup>4–6</sup> However, there are few evidence-based prevention, supportive and treatment programmes developed for these children, likely due to inherent issues in identifying and reaching this population.<sup>7</sup> Thus, few children exposed to parental AUD are likely to

receive any kind of help, despite robust evidence showing that these children experience more adverse events while growing up, are at increased risk of early-onset and heavier drinking themselves, as well as developing mental health issues such as depression and anxiety, both in adolescence and adulthood.<sup>8–11</sup> Meta-analyses suggest that the intergenerational transfer of AUD is only 50% genetic.<sup>12</sup> Research suggests that non-optimal parenting behaviours may in part explain the association between parental AUD and child/adolescent mental health and alcohol problems, including inconsistent parenting practices and lower relational warmth.<sup>13–15</sup> Related risk factors (eg, concurrent conduct problems and provision of alcohol by parents) also increase the risk of child alcohol use.<sup>16</sup>

Very little is known about the parental dynamics in cases where one parent presents with AUD but the other does not.<sup>17</sup> While having one parent with AUD increases the odds of the child developing AUD and mental disorders, having one parent without AUD appears to be associated with somewhat lower risk of escalation of alcohol consumption during adolescence and young adulthood, and progression to AUD in the child,<sup>18</sup> suggestive of a partial protective factor. Qualitative research suggests that it is not uncommon for the parents without AUD to attempt to protect children from the negative consequences of the other parent's drinking, for example, by not leaving the AUD parent alone with the children or not allowing them to stay with the AUD parent, not engaging in arguments in front of the children and attempting to resolve negative consequences before there is impact on the children.<sup>19</sup> Such practices may have short-term benefits, but may also strain the parent–child relationship, with negative long-term consequences. Partners to individuals with AUD in general report lower relationship quality and rate the consequences of the AUD partner's drinking as more severe than the AUD partner themselves,<sup>20</sup> although it is unclear how this is moderated by having shared children.

Supporting the parent without AUD through targeted interventions is a potentially attractive method of improving the well-being of both the parent and child. Parent-training (PT) programmes, tailored to the needs and circumstances of this particular population, have the potential to provide support and teach parenting practices that improve the relationship between the child and the parent without AUD, and reduce behavioural problems and emotional distress of the child. PT programmes typically involve teaching participating parents to analyse and shape the child's behaviour through contingency management that reinforces desired behaviours, and ceases to reinforce undesired behaviours.<sup>21–22</sup> This includes learning how undesired, yet reoccurring behaviours have been reinforced unintentionally in the past, and how desired behaviours should be reinforced for maximum long-term effect. PT programmes are efficacious in reducing children's externalising behaviours,<sup>23</sup> in both younger<sup>24</sup> and older children.<sup>25</sup> Recent research

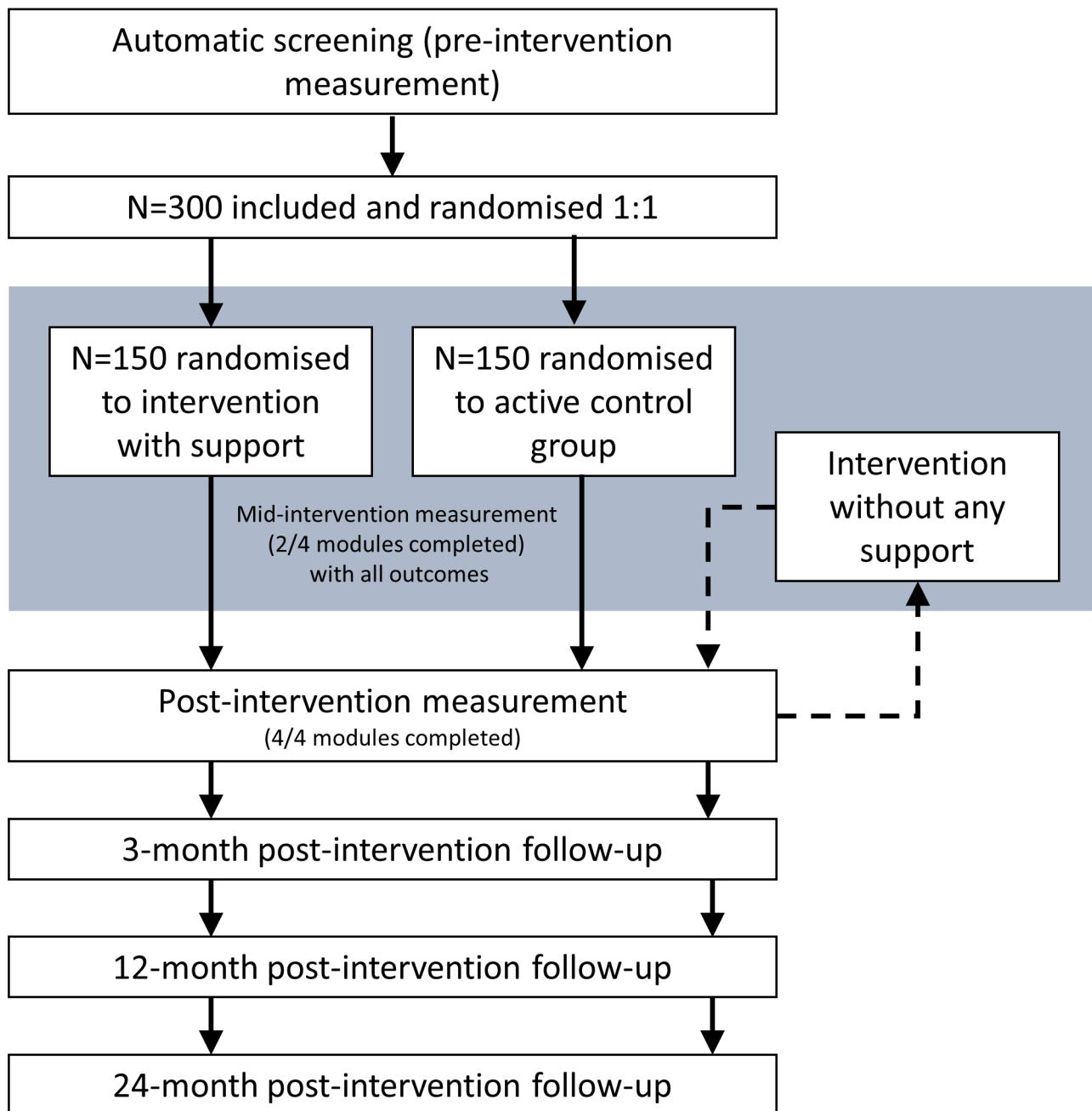
suggests that these programmes may be delivered as online self-help interventions, with and without guidance from a therapist.<sup>26–29</sup> PT programmes not specific to externalising behaviours also show promising efficacy.<sup>26</sup>

Behavioural PT programmes share many similarities with Community Reinforcement Approach and Family Training (CRAFT), an intervention developed for concerned significant others (CSOs) of individuals with AUD.<sup>30</sup> Rather than promoting distancing from the individual with AUD, a common theme in other types of CSO interventions,<sup>31</sup> CRAFT teaches CSOs to change environmental contingencies (eg, how to effectively reinforce non-alcohol-related behaviours and cease interfering with the natural negative consequences of their partners drinking), and promote help-seeking behaviours in the individual with AUD, while at the same time improving their own psychological health.<sup>30</sup> Several randomised trials involving both AUD and substance use disorder have shown that CRAFT programmes are more successful in engaging patients to seek treatment than comparison interventions.<sup>32</sup> So far, these trials have primarily evaluated programmes with a traditional format of repeated sessions with a therapist.<sup>31–33–35</sup> One low-powered study suggests that self-help bibliotherapy may also be an attractive method of delivering treatment.<sup>34</sup> There has been no study featuring a full, online self-help CRAFT programme for CSOs of individuals with AUD, as has recently been done in gambling disorder.<sup>36</sup>

We reasoned that a programme combining PT and CRAFT elements, aimed at parents with partners with AUD and shared children, will have both a direct and indirect positive impact on the children's well-being. Previous studies have shown that a dual-treatment approach, combining PT and substance abuse treatment for substance abusing parents themselves, show promising results.<sup>37</sup> There has been no study on combined treatment aimed at CSOs. We hypothesise that such an intervention would lead to changed parenting practices that decrease conflict and increase warmth between the child and the participating parent (CSO), as well as decreased alcohol consumption in the parent with AUD, both of which in turn will increase the child's mental health.

### Aims and hypotheses

The aim of the current study is to develop and evaluate an accessible, brief, online intervention, combining PT and CRAFT elements, for partners of individuals with AUD who share children. This will be examined in a randomised controlled superiority study. In order to be able to blind participants to allocation and to disentangle the impact of the core behavioural exercises presumed to promote change in the outcome measures, this novel intervention will be compared against an active control condition consisting of brief psychoeducational material only. We hypothesise that participants in the intervention group will report small to medium-sized increases in the child's mental health compared with the control group postintervention.



**Figure 1** Study flow chart.

## METHODS

### Procedure

See [figure 1](#) for study flow chart. Participants will be recruited from the Swedish general public, primarily through advertisements on established web sites, run by healthcare authorities, targeting individuals with AUD and their CSOs. Potential participants will be directed to a website presenting study information and terms of participation, where they provide informed digital consent, can create a personal, anonymous account and answer the screening battery serving as the preintervention measure. Participants will be informed that they will be randomised

to one of two interventions, both of which are expected to be effective (ie, no placebo).

Inclusion or exclusion will be automatically decided by the responses to the screening items. Participants eligible for inclusion will be automatically randomised (allocation tickets drawn from a predetermined block-randomised scheme that is reshuffled prior to each draw; no stratification) on accessing their assigned (blinded) treatment programme for the first time, within 1 week of completing the screening battery. After completing the control intervention and the postmeasurement, participants in the control arm who still meet the inclusion criteria applied

at study screening will be informed that they can access the full intervention programme if they so desire. Participants in this round will not have access to staff to answer questions.

Participants who are excluded either for not having a child, not having a child in the required age span or scoring above the symptom threshold, for being exposed to physical violence, having a CSO with drug problems, or having their own problematic drinking, will be offered inclusion in one of two separate, parallel intervention studies with similar designs and featuring similar interventions, and prompted to seek help elsewhere when necessary.

### Sample

We aim to recruit  $n=300$  anonymous participants whom will be randomised 1:1 to each of the two arms. This study is powered to detect a minimum between-group effect size of Cohen's  $d > 0.4$  at postintervention (t-test with 80% power, two-sided  $p=0.05$ ) with maximum likelihood estimation of missing data, expected to fall in the range of 10%–30% at the postmeasurement based on past studies on similar online parenting interventions.<sup>26–29</sup> The effect size threshold was based on the medium-sized effect reported in the validation study of the PT programme incorporated in the current study.<sup>26</sup> Participants must have a child (aged 3–11) presenting some impairments in mental health, together with an individual presenting AUD (cohabitating or not), but

must not present with AUD themselves. See [table 1](#) for full inclusion and exclusion criteria.

### Interventions

#### Intervention programme

The intervention programme will consist of four sequential modules, each covering both PT<sup>26</sup> and CRAFT components,<sup>30</sup> corresponding to roughly 10 pages of written material per module together with short films that illustrate core components of the programme. All four modules will be divided into three different themes: (1) enhancing own well-being, (2) strategies as a CSO, (3) parental strategies. Each module will also contain a number of exercises aimed at promoting behavioural change and improving skills. See [table 2](#) for a summary of content and exercises in each module. Modules will be made available as completed, although with a 1-week minimum waiting period in-between. An additional information and frequently asked questions module, available at all times, will include information on alcohol and dependence, advice and details of legal aspects, the responsibilities and duties of social services, and other practical information. A moderated discussion forum is also available at all times through the website from which participants were recruited.

Participants will be informed at programme onset that support staff are available to answer questions about programme content and use. Support staff are however not considered treatment providers; thus, if issues arise that are beyond the scope of the treatment programme

**Table 1** Inclusion and exclusion criteria

	Inclusion criteria	Exclusion criteria
Concerning the shared child	Aged 3–11.	Has participated in any kind of intervention for children to parents with AUD in the last 3 months.
	Lives $\geq 4$ days/month with parent who meets AUD criteria.	Has been exposed to family physical violence once or more within the last 3 months.
	Scores above population means on any of the five subscales, or the total score, of the SDQ, indicative of poor mental health.	Scores above 95th percentile population norms on any of the five subscales, or the total score, of the SDQ, indicative of severe distress or impairment.
Concerning parent with AUD	Indicated AUD, defined as a CSO-rated AUDIT-C score $\geq 4/5$ (women/men) and/or $\geq 2$ CSO-rated ICD-10 dependence criteria.	Use of illicit drugs $\geq 1$ per week during the last 12 months, as reported by CSO.
Concerning the participant (CSO)	18 years or older.	Meets criteria for AUD (defined above).
	Sufficient grasp of written Swedish to follow instructions, complete screening battery and provide comprehensible, coherent answers.	Use of illicit drugs $\geq 1$ per week during the last 12 months.
		Severe mental health problems, defined as either scores in the severe range on all three DASS subscales, or in the extremely severe range on two of three subscales.
		Already participates in any kind of intervention for partners to individuals with AUD.

AUD, alcohol use disorder; AUDIT-C, Alcohol Use Disorder Identification Test; CSO, concerned significant other; DASS, Depression Anxiety and Stress Scale; SDQ, Strengths and Difficulties Questionnaire.

**Table 2** Summary of intervention programme and control intervention

Module	Intervention programme		Control intervention
	Content	Exercises	Content
#1	# General information about programme # Setting a goal for own well-being # Decreasing ineffective strategies towards the drinking parent # Safety precautions # Spending positive time with the child (dedicated parent–child time, DPCT)	# Make time for own positive activities # DPCT	# Information about being a CSO to an individual with AUD
#2	# How to enhance own well-being # Detailed analysis of drinking situations # Talking about alcohol with children # Giving attention to positive child behaviours	# Goal setting # Detailed analysis of specific drinking situation # Focus on functional child behaviours # DPCT	# Information about AUD and dependence
#3	# Self-respect # Positive communication # Analysis of interplay with the drinking parent # Problematic parent situations # Rewarding positive child behaviours	# Exercise in positive communication # Mapping interactions # DPCT	# Information about taking care of yourself and your family
#4	# Handling negative emotions # Find support for self or children # Encouraging help seeking in drinking parent # How not to protect against natural negative consequences of drinking # Strategies for conflict situations with children	# Planning ahead # DPCT	# Information about finding help

AUD, alcohol use disorder; CSO, concerned significant other.

(such as violence and child abuse), support staff will suggest other alternatives where the participant can seek help. There will be no regular feedback or compliance checks that is typical of guided internet-based cognitive-behavioural therapy (CBT) for psychiatric and psychosomatic disorders.<sup>38 39</sup>

#### Active control

The control group will be given access to a brief psychoeducation programme, split into four modules and distributed in the same manner as the intervention programme (modules made available as completed, although with a minimum 1-week waiting period). The psychoeducation programme will cover basic aspects of AUD, being a CSO to an individual with AUD and having shared children, but will not contain any exercises aimed at promoting behaviour change. See [table 2](#) for details. Participants will also have access to a discussion forum.

#### Measures

All measures are self-reported and will be collected via a secure online platform using either validated instruments or tailored questions. Participants who do not respond will be sent automatic reminders according to a predefined schedule. After completing the second of four modules or after a maximum of 4 weeks, participants will respond to the mid-intervention measurement. Once the fourth and last module is completed or after a maximum of 8 weeks, participants will respond to the postintervention

measurement. All outcome measures will be collected at all measurement occasions.

#### Primary outcomes measure

The primary outcome measure will be the Swedish, parent-rated version of the Strengths and Difficulties Questionnaire (SDQ) for children,<sup>40</sup> a common measure of child and adolescent mental health validated for use as an outcome measure.<sup>41 42</sup> In cases where the participant has several children with the co-parent with AUD, participants are instructed to assess the child believed to be worst off and keep assessing this child throughout the intervention. The SDQ features 25 items, mapped onto five subscales: emotional symptoms, peer relationship problems, conduct problems, hyperactive/inattention and prosocial behaviours. The item response format is a three-step Likert-style scale scored 0–2. For screening purposes, the original five subscales and total score will be used, together with Swedish population mean and 95th percentile norm data.<sup>43 44</sup> In turn, the SDQ total score will serve as the primary outcome measure. The subscales of the collapsed three-subscale solution (internalising behaviours, externalising behaviours and prosocial behaviours), recommended for community samples,<sup>45</sup> will serve as secondary outcome measures.

#### Secondary outcome measures

Additional secondary outcome measures will cover alcohol consumption, mental health, social functioning

and help seeking among the participant, the child and the AUD parent. The participants own mental health will be measured using the 21-item Depression Anxiety and Stress Scale,<sup>46</sup> with each subscale analysed separately. The participants own, and the AUD parent's estimated alcohol consumption will both be measured using the three consumption questions of the Alcohol Use Disorders Identification Test (AUDIT-C).<sup>47</sup> Relational warmth and conflict between the participant and the child will be measured using the Adult-Child Relationship Scale (ACRS).<sup>48</sup> Estimated number of ICD-10<sup>49</sup> alcohol dependence criteria met by the AUD parent will be measured using a tailored questionnaire. Help-seeking behaviour of the child, AUD parent and the participant will also be measured using tailored questionnaires. Finally, parental self-efficacy will be measured using a questionnaire developed for and used in a previous study on the same PT programme used in the current study.<sup>26</sup>

### Programme engagement

Programme engagement will be measured by automatic data collection on number of modules accessed, tasks completed, interactions with support staff, forum activity, as well as by asking participants at the beginning of each module (starting with the second) to report number of dedicated parent-child time occasions in the last week. Associations between programme engagement metrics and treatment outcomes will be explored.

### Analytical plan

Outcomes will be analysed according to the intention-to-treat principle, using mixed-effects models, either linear (numeric outcomes, eg, symptom scores), Poisson (count outcomes, eg, alcohol dependence criteria met) or logistic (binary outcomes, eg, treatment seeking). By modelling change at both group (fixed) and individual (random) levels, mixed models are well suited for clustered (dependent) data such as repeated observations, and can handle missing data more flexibly using maximum likelihood estimation,<sup>50</sup> as will be done in the current study. Per-protocol analyses will also be performed using linear measures of treatment completion. Additionally, subgroup analyses contrasting cohabiting versus non-cohabiting partners (regardless of marital status) will be performed, with larger hypothesised effects for cohabiting partners based on the assumption that they spend more time together. Separate piecewise regression models featuring the premeasures, middle measures and postmeasures (segment 1), and the 3, 12 and 24 months' follow-up measures (segment 2), as separate segments will be used to analyse long-term effects of the intervention programme (the comparison group will not be included since no equivalent measures are available after the postmeasurement).

Cohen's *d* effect size will be calculated based on observed values at any given time, under the missing at random assumption. Mediation will be examined in latent growth models as indirect effects on the primary

outcome measure.<sup>50</sup> The latent slopes of the two mediators (AUD parents AUDIT-C scores and ACRS scores, respectively) will be modelled as separate indirect effects such that in addition to a direct path (*c'*) between intervention and the primary outcome slope, the product of the paths between intervention and the respective mediator slope (*a*), and between the respective mediator slope and the outcome slope (*b*) will also be modelled. A significant indirect effect (*a\*b*), along with a significant direct effect, is indicative of partial mediation.

### Patient and public involvement

The need for the intervention was informed by clinical experience. An interview study was conducted in preparation for this trial and the development of the intervention. This interview study recruited help-seeking CSOs who share children with an individual with AUD. The focus of the semistructured interviews was: (1) Experiences of being a parent in such a situation and the impact on the child; (2) What support do they need in their role as parents. The results informed the development of the intervention; full methods and results will be presented in a separate study.

Patients were not involved in the design or execution of the trial. Results of the trial will be disseminated to participants through a notification on the intervention platform. Burden of the intervention was not assessed by patients prior to commencing the trial; patient experiences of using the intervention will however be collected as part of the postintervention assessment.

### DISCUSSION

This study protocol describes the first study on the efficacy of an online intervention programme combining CRAFT and PT elements, for parents who share children with individuals with AUD, with the primary aim of improving the mental health of the child. Children exposed to parental AUD are at increased risk of adverse childhood experiences,<sup>11</sup> present impaired quality of life and increased rates of mental health problems.<sup>8-10</sup> However, there are few evidence-based supportive interventions developed and disseminated for these children.<sup>7</sup>

The intervention programme evaluated in this randomised controlled superiority trial is designed to be accessible and easy to use, and could be made available at very low cost to the public by a stakeholder. Widespread dissemination of such a programme has the potential to reduce public health costs, both immediate and in the future. Stigma and shame, along with misconceptions about available treatment options are strong barriers to treatment seeking among individuals with AUD themselves,<sup>51</sup> and only around a quarter will eventually seek treatment.<sup>52</sup> Interventions aimed at CSOs, like CRAFT, are thus an attractive, pragmatic way of reducing excessive drinking and its negative consequences in the present. Given the well-known intergenerational transfer of AUD, along with other negative outcomes of having

a parent with AUD while growing up, PT programmes aimed at children with parents with AUD have the potential to reduce the adolescent and adult prevalence of AUD and other mental health disorders among parental AUD-exposed children. We expect both the CRAFT and PT elements to have effects on the child's mental health. While the CRAFT exercises are aimed at decreasing the AUD parent's drinking and improving the participants own well-being, reducing the negative consequences experienced by the child, the PT elements are aimed at promoting positive parenting practices that increase parent-child relationship warmth and decrease conflict, both of which would likely improve the child's mental health. CRAFT and PT both rely on contingency management and other behavioural techniques and can thus with ease be taught in conjunction.

Participants in the comparison group will be offered the full intervention programme after the first phase of the trial, assuming they still meet the inclusion criteria applied at baseline. No support staff will however be available to this group. Comparing achieved within-group effect sizes (without a direct statistical contrast) will give a cautious, preliminary indication (akin to comparisons across studies) about the added effect of having support staff versus not, which is an important aspect to evaluate for future implementation and dissemination purposes. In online CBT self-help interventions for depression and anxiety disorders, guidance is associated with greater treatment engagement and greater effect sizes.<sup>50</sup> Guidance in this setting typically involves the therapist sending regular feedback on exercises and reminders to engage with the treatment material,<sup>38</sup> with specific therapist behaviours having been associated with better outcomes,<sup>53</sup> although the direction of this causality is unknown. In the current study, support staff will only engage with participants to answer questions posed by the participant. Automated feedback on tasks will however be implemented.

## LIMITATIONS

The current study was not designed to disentangle the unique impact of each intervention component (PT and CRAFT), opting instead for an integrated approach. Mediating factors associated with each component will however be investigated using carefully selected measures and a study design suitable for these purposes. Because still-eligible participants randomised to the active control group will be offered the full intervention programme after the first phase of the trial, there will be no comparison data for the follow-up period.

## ETHICS AND DISSEMINATION

All participants will provide informed consent digitally by checking a box prior to completing the screening battery.

Results will be disseminated through journal articles (compliant with Consolidated Standards of Reporting Trials criteria<sup>54</sup>), conference presentations, media

appearances and reports to the funding agency. Principal investigator AH is responsible for data storage and will consider reasonable requests for access.

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**Competing interests** None declared.

**Patient consent** Not required.

**Ethics approval** This trial has received ethical approval from the Regional Ethical Review Board in Stockholm (2016/2179-31).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Author note** The trial began recruitment in early December 2017. Recruitment will continue until target sample size is met. There has been no revision to the original study protocol.

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