

Article

Efficacy of an Internet-Based Community Reinforcement and Family Training Program to Increase Treatment Engagement for AUD and to Improve Psychiatric Health for CSOs: A Randomized Controlled Trial

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Abstract

Aims: Community Reinforcement Approach and Family Training (CRAFT) is a support program for concerned significant others (CSOs) to identified persons (IPs) with alcohol use disorders, with the purpose of engaging IPs to treatment and to improve CSO functioning. The purpose of the present study was to investigate the efficacy of an internet-based version of CRAFT (iCRAFT).

Methods: Randomized controlled trial comparing iCRAFT with a wait-list (WL) condition with a nation-wide uptake in Sweden. A total of 94 CSOs to a treatment refusing IP, who described the IP according to DSM-IV criteria for alcohol dependence or abuse, were included in the study. iCRAFT consisted of five weekly administered therapist-guided modules with the following content: (a) improve CSOs' own mental health, (b) improve the CSOs skills in asking the IP to seek treatment, (c) positive communication skills training, (d) contingency management of IP drinking behavior. Main outcome measure was IPs initiative to seek treatment measured at 24 weeks. Secondary outcomes were IP's daily alcohol consumption, CSOs mental health, quality of life and relational satisfaction.

Results: Of 94 participants, 15 CSOs reported IP treatment initiative during the study period. Of these, 10 belonged to the iCRAFT condition and five to the WL condition. The difference between conditions was nonsignificant, and the results were inconclusive. Participants in iCRAFT showed short-term improvements regarding depressive symptoms, quality of life and relational happiness.

Conclusion: This study was unable to demonstrate substantial changes in the iCRAFT program regarding IP treatment seeking or CSO mental health.

INTRODUCTION

The severe effects of alcohol use disorders (AUD) do not only affect the individual but also have a great impact on concerned significant others (CSOs) within the social network. CSOs consistently indicate lower quality of life and impaired physical and mental health (Ray *et al.*, 2009; Casswell *et al.*, 2011), higher levels of psychological distress (Velleman *et al.*, 1993; Tempier *et al.*, 2006) and an increased risk of being diagnosed with substance use disorders (SUDs) compared with controls. The CSOs are also subjected to an increased risk of intimate partner violence (Cunradi *et al.*, 2002). Furthermore, only 10–15% of individuals suffering from AUD enter treatment (Stinson *et al.*, 2005; Degenhardt *et al.*, 2017). Together, this points to a great need for support programs tailored to alleviate CSOs from stress and strain, while at the same time increasing the motivation for the identified person (IP) to seek treatment for AUD. Traditionally, support programs for CSOs have been based on the premise that CSOs should detach from responsibility for trying to alter IP's drinking problem (Groups, 1995). Other programs center around a confrontational meeting in which one or several CSOs meet with an IP, in order to motivate the IP to seek help. Little is known about the efficacy of such models due to lack of well-designed studies (Landau *et al.*, 2004). Community Reinforcement Approach and Family Training (CRAFT) is a support program for CSOs to IPs who are not currently motivated to seek treatment. CRAFT is based on core principles used in behavioral therapy. CRAFT have the following main aims: (a) to increase the quality of life of CSOs by increasing engagement in recovering activities; (b) to decrease IP's alcohol use by teaching CSOs how to change their own behavior in order to minimize the positive consequences of alcohol use for IPs, to increase positive consequences of IPs sober and healthy activities and to communicate in a clear and positive way; and last (c) to increase IP's treatment engagement by developing CSOs skills in proposing treatment seeking (Smith and Meyers, 2004). The efficacy of CRAFT has been investigated in different populations, including drug users (Meyers *et al.*, 1998) and problem gamblers (Nayoski and Hodgins, 2016). Concerning CSOs for individuals suffering from AUD, CRAFT has shown to improve rates of treatment engagement for IPs compared with other support programs, while at the same time improving the physical and mental health status and quality of life of CSOs (Miller *et al.*, 1999; Bischof *et al.*, 2016).

Therapist-guided internet interventions are now an established alternative for the treatment of a wide range of psychiatric and somatic disorders (Andersson, 2016). Internet-based treatments also have the advantage of high availability with the potential of attracting participants who would otherwise not participate in treatment due to practical concerns or time constraints (Carlbring *et al.*, 2018). In the area of AUD, internet-based approaches have shown corresponding efficacy as face-to-face treatment (Riper *et al.*, 2008; Wallace *et al.*, 2011; Sinadinovic *et al.*, 2014). It has still not been investigated whether internet-based CRAFT has an effect on IP treatment seeking, IP alcohol consumption and mental health of CSOs.

Thus, this study is the first to investigate the efficacy of an internet-based version of CRAFT (iCRAFT). Since no previously evaluated treatment as usual for CSOs with the aim of engaging unmotivated IP's to treatment exist in Sweden, a wait-list (WL) design was chosen in the present study. Differences in IP treatment engagement and alcohol consumption as well as mental health, quality of life and relational happiness for CSOs were expected in favor of participants in the iCRAFT condition compared with the WL-condition at 6, 12 and 24 weeks following inclusion in study.

MATERIAL

Trial design

This randomized controlled trial compared the efficacy of iCRAFT for CSOs with a WL as the comparison group. Assessment of primary and secondary outcomes was conducted at baseline, at 6, 12 and 24 weeks after inclusion in study. The full trial protocol is available in the ISRCTN-registry: <https://doi.org/10.1186/ISRCTN38220020>.

PARTICIPANTS

Recruitment

Participants were recruited nationwide in Sweden by advertisements at different internet sites and in a local newspaper. In the advertisement, it was expressed that important goals with the iCRAFT program were to improve CSOs own mental health and to increase the likelihood for IPs treatment engagement. Individuals who were interested in participating registered on a secure website and completed a short online screening including age, sex, relational status and occupational status for both CSO and IP, questions about the CSO's relation to the IP, amount of time spent with the IP, whether or not the IP would seek treatment if prompted and whether IP had sought treatment during the last 6 months. Registered individuals aged 18 years or older who provided their phone number were contacted and scheduled for a telephone-based structured interview with a licensed clinical psychologist to assess study eligibility. To determine the presence of other comorbid psychiatric disorders, the Mini-International Neuropsychiatric Interview (MINI) was used (Sheehan *et al.*, 1998). All interviewers had undergone training in structured diagnostic interviewing. Telephone-based interviews have previously been shown reliable for structured psychiatric assessments (Rohde *et al.*, 1997). During the interview, potential participants received detailed study information.

Inclusion criteria for CSOs were as follows: (a) ongoing relation with a treatment resistant IP meeting the DSM-IV diagnosis of alcohol dependence or abuse; (b) age of at least 18 (both the CSO and the IP); (c) spending time with the IP in at least 40% of the last 90 days, with no planned future change in this respect (the cut-off level was chosen so as to be in accordance with previous CRAFT studies, e.g. (Meyers *et al.*, 1998); (c) confirmation from CSO that IPs have consumed alcohol in at least 30 of the last 90 days; (d) confirmation of having a goal of engaging the IP to treatment if possible; and (e) consenting to participate in the study.

Exclusion criteria were as follows: (a) CSO confirming that IP was not treatment resistant, i.e. that IP would agree to seek alcohol-related treatment if asked; (b) alcohol-related treatment for IP within the last 6 months, which may be considered as an indication of that IP was not completely negative regarding to seek treatment (Meyers *et al.*, 1998; Bischof *et al.*, 2016); (c) major psychiatric or somatic illness for CSO or IP; (d) CSO describes IP as meeting the DSM-IV diagnosis of substance dependence or abuse (not alcohol or nicotine); (e) insufficient skills in the Swedish language; (f) participation in a CSO support program (e.g. Al-Anon) during the last 12 months; and (g) risk for domestic violence from IP. CSOs who were found ineligible were guided to relevant help tailored to the individual. In cases where risks for violence were identified, CSOs were referred to a national support helpline primarily aimed at women exposed to threats and violence but who also invites men to call, or if necessary, appropriate health care service. All participants provided informed consent before inclusion in the study, following the screening interview. The study was performed in accordance with the Helsinki declaration and was

approved by The Regional Ethical Review Board in Stockholm (Dnr: 2014/2157-31/4).

Eligible participants ($n = 94$) were then asked to fill out the baseline assessments. Following baseline assessments, participants were automatically randomized to iCRAFT or WL in blocks of 10 using an automated and concealed procedure in the online platform (see Fig. 1). There was no blinding to study allocation. Participants were enrolled between May 2015 to December 2016.

INTERVENTIONS

The iCRAFT program

iCRAFT was modeled according to the treatment manual developed by Smith and Meyers (Smith and Meyers, 2004) and contained the same basic elements. In previous studies in which the CRAFT program comprised 10–12 weekly sessions administered in a face-to-face fashion, the average number of sessions until treatment engagement of IPs was 4–6 (Miller *et al.*, 1999). Previous studies on internet delivered treatments have indicated that the attrition rate increases with the number of modules (Christensen *et al.*, 2009). Hence, the number of modules were reduced to five in order to encourage treatment adherence to iCRAFT. The modules were delivered once a week for 5 weeks, and each module comprised one or more CRAFT elements. Each iCRAFT module comprised information in text-form and short films, exercises designed to plan an actual behavior change and a homework assignment designed for CSOs to initiate and to practice new behaviors. No face-to-face, telephone or other mode of interaction occurred between participants and study therapists. iCRAFT was administered according to the following sequence: (1a) introduction and rationale for the program in order to strengthen the motivation of the CSO; (1b) strategies for CSOs to improve own mental health (part 1). Homework assignment comprised a plan for improvement of CSOs own mental health; (2a) strategies to improve the likelihood of a positive response when asking IP to seek treatment (part 1); (2b) positive communication skills training. Homework assignment comprised the practicing of eight helpful communication skills; (3) contingency management of IP drinking behavior, i.e. functional analysis of drinking behavior. Homework comprised the practicing of analyzing IP's drinking behavior according to the principles of functional analysis; (4) positive reinforcement of abstinence. Homework assignment comprised the practicing of formulating a plan for reinforcing nonalcohol-related behaviors; (5a) not interfering with negative consequences of drinking and removal of planned reinforcers in situations where IP drinks; (5b) strategies to improve the likelihood of a positive response when asking IPs to seek treatment (part 2); (5c) strategies for CSOs to improve own mental health (part 2). Homework assignment comprised a plan for withholding planned reinforcers in situations where IPs consume alcohol, a plan for having a conversation with IP concerning treatment seeking and lastly to have a plan concerning how to handle relapses to previous drinking behaviors.

Both exercises and homework assignments were reported in text to the therapist via the study platform. The therapist provided feedback adjusted to improve the CSOs adaptation of the CRAFT components and to reinforce CSO behavior change according to the CRAFT protocol. The basis for this feedback is the manual for CRAFT (Smith and Meyers, 2004) in which the content for each CRAFT procedure is described. The personalized feedback was based on the principles of motivational interviewing (Miller and Rollnick, 2013), and all study therapists were licensed psychologists trained in

the CRAFT method. Study therapists were supervised by one of the first authors (K.R.) to ensure treatment fidelity.

Participants were assigned a new module after completing the homework assignment associated to the previous module. In cases where the participants did not complete homework assignments, therapists contacted the inactive participants to encourage them to proceed with the intervention. Modules for which the CSOs did not report the homework assignment to the therapist were considered as incomplete. In line with the procedures used in a study on CRAFT administered as self-help material (Manuel *et al.*, 2012), participating CSOs had continuous access to completed modules until end of study (6 months after inclusion).

Since a heightened risk for violence was an exclusion criteria, the iCRAFT program did not include a mandatory module with violence precaution strategies. Instead, participants in the iCRAFT condition indicating an incidence of threats of violence during the study period were contacted by telephone by the study coordinator in order to conduct a violence risk assessment. In addition, participants in both the WL- and iCRAFT-condition were referred to the national helpline for victims of interpersonal violence previously described. In total, 26 participants were contacted according to this procedure, whereof all participants remained in the study (see Fig. 1).

WL CONDITION

WL participants participated in the iCRAFT program 24 weeks after inclusion in the study, i.e. after study termination. During the first 24 weeks, WL participants went through the same study assessment procedures as the iCRAFT participants.

PRIMARY AND SECONDARY OUTCOMES

All primary and secondary outcomes were based on CSOs reports, and assessments were filled out on the study platform. The primary outcome was the proportion of IPs seeking treatment during the 24-week follow-up period. Secondary outcomes were as follows: (a) IPs alcohol consumption according to the following definitions: (i) proportion of days with any alcohol consumption and (ii) proportion of days with heavy drinking according to Swedish guidelines (i.e. ≥ 48 g of alcohol for women and ≥ 60 g for men) and (iii) mean number of drinks (1 drink = 12 g of alcohol) per week during the 90 days before inclusion in the study compared with the period from baseline to 6, 12 and 24 weeks respectively; (b) mental health (depression, anxiety and stress); (c) quality of life for CSOs; and (d) relational satisfaction.

INSTRUMENTS

The primary outcome, IP treatment seeking behavior, was measured by the following question: 'Have your close one during the last () weeks taken any initiative to seek treatment for alcohol problems?' on which the participant indicated a positive or negative response. If a CSO indicated a positive response, he or she was asked to specify which forms of treatment that the IP had sought, from a list of 10 prespecified options and one free text alternative. IP alcohol consumption was measured using the timeline follow back technique (Sobell and Sobell, 1996). CSO reports on IP treatment engagement and alcohol consumption has shown acceptable reliability in previous studies (Kirby *et al.*, 1999; Miller *et al.*, 1999).

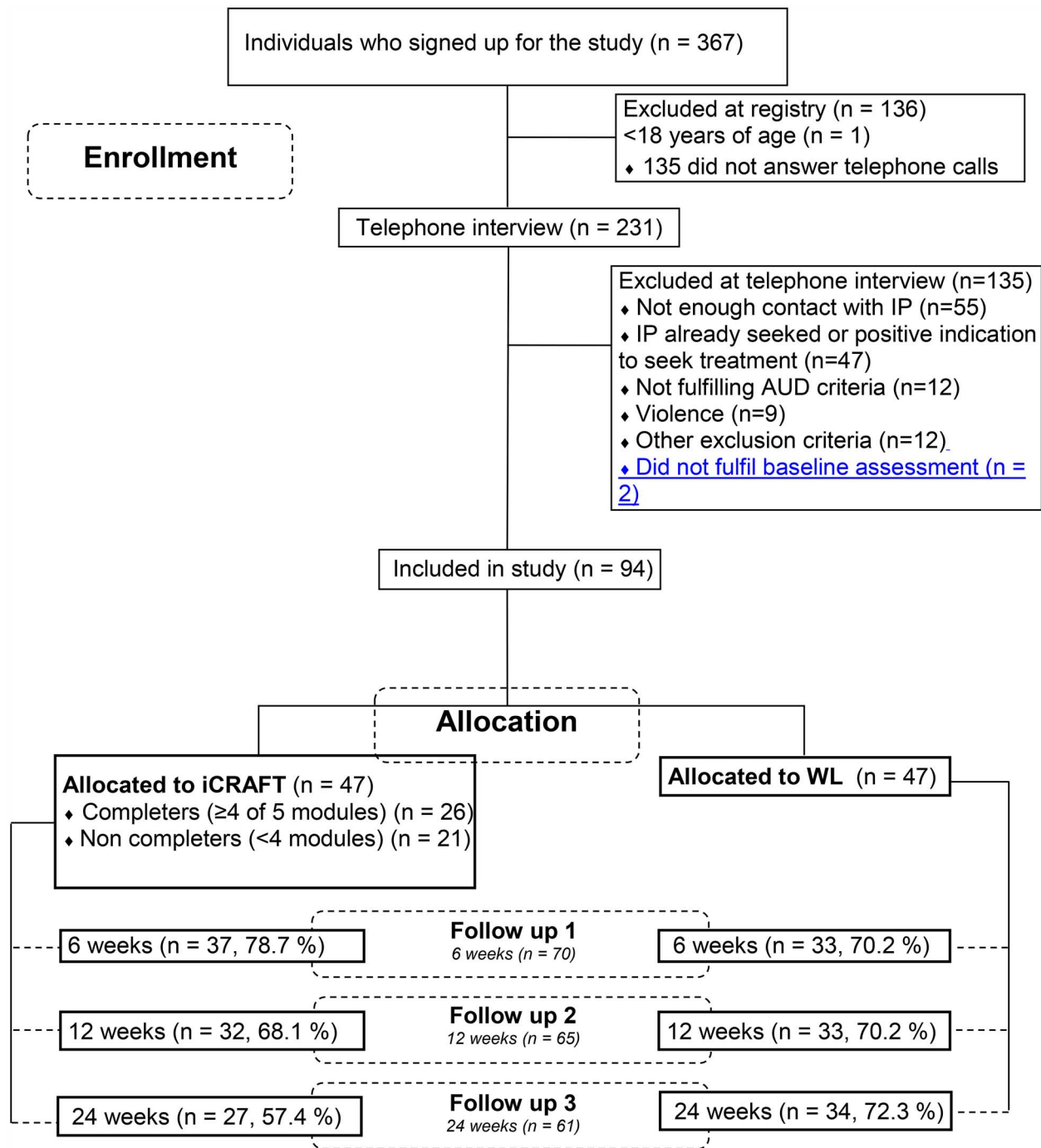


Fig. 1. Flow chart of study enrollment and allocation.

Mental health of CSOs was measured using (a) General Anxiety Disorder seven-item scale (GAD-7)(Spitzer *et al.*, 2006) for anxiety where a score above 5 indicates mild, above 10 moderate and above 15 severe anxiety; (b) Montgomery Åsberg Depression Rating Scale (MADRS-S)(Svanborg and Åsberg, 1994) for depression where a score between 13 and 19 indicates mild depression, 20–34 indicates moderate depression and above 34 indicates severe depression; (c) Depression, Anxiety and Stress Scales (DASS 42)(Lovibond and Lovibond, 1995) where for depression a score between 10 and 13 indicates mild, 14–20 indicates moderate, 21 and above indicates severe depression, for anxiety a score between 8 and 9 indicates mild,

10–14 indicates moderate, 15 and above indicates severe anxiety, for stress a score between 15 and 18 indicates mild, 19–25 indicates moderate, and 26 and above indicates severe stress; and (d) Acceptance and Action Questionnaire (AAQ)(Bond *et al.*, 2011; Lundgren and Parling, 2017).

Quality of life of CSOs was measured using Satisfaction With Life-Scale (SWLS)(Pavot *et al.*, 1991; Pavot and Diener, 2008). Relational satisfaction of CSOs was measured using Relationship Happiness Scale (RHS)(Azrin *et al.*, 1973) (one item concerning affection/sex was excluded to enable use in different types of relationships).

IP alcohol consumption was assessed weekly. Nonresponders of the weekly assessments were sent one automatic reminder after 2 days without a response. All other assessments were conducted at inclusion and then again at 6, 12 and 24 weeks after inclusion. Nonresponders were sent an automatic reminder every other day for up to 6 days. After receiving the last reminder for both the follow-up measures and the weekly assessments, nonresponders were contacted by the study coordinator via telephone and encouraged to fill out the questionnaires.

ANALYSES

Sample size determination and power calculation

There were no previous studies on an internet-based CRAFT program for IPs suffering from AUD at the time for the planning of this study. Hence, the power analysis had to be based on assumptions drawn from previous studies applying a regular face-to-face CRAFT program for CSOs. Previous studies have used 'active' programs as control (Al-anon; JII) (Kirby *et al.*, 1999; Miller *et al.*, 1999), and since the comparison group in the present study received no active intervention, we might expect effect sizes at least equal to previous studies. However, due to a mode of administration not previously evaluated and a probably less stable primary outcome measure based on CSO reports of IPs treatment engagement, we applied a more conservative estimation for the present study. Based on these assumptions, we anticipated an effect size of 0.3 according to Cohen's definition, with a power of 0.8 to detect differences between groups, with an alpha level of 0.05. The sample size was initially determined to 140 participants. However, the pace of inclusion in the study was unexpectedly slow, which brought enrollment to be stopped prematurely when 94 participants had been included.

Statistical analyses were by intention-to-treat (ITT). The treatment effect for the primary outcome (proportion of IPs who according to CSOs in iCRAFT vs WL had engaged in treatment during the time from baseline to end of study (24 weeks)) was estimated by conditional logistic regression utilizing multiple imputation by chained equations based on a distribution given other available variables. The results of the logistic regression on each iteration of imputation are pooled based on Rubin's rules. As a test for overall significance considering proportion of treatment seekers in iCRAFT vs WL, chi-square statistics were calculated.

Secondary outcomes were calculated using mixed models. Proportion of days with any alcohol consumption and heavy drinking was compared between iCRAFT and WL at different time points using mixed binomial model due to the fact that data was represented as a categorical variable (any alcohol consumption/no alcohol consumption). No explicit methods were used to account for missing data. However, since the mixed model approach uses all the available information, it handles the intra-subject correlation and is robust to data missing at random.

Differences in mean number of standard drinks per week for iCRAFT compared with WL over the different time-points were analyzed using a Poisson mixed model due to the fact that data was represented as count data.

Scores on mental health, quality of life and relational happiness were compared between iCRAFT and WL using a normal mixed model.

A secondary completer's analysis was also carried out in which a completer was defined as a CSO completing at least four of five iCRAFT modules. Completion was defined as when a participant had completed a homework assignment in the form of a report sent to

the therapist through the study platform. Corresponding statistical analyses were used as for the ITT analyses.

Analyses were carried out using R version 3.4.2 software.

RESULTS

Figure 1 outlines the study design and the flow of participants during the trial. In total, 367 individuals registered on the study platform. Of these, one individual was automatically rejected for inclusion due to too low age. A total of 135 did not answer telephone calls from the study coordinators and did not go through further screening procedures. A total of 231 individuals went through the structured telephone screening. Among included participants in the study, 74.4% ($n = 70$) filled out assessment questionnaires after 6 weeks, 69.1% ($n = 65$) after 12 weeks and 64.9% ($n = 61$) after 24 weeks. There were no differences in baseline characteristics between participants who remained in study until 24 weeks follow-up, compared with those who dropped out of study, neither regarding participants in the CRAFT or WL condition. Among those who dropped out in the iCRAFT condition, out of the five modules that constituted the iCRAFT program, the participants completed on average 3.02 (median 4) modules.

Sample

Baseline characteristics of participants are presented in Table 1. As can be seen in the table, the vast majority of participants were females (97.9%, $n = 92$), which is in accordance with previous studies on CRAFT. About 86.2% were in a partner relationship with the IP. For the most part, both CSOs and IPs were employed or self-employed (70.2 vs. 77.7%). Concerning contact frequency between CSO and IP, 74% of CSOs indicated contact every day, 19.1% almost every day, while 6.3% indicated contact 50% of days or 3 days per week.

As also seen in Table 1, CSOs reported that IPs generally consumed in average 5.4 drinks per day on 4.8 days per week. On average, CSOs reported heavy drinking for IPs on 45.9% of the 90 days before inclusion. Further, IPs fulfilled 5.3 DSM-IV criteria for alcohol dependence at baseline. A small proportion (7.4%) of IPs had used a non-prescribed substance during the last 12 months, and 23.4% had an ongoing depression episode, all according to CSO reports.

Concerning alcohol consumption, CSOs in general indicated a modest consumption with a mean of approximately two drinks per week (not displayed).

Intervention outcomes

Primary outcome Results for the primary outcome are presented in Table 2a. Of CSOs in the iCRAFT condition, 10 (21.3%) reported a treatment initiative for his or her IP on at least one occasion during the study period, while five (10.6%) CSOs reported a treatment initiative for an IP in the WL condition. This difference between conditions in proportion of treatment seeking IPs was, however, not statistically significant, odds ratio (OR) = 2.47 (0.96–6.39), $P = 0.062$.

CSOs indicated that IPs had initiated the following types of treatments: five cases to county council-based addiction treatment units, three cases to the occupational health services, two cases to primary care services, two cases to municipality-based addiction treatment units and one case to internet-based treatment. Two CSOs indicated the alternative 'other' (not specified) for their IPs. No

Table 1. Baseline characteristics for CSOs and IPs

CSO			
<i>Sociodemographic characteristics</i>			
Age (years), M (SD)	All participants (N = 94)	iCRAFT (N = 47)	Waitlist (N = 47)
Gender, female, n (%)	46.8 (12.3)	45.8 (12.5)	47.7 (12.1)
Married or cohabiting, n (%)	92 (97.9)	47 (100)	45 (95.7)
	74 (78.8)	36 (76.6)	38 (80.9)
<i>Work characteristics n (%)</i>			
Employed or self-employed	66 (70.2)	34 (72.3)	32 (68.1)
Student, trainee, unemployed, age senior or sickness/activity allowance	20 (21.3)	9 (19.1)	11 (23.4)
Other	8 (8.5)	4 (8.5)	4 (8.5)
<i>Type of relationship to IP n (%)</i>			
Partner/intimate relationship	81 (86.2)	38 (80.9)	43 (91.5)
Parent	2 (2.1)	2 (4.3)	0 (0)
Child	6 (6.6)	5 (10.6)	1 (2.1)
Friend	1 (1.1)	1 (2.1)	0 (0)
Other	4 (4.3)	1 (2.1)	3 (6.4)
<i>Contact frequency with IP n (%)</i>			
Every day	70 (74.5)	35 (74.5)	35 (74.5)
Almost every day	18 (19.1)	9 (19.1)	9 (19.1)
50% of days per week	3 (3.2)	2 (4.3)	1 (2.1)
3 days per week	3 (3.2)	1 (2.1)	2 (4.3)
IP			
<i>Sociodemographic characteristics</i>			
Age IP (years), M (SD)	49.2 (12.0)	49.0 (12.0)	49.4 (12.2)
Gender IP, female, n (%)	8 (8.5)	5 (10.6)	3 (6.4)
<i>Work characteristics n (%)</i>			
Employed or self-employed	73 (77.7)	33 (70.2)	40 (85.1)
Student, trainee, unemployed, age senior or sickness/activity allowance	27 (28.7)	12 (25.5)	14 (29.8)
Other	2 (2.1)	1 (2.1)	1 (2.1)
<i>Alcohol consumption</i>			
Number of standard glasses/day (SD)	5.4 (3.67)	5.39 (4.07)	5.4 (3.27)
Days drinking per week (N)	4.86 (69.4)	4.85 (69.3)	4.87 (69.5)
Proportion of days with heavy drinking**	45.9%	42.8%	48.9%
<i>Alcohol dependence (%)</i>			
Alcohol dependence (%)	89 (94.7)	45 (95.7)	44 (93.6)
Dependence criteria, M (SD)	5.28 (1.47)	5.43 (1.41)	5.13 (1.53)
Alcohol abuse (%)	5 (5.3)	2 (4.3)	3 (6.4)
Substance use*** (%)	7 (7.4)	2 (4.3)	5 (10.6)
Major depressive episode (%)	22 (23.4)	8 (17.0)	14 (29.8)

All data according to CSOs reports.

Last item indicating participants estimated health today, ranging from 0 to 100.

**For men: ≥ 5 drinks/day, for women: ≥ 4 drinks/day.

***Indicated a positive response to the question: in last 12 months, did your relative use any of these drugs (from a list), more than once, to get a high, to feel better or to change his/her mood?

differences in the pattern of types of treatments could be traced between participants in the iCRAFT- vs WL-group.

Secondary outcomes Alcohol consumption for IPs: In Table 2b–j, the results for a selection of the secondary outcomes are presented. First, there was a general decline in the predicted proportion of days with alcohol consumption (Table 2b) and proportion of days with heavy drinking days (not displayed) for IPs according to CSO estimations (OR = 0.56, 95% CI 0.47–0.66, $P < 0.001$ and OR = 0.48, 95% CI 0.40–0.58, $P < 0.001$, respectively), but with no differences between participants in the iCRAFT and WL conditions at weeks 6, 12 or 24 (n.s.). The same pattern was seen for the predicted mean

number of drinks consumed per week, with a decline for the sample as a whole (RR 0.66, 95% CI 0.64–0.69, $P < 0.001$), but with no differences between conditions during the follow-up period (n.s., not displayed).

Mental health for CSOs: Several differences between participants in iCRAFT and WL were observed in the measures of CSOs mental health post treatment (Table 2a–j). First, the iCRAFT-group decreased in symptoms of depression at 6-week follow-up as measured by MADRS-S (Table 2d), compared with the WL-group (coefficient = 4.99, 95% CI 2.45–7.53, $P = 0.0002$). This difference was however no longer apparent at follow up after 12 and 24 weeks. The same pattern was visible on the depression subscale

Table 2. Data for primary and secondary outcomes for the different timepoints: (a) treatment seeking for IP according to CSOs; (b) predicted proportion of days with alcohol consumption; (c) predicted mean GAD score; (d) predicted mean MADRS-S score; (e) predicted mean DASS Depression score; (f) predicted mean DASS Anxiety score; (g) predicted mean DASS Stress score; (h) predicted mean AAQ score; (i) predicted mean SWLS score; (j) predicted mean RHS score

	Condition	Baseline	6 weeks	12 weeks	24 weeks
a. IP treatment seeking (accumulated)	iCRAFT	0	6	9	10
	Waitlist	0	5	5	5
b. Days with alcohol for IP %	iCRAFT	76.5 (72.7–79.9)	66.6 (61.0–71.8)	61.4 (55.4–67.2)	67.7 (61.8–73.2)
	Waitlist	76.6 (72.8–80.0)	69.5 (64.3–74.2)	64.3 (58.6–69.5)	64.6 (58.9–69.9)
c. Mean GAD for CSO	iCRAFT	6.1 (5.2–6.9)	4.8 (3.9–5.8)	4.4 (3.4–5.4)	4.9 (3.8–6.0)
	Waitlist	6.0 (5.2–6.9)	5.8 (4.7–6.8)	4.8 (3.8–5.8)	5.4 (4.5–6.4)
d. Mean MADRS-S for CSO	iCRAFT	12.2 (10.6–13.8)	9.1 (7.3–10.9)	9.2 (7.3–11.1)	9.6 (7.5–11.6)
	Waitlist	12.1 (10.5–13.7)	14.1 (12.2–16.0)	10.4 (8.5–12.2)	11.0 (9.1–12.8)
e. Mean DASS Depression for CSO	iCRAFT	7.2 (5.6–8.8)	5.4 (3.6–7.2)	5.9 (4.0–7.7)	7.6 (5.5–9.6)
	Waitlist	7.5 (5.9–9.1)	8.3 (6.4–10.1)	7.4 (5.6–9.3)	6.6 (4.7–8.4)
f. Mean DASS Anxiety for CSO	iCRAFT	3.6 (2.4–4.7)	3.5 (2.3–4.7)	3.2 (1.9–4.5)	3.6 (2.2–5.0)
	Waitlist	3.6 (2.5–4.8)	4.4 (3.1–5.7)	3.5 (2.2–4.7)	3.3 (2.1–4.6)
g. Mean DASS Stress for CSO	iCRAFT	11.3 (9.8–12.8)	8.6 (7.0–10.3)	8.7 (7.0–10.5)	8.8 (6.9–10.7)
	Waitlist	11.3 (9.8–12.8)	10.4 (8.7–12.2)	10.5 (8.8–12.3)	10.4 (8.7–12.2)
h. Mean AAQ for CSO	iCRAFT	15.2 (14.0–16.5)	13.7 (12.3–15.1)	12.8 (11.3–14.3)	14.5 (12.9–16.1)
	Waitlist	15.5 (14.3–16.7)	14.9 (13.4–16.3)	14.7 (13.3–16.2)	14.1 (12.7–15.6)
i. Mean SWLS for CSO	iCRAFT	20.8 (19.7–21.8)	23.3 (22.2–24.5)	22.5 (21.3–23.8)	23.0 (21.6–24.3)
	Waitlist	20.8 (19.7–21.8)	21.1 (19.9–22.3)	22.1 (20.9–23.4)	22.7 (21.5–23.9)
j. Mean RHS for CSO	iCRAFT	47.5 (43.6–51.4)	55.4 (51.0–59.8)	54.5 (49.7–59.3)	58.1 (52.9–63.2)
	Waitlist	47.8 (44.1–51.5)	46.0 (41.8–50.3)	50.4 (46.1–54.6)	53.4 (49.2–57.6)

Confidence intervals for all mean values within brackets.

of DASS (Table 2e), where CSOs in the iCRAFT condition reported a reduced depression score compared with WL at 6-week follow-up (coefficient = 2.89, CI 95% = 0.36–5.42, $P = 0.0276$) while there were no significant differences between groups at 12 and 24 weeks post inclusion in the study.

For the stress and anxiety measures (Table 2f and g), a general trend toward a reduction in symptoms for the iCRAFT condition compared with WL at 6 weeks was visible, however not reaching statistical significance (for GAD-7: coefficient = 0.94, 95% CI 0.43–2.3, $P = 0.18$; for the DASS stress subscale: coefficient = 1.83, 95% CI –0.53 to 4.19, $P = 0.13$).

The results for the emotional avoidance measure AAQ (Table 2h) showed a trend for iCRAFT participants to decrease in emotional avoidance at 12 weeks. However, this difference just failed to reach statistical significance (coefficient = 1.95, 95% CI = –0.09 to 3.99, $P = 0.06$).

Important to note is that on average, CSOs in this study indicated subclinical levels of mental health scores except for GAD-7, where the average score for participants at baseline indicated mild anxiety ($m = 6.0$) (Table 2c).

Quality of life and relational happiness for CSOs

There was a difference in quality of life between groups at 6 weeks after inclusion, where participants in the iCRAFT-group reported higher predicted scores on the SWLS (coefficient = –2.23, 95% CI –3.9 to 0.55, $P = 0.01$), but this difference did not sustain at weeks 12 and 24 (Table 2i).

Last, CSOs in the iCRAFT condition showed higher predicted scores on RHS compared with WL at 6 weeks (coefficient = –9.39, 95% CI = –15.41 to 3.37, $P = 0.003$) while the difference failed to reach significance at 24 weeks (coefficient = –4.64, 95% CI = –11.13 to 1.84, $P = 0.16$) (Table 2j).

Completer's analysis

In the iCRAFT condition, 26 participants (45.7%) completed at least four (of five) iCRAFT modules and were hence included in the completer's analyses. The results (not displayed) showed no differences in primary or secondary outcomes for completers compared with participants in the WL condition.

DISCUSSION

This was the first study to investigate the efficacy of an internet-based CRAFT program for CSOs to IPs suffering from AUD. The results showed that although twice as many CSOs in the iCRAFT condition reported an IP treatment engagement (21.6 vs 1.6%), this difference was not statistically significant. The results for the secondary outcomes showed a common pattern in that CSOs indicated short-term improvements in mental health, but that this difference was not sustained over time. IP alcohol consumption did not differ over time between conditions according to CSO reports. The results from this study have important implications for future investigation of internet-based CRAFT programs.

First, it needs to be addressed that against the background of a premature closure of enrollment to the study, the results from this study should be interpreted with caution. The lack of a significant effect on treatment seeking may be due to a lack of power to detect a difference between the iCRAFT and WL conditions. Even so, the rate of treatment seeking reported for CSOs in the iCRAFT-group was lower compared with previous studies (Miller *et al.*, 1999; Manuel *et al.*, 2012; Bischof *et al.*, 2016). There are several possible explanations to this finding. It should first be noted that sociodemographic characteristics and mental health of CSOs and IPs in this study did not seem to differ substantially compared with previous CRAFT studies on CSOs to IPs suffering from AUD

(Miller *et al.*, 1999; Roozen *et al.*, 2010; Bischof *et al.*, 2016). Hence, the lack of a treatment effect cannot be attributed to, for example, differences in age, gender distribution, occupational status or baseline levels of anxiety or depression. One explanation to the small effect of iCRAFT on IP treatment engagement may be a possible overconfidence in the validity of CSO self-reports of IP treatment engagement. There may have been cases of IPs seeking treatment without informing their CSO, resulting in an underestimation of the number of treatment seeking IPs in the sample. Another explanation to the comparably low number of reported treatment seekers in the study sample may be a large regional variation in how the SUD treatment services are organized in Sweden. Previous CRAFT studies have generally been conducted with participants residing in a specific region (Miller *et al.*, 1999; Bischof *et al.*, 2016) resulting in a more homogenous range of AUD treatment providers and where IPs in many cases had the possibility to accompany the CSO to the same treatment facility. In the present study using a nationwide uptake, IPs may have had unequal access to treatment depending on geographical location, although we have no data to support this explanation.

The nonconclusive result concerning the primary outcome may of course be discussed from the viewpoint of how well the original CRAFT manual was transformed to the internet-based version used in the present study. First, in order to avoid a high rate of dropouts due to a too long treatment period—a feature seen in internet studies from other fields (e.g. 22)—the number of treatment sessions was reduced to five compared with 10–12 sessions in previous studies. In treatments for AUD, the length and intensity of treatment has shown to be of less importance—brief treatment programs in general show comparable efficacy compared with more extensive programs (Project MATCH Research Group, 1998; Hammarberg *et al.*, 2004). The median number of completed modules for iCRAFT participants was four, which can be considered as a high rate of program completion within the field of internet treatments (e.g. 38). However, for CSOs to acquire an adequate level of competence in skills involved in the task of inducing behavior change (i.e. treatment seeking or a reduction of alcohol consumption) in a third party (i.e. IP in the case of CRAFT) may require a longer time period of specific skills training than was offered within the iCRAFT program.

Related to this is the question of compressing more than one core theme of CRAFT into the same module. Components such as positive reinforcement of non-alcohol-related behavior, positive communication or to have a conversation on treatment seeking may have been a too complex task for participants to practice simultaneously with other themes.

Further, the information exchange in written form implicated a difference compared with face-to-face administered CRAFT. Although there was a strong emphasis on study therapists to provide participants with structured feedback on exercises and home assignments, role-playing—a key ingredient in face-to-face CRAFT—was not possible using the present study platform. Future studies on internet-based CRAFT programs may investigate alternative modes of communication, e.g. video conferencing with the therapist, in which a higher degree of resemblance to face-to-face CRAFT is possible, shows promising results in depression treatment (Berryhill *et al.*, 2018).

We found a beneficial effect of iCRAFT on CSOs mental health, in this respect corroborating the findings in Bischof *et al.* (Bischof *et al.*, 2016). iCRAFT participants showed reduced scores on scales for depression, while the results for anxiety, stress and emotional avoidance were less clear. Further, iCRAFT participants indicated

increased quality of life and satisfaction with the relationship to the IP. The results overall suggest that the iCRAFT program was initially beneficial regarding mental health for participants, but the improvements failed to sustain over a longer period of time. It must also be taken into consideration that CSOs showed relatively low levels of mental ill health at baseline, leaving less room for tracing improvements.

There were some limitations to the study that needs to be mentioned. First, there was insufficient power to allow for a statistically significant result due to the pre-emptive study closure. However, the lack of power is unlikely to singlehandedly explain the low treatment effect in the study. Previous studies of CRAFT have shown rates of treatment engagement as high as 40–86%. Furthermore, the high rate of lost to follow-up at week 24 (42.6%) in the iCRAFT-group compared with in the WL-group (27.7%) needs to be mentioned. As expressed in the results section, there were no differences in baseline characteristics between completers and those lost to follow-up that could account as a probable cause for this difference in attrition between conditions. One probable cause for the difference may instead be that WL participants felt obliged to comply to treatment procedures while in wait for taking part in the iCRAFT program. In contrast, iCRAFT participants may have felt less obliged to fulfill study procedures following termination of the program short. This explanation points to that the WL design in itself implies weaknesses, addressed in several contexts (Patterson *et al.*, 2016). However, since no established and validated support program (including internet-based programs) for CSOs exists in Sweden, including an active comparison group would have induced uncertainties in interpreting the results. Last, the design did not allow for follow up of outcomes in the WL-group following treatment entry, which would have enabled us to consider these participants as their own controls in the study.

CONCLUDING REMARKS

Taken together, this is the first study investigating CRAFT delivered over the internet for CSOs to IPs with AUD. The results did not give us evidence that iCRAFT in its present form was sufficient to increase treatment seeking behavior among IPs. Future studies should investigate the optimal design for an iCRAFT. Since only 10–15% of individuals suffering from AUD enter treatment (Degenhardt *et al.*, 2017), there is an urgent need for programs that concomitantly increase motivation to seek treatment while at the same time addressing the stress and strain experienced by CSOs. Access to face-to-face delivered CRAFT is scarce in large parts of Sweden and also internationally. Developing new modes of administering CRAFT would enable us to reach a larger proportion of those in need for support.

RANDOMIZED TRIAL REGISTRATION

This trial was registered at: ISRCTN38220020.

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CONFLICT OF INTEREST STATEMENT

No conflict declared.

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