Telephone Coaching of Family Members of Veterans With Substance Abuse Problems

NCT03246646

September 8, 2015

2a. Research Plan

Background and Significance

One of the barriers to successful reintegration for many Veterans of the wars in Iraq and Afghanistan is the development of substance use disorders (SUDs). Many of the new Veterans with illicit substance or alcohol misuse are reluctant to initiate or fully engage in treatment. Since 2001, over 1.8 million service members deployed to Iraq or Afghanistan have become Veterans and only about 60% of these recent Veterans have accessed general health care in VA [1]. Recent studies of OEF-OIF-OND Veterans indicate that 11% of first-time users of the VA healthcare system were diagnosed with an illicit substance use disorder, alcohol use disorder, or both [2]. There is evidence that only about half of those with mental health or SUDs attend an initial mental health treatment session when referred [3]. The concern about stigma from others [4], as well as negative personal beliefs about treatment for mental health and SUDs [5], are barriers to Veterans' seeking treatment. Thus, many SUDs are likely to remain untreated or undertreated due to lack of engagement in care. This difficulty is an important but not unique problem among Veterans; data for the US general population indicate that fewer than 20% of individuals with SUDs seek care [6].

Family members appear to play a significant role in encouraging Veterans with SUDs to engage in treatment. In general, Veterans tend to welcome family members' involvement in care for medical and mental health problems [7-9] and report that improving relations with family members are significant reasons for entering treatment [10]. As a response, in June 2011 VA launched *Coaching Into Care* (CIC) [11] a national call center whose goal is to help the family members and friends of Veterans who believe that the Veteran in their lives needs mental health or substance abuse treatment. Typically, callers are concerned about the functioning of a Veteran who is reluctant to seek care. CIC has developed a manualized, flexible telephone-based coaching strategy that consists of social support, problem solving, communication training, and referral in working with callers, usually over a series of telephone calls (see Appendix). Initial quality assurance data suggest that CIC services lead to an increase in treatment seeking (see Preliminary Studies). Unfortunately, our data also indicate that family members calling about a Veteran with substance misuse have a greater difficulty in encouraging the Veteran to seek care.

Acronyms/terms:
SUD = Substance Use Disorder
OEF-OIF-OND = Veterans of the Iraq and Afghanistan wars
CSO = Concerned Significant Other
CRAFT = Community Reinforcement and Family Training intervention
CIC = VA's Coaching Into Care call center
VA-CRAFT = Web-based online course for delivering CRAFT
Coaching-CRAFT = CIC coaching + VA-CRAFT online course

Our goal is to enhance the usual CIC coaching strategy using a variant of an intervention that has strong empirical support, the Community Reinforcement and Family Training (CRAFT). CRAFT is a face-to-face intervention that was designed to increase the likelihood that an individual with an SUD will seek treatment through positive reinforcement. CRAFT works with a concerned significant other (CSO) as the client. An initial step is to help the CSO with safety planning to reduce the risks of relationship violence, especially when the Veteran is not sober. A major goal is to help the CSO make changes to reinforce clean and sober behaviors (e.g., spending time with the Veteran only when he or she is sober). The intervention helps the CSO decrease inadvertent support for substance/alcohol misuse (i.e., cease being attentive when the Veteran is hung-over from drinking). It also supports the CSO so he or she can help the Veteran enter treatment when the Veteran signals readiness for treatment. Finally, CRAFT seeks to reduce the CSO's ineffective coercion toward the Veteran about treatment (e.g., demanding the Veteran get help).

CRAFT has received a great deal of empirical support for the ability to increase treatment seeking and engagement in SUD treatment [12]. In 4 randomized clinical trials comparing CRAFT to a traditional approach (i.e., Al-Anon or Nar-Anon) in getting the person with alcohol or substance use problems to seek treatment, CRAFT demonstrated consistent superiority. The smallest between-group margin was 64% (CRAFT) vs. 30% (Control) [12, 13]. The largest margin reported was 86% vs. 0%, and most of the studies showed that CRAFT increases CSOs' mental and physical health. Despite

this empirical support, it is a face-to-face intervention that requires a great deal of time, resources, and access to trained providers, all of which may limit availability and successful outcomes.

Our approach is to combine the strengths of a telephone-based coaching strategy for CSOs with the structure of the CRAFT concepts in an intervention we call Coaching-CRAFT. Our research team for this proposal has developed a systematic web-based delivery of CRAFT (VA-CRAFT) in an educational course that focuses on the CSO helping the Veteran to engage in treatment (see Preliminary Studies, below). Our initial data show that this web-based material may not fully engage CSO's in changing their behavior toward the Veteran without some additional support, encouragement and guidance. Thus, neither the existing CIC coaching strategy nor the VA-CRAFT educational course alone appear sufficient to increase Veteran engagement in care for substance misuse; however, combining the telephone based service (i.e., Coaching Into Care) with the web course to help deliver CRAFT concepts is promising.

Preliminary Studies

Coaching Into Care (CIC) call center

Dr. Sayers began CIC in 2010 as a pilot project and continues as the Director. Coaching Into Care has grown significantly since 2011 *when it became a national program*; in 2014 alone, CIC received over 3000 initial (incoming) calls. About 50% concerned a Veteran from the OEF/OIF/ OND eras. About 70% of the calls in 2014 concerned psychosocial issues, including mental health, substance abuse, and/or behavioral concerns that may have an impact on the Veterans' or others' physical safety. Seventy-five percent of the callers were female, with 28% of them being a spouse or other intimate partner, 19% parents, 12% were sons, daughters or siblings, 28% were other types of family members, friends or other relationships. Thirteen percent of the calls were directly from Veterans about mental health, benefits, or other concerns. Virtually all of the callers to CIC have internet access; exceptions tend to be older callers and/or those with lower financial resources.

Quality Assurance (QA) data from our call center operations have indicated that the service is highly rated by callers but the impact of the service may be limited, especially in the cases of substance misuse. Within about 3 months of first calling, the treatment engagement of the Veteran who is the subject of the calls with CIC rises modestly [11]. In 939 CSO callers who started coaching since November 2014 whose concerns were specifically focused on mental health problems and no substance misuse of the Veteran, 248 of the Veterans were engaged in mental health care; this number rose 54% to 382 at follow-up. CSO callers had at least one call with a coach and some had more than 20. For a separate subsample of 109 callers of Veterans with substance misuse who entered coaching, the rate of treatment rose a more modest 40%, or 35 to 49 Veterans in care. In these uncontrolled findings the initial treatment engagement rate of those who entered coaching was somewhat higher for those with substance misuse vs. no substance misuse (34% vs 26%). It does appear, however, that additional systematic strategies are needed for those Veterans with substance misuse problems. See the Appendix for CIC Manuals.

Preliminary feasibility test of the web-based delivery of CRAFT for PTSD

Co-Investigators Erbes and Kuhn have recently led a group in the development of a web-based version of CRAFT (VA-CRAFT) for CSOs of Veterans. They are currently completing an HSR&D funded pilot randomized clinical trial of the VA-CRAFT among family members of Army National Guard Veterans who had returned from combat missions to Iraq and Afghanistan. Family members of Veterans who had screened positive for PTSD (some had comorbid SUD) but who were not engaged in mental health services were randomly assigned to complete the VA-CRAFT online training (n = 34) or a wait-list condition (n = 32). VA-CRAFT participants were reminded to log in every few weeks when needed but no coaching or support was provided. Preliminary analyses suggested that VA-CRAFT did not lead to greater engagement in VA mental health or SUD treatment in the three months following initiation of VA-CRAFT than the CSOs in the wait-list condition. However, there was a significantly greater decrease in CSOs reports of caregiver burden in the VA-CRAFT group (from 1.92 to 1.56) than the control group (from 1.81 to 1.84, interaction $p < .0001$). Qualitative interviews with 20 CSOs who

were in the VA-CRAFT condition suggested that 1) most CSOs perceived the course's benefit and would recommend it to others, 2) CSOs reported that it enhanced their understanding of their Veteran, reduced conflict, and increased shared positive activities and 3) CSOs did not actually talk with their Veterans about getting into treatment due to past failures in these conversations. These findings suggest that more structure and support is needed to help CSOs to actually engage in some of the changes in communication behavior consistent with CRAFT. Thus, a telephone-based coaching intervention that uses the CRAFT approach in concert with the website could be a significant enhancement of CIC coaching as currently practiced. As such, integrating the structure and content (e.g., communication skills training, reinforcement techniques) of VA-CRAFT with the delivery method and coaching approach of CIC represents a significant enhancement over both programs. The project also tested version of VA-CRAFT in 6 participants focused primarily on the Veteran's substance misuse problems (see Appendix 2 for screen shots of the course and outline). The feasibility and acceptability of this version was very similar but the sample was too small for formal testing of the effects. This is the version that will be utilized in the Coaching-CRAFT intervention to be developed and manualized in the proposed study.

The VA-CRAFT sample was identified by clinical screening and only a small portion (~19%) of potentially eligible family member participants were enrolled. However, most of those who withdrew did so because they did not remain concerned about the Veteran's symptoms as they went through the enrollment process. We anticipate a higher enrollment rate for the proposed study. Nearly all of the CIC callers persist in their concern about the Veteran's symptoms.

Experience with manualized telephone-based intervention research

Members of our team are experienced developers of manualized telephone-based interventions for substance abusing populations. Co-I McKay and colleagues have developed a method of monitoring and counseling following acute care for people with alcohol and substance dependence [14, 15]. This manualized treatment has shown efficacy relative to controls in several randomized controlled trials [14-16] (see Appendix 2). In addition, Mavandadi and colleagues have developed an intervention for caregivers of Veterans with dementia to decrease caregiver burden and improve engagement in dementia care. A feasibility pilot has just been completed and will be tested in a VA MERIT award (see biosketch). *Dr. Sayers (PI) continues as Director of CIC and has experience in developing the manualized coaching procedures currently used by CIC.*

Research Design and Methods

Overview

First, we will develop a detailed manual for Coaching-CRAFT, which will be a telephone-based model of coaching that uses the web-version of the CRAFT intervention already developed and available to the investigators. Second, we will conduct a preliminary nonrandomized feasibility trial of the use of Coaching-CRAFT with a sample of 50 family member callers recruited from the CIC call center. We will select for this trial close family member callers who reach CIC with the concern about an OEF-OIF-OND Veteran in their family whom they believe is in need of treatment for a SUD.

An important goal will be to compare the findings to CIC Quality Assurance (QA) data of callers matched on the type of substance misuse of the Veteran and demographic variables (see Trial Procedures). We propose an uncontrolled trial in order to maximize the intervention sample size and based on the strength of our ability to use existing CIC QA data. We will also conduct a test of the assessment of the Veterans regarding their perception of their family members' involvement in their decisions to seek or not seek care, their actual decisions to seek care, and their current symptoms.

Intervention and manual development process

The Coaching-CRAFT intervention is meant to be a combination of CIC's coaching strategy combined with the didactic material in the recently developed web-based CRAFT intervention, VA-CRAFT [17]. The VA-CRAFT course for substance misuse has 8 modules that follow the original CRAFT intervention [9] (see Appendix 2 for module details): 1) Introduction to CRAFT, 2) Overview of CRAFT, 3) Getting Started with CRAFT: Safety Planning, 4) Understanding substance abuse, 5)

How to respond to substance abuse, 6) How to rebuild your life together, 7) How to help someone consider treatment, 8) Wrapping up. The goals of the intervention include understanding triggers and long-term reinforcement of substance misuse, ignoring unhealthy behaviors and rewarding healthy behaviors, getting support, and how to help the CSO caller help the Veteran enter treatment.

The PI will work with the Key Personnel to discuss the following factors: 1) format of the manual, 2) level of manual detail, 3) optimal pace of work with the CSO using the web-based CRAFT content, 4) optimal number and length of calls, 5) points of individualizing the material in CRAFT to the CSO's' specific situation, and 6) the coach's role in identifying appropriate programs and facilitating entry into treatment soon after the Veteran indicates his or her readiness. *The group will meet by conference call regarding these factors, the PI will draft the manual, and the Key Personnel will meet again to discuss the draft. This iterative process will continue until we have a suitable draft manual. We will then seek feedback from volunteer Veterans and their family members at the CPL Michael J Crescenz VA Medical Center (Philadelphia). This feedback will be incorporated and the draft will be discussed again by the Key Personnel and the PI will produce a final draft for the trial.* We will also develop a fidelity scale for the essential targets for the telephone interventionist of Coaching-CRAFT. The manual development will occur in months 1-4.

Clinical Trial

Sample and recruitment procedures

Recruitment for the sample in the trial will occur within the regular workflow of the CIC call center. We have estimated that on a yearly basis approximately 600 callers to CIC are first degree relatives of an OEF-OIF-OND Veteran who has a primary difficulty with substance misuse, yielding 300 potential referrals for the 6 active recruitment months of the trial. Initial assessment and problem identification has typically been conducted by a CIC call responder in the first 1-3 calls, often involving consultation with a licensed supervisor. Potential participants include the following: 1) CSO is a sibling, spouse/ intimate partner, or parent of a US military Veteran who served in Iraq or Afghanistan since 2001, 2) by the report of the CSO the Veteran of interest has a substance abuse problem that has led to interpersonal, legal, occupational, and/or health related negative consequences, 3) the CSO reports that the Veteran is not currently receiving treatment for this problem, and 4) the CSO has contact 4+times/week and lives with or within 30 min. of the Veteran. Exclusion criteria include: 1) CSO has an SUD (Form 90, see Measures), 2) the Veteran is currently incarcerated, 3) the CSO has no computer or other device with Internet access able to view video content, and 4) the CSO or Veteran likely has a psychotic disorder (CSO report on the MINI) (see Measures). Potential participants will be presented the option of being involved in the research trial, and if interested, will be contacted by the research staff. If the CSO is interested after hearing more details the research staff will conduct the additional screening, consent procedures, and baseline assessment. *We will also engage Veterans in the study at two points. First, if/when the CSO indicates that the Veteran wants treatment, we will offer help to the Veteran in an initial telephone conversation. In this conversation we will ask to use their responses as research data. Second, we will ask the CSO at 12 months after the baseline to invite the Veteran to participate (see below).*

Measures.

Demographic information (from CSO). Age, gender, race, marital status, relationship of CSO to the Veteran, living status (i.e., with the Veteran), hours in contact per week, Veteran's military service details (branch, highest rank, combat deployments, National Guard/Reserve component vs. regular Army/Navy/Marines/Air Force), Veteran's age, race, marital status, and number of children.

Alcohol and substance misuse—CSO and Veteran. Form 90 will be used to assess abuse (including alcohol) [18] for the target Veteran and the CSO. Responses on this form will be used to confirm initial reports by the CSO to screening staff. Form 90 also assesses employment, treatment, and health care utilization. This measure was developed for the well-known Project MATCH [19]. It has demonstrated high reliability and validity for assessing substance misuse [20] and allows for telephone assessment. It has also been shown to have adequate correspondence through collateral (i.e., family member) reports [20], and is maximized when the CSO has greater contact (>40% of

days), and lives with the target person with substance abuse. Because of the nature of the collateral report, it will not be possible to confirm SUDs among the Veterans. The measure, however, will be used with those Veterans who agree to the 12-month telephone assessment after the intervention. *To assess the CSO's perceptions and preferences of substance use, we will add two questions for each substance identified: "Do you believe [Veteran] should drink/use [substance] less often?" and, "How much problem does [Veteran's] use of [substance] cause for him/her or for others?"*

CSO and Veteran symptoms. In order to characterize the sample of CSOs, we plan to use the Mini International Neuropsychiatric Interview (MINI) [21] to assess generalized anxiety disorder, panic disorder, current mania, and psychosis, and the PHQ-9 [22, 23] for depression. These measures have demonstrated good reliability and validity, and have been used successfully in telephone-based assessment and depression management in a primary care setting [24-26]. We will measure the subjective burden felt by the CSO using the Montgomery Borgatta Caregiver Burden Scale [27].

We will also use the CSO's report of Veteran symptoms on the MINI-psychosis module, to exclude CSOs in which the Veteran may have a psychotic disorder, and the PTSD Checklist 5 (PCL-5) family member version [28] to assess the CSO's perceptions of the Veterans trauma symptoms. The MINI, PCL-5, and PHQ-9 will also be used with the Veterans in the 12 month telephone assessment.

Intervention acceptability, satisfaction, and engagement. We will measure satisfaction with the intervention using questions used currently by the CIC call center which asks the caller's expectations of service, helpfulness, changes in hopefulness, and report of the Veterans desire for and engagement in care (see Appendix 2). Additional open-ended questions will assess how the telephone-based support or VA-CRAFT content could be changed to improve convenience, acceptability, or effectiveness. *We also plan to secure a HIPAA waiver to obtain VHA administrative data to verify the CSO's report of the Veteran's engagement in VHA care (see Human Subjects).*

We will assess the engagement of the CSO in the intervention by tracking the number and length of telephone calls with the interventionist, and the number of sessions the CSO logs in to use the web-based CRAFT material, *repeat visits to sessions,* and the degree of completion of each of the modules. Drop-outs from the intervention and drop-outs from assessment follow-up will also be carefully tracked. Drop-outs will be defined as no response after 3 attempts over 1 month.

Schedule of Assessments

Measure (source: domain)	Baseline	6 months	12 months
CSO: CSO's alcohol & substance misuse, Veterans alcohol & substance misuse	Form 90	Form 90	Form 90
Treatment utilization	Form 90	Form 90	Form 90
Burden	Caregiver Burden Scale	Caregiver Burden Scale	Caregiver Burden Scale
CSO Symptoms, CSO perceptions of Veteran's PTSD symptoms	MINI, PHQ-9, PCL- 5 (family ver.)	MINI, PHQ-9, PCL- 5 (family ver.)	MINI, PHQ-9, PCL- 5 (family ver.)
CSO perceptions of intervention			Open-ended questions
Web-host tracking: Engagement in interventions			*Website use (time on sessions, repeat visits to sessions, completion)*
Veteran: Vet's subst. abuse & Treatment			Form 90
Veteran symptoms			MINI, PCL 5, PHQ-9
Veteran perceptions of interaction with CSO			Open-ended questions
Veteran's MH/SA treatment engagement	*Questions about treatment engagement, if/when the Veteran agrees to treatment*		*VHA administrative data*

Trial procedures

The primary goal of the trial intervention will be a test of the feasibility of Coaching-CRAFT, CSO's experience and engagement in the intervention, and within-subject estimates of changes in Veterans' engagement in treatment. We will seek to enter 50 family member callers into a nonrandomized trial over 6 months. Each research-based telephone contact will be audio recorded for examination using the fidelity scale developed in months 1-4.

An additional goal is to compare the outcome in the trial to a usual-care sample of at least 50 CIC callers that have not been offered Coaching-CRAFT, matched on the basis of the Veteran's primary substance use problem(s), relationship of CSO to Veteran, contact time and co-habiting

status, Veteran age and gender, and race. We will select comparison cases from a several year time-frame to ensure an appropriate comparison.

The length of the active coaching of the CSO using the web-based CRAFT material is anticipated to last no longer than 6 months, but this will be determined by the treatment manual development phase. Additional assessments will occur at 6 and 12 months after study entry and will include the measures as detailed in the table (above). *At 12 months, w*e will *ask the CSO to invite the Veteran to engage in the study and answer study questions about their symptoms, treatment, and the CSO's approach to them*. We will carefully assess the safety and risk to the CSO-Veteran relationship prior to making the decision to pursue this assessment. Working with the CSO, we will ask the CSO to ask the Veteran to be involved, including type of discussion between CSO and Veteran might be helpful, and ask the CSO to ask the Veteran to call the study staff (see Human Subjects).

Timeline

We anticipate the trial will begin in Year 1 with initial recruitment occurring from months 5-10. The trial will end in Year 2, month 22. Analyses of feasibility, satisfaction and treatment engagement will occur in months 19-24. After the formal participation in the trial, any caller who needs additional support or treatment referral will be referred to the CIC call center.

Data Analysis, Sample Size considerations, and intervention modification

Feasibility Outcomes

We will examine CSOs ratings of the intervention with a criterion of at least 80% of those rating the intervention as helpful, leading to increased hopefulness and preparedness to help the Veteran, and that the intervention had helped the family overall. We will also examine the degree to which the subjective symptoms of distress (PHQ-9, subjective burden), decline over the Baseline, 6 month, and 12 month assessments, using a mixed methods model test of within-subjects change over time. We will compare the completion rates of the Coaching-CRAFT sample of CSOs with a sample of CSOs from the CIC QA data. "Completion" will mean at least 6 months of telephone coaching of 8+ calls. We will match CSOs receiving Coaching-CRAFT with the treatment as usual data (see above).

Intervention comparisons

In a key analysis we will also plan to test the proportion of the Veterans of the CSOs who entered treatment for substance misuse against the matched CSOs from the CIC QA data. We will use an intent-to-treat approach. Those CSOs lost to follow-up will be deemed intervention failures regarding the Veterans' engagement in treatment. We plan to use a basic test of difference between proportions in independent samples (a two sample z-test). To detect a difference between the rate of engagement in treatment using CIC QA data (i.e., 41%) and conservative outcomes drawn from the CRAFT RCTs (67%), the sample group needed to detect a difference with power of 80% in post-intervention treatment engagement outcomes, is N = 45, for each group [29]. Our intent-to-treat sample size of N = 50 exceeds this number.

Review of CSO and Veteran report: *Qualitative and treatment engagement reports*

We plan to conduct a systematic review of the responses to the post-intervention open-ended questions in order to modify the intervention as needed in preparation for a large RCT. In addition, we plan to assess the rate of Veteran inclusion in the study at 12 months, *the CSO report, the VHA report of Veteran treatment utilization, and the comparison of these different data sources.*

Considerations of alternative approaches

Focusing on SUD or PTSD population. We could focus development of Coaching-CRAFT on PTSD treatment given the importance of trauma-related symptoms in the population of combat Veterans and in the etiology of a portion of those with SUDs. But, substance misuse likely creates a greater impediment to treatment than other conditions, including PTSD. Our informal CIC QA data show that the percentage increase in treatment engagement success is lower in the cases that involve substance misuse. Also, most systematic RCT's have focused on CRAFT for SUDs, even when trauma related symptoms may be an important clinical focus for these populations.

Narrowing the SUD focus to alcohol misuse-only or illicit substance misuse-only. There are perhaps different issues associated with alcohol misuse compared to illicit substance misuse (e.g.,

legal issues overlay the situation with illicit substance misuse). However, we chose not to choose one category of SUD for several reasons: 1) there is high comorbidity of alcohol misuse with illicit substance misuse, 2) there is a predominance of alcohol misuse compared to illicit substances in this population, 3) the primary focus of this pilot study is proof of concept and testing feasibility, rather than testing efficacy. We will have the opportunity to make our choices of the specific population to test Coaching-CRAFT at the next phase when conducting an RCT.