Cover Page: Study Protocol
We The Village Counselor Training Study
NCT05875142

Document Date: 03.22.23

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PROTOCOL OVERVIEW

Protocol Number	2202
Protocol Title	Scalable digital delivery of evidence-based training for addiction professionals to maximize treatment admission and retention rates of opioid use disorder in affected families: Phase I
Protocol Version (*mm/dd/yyyy*)	3/22/2022
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Funder/Sponsor	NIH/NIDA
Funding Start Date	07/15/2022
Funding End Date	02/01/2023
Anticipated IRB Closure Date	09/01/2023

1. PROTOCOL BACKGROUND

1.1 Describe the scientific/scholarly rationale and background for your project. Describe the gaps in current knowledge your project is intended to address.

Importance of the problem. There were nearly 100,000 overdose deaths in 2020, with 75% of the 93,331 related to opioids.[21] Many Americans suffer because of the loss of a family member to opioid use disorder (OUD), and the direct and indirect costs of substance use disorders (SUDs) to society are estimated to be over $600 billion annually.[22] Because only 17% of people with OUD get medication assisted treatment (MAT) each year, the majority remain at heightened risk for overdose, death, and other harmful personal and societal outcomes. Community Reinforcement and Family Training (CRAFT) significantly improves treatment entry and retention of treatment-resistant individuals.[2,24] It is delivered by counselors to a family member or concerned significant other (CSO) motivated to help their loved one with an OUD (Identified Persons, or IPs). It has strong empirical support, having been tested by multiple investigators in 10 well-controlled clinical trials,[2-3,11-16,28,63] with consistently moderate to large effects on treatment entry (62-77%) vs treatment controls (17-40%).[11,26] In addition, two OUD-focused studies found that CRAFT improved retention in MAT such that IPs were less likely to drop out of treatment compared to usual practices.[2,28] Unfortunately, CRAFT is broadly inaccessible to families because most counselors do not receive CRAFT training.

Approximately $70 million is spent annually to train SUD treatment providers[17] and billions of dollars are spent to develop and validate the efficacy of Empirically Supported Treatments (ESTs) like CRAFT, but these treatments are rarely used in treatment programs. Moreover, when they are used, the quality of their implementation is usually poor. It is

critical that we find effective ways to train counselors to implement CRAFT if we are to address the toll that OUDs are taking on individuals, their families, and the American public.

Critical barrier to progress. Currently, CRAFT counselor training lacks scalability. Training workshops are held in-person or through web-conferencing by Dr. R.J. Meyers, the developer of CRAFT, or by a few trainers approved by him. Dr. Meyers has a post-workshop certification process that is user-friendly and allows counselors to securely upload digital audiotapes to a server where they are manually coded by trained raters who generate written feedback on CRAFT adherence and skill. During web-based coaching sessions, additional feedback and advice is provided. This process trains counselors to proficiency in CRAFT and then certifies them; however, it is expensive, has limited scale, is largely dependent on one person (Meyers), and has not been leveraged to take full advantage of a digital format. *No comprehensive digital CRAFT training and certification programs for **counselors** exist.*

Research. Current methods for training counselors and disseminating ESTs, including CRAFT, rely on brief online or in-person workshops. However, research shows this format is minimally effective in facilitating adoption and implementation of ESTs.[29] Counselors who receive post-workshop feedback and coaching on taped sessions with clients show larger gains in proficiency and maintain them longer.[7,31] Much of this well-controlled research has examined in-person counselor training for motivational interviewing and cognitive behavior therapies.[7,10,31-32] Because CRAFT uses a motivational interviewing approach and is based in cognitive behavior therapy, it is very likely that the effectiveness of these procedures generalizes to CRAFT training; however, no studies have specifically examined CRAFT counselor training and very few controlled studies have evaluated scalable online training.

Most internet training studies have had small sample sizes,[33] no control group,[33-37] and/or relied on knowledge-based and self-report measures [33,35-36,38-39] that do not necessarily reflect actual change in counselor behavior.[7,30] Of the three studies that used the preferred method of direct observation of counselor proficiency, two had no control comparison but found pre to post training improvements after an online tutorial followed by live remote observation with feedback and coaching.[34,35] The third study found improvements in Motivational Interviewing proficiency for counselors receiving feedback on taped sessions or live supervision of sessions at 8 and 20 weeks post-workshop and these improvements were greater than for a workshop alone group.[41] We found no randomized controlled trials of counselor web-based training that examined CRAFT.

Contributions. The development and rigorous testing of a scalable CRAFT counselor training product will contribute to scientific knowledge because:

1. Replication and generalization of the previous counselor training research is needed. Research on web-based counselor training is limited, and no studies have examined training in CRAFT.
2. Most studies have not examined the feasibility and necessity of training counselors to proficiency. This project will be the first to explore the effect of different levels of training on family outcomes.
3. Web-based training programs have not fully explored the potential of the digital format to leverage automation in training staff efficiently. It is possible that fully digitized self-study materials could allow some counselors to significantly improve their proficiency or even prepare to achieve certification.
4. Additional studies would better establish methods for maintaining EST skills. Few web-based training trials have examined skills maintenance past the end of the most intensive training group.

1.2 List the primary and secondary aims, research questions, and hypotheses.

The goal of this project is to develop and evaluate the technical feasibility and commercial viability of a scalable digital counselor training program for CRAFT. This Phase I project will develop an enhanced training model for CRAFT and digitize it to maximize scalability. In this project, we will:

Aim 1: Produce the digital counselor training prototype and coaching process, tailored to OUD - with stakeholder input.
Aim 2: Conduct a pilot study of 3 levels of digital training (Level 1 – Digital tutorial only [T]; Level 2 – Tutorial & digital training materials for self-study [TM]; Level 3 – Tutorial, digital materials, feedback and coaching [TMC]) to

establish feasibility, acceptability, and examine the effects of training on CRAFT knowledge, fidelity, and treatment entry and retention.

1. Primary Hypothesis
   1.1. At 12 weeks (after study start), participants assigned to the TMC condition will demonstrate the highest CRAFT procedure fidelity (measured in audiotaped sessions with a standardized patient) followed by TM and then T.
   Rationale: Direct observation measuring content of CRAFT delivered in treatment sessions is our primary outcome as this provides the best assessment of counselor adherence and skill and is consistent with previous studies.[7,10,41] Our hypothesis that TMC will produce greater use of CRAFT than T (or TM) is based on the results from previous trials comparing a workshop only to workshops plus feedback and coaching.[7,10,41]
2. Secondary Hypotheses
   2.1. Participants assigned to the TMC condition will demonstrate the highest CRAFT knowledge followed by TM and then T, in their 12-week knowledge test.
   Rationale: Results from previous controlled trials have shown no differences in counselor knowledge pre- to post-workshop, but increases have been seen when fact sheets and supervision are added after the workshop.[39,57-58]
   2.2. Participants will rate the programs satisfactory, useful and usable with similarly positive scores (3 on a 5 point scale or above) at each follow-up assessment point.
   Rationale: Research shows (and with our own CRAFT Family product) that all programs are rated similarly satisfactory and useful.[39]
   2.3. Participants in all conditions will perceive increased implementation potential over time (pre-tutorial, post-tutorial, 12 week follow up), but at 12 weeks implementation potential will be lower for TMC compared to TM and T.
   Rationale: In a CBT (Cognitive Behavioral Therapy) web-based training study implementation potential of three training programs increased over time, but a condition involving expert supervision was seen as more difficult to implement.[39]
   2.4. Participants assigned to the TMC condition will assign the highest monetary value to the tutorial, digital training and certification components, followed by TM and then T participants, in their 12-week follow-up surveys.
   Rationale: The pilot study of our CRAFT Family product showed participants assigned to the CRAFT private coaching condition valued all components of the program substantially higher than those who received less coaching in the group condition, or digital only (no coaching) condition.
   2.5. Participants assigned to the TMC condition will report that more IPs have entered treatment compared to TM and T at 12-weeks (after study start) follow-up surveys.
   Rationale: This hypothesis is based on the results from previous trials examining counselor fidelity [7,10,41] and studies showing that CBT fidelity enhances treatment outcome.[59-60] ***We consider this hypothesis exploratory because the*** *6 month timeline will not be sufficient to adequately test for differences in treatment entry, as there would not be much time after all counselors completed training for them to complete CRAFT with CSOs.*

1.3 List the primary and secondary outcomes.

The primary outcome variable is the participant's demonstration of procedure fidelity, measured in audiotaped sessions with a standardized patient.

Secondary outcome variables include participant's CRAFT knowledge; participant's satisfaction with the program (website content and delivery); participant's perceived implementation potential; participant's monetary valuation of the program; and participant's report of IPs entering treatment via CSO report.

2. PARTICIPANTS

2.1 Describe the general characteristics of the intended primary participant populations, including age range, gender, sexual orientation, racial/ethnic background, socioeconomic status, health status, criminal history, and any other characteristics relevant to the study.

Aim 1 - Qualitative Review:

We will sample individuals from 4 groups (n=3/group) with a group of: 1) subject matter advisory board (SMAB) members representing customer perspectives (state-level counselor training decision-makers, payors, SUD program administrators), 2) CRAFT trainers and expert supervisors, expanding beyond our immediate network: 3) counselors, and 4) addiction program leaders (Addiction Administrators). Participants will include individuals identified as subject matter experts in the addiction industry and represent different customer audiences. Participants must be older than 19 years (given the profile of addiction professionals we expect no participants will be excluded on this basis).

Gender Representation: We anticipate that about 66% of our research participants will be women. We will monitor gender balance of the counselors at the participating clinics and make extra effort to recruit men (e.g., directly conducting outreach to them through addiction treatment providers and emphasizing the benefits of participation) if they appear to be appreciably under-represented.

Racial/Ethnic Representation: Given the Phase I timeline and the early stage and budget we do not anticipate conducting extensive explicit efforts.

Socioeconomic status: Because we will be sampling from counselors, counselor training decision makers, payers and administrators we would expect a wide range of income - from around $30,000 to $200,000.

Aim 2 - Training Intervention:

The target population is United States based addiction professionals and counselors working with concerned significant others (CSOs), as well as the family members and friends of identified persons (IPs) with an opioid use disorder (OUD). Participants must be older than 19 years old, and given the profile of the current counselor working in the addiction profession, we expect that none will be excluded on this basis. Participants will be recruited and enrolled using phone outreach and online methods, including WTV developed relationships with SUD treatment providers, SAMHSA listed treatment providers and professional listservs, as well as the WTV website, Google, Facebook, and Instagram. Our recruitment strategy drawing from those employed at SUD treatment providers and related listservs gives us a high chance of reaching many counselors. This will produce a sample that is representative of this group but not representative of all counselors working with CSOs. CSOs may seek private counseling outside of the addiction services providers when someone they love has an OUD. We will make efforts to target this broader counselor audience by recruiting through more general counseling listservs. The sample will be limited to participants who have internet access and are willing to receive training from web-based sites.

Gender Representation: Based on population estimates[64] for substance abuse counselors in the United States, we anticipate that 50 – 60% of our research participants will be women. We will monitor gender balance of the counselors at the participating clinics and make extra effort to recruit men (e.g., directly conducting outreach to them through addiction treatment providers and emphasizing the benefits of participation) if they appear to be appreciably under-represented.

Racial/Ethnic Representation: Given the Phase I timeline, and budget we do not expect to conduct extensive explicit efforts to recruit for racial/ethnic representation beyond reaching out to specific minority represented list-serves such as the Association of Black Social Workers. Given the small sample size for this early stage pilot and feasibility study we do not anticipate having enough racial/ethnic minorities in any group to allow demographic analysis. Regardless, we expect to have some racial/ethnic minority representation among our participants.

Socio-economic Representation: Given our recruitment of addiction professionals, we anticipate a relatively consistent socioeconomic range for the participants. We expect that within the sample there will be a few counselors with a higher socio-economic level, however, because some may be working in private practice or be physicians. We anticipate most

participants will fall within a middle to low socioeconomic status as the median salary of an addictions counselor is $48,520 per year, or $23.33 per hour, according to the US Bureau of Labor Statistics.

2.2 Select all populations, settings, or records that will be involved in the research. Complete the corresponding appendix for each selection.

☐ People who use substances, substance use treatment sites, and/or substance use records (**Appendix J**)
☐ Students, school settings, and/or student education records (**Appendix L**)

For protocols that meet the criteria for exempt research, skip to Section 4.

2.3 Select all intended primary participant populations. Complete the corresponding appendix for each selection.

☐ Pregnant women (**Appendix G**)
☐ Prisoners (**Appendix H**)
☐ Children (**Appendix I**)
☐ People with limited decision-making capacity (**Appendix K**)

2.4 List the study inclusion criteria.

Aim 1 - Qualitative Review: We will sample individuals from 4 groups (n=3/group) including:

- Members of WTV's Subject Matter Advisory Board (SMAB)
- CRAFT trainers or experts
- Counselors working in addictions, or
- Addiction program leaders (Addiction Administrators)

These individuals must be

1. 19 years or older
2. Able and willing to participate in audio recorded focus groups and individual interviews
3. Demonstrates complete understanding of the requirements for participation in the study by reading and signing the consent form

Aim 2 - Training Intervention: We aim to enroll 45 participants, meeting the following criteria.

1. Is over 19
2. Lives in the US
3. Working in a counselor-related profession
4. Has not been trained in CRAFT
5. Could provides at least 45 minute individual counselor sessions to at least one CSO (CSO)
6. Counseling work involves clients affected by OUDs, or might if they learned CRAFT
7. Is able and willing to submit the required session audiotapes and participate in the tutorial and training and intervention activities over the course of the 12-week study
8. Reports having access to a computer and smartphone with internet access, email, and word processing capability
9. Demonstrates complete understanding of the requirements for participation in the study by reading and signing the consent form
10. Provides valid locator information to allow research and CRAFT training staff to contact them to schedule study-related appointments
11. Completes the first assessment mock session with our standardized patient (SP) and pre-tutorial surveys

2.5 List the study exclusion criteria.

Aim 1 - Qualitative Review: Participants from the four groups will be excluded based on the following criteria:

1. Does not agree to participate
2. Does not attend focus group
3. Is not English-speaking

Aim 2 - Training Intervention:

1. Does not agree to participate
2. Does not complete the baseline assessment requirements
3. Is not English-speaking
4. Participated in the Qualitative Review study

2.6 Provide justification for the exclusion of broad population groups.

For this study we are excluding people under 19 years of age, and there is no upper age limit. The study design excludes anyone under 19 years old. The primary hypothesis for the study is to help professionals increase treatment utilization among IPs by counseling CSOs in CRAFT. Because the participants in this study are working counselors and addiction professionals, it is not anticipated that any will be children or adolescents.

3 RECRUITMENT AND SCREENING

3.1 Identify the expected number of individuals screened and the expected number of individuals consented/enrolled to reach your target sample size. If multi-site, break the total down per study site. If multi-year, break the total down per study year.

Aim 1 - Qualitative Review: We will sample individuals from 4 groups (n=3/group) for a total of 12 participants. Our first two target groups are already identified via our already committed SMAB, close ties to the CRAFT trained counseling community, our status in the addiction professional networks, and access through professional listservs. We therefore anticipate filling our focus groups expediently with a 1 in 2, or 1 in 3, chance of targeted participants being eligible after screening and accepting the invitation to participate. As such, we expect to screen no more than about 40 individuals to reach our target sample of 12.

Aim 2 - Training Intervention: We will enroll 15 participants per study arm, resulting in enrollment of a total of 45 participants in the study period (6-months). Our previous family training pilot study (also with a total of 45 participants in the same project timeline) experienced a large drop off during recruitment. Although 1275 individuals began the screening process in that previous study, only 129 completed a consent form online, and only 35% of these potential participants completed the entire informed consent process, were randomly assigned and began the intervention. Given this experience with online recruitment procedures, it is possible that around 1300 participants will need to initiate the screening process in order for us to recruit, consent, enroll, and randomly assign 45 participants. We will continue to recruit via a waitlist (facilitated by online Alchemer surveys) after we have reached our goal of 45 enrolled participants. This waitlist will enable us to reach out to other eligible participants in the event that someone drops off before the baseline survey and start of intervention.

3.2 Describe how prospective participants will be identified and recruited. Include information about: how, when, where, and by whom (by position or role, not by name). Describe any recruitment materials that will be used to recruit prospective participants.

Aim 1 - Qualitative Review:

Participants will be recruited and enrolled using phone outreach and online methods, including WTV developed relationships with SUD treatment providers, as well as SAMHSA listed treatment providers and professional listservs. We will start with our immediate network to fill the groups and reach out for referrals via our network as needed.

WTV will telephone or email identified individuals and professional networks (if needed) informing recipients of the opportunity to provide feedback in a focus group for this study. When necessary, they may also telephone treatment programs and ask to speak with the person in charge of counselor training, family programs, or another appropriate administrative staff member (e.g., program director). Staff will inform that person of the purpose of the call (seeking feedback as part of federally-funded CRAFT Counselor training study), and for those who express an interest in the study, provide a detailed description of the focus group and individual interview, including the voluntary nature of research participation and requirements for audio taping focus groups and interviews. If appropriate, we will ask treatment programs or professional networks to email potential participants a description of the study and provide a link to a webpage for online screening. Subsequent 15-minute telephone/video meetings will be scheduled with interested individuals to complete the screening process (if not completed online) and enroll individuals in the focus group sample. Those who are not interested in volunteering for the study will be thanked, and no further action will be taken.

Aim 2 - Training Intervention:

Because we believe that counselors may have heightened willingness to participate in the study if the tutorial is supported by their place of employment, we will recruit through free tutorials offered to OUD treatment clinics targeting those focused on family services. Our recruitment efforts will be limited to the United States and will begin in the first project quarter following IRB approval and grant award. Recruitment will continue through the first quarter of the project or until we recruit up to 45 eligible participants, whichever comes first. We will track and document which recruitment strategies yield the best engagement. Please see examples of images and messaging we will use for different methods of recruitment. We plan to implement the following recruitment methods:

1. Recruitment channels for Training Intervention
    a. WTV Promotions (e.g., website callouts, emails, social media posts and 1:1 message) to existing and future WTV members.
    b. Engagement of the WTV membership group to suggest this opportunity to their network and make a referral if they know anyone who fits the participant description.
    c. Outreach to existing partners who provide services to patients with OUD.
        i. Wholeview Wellness
        ii. Center for Motivation and Change
        iii. JoinGroups.Com (medication-assisted treatment (MAT) for opioid addiction)
    d. Provide free tutorials offered to OUD treatment clinics targeting those focused on family services and programs
        i. Counselor listservs (such as: State chapters of Professional Liaison's Association, e.g. NYPLA, American Counseling Association, National Board of Certified Counselors)
        ii. Listings of treatment programs will be obtained from the SAMHSA website and web-based directories associated with state related SUD offices.
    e. Develop recruitment strategies to increase diversification of study participants
        i. Promote research study on the following professional counseling member websites:
            - Association of Black Psychologists (ABPsi)
            - National Association of Black Social Workers (NABSW)
        ii. Develop new partnerships with providers who serve more diverse populations, including communities of color and lower SES
    f. Targeted digital and local advertising efforts.
        i. NADAAC
        ii. Facebook
        iii. Instagram
        iv. Google

Listings of treatment programs will be obtained from the SAMHSA website and web-based directories associated with state SUD offices. We will also promote the free workshop and training through relevant counselor listservs (such as: State chapters of Professional Liaison's Association, e.g. NYPLA, American Counseling Association, National Board of Certified Counselors) as we anticipate that these individuals have a high likelihood of opting into the study. We will also run a small targeted digital ad to expand our reach.

WTV will call treatment programs and ask to speak with the person in charge of counselor training, family programs, or another appropriate administrative staff member (e.g., program director). WTV will inform that person of the purpose of the call: offering a free online CRAFT workshop and the potential for their staff to receive training as part of federally-funded CRAFT Counselor training study. Those who express an interest in the study will be provided a detailed description of the training study emphasizing the voluntary nature of research participation, and describing requirements for audio taping sessions, participation in digital lessons and then random assignment to the T, TM, or TMC conditions. Treatment programs that express interest will be provided with an email describing the study and inviting counselors to participate, and they will be asked to forward the email to their counselors.

Interested counselors will be asked to click on a link that takes them to a description of the study and asks them to complete an anonymous screening form. After completing screening, counselors who are not eligible will be informed and thanked, and no further action will be taken. Counselors that are eligible and still interested in participating in the study will be asked to click on a link that begins the consent procedure.

3.3 Describe how prospective participants will be <u>screened</u>. Include information about: how, when, where, and by whom (by position or role, not by name). Describe any instruments that will be used or tests that will be performed during the screening process.

<u>Aim 1 - Qualitative Review</u>: Screening will occur by telephone or online. During a 15-minute phone call with participants or by email linking to an online form, study staff will provide a brief overview of the focus groups and individual interviews, and the requirements, risks and benefits of participating in the research. Those expressing interest will be asked to answer questions assessing inclusion criteria including which of the four categories of participants they belong to (WTV SMAB member, CRAFT trainer or expert; counselor working with CSOs or individuals with OUD; an addiction program leader), whether they are over 19 years of age, and if they would consent to being audio-recorded during the focus group and interview. Online screening will be a self-administered multiple choice online Alchemer tool asking the same questions and programmed to inform participants immediately if they are eligible. Those meeting the inclusion criteria will be sent a link to a consent to review and digitally sign. Individuals who do not meet the inclusion criteria will be thanked and no further action taken.

<u>Aim 2 - Training Intervention</u>: When a prospective participant responds to a recruitment message, flyer, or referral, they will be directed to visit the We the Village Counselor Training study webpage. On the study website, prospective participants will have the opportunity to read a description of the study, including goals and expectations. If individuals are still interested, they will be directed to click the Screening Survey link. The link will take them directly to the start of the Screening Survey. The Screening Survey is a self-administered multiple choice online Alchemer tool. Potential participants will be asked screening questions to confirm their year of birth, interest in learning CRAFT, that they are working in a counselor-related profession, could provide 45 minute sessions of individual counseling sessions to at least one CSO client, work or could work with clients affected by OUD, have no previous training in CRAFT, are able and willing to submit the required session audiotapes and participate in the training activities over the 12-week study period, have access to a computer or smartphone with internet access, email and word processing capabilities, and reside in the United States. We will program automated scoring to inform participants immediately after filling out the screening survey if they are eligible, unless their answers are not clearly eligible or ineligible. If the results of their screening survey are indeterminate, they will receive a message to call the study number to speak with a study staff person or fill out a contact form to request a call.

3.4 Describe the information you will obtain for screening. Explain whether you will retain this as part of the study data.

Aim 1 - Qualitative Review & Aim 2 - Training Intervention: We will not collect personal identifiers during the screening process and will retain all the information we received as part of the screening process in a secure location. All screening data will be de-identified and will not be connected to any future data collection activities.

3.5 Describe how screen failures will be handled and, if applicable, describe the conditions and criteria upon which re-screening is acceptable.

Aim 1 - Qualitative Review: For the qualitative focus group study, potential participants will be screened live on a call or via email and informed of their eligibility near the end of the phone call. Screen failure will be thanked, and no further action taken. Rescreening will not occur.

Aim 2 - Training Intervention: A study phone number and email address will be listed on the study landing page for prospective participants if they experience technical difficulties or have questions. If a prospective participant's answers do not make them clearly eligible or ineligible, they will be encouraged to call, or email the Research Coordinator for additional information. We will attempt to communicate with participants within one business day. The Research Coordinator will re-screen participants without collecting any identifying information to determine eligibility. If the person is eligible, they will be redirected to complete the informed consent process and re-enter the digital enrollment flow. This procedure will improve screening rates and minimize potential eligible participants screening out of the study. If the person is not eligible, study staff will inform the person and ask them if they are interested in learning more about other We the Village offerings.

Figure 1. Qualitative Focus Groups:

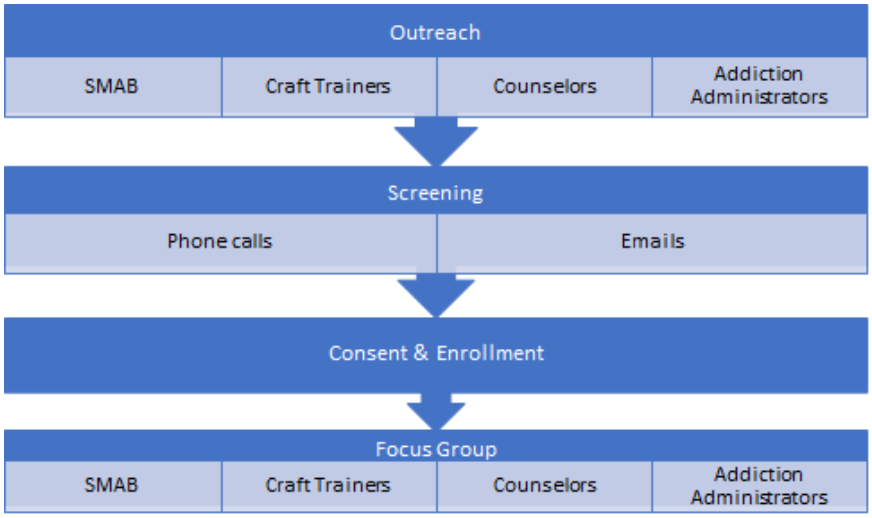
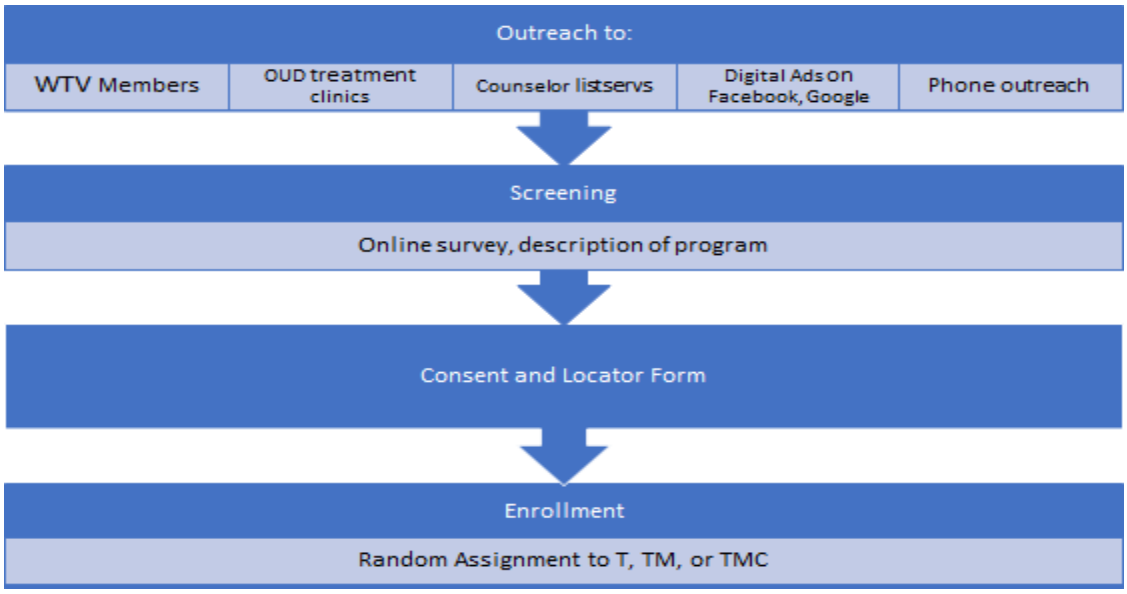


Figure 2. Training Intervention Pilot



4 STUDY PROCEDURES

4.1 Provide a detailed description of the study procedures in chronological order. As applicable, include information on: differences between the control and experimental groups, the number of follow-up visits, study visit windows, participant time commitment per activity, and the setting/location per activity.

Aim 1 - Qualitative Review:

After completing the consent form, participants will be contacted to schedule a meeting time for the focus group. Once scheduled, they will be emailed information allowing them to join the secure web-based conferencing platform (i.e. Zoom) to participate in the focus group. Prior to beginning the focus group we will ask that participants read and acknowledge their adherence to a simple confidentiality agreement due to the sensitive commercial nature of the various concepts or ideas presented in the focus groups. With supervision from our qualitative research consultant (Sosinsky), and CRAFT experts (Kirby & Meyers), we will create interview guides with open-ended questions to guide the discussions in virtual focus groups to surface insights from target end-users. Interview guides will build off quality assurance testing that Mr. Handley, product marketing manager, will conduct, and cover all aspects of the CRAFT counselor product including implementation potential. Focus groups will be led by research staff under the supervision of our qualitative research consultant and will last about 60 to 90 minutes.

If needed, participants will be individually contacted to schedule a follow-up call to ask questions clarifying topics discussed during the focus group. These follow-up contacts will be conducted within about six weeks of the initial focus group and may occur by telephone or secure web conference. They may also include follow-up questions suggested by our qualitative research consultant and CRAFT experts to elucidate focus group responses needing further clarification. We anticipate that these follow-ups will take up to 45 minutes.

This study involves a total of four focus groups and up to twelve individual follow-up contacts (each participant is involved in one focus group and one follow-up contact). All focus group and individual meetings will be audio recorded, transcribed, and coded. An inductive approach will be used to identify themes and subthemes in the audiotaped recordings. Under Dr. Sosinsky's guidance, 3 reviewers will read a selection of audiotape transcripts and create an initial codebook to undergo a grounded theory approach producing iterative revisions. The final codebook will be used in NVivo software to assess transcripts. A content analysis will be performed and at least two coders will generate themes and subthemes of key product refinements. Thematic content analysis will be conducted and used to identify refinement themes. The product team (led by Macky & Handley) will confer with team experts where appropriate to propose product solutions to the refinements surfaced and then create a prioritized product backlog based on an impact versus

effort analysis of individual solution implementation. This analysis will inform which product refinements are made pre-pilot, and which are stored in the product backlog for future implementation. We anticipate that all activities will be completed within two months.

Aim 2- Training Intervention:

Study procedures are outlined in the figure below. After screening, eligible participants complete the online informed consent form and the locator form. The locator form records the participant's home and work telephone, address, email, and the contact information of others who may be able to assist research staff to reach the participant, if needed. This information will be used to prompt participants to join the scheduled interview. Only study staff will have access to this information. Participants will be contacted primarily through email to ask them to complete surveys or to schedule online mock counseling sessions, but we will secondarily use text, calls, letters, and social media direct messaging as reminders. Participants will complete the self-administered baseline instruments using Alchemer software and be scheduled to complete an online mock counseling session.

After both the baseline survey and mock counseling session have been completed, participants will be randomized into one of three groups using a blocked randomization procedure. The block randomization procedure is used to control for level of education (high school/GED, bachelors, masters, PhD) and training and experience in Cognitive Behavior Therapy (CBT) and Applied Behavior Analysis (ABA), as CRAFT is a CBT based on ABA principles.

We will use an additive components design consisting of: 1) digital tutorial only (T), 2) digital tutorial plus digital training materials (TM), and 3) digital tutorial and digital training materials plus feedback and coaching (TMC). This design will allow us to assess whether the digital training materials improve counselor outcomes relative to the tutorial only, but will not allow us to access their contribution, if any, to the full training product (TMC).

Follow-up assessments will be conducted after all three groups have completed the tutorial (at 2 weeks) and again at 12-weeks post baseline. All aspects of the study will be conducted completely virtually.

Table 1. Treatment Conditions

TREATMENT CONDITION	Pre-tutorial Assessment	Tutorial	Post-Tutorial Assessment	Experimental Manipulation	12-week Follow-up
	Week 0	*Week 1-2*	*Week 2*	*Post-Workshop to Week 12*	*Week 12*
Digital Tutorial **(T)**	**A**	Digital Tutorial	**B**	*Weekly emails encouraging review of specific modules and continued use of the online tutorial*	**C**
Digital Tutorial & Training Materials **(TM)**	**A**	Digital Tutorial	**B**	*Access to additional online training materials* *Weekly emails encouraging completion of new modules and continued use of the online training*	**C**
Digital Tutorial, Training & Coaching **(TMC)**	**A**	Digital Tutorial	**B**	*Access to additional online training materials* *Feedback on up to 12 sessions with actual clients* *Weekly emails, plus weekly video / call coaching*	**C**

A,B,C = surveys and taped role-plays with standardized patient.

Treatment Conditions:

Digital Tutorial (T) - All participants will continue to have access to tutorial materials throughout the study. Participants assigned to the T condition receive ONLY the tutorial. Afterwards they will be encouraged via weekly emails that are a component of the training program to continue using the resources in the online tutorial to revisit the CRAFT lessons on their own during the 10-week period between post-tutorial follow-up and the final follow-up assessment.

Digital Tutorial, with training materials (TM) - Participants assigned to the TM condition will complete the tutorial and then receive access to the additional training materials. They will not receive any feedback or video-calls for coaching. They will be encouraged via weekly emails to continue to learn CRAFT on their own during the 10-week post-tutorial period by using the new resources in the online tutorial and the digital training materials.

Digital Tutorial, with training materials plus feedback and coaching (TMC) - Systematic feedback and coaching during the 10-week post-tutorial to final assessment period (12 weeks post-baseline) will be provided to only to the 15 participants assigned to the TMC condition. Participants will be required to submit audio taped sessions with clients. They will be provided with consent-to-audiotape forms that they will need to have the client complete prior to

audiotaping sessions with that client. If their place of work also has required client consent-to-audiotape forms, they will need to have the client sign both forms, or receive permission from their place of employment to use the form we provide instead. We will provide a brief training to prepare the counselors to attain informed consent to audiotape from clients. The training will be delivered via a zoom session with supporting written materials. The training will emphasize that the informed consent process is based on respect for the individual, and, in particular, the individual's autonomy or capacity and right to make choices. They will be taught to convey accurate and relevant information about their reasons for requesting permission to audio record, namely, to meet the requirements of a study that they are participating in, letting the client know that the purpose of the study is to examine different counselor training methods and that it is the counselor's behavior that is the target of these recordings. Counselors will be taught to inform clients of the known risks (the potential of breach of confidentiality) and that all audiotaping and management of audio files will be done using HIPAA compliant methods to reduce risks. Counselors will be trained to inform clients that they may experience no direct benefit from agreeing to audiotaping. We will emphasize that clients must be informed that they may refuse taping without any penalty; they must not be treated any differently by the counselor or the clinic. They will be instructed to allow clients to ask questions and have them answered so that they can make an informed decision about whether to participate. The training will also emphasize that consent is always voluntary, and participants may withdraw consent at any point in time. They will be asked to store the forms in a secure place where they normally keep confidential patient materials. In order to protect client confidentiality, we will not collect or keep copies of these forms, as they would provide additional client identifying information that is not required for the study.

In addition to providing training in the informed consent procedure, counselors will be trained in procedures to protect the confidentiality of the audiotaped sessions. They will be trained to ask clients to avoid using names and instead to refer to the IP in terms of their relationship (e.g., my son, my partner). Sessions will be taped using one of three procedures. First, if the counselor has access to a HIPAA compliant electronic patient health platform that supports audio recording sessions (e.g., SimplePractice) and securely transmitting them (e.g., vis encryption), we will accept use of their established system. Second, if their practice does not provide this type of software, we will have counselors download free software (i.e., Pocket Dictate Mobile Dictation Recorder) that allows them to audiotape the session on their telephone and send the encrypted recording to us. Counselors will be instructed to delete the recording immediately after receiving confirmation of receipt. As an additional precaution , they will be shown how to adjust the application settings so that the audio recordings are automatically deleted after 24 hours and instructed to password protect their phone so that only they can access it. Third, if the counselor does not have access to either a HIPAA compliant electronic patient health platform or a smartphone, we will provide them with a digital audio recorder that allows them to securely upload files directly to a HIPAA-compliant server. They will be instructed to delete the audio recording from the device immediately after uploading to this system.

Participants will digitally receive written feedback and live video-call coaching on their tapes (up to 12 allowed). They will be encouraged to re-submit their audio taped sessions until they meet the criteria needed for certification in the CRAFT procedure or until the phase is over (whichever occurs first).

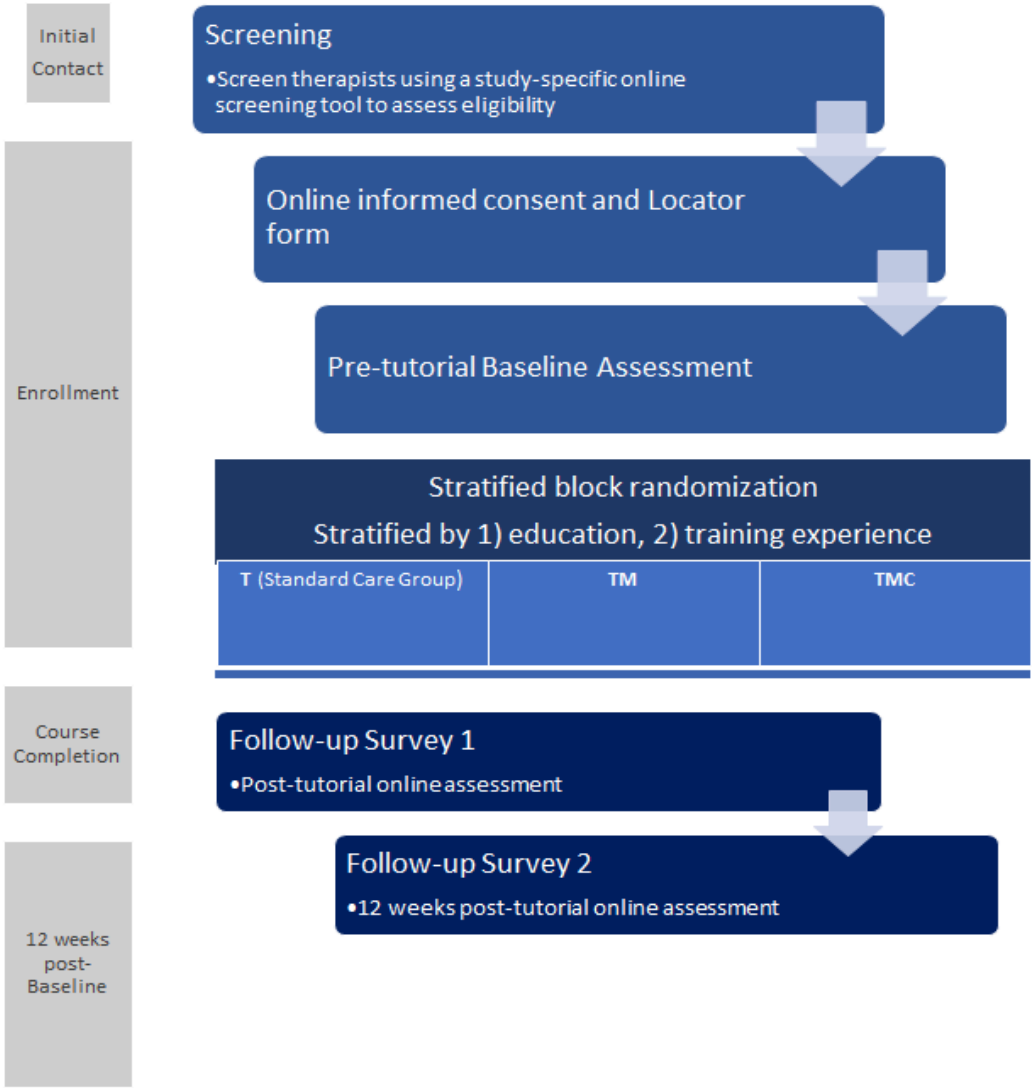
Participants will receive individual written Personal Performance Feedback on all audio taped sessions that they submit. This feedback is generated by two CRAFT certified trainers (i.e., CRAFT Trainer or CRAFT Coder) who access the digitally audio taped sessions via a secure server. The trainer listens to the audiotape and records a session content checklist that indicates key procedures for each module. For each key component, the trainer indicates whether it was addressed in the session, rates the quality of implementation for that component (1=poor to 5-excellent), and writes comments praising specific behaviors or making suggestions for further improvement. This feedback is password protected and emailed to the counselor. TMC participants will participate in weekly 30-min video-call Coaching Sessions. In addition, the audio taped client sessions will be accessed by research team members charged with developing software that would automatically complete the coding currently done by the CRAFT trainers.

Table 2. Study Activities By Program

STUDY ACTIVITIES BY PROGRAM		
Tutorial	**Tutorial + Materials**	**Tutorial, Materials, & Coaching**
● Digital Tutorial providing CRAFT principles overview.	● Digital Tutorial providing CRAFT principles overview.	● Digital Tutorial providing CRAFT principles overview.

• Weekly emails encouraging continued use of the online tutorial to revisit CRAFT lessons.	• Additional training materials providing in-depth instruction on CRAFT protocol nuances and techniques.	• Additional training materials providing in-depth instruction on CRAFT protocol nuances and techniques.
	• Weekly emails encouraging continued use of the online tutorial and materials to revisit CRAFT lessons.	• Systematic feedback and coaching on CRAFT protocols and techniques 10-week period.
		• Program weekly emails encouraging continued use of the online tutorial and materials to revisit CRAFT lessons.

Figure 3. Recruitment and Enrollment Flowchart



4.2 Briefly describe the sources or measures that will be used to collect data about participants. As applicable, include information on: instruments or surveys that will be administered, tests that will be performed, and the time points when each data will be accessed or obtained.

Aim 1 - Qualitative Review:

The audiotaped focus group and individual interview is the primary data that will be collected from participants. The only other information collected will be on a locator form. The locator form records the participant's home and work telephone, address, and email. This information will be used to schedule and prompt participants to join their focus group and to contact them for any follow-up questions after the focus group, if needed for clarification.

As indicated above, an inductive approach will be used to identify themes and subthemes in the audiotaped recordings. A codebook will be used in NVivo software to assess transcripts. A content analysis will be performed and used to identify refinement themes. The product team will confer with team experts where appropriate to propose product solutions to the refinements.

Aim 2- Training Intervention:

Data collected directly from participants:

Surveys for baseline, post tutorial (i.e, 2-weeks post baseline), and 12-weeks post baseline assessments will be self-administered using Alchemer software since participants may be located anywhere across the country. The baseline survey consists of socio-demographic questions, such as gender, age, race/ethnicity; other standardized socio-demographic measures adapted from the GPRA instrument; a CRAFT Knowledge Test; and a Training Expectations Form.

Each assessment point also will include an audiotaped mock client session conducted via web conferencing with a standardized patient portrayed by a professional actor. Using a standardized patient will provide a consistent context for measuring counselors' CRAFT skill level at each time-point. The mock session will present the counselor with an opportunity to roleplay CRAFT procedure: teaching the CSO to invite the IP to enter treatment (the same procedure is required for the follow-up assessments). We chose to assess this procedure because a component analysis study[12] showed it positively impacted treatment entry rates and it requires CRAFT skill accumulation (i.e., it incorporates and builds upon skills trained in communication and positive reinforcement). Audio tapes will be coded using the CRAFT Therapist Coding Manual[32] used by Dr. Meyers to certify counselors.

At the post-tutorial and 12-week follow-up assessments additional surveys will be added regarding satisfaction with the training program, perceptions of usefulness and usability, implementation potential, and program value. Finally, at the 12-week follow-up only, participants will be asked to report the number of CSOs they have worked with over the past 10 weeks, how many of them they implemented CRAFT with, and how many of those CSOs had a loved one who entered new treatment. The measures, their purposes, related hypotheses, and assessment points are provided in the **Measures Table** below.

Table 3. Measures

Purpose	Hypothesis	Measure	Assessment points[1]
Counselor Knowledge and Skill	i. TMC>TM>T	CRAFT Therapist coding Manual***	Pre-Tutorial, Post-Tutorial, 12 weeks
	ii TMC>TM>T	CRAFT Knowledge Test**	Pre-Tutorial, Post-Tutorial, 12 weeks
Acceptability and Feasibility	iii	Training Expectations Form[x]	Pre-Tutorial
	iii	Training Satisfaction Survey[x]	Post-Tutorial, 12 weeks
	iii	Usefulness and Usability Assessment[x]	Post-Tutorial, 12 weeks
	iv	Implementation Potential Scale[x]	Post-Tutorial,12 weeks
	v	Price Sensitivity Survey*	Post-Tutorial, 12 weeks
	vi	Treatment Entry and Retention	12 weeks

[1] Phase 2 will use the same assessment points plus a 6 mo follow up. *Note*: Training Expectations Form is a baseline version of the Training Satisfaction Survey.

Revised measures have been adapted specifically for professional participants as appropriate.

Data collected from other sources (identify each source; e.g., health care provider, parent, public records):

N/A. We will only collect information directly from the study participants. We will not collect information from clinic records or directly from CSOs who participate in audio taping.

4.3 Describe pre-defined criteria for removing participants from the study and the procedures for informing participants of their removal from the study. Include information on the handling of their data and measures to ensure individuals' safety and privacy after ceasing research activities.

We do not anticipate removing participants from the study, but participants may be removed if:

a) they break the confidentiality of other participants in the focus group (Aim 1) or clients in audiotapes (Aim 2)
b) it becomes clear after enrollment that they do not meet the inclusion/exclusion criteria.

Participants will be notified of their removal from the study by the Principal Investigator, Jane Macky. The PI will call the participant to explain the reason for their removal. In addition, a formal letter will be sent to participants via email. Both the phone call and letter will explain the reason for their removal, how their data will be handled, and provide referrals for support, if needed.

If any participants are removed due to breaking confidentiality during the 10-week post tutorial period when client audio tapes are submitted, we would use the data they had provided up to that point. Any participants who are removed because it is discovered that they do not meet the inclusion/exclusion criteria will have their data deleted and will not be included for analysis. All contact information will be deleted within two weeks after informing the participant of their removal. We will track and document all reasons for removing participants in order to ensure they are not rescreened and re-enrolled into the study.

For protocols that meet the criteria for exempt research, skip to Section 7.

5 PARTICIPANT PAYMENT

5.1 Describe any compensation that will be given to participants for the completion of research-related activities. Include the monetary value and type of compensation per activity.

Aim 1 - Qualitative Review: All participants will receive a $30 Amazon gift card for participating in their 60-90 minute focus group, and may be contacted for a brief follow-up to answer clarification questions if needed.

Aim 2 - Training Intervention: In addition to the free training, all counselor participants will receive a $50 Amazon gift card for each of the three (pre- and post-tutorial and 12-week follow-up) audio taped sessions ($150 total). Participants in the TMC condition will have the opportunity to get certified in CRAFT at the end of the 12 week training, and participants in conditions T and TM will have the opportunity to do so after their participation in the study is complete.

5.2 Describe any reimbursements that will be given to participants to repay them for costs they may have incurred over the course of the study. Include the monetary value and type of compensation per activity.

N/A. We will not reimburse participants for any costs that they may incur for participating in this online study, including data or internet plans.

6 INFORMED CONSENT

6.1 Provide a brief summary of the informed consent process by selecting all of the consent procedures you will use and specifying for which study procedures. Complete the corresponding appendix as indicated.

Consent Process	Specific Study Procedures
☒ Standard written informed consent	All Aim 1 and Aim 2 activities
☐ Waiver of documentation of consent (Appendix D)	
Alteration of informed consent (Appendix D)	
☐ Waiver of informed consent (Appendix D)	
☐ Short form (Appendix E)	
☐ Child assent and parental permission (Appendix I)	
☐ Waiver of child assent (Appendix I)	
☐ Waiver of parental permission (Appendix I)	

6.2 Describe in detail the assent and/or consent procedures in chronological order. Include information about: how, when, where, and by whom (by position or role, not by name).

Aim 1 - Qualitative Review:

All participants will be consented using the IRB-approved digital consent form prior to enrollment in the study. Upon completing screening and meeting eligibility requirements via phone or online survey, participants will have the option to complete the informed consent process immediately. They will be sent a link to the written digital consent form that will remain open for a period of 48 hours. The form will provide a description of the study and specify risks and discomforts, potential benefits, confidentiality measures, compensation, and the voluntary nature of their participation. A contact number will be provided for those who wish to ask questions before signing.

Because informed consent will be obtained using online methods, a written signature will not be possible. We will require participants to check a box agreeing to join the study and to type in their first and last name. We will download the checked consent form and save the file as a PDF in a protected folder secured on PHMC's network drive. All participants will receive an automatic email from Alchemer after completing the consent form. In addition, all participants will be able to download a copy of the informed consent form with the box agreeing to join the study checked off and with their name typed into the "I agree" section.

Aim 2 - Training Intervention:

Eligible participants will have the option to complete the informed consent process immediately after completing the Screening Survey if they meet eligibility requirements. They will be directed to click a link that will remain open for a period of 48 hours. They will be provided a brief explanation of time estimates for enrollment activity prior to clicking the appropriate link. After clicking the link, they will be directed to a self-administered online consent form. The form will provide a description of the study, specify risks and discomforts, potential benefits, confidentiality measures, compensation, and the voluntary nature of their participation. A contact number will be provided for those who wish to ask questions before signing.

Informed consent will be obtained using online methods, so a written signature is not possible. We will require participants to check a box agreeing to join the study and to type in their first and last name. We will download the checked consent form and save the file as a PDF in a protected folder secured on PHMC's network drive. All participants will receive an automatic email from Alchemer after completing the consent form. In addition, all participants will be able to download a copy of the informed consent form with the box agreeing to join the study checked off and with their name typed into the "I agree" section.

6.3 Describe any measures to ensure or test participants' understanding of the information presented during the informed consent process.

All participants will be provided with a telephone number for a research coordinator who will provide the opportunity to ask questions about the consent forms or to receive additional information about the study.

6.4 If a child who provided assent to participate in the study becomes 18 years old during the course of the study, describe the process to re-consent the participant.

N/A. We will not enroll children. Study participants must be over 19 years old (which meets or exceeds the criterion age of legal consent in all 50 states).

7 STUDY DATA

7.1 Select all of the personal identifiers you will access and obtain during this study.

Access *means to view or to perceive data, but not to possess or record it.* ***Obtain*** *means to possess or record in any fashion (writing, electronic, video, email, voice recording, etc.) and to retain for any length of time.*

☒ Names
☒ Address (street address, city, county, precinct, ZIP code)
☒ Dates related to an individual (birth date, admission/discharge dates, date of death)
☒ Telephone numbers
☐ Fax numbers
☒ Electronic mail addresses
☐ Social security numbers
☐ Medical record numbers
☐ Health plan beneficiary numbers
☐ Account numbers
☐ Certificate/license numbers
☐ Vehicle identifiers and serial numbers
☐ Device identifiers and serial numbers
☒ Web URLs
☒ Internet protocol (IP) addresses
☐ Biometric identifiers including fingerprints and voiceprints
☐ Full-face photographic images
☒ Any other unique identifying number, characteristic, or code

7.2 Does your study involve PHI and need to comply with HIPAA regulations?

HIPAA regulations apply to covered entities that access, collect, use, or disclose protected health information (PHI). PHMC is a HIPAA-covered entity and thus, ***any study that involves PHI must comply with HIPAA regulations****. HIPAA only covers identifiable health information. Studies that involve only (A) health information without any of the 18 personal identifiers listed above or (b) non-health related information that contain identifiers do not need to comply with HIPAA because neither form of data meets the definition of PHI. Use the guide below to verify if your study involves PHI.*

All or some study data:

(a) Contain one or more of the 18 personal identifiers.	☒ Yes ☐ No	If you answered "No" to (a), then HIPAA regulations do NOT apply. If you answered "Yes" to (a) **AND** (b), (c), **or** (d), then **HIPAA regulations apply to this project.** Submit Appendix C.
(b) Relate to an individual's past, present, or future physical or mental health or condition.	☐ Yes ☒ No	
(c) Relate to an individual's past, present, or future provision of healthcare.	☐ Yes ☒ No	

(d) Relate to an individual's past, present, or future payment for the provision of healthcare.	☐ Yes ☒ No	

7.3 Is there a possibility that *de-identified* information or biospecimens will be used for future research studies or distributed to another investigator for future research studies without additional informed consent from participants?

This only applies to studies that prospectively collect information or biospecimens. Select "No" if your study involves secondary analysis only.

☒ Yes, de-identified information or biospecimens may be used or distributed for future research.
☐ No, de-identified information or biospecimens will not be used or distributed for future research.

8 PRIVACY AND CONFIDENTIALITY

8.1 Describe procedures to protect participants' privacy *during* the study (i.e., precautions you have taken to protect the participant from being recognized as a research subject).

1. The participant enrollment spreadsheet will be password-protected and sent to WTV via encrypted email. (WTV will be responsible for contacting enrolled participants to inform them of their random assignment, to discuss next steps, if needed, and to provide a $50.00 gift card incentive payment for completing a survey.)
2. Electronically obtained consent forms will be stored in a separate, restricted folder located on a secure network drive at Public Health Management Corporation, accessible only by key study staff.
3. When contacting participants for study-related purposes, staff will follow a locating and contact protocol that will decrease the chances of someone being identified as a research subject. They will leave messages approved by the participant that do not identify the person as a research participant.
4. Participants will be instructed to create a username that does not use their last name or email address. Participants can request for their usernames to be changed at any time during the study.
5. Participants will be instructed to make sure that they are in a private area before revealing any personal information while completing assessments and during an online focus group, interview, training, or, if applicable, during a video or telephone meeting with a CRAFT trainer or an audio taped session with a client. They will also be asked to consider using private telephones (no extension lines) when possible. For those participating via Zoom, Zoom ensures information is not stored in their network; the data is only transmitted during a session. WTV will pay to use a HIPAA protected Zoom account to reduce risks associated with privacy. Participants will receive a secure link to access sessions, so no one other than the intended counselor and staff can attend. Participants who elect to receive text messages or emails will be instructed to use a password to access telephone/email content and to delete messages immediately after responding to them. Focus group participants will be instructed to keep the identity of other participants in the group private.

8.2 Describe all of the procedures you will use to protect participants' confidentiality *during* the study (i.e., precautions you have taken to protect participants' data from being unnecessarily and inappropriately disclosed; e.g., authorization of access, password protection, encryption, physical controls, certificates of confidentiality, separation of identifiers and data). Include information on any measures that will be taken during storage, access, use, and transmission of study data.

If you will obtain information on participants' substance use disorder from a treatment provider, then only answer this question for all other data not related to substance use records (e.g., self-report data). All confidentiality and data security questions around substance use records should be recorded in Appendix J.

1. Participants will be assigned an identification number which will be affixed to all collected assessment data. Linkage between participant identity and identification numbers will be stored in a password protected electronic file on a secure network drive at Public Health Management Corporation accessible by key study staff.
2. The password-protected participant enrollment sheet will not be connected to study data. Data collected in the study will be kept strictly confidential and will not be shared with anyone outside of the research team.
3. All computer spreadsheets containing data and SPSS data sets will be saved in password protected files on a secure server located at Public Health Management Corporation and accessible only to designated research staff.
4. All research instruments will be computerized for this study, and the data will be entered via the Web using SurveyGizmo platform. R&E Group maintains a Business Associate Agreement with Alchemer (formerly called Surveygizmo), allowing staff to securely collect private and confidential information in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), and other applicable data security and protection laws.
5. All study staff will be required to undergo training in confidentiality procedures which reviews data handling procedures as well as addresses questions about participants posed by individuals outside of the immediate project staff and by project staff members who do not need the information requested. Certification of successful completion of this training is kept in the appropriate project folder. Should any breaches of participant confidentiality occur during the course of the study, they will be reported to the relevant IRB and DSMB.
6. Focus group participants will be instructed to keep the information shared by other participants in the group confidential.

   In addition, for Aim 2:
7. Data collected as part of the online training activities will also be kept confidential. Participants will be instructed to create a unique username that does not use their last name or email address. For those participating in training activities via Zoom, Zoom ensures information is not stored in their network; the data is only transmitted during a session. We will provide participants with a secure link to ensure no one other than the participant can enter. WTV agreed to purchase the higher-level membership account that is HIPAA compliant.
8. Participants will be completing standard patient sessions for review and coding. Audio will be recorded by our trained SP and uploaded to a secure system similar to the one that Dr. Meyers uses when providing counselor training, and then deleted from the recording device. Participants in the TMC condition (n=15) will also be submitting their own audiotaped sessions with actual clients for review, coding, and feedback by our CRAFT trainer. Once the counselor has uploaded the audiotape and it has been verified by the CRAFT trainer, it will be deleted from the recording device.
9. CRAFT trainers will code CRAFT procedure session fidelity using the coding checklist. Additional research team members will access the audiotapes and checklists for the purpose of developing an automated system to electronically code procedure fidelity in the same manner that CRAFT trainers. The checklists will not have a participant's name or other identifying information on them. They will only have their ID numbers.
10. After collecting and cleaning all data from the baseline and follow-up time points, PHMC will upload the final clean and de-identified data set to the study's secure Google drive in order to share the data with the study's statistician for analysis purposes.

8.3 If identifiers will be obtained, indicate how the identifiers will be stored.

If you will obtain information on participants' substance use disorder from a treatment provider, then only answer this question for all other data not related to substance use records (e.g., self-report data). All confidentiality and data security questions around substance use records should be recorded in ***Appendix J****.*

☐ Not applicable; identifiers will not be obtained.

☒ Identifiers will be stored separately from study data and a key or code will be kept.

Describe where the data study, identifiers, and key will be stored, and state the retention period:

1. Participants will be assigned an identification number which will be affixed to all collected data. Linkage between participant identity and identification numbers will be stored in a password protected electronic file on a secure network drive at Public Health Management Corporation accessible only by key study staff.
2. Participant enrollment spreadsheet containing identifying information will be sent to WTV via encrypted email and in a password protected spreadsheet. This file will not be connected to study data.
3. Electronic obtained consent forms will be stored in a separate restricted folder located on a secure network drive at Public Health Management Corporation accessible only by key study staff.
4. Identifying data (e.g., informed consent forms), screening data, and survey data will be kept for a period of five years after the end of the pilot study as required by NIH/NIDA and then deleted. The information will enable us to ensure pilot study participants do not enroll in a future full research trial.
5. Contact information will be deleted one year after the end of the pilot study.

☒ Identifiers will be removed or destroyed.

Describe how identifiable data will be de-identified or destroyed. Include information on how, when, and by whom (by role or position, not by name):

5 years after study completion, all identifying information will be destroyed by PHMC staff.

☐ Identifiers will not be removed or destroyed.

Provide the rationale for retaining identifiable data and state the retention period. Include information on how and where the identifiable information will be stored:

9 RISKS AND BENEFITS

9.1 Select all of the reasonably foreseeable risks of harm, discomforts, and hazards to the participants and others as a result of study participation.

☒ **Breach of confidentiality** to records containing identifiable private information or biospecimens
☐ Disclosure of participants' responses outside of the research context could place the subjects at risk of **criminal or civil liability**
☐ Disclosure of the participants' responses outside of the research context could be **damaging** to the participants' financial standing, employability, insurability, education, reputation, social relationships, services, or eligibility services
☒ **Psychological discomfort or distress** from providing or being exposed to personal or sensitive information
☒ Possibility of or perceived **invasion of privacy** to the participant or their family
☒ Possibility of or perceived **coercion or undue influence** to participate in the study (in Aim 2)
☐ Presentation of materials which some participants may consider **sensitive, offensive, or threatening**
☐ **Physical or psychological harm** such as pain, injury, or disease including side effects from drugs and devices
☒ Other (please specify): Disappointment with the randomly assigned training program.
☐ No risks

9.2 For each risk selected above, describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard.

This study poses minimal risks to participants. Any individuals experiencing significant psychological distress or perceived invasion of privacy from audiotaping are free to refuse to participate or to withdraw from the study. For other participants, if the risks outlined above do occur, we anticipate the magnitude to be low because of the protections we have put in place to protect identity, privacy and confidentiality of participants. The possibility of perceived or undue

influence to participate in the study is likely to be low due to the precautions we have put in place to mitigate this risk. All of these potential harms are transitory or reversible.

9.3 For each risk selected above, describe how you will manage or minimize the risk.

1. **Risk Resulting from a Breach of confidentiality** – Data collected in the study will be kept strictly confidential and will not be shared with anyone outside of the research team. We have developed strict protocols for collecting, securing, storing, and transmitting data. All study staff must complete a Human Subjects training protocol.
   All research specific materials will be coded with a research number to de-identify the data and will contain no other identifying information to protect participant confidentiality. Participants will be assigned an identification number which will be affixed to all collected data. Linkage between participant identity and identification numbers will be stored in a password protected electronic file. In addition, linkage between participant identity and online user name will be stored in a password protected electronic file. PHMC computer spreadsheets containing data and SPSS data sets will be saved in password protected files on a secure server located at Public Health Management Corporation and accessible only to designated research staff. WTV computer spreadsheets containing data will be saved in a restricted project folder on a secure Google drive. All research instruments will be computerized for this study, and the data will be entered via the Web using Alchemer platform. R&E Group maintains a Business Associate Agreement with Alchemer, allowing staff to securely collect private and confidential information in compliance with the Health Insurance Portability and Accountability Act (HIPAA), Family Educational Rights and Privacy Act (FERPA), and other applicable data security and protection laws.
2. **Risk Resulting from Discomfort or Distress Completing Research Measures and Procedures** – Before giving consent, participants will be informed of potential discomforts from completing research activities.
   a. **Discomfort associated with being audiotaped during the focus group, individual interviews, or mock or actual sessions.** We will help participants to understand that feeling uncomfortable when being audiotaped is usually transitory. For participants submitting audiotapes of mock or actual client sessions, we will clarify that our goal is to evaluate the training programs, not their abilities per se. If participants experience significant distress such that it makes participation uncomfortable for them, they will be reminded that they can leave the study at any time.
   b. **Discomfort associated with the training intervention (Aim 2 only)** - The level of distress associated with training interventions is expected to be similar to that which they would experience during any training program and is not a function of the research participation per se. Nonetheless, participants will be informed about this possible risk before consenting and will be told that they can withdraw from the study at any time without penalty. If participants in the TMC condition are experiencing difficulty, discomfort, or distress associated with locating CSOs for actual client sessions, we will help facilitate a client match for them from our We The Village community of family members with a loved one struggling with OUD. If they are experiencing discomfort due to concerns about protecting client confidentiality for those clients participating in videotaped sessions, we will discuss with them steps to ensure client consent and to protect client confidentiality.
3. **Disappointment associated with the training intervention (Aim 2 only) –** It is possible that counselors will be disappointed with the training condition to which they are randomly assigned. Counselors assigned to the T and TM conditions may be disappointed that they did not receive a more intensive training opportunity that would allow them to become certified as CRAFT counselors. Should these individuals wish to pursue CRAFT certification through We The Village after their research participation has ended they will not be charged for the components they have already received and can complete certification at a reduced cost Counselors who are randomly assigned to the TMC training program may be disappointed that they did not receive a less intensive training program. These individuals, like all study participants, are free to withdraw from the study at any time.
4. **Risk Resulting from Possible or Perceived Invasion of Privacy** - Participants are at risk for harm as a result of being identified as a study participant. Participants will be informed of this risk during the consent process. Participants will receive instruction on how to protect their identity by creating strong passwords, completing training and research activities when they have enough time and privacy to participate, and using unique usernames when participating in online study activities. The likelihood of this occurring is small.

a. All project staff will be required to undergo training in confidentiality procedures), which reviews data handling procedures as well as addressing questions about participants posed by individuals outside of the immediate project staff and by project staff members who do not need the information requested. Certification of successful completion of this training is kept in the appropriate project binder. Should any breaches of participant confidentiality occur during the course of the study, they will be reported to the relevant IRB and DSMB.

Aim 2 only:

b. Efforts to contact participants for the 12-week post enrollment follow-up assessment will make no mention of the study until it is established that the participant has been reached. Access to participants' contact information will be limited only to research staff members who need to contact a participant for study purposes. Any information on paper documents containing participant identifiers will be kept in a locked filing cabinet separate from the data. Research staff affiliated with this project will destroy all identifying information 5 years after the study has been completed.

c. Data collected as part of the online training procedures will also be kept confidential. Participants will be instructed to create a username that does not use their last name. Participants can request for their user names to be changed at any time during the study. Participants will be instructed to make sure that they are in a private area before revealing any personal information during an online session or, if applicable, during a video or telephone meeting with a CRAFT trainer. They will also be asked to consider using private telephones (no extension lines) when possible. For those participating via Zoom, Zoom ensures information is not stored in their network; the data is only transmitted during a session. WTV will pay to use a HIPAA protected Zoom account to reduce risks associated with confidentiality and privacy. Participants will receive a secure link to access sessions, so no one other than the intended counselor and staff can attend. Participants who elect to receive text messages or emails will be instructed to use a password to access telephone/email content and to delete messages immediately after responding to them. Audio recorded sessions will be recorded by our trained standardized patient (SP) or participants who have been assigned to receive coaching (Program 3). Both will be trained to upload the audiotape immediately to a secure system, which is no different than if they were to seek certification outside of the study. Once uploaded it will be deleted from the recording device.

5. **Risk Resulting from Perceived Pressure to Participate by Employers** – It is possible that some participants (e.g., counselors) could learn of the focus groups or the training pilot study from their employers and feel pressure to participate or to answer questions or give feedback in a particular way. To protect against this risk:

   a. All employers who are approached to assist with recruitment will be informed of the necessity that research participation is voluntary. They will be told that they cannot require counselors to participate and cannot administer consequences to counselors who do not participate. They will be told that counselors must meet eligibility criteria to participate, so the fact that a counselor does not participate does not mean that they refused to do so. Should an employer inquire about the reasons a counselor did not participate, they will be told the person was not eligible (voluntary participation is an eligibility criterion) and reminded that they should not pressure employees to participate.

   b. All participants will be assured that their participation is voluntary and that we will not provide any information about their participation (i.e. whether they agreed to participate or their responses) to any outside parties. Counselors will not participate in the same focus groups as their supervisors or administrators at their place of employment.

For protocols that meet the criteria for exempt research, skip to Section 10.

9.4 Are there any risks to individuals related to pregnancy, fertility, lactation, or effects on a fetus or neonate? If yes, describe how you will manage or reduce this risk.

Some studies will require unique considerations if a participant becomes pregnant during the study (e.g., discontinuation of a diet-based intervention or medications).

No. We are conducting a behavioral online intervention that poses no risks to participants who are pregnant or who become pregnant during the study.

9.5 Describe whether participants who become pregnant will be able to continue their participation in the study. If they will continue to be included in the study, describe any measures to accommodate the pregnancy, if applicable.

Yes. Participants who become pregnant during the study will be able to continue. The proposed study is a behavioral health training intervention and is conducted online. We do not expect pregnant participants to require additional accommodations, because they can participate via a smartphone or computer at any location.

9.6 Describe the potential direct benefits to individual participants or to others as a result of study participation. Indicate if there may not be any direct benefits to participants or to others.

Aim 1 - Qualitative Review: Some professionals enjoy providing feedback and sharing their experience to improve future programs; however, we anticipate no direct personal benefit to participants beyond this.

Aim 2 - Training Intervention: All counselor participants receive training free of charge, which they may perceive as a benefit. It is possible that the training will increase their effectiveness as counselors or allow them to work with new populations (e.g., CSOs), which they may perceive as benefits. However, we anticipate no direct benefit to counselors beyond this.

9.7 Define reportable and non-reportable Adverse Events (AEs).

Reportable AEs:
Will be defined as: significant discomfort from answering research questions or participating in the focus group, individual interview, or training intervention such that the participant decides to stop their participation or reports new diagnoses of depression, anxiety, or panic attacks. We will also report coercion or perceived coercion to participate in the study as an AE.

Non-reportable AEs:
Clinically insignificant events are not considered AEs. Examples of clinically insignificant events include mild viral illness (e.g., colds, flu, and runny nose), common headaches, minor scratches, and mild symptoms or problems associated with medical conditions or accidents. As per the definition of AEs, only significant worsening of problems or new problems will be reported as AEs. We will monitor attrition rates, but drop out from the study will not be reported as an AE.

Reportable SAEs: will be defined as death; a life-threatening event such as suicidal attempt, or inpatient hospitalization (including psychiatric hospitalizations) due to suicidal behavior, or psychiatric distress; or substance use overdose; or an event that extends an existing hospitalization as defined above.

9.8 Define reportable Serious Adverse Events (SAEs). Choose one or both as applicable to your study.

☒ Any adverse event that:

1. Results in death;
2. Is life-threatening (places the subject at immediate risk of death from the event as it occurred);
3. Results in inpatient hospitalization or prolongation of existing hospitalization;
4. Results in a persistent or significant disability/incapacity;
5. Results in a congenital anomaly/birth defect; or

6. Based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed above.

(*OHRP Guidance on Unanticipated Problems and Adverse Events; January 15, 2007)*

☐ Other, or in addition to the above (*please describe*):

9.9 Describe plans to identify, monitor, manage, and report AEs and SAEs. Include information on the method and frequency of collecting AE and SAE information (e.g., weekly through telephone calls, monthly at study visits, every time the subject comes to the clinical setting), the individuals responsible for collecting this information (e.g., research assistants, case managers, counselors), and the start and end of collection (e.g., from the participant's first exposure to the intervention to their last study visit).

All WTV and PHMC staff who interact with participants will be trained on the definitions of reportable and non-reportable AEs and SAEs and the way to complete the forms reporting them. The PI and Dr. Kimberly Kirby meet regularly with CRAFT trainers to track and to document any AEs and SAEs. The WTV clinical team will be interacting with participants in the CRAFT interventions on a regular basis and will be responsible for collecting AE and SAE information shared during their interactions and reporting them to the PHMC team. In addition, the Research Coordinator will document information related to AEs and SAEs shared when contacting participants.

All adverse and serious adverse events occurring during the study are documented on a form, reviewed and signed by the PI, Jane Macky or Dr. Kirby, and reported to the IRB. All SAEs are reported to the IRB within 48 hours of our awareness of the event (24 hours for fatal events). A summary of all SAEs and AEs that occurred during six-month pilot study will be included in any progress reports to the IRB. We will begin to collect AE and SAE information between the first intervention session and their 12-week post enrollment assessment.

9.10 Will you submit or have you submitted the protocol for additional oversight by a Data and Safety Monitoring Board (DSMB)?

☒ Yes:

☒The protocol will be submitted to PHMC's DSMB.

☐ The protocol will be submitted to an external DSMB.

☐ An external DSMB or monitoring committee has reviewed the study. All reports are attached.

☐ No, a DSMB is not needed for this study

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