Cover Page: Protocol
We The Village Family Support Study
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PROTOCOL OVERVIEW

Protocol Number	1906
Protocol Title	SBIR Phase 1: Scalable digital delivery of evidence-based training for family to maximize treatment admission rates of opioid use disorder in loved ones--We The Village Family Support Study
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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.

The United States is in the midst of an opioid crisis--opioid use problems (OUPs) are increasingly widespread and lethal. In 2016, more than two million Americans were diagnosed with opioid use disorder (OUD) and more than 42,000 have died of an overdose involving opioids (SAMHSA, 2019). The death rate is more than any year on record and has quadrupled since 1999 (Vice Chairman's Staff of the Joint Economic Committee, 2017.) Several effective medications are now available for treating OUD but many people, who could benefit from medication, do not receive them (Sarlin, 2018). Despite the fact that effective treatments for opioid use disorder exist, only about one in four people (28.6 percent) with this disorder received specialty treatment for illicit drug use in the past year (Center for Behavioral Health Statistics and Quality, 2017.) For those struggling with opioid addiction, compared to others dependent on drugs, "the recovery period is longer, and the chance of relapse is higher." (Wogan, 2017.) Smith and colleagues (2010) interviewed 109 residential addiction treatment patients after

discharge and found over nine in ten patients reported a relapse, with nearly six in ten patients relapsing in first week after discharge.

Substance use impairs executive decision making and depletes defenses against impulse reactivity (Office of the Surgeon General, 2016), creating challenges for the person with an OUP to recognize the need for treatment as well as navigate the treatment entry process. Having concerned significant others, including family members (hereinafter known as CSOs) trained in best-practices and equipped with effective tools to take action is game-changing. Family members have been filling gaps in the substance use disorder (SUD) care continuum for decades, frequently without recognition from the health care system. Cycles of urgent acute care followed by discharge home with no formal support are common in the US addiction treatment system as well as waiting weeks or months to move from one level of care to the next. To fill this gap, untrained family members often have no choice but to provide life-sustaining transitional care at home. Research shows that family members make the majority of the decisions around treatment, including financial decisions (Ventura et al., 2017) and thus, have high potential to impact the trajectory of their loved one's OUP for better or worse.

One study showed that social and familial reasons were the most expressed reasons for entering drug treatment and people with substance use disorders perceive treatment entry as an important way to obtain positive contingencies in their interpersonal relationships, which further underscores the potential utility of conjoint interventions with CSOs. It also suggested that the informal pressure of one's natural social network, of which CSOs are an integral part, to be influential in improving treatment retention and abstinence (Marlowe, D. et al., 1996). Despite continued and mounting empirical support that family members and loved ones play an integral role in the success and wellbeing of individuals' engagement along the OUP care continuum and contribute to health outcomes and mortality rates, family members remain on the periphery, overlooked by our current healthcare system. Similarly, they are overlooked by entrepreneurs. There has been little innovation in tools to provide help for family members and friends of an individual with an OUP (hereinafter known as identified person or IP). The significance of this project is to address this critical gap in OUP treatment by providing evidence-based training and tools to CSOs to reduce fatal and non-fatal overdoses and to increase treatment utilization.

Since it has been shown that training a CSO in CRAFT improves ability to get a treatment-resistant individual into life-saving treatment, it is highly valuable. Furthermore, new laws around delivering medical assisted treatment (MAT) online via telemedicine provides the proposed project the opportunity to fill a gap for CSOs using online technology to help them increase their treatment resistant IP's motivation to engage in treatment and connecting them to treatment online, whether it be booking a bed or accessing telemedicine and prescriptions for MAT. The project team involves We The Village, Inc, a small business already providing support to CSOs using consumer technology, Dr. Robert Meyers, creator of CRAFT, Dr. Kimberly Kirby, research expert in the field of substance use disorders, Dr. Ben Bearnot, primary care physician specializing in addiction treatment, and certified CRAFT coaches. Phase One of this project will develop and refine digital delivery of two modified CRAFT (Community Reinforcement and Family Training) interventions: automated and Group CRAFT protocol (CRAFT-A) and automated CRAFT protocol with live coaching (CRAFT-C) and assess the effectiveness of the adapted CRAFT protocols with WTV's business as usual model of Peer Support Forum (PEER). The goal of the project is to deliver an innovative and effective evidence-based behavioral intervention with consumer technology to an existing and growing online audience.

Abbreviations:
OUP - Opiate Use Problem - this is opioid use that has been identified by a concerned significant other as problematic but has not necessarily been formally diagnosed as an opioid use disorder. MAT - Medically Assisted Treatment. IP - the identified treatment-resistant person (in our case, with an OUP.) CSO - concerned significant other - this is the friend or family member of the IP.

CRAFT - Community Reinforcement and Family Training. WTV - We The Village. Live coach - trained human coach. CRAFT-C - digital CRAFT + digital or telephone live coaching. CRAFT-A - digital automated CRAFT plus digital or telephone live group. PEER - Peer support (current WTV platform.)

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

Primary Hypothesis:

a. At the 3-month post study intake survey, we expect that CSOs assigned to CRAFT-C will report a greater proportion of IPs entering treatment as compared to the CRAFT-A and PEER groups, and the CRAFT-A group will report a greater proportion of IPs entering treatment as compared to the PEER group.

Secondary Hypotheses:

b. At the 2-month and 3-month post study intake survey, CSOs in all three groups will report that their relationship happiness has improved relative to baseline as measured by the Relationship Happiness Scale (RHS).
c. At the 2-month and 3-month post study intake survey, CSOs in all three groups will self-report that their own anxiety, depression, anger and physical illness has improved relative to baseline as measured by the POMS survey, SF12 Health Survey, and the SAS-SR work subscale.
d. At the 2-month and 3-month post study intake survey, CSOs assigned to CRAFT-C and CRAFT-A will demonstrate higher fidelity of learning CRAFT principles as compared to the CSOs assigned to the standard condition (PEER), as measured by correct answers on the revised CRAFT knowledge test.
e. At the 3-month post study intake survey, all three groups will report similar high satisfaction (average score above 3.5 on a 5-point scale) on Usability of the website and the CRAFT-C group will report the greatest satisfaction in the Usefulness of the website relative to the CRAFT-A and PEER groups as measured by the User Satisfaction Survey.

1.3 List the primary and secondary outcomes.

The primary outcome variable that will be measured is the CSO's reporting their IP entered treatment for their OUP or received additional treatment for their OUP.

Secondary outcome variables that will be measured include CSO and IP relationship happiness; CSO's physical and mental health status; CRAFT knowledge of CSOs; and CSO's satisfaction with website content and delivery.

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.

Proposed initial and primary recruitment strategy drawing from the existing WTV member base will produce a sample that is representative of this group but not representative of all CSOs of an IP with an OUP. Many CSOs may have drug or mental health problems themselves, distrust mental health services, or are content being distanced from their problem-wrought IP (Slesnick et al., 2000). These CSOs often do not seek help and they are not the target population for this

study. The target population consists of CSOs who are concerned about their loved one's problems in general and their opioid use in particular, and whose own functioning is not seriously impaired by their own drug use or mental health issues. Also, the sample will be limited to CSOs who have internet access and are willing to receive services from web-based sites. Although this is not representative of all CSOs of individuals with OUP, it is representative of those who would use the services being evaluated.

Gender Representation: In past CRAFT studies, the vast majority (anywhere from 75%-90%) of participants are female. Because women are more likely to seek help (Trudeau et al., 2002), we expect CSOs in this study sample will continue to be predominantly female. Because this is an early stage pilot and feasibility study, we will not conduct targeted recruitment efforts to recruit male CSOs but in the future this would be possible.

Racial/Ethnic Representation: Given the proposed small sample size (up to 84 CSOs) for this pilot and feasibility study, we anticipate that we will not have a sufficient number of minorities in any group to do demographic analysis. Still we expect to have some minority representation in our participants. If we receive an overwhelming response to our recruitment efforts, if eligible, we will over include individuals in those groups to increase representation. Relative to the racial demographics in the 2017 Census for the United States (60.7% White, 13.4% Black, 5.8% Asian, 18.1% Hispanic or Latino, 1.3% American Indian or Alaska Native, 0.2% Native Hawaiian Other Pacific Islander), if we were to represent this makeup in our study, we might expect: 27, 6, 2, 8, 1 participants respectively; we'd expect this distribution adjusted for the online over-indexing of white participants.

Socio-economic Representation: Given the study is to be implemented completely online using digital intervention and data collection methods, we expect the sample to skew with CSOs from a higher SES background. Furthermore, inclusion criteria require CSOs to have smart phones with data or computers with internet, which may be a barrier for some people with limited internet/data plans or CSOs who do not have their own smart phone or computer. However, this may not occur given many people across SES levels do have their own smartphones and computers with internet capability.

While the increase in opioid use has increased across diverse groups, white, non-Hispanic adults continue to experience higher rates of opioid use problems and overdose deaths. According to an analysis of National Vital Statistics by the Kaiser Family Foundation, the overall rate of opioid overdose death in 2017 was 14.9 per 100,000 persons in the United States. In 2017, white, non-Hispanic persons had the highest fatal opioid overdose rate (19.4 per 100,000 adults) compared to their black and Hispanic counterparts (12.9 & 6.8 per 100,000 persons, respectively). In addition, the rate of opioid overdose deaths among males is approximately twice as high for males compared to females (20.4 vs. 9.4 per 100,000 persons, respectively). Persons from a lower SES background, including those "living in poverty, being unemployed and having Medicaid," continue to experience opioid use problems and overdose deaths at higher rates compared to their more well-off counterparts (Ghertner & Groves, 2018).

We The Village currently does not collect demographic information from members; however, anecdotal review of their existing membership found the majority were white, female and from a higher SES background. During the pilot study, WTV will collaborate with organizations serving a wider, diverse population, especially communities of color and lower SES backgrounds.

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.

1. Identify as a concerned significant other (CSO) of a loved one with an OUP
2. Be 19 years or older
3. No substance use disorder
4. Has concern about the opioid use of a loved one (IP)
5. Plans to be in close contact (phone/face-to-face) with the IP
6. The IP is not currently receiving treatment, or the IP is in treatment, but the CSO perceives the IP may benefit from additional treatment (e.g., receiving MAT but the IP may benefit from attending outpatient services, or in residential treatment, but will need to enter outpatient treatment upon discharge).

2.5 List the study exclusion criteria.

1. Does not agree to sign the consent form
2. Is not English-speaking
3. Is not able to understand the consent form
    a. Pass a multiple choice consent quiz (i.e., 100% correct responses) that tests the participant's comprehension of basic elements of informed consent and the requirements of the protocol administered by the research team over the phone.
    b. Participants will be given up to three opportunities to pass the consent quiz
4. Does not have personal access to a smart phone with data or a computer with internet to be able to access the digital platform for the study conditions, quizzes, questionnaires, and follow-up communication
5. Reports that they have a drug abuse problem or a history of drug abuse or dependence and that they have not been in recovery for at least 2 years
6. Resides outside the United States

2.6 Provide justification for the exclusion of broad population groups.

The study design excludes anyone under 19 years old. The primary hypothesis for the study is to help CSOs increase treatment utilization among IPs. Children are typically not the CSO who is responsible for treatment decisions of the IP with an OUP.

While the adult population may include persons age 18 years old, the proposed study is excluding potential 18-year-old participants because they may still be in high school and not the primary CSO to support treatment decisions.

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.

For this pilot and feasibility study we plan to enroll up to 84 CSOs

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.

As shown in Figure A, we will conduct outreach using multiple recruitment methods. We expect the majority of participants may be recruited from the existing 1,500 WTV member base, who currently engage in We The Village's peer support online forum; however, we will also utilize personal WTV member referrals, social media platforms, print media, and referrals from partner organizations. Currently, WTV's social network outreach could potentially reach 15,000 persons. WTV team (PI, coaches, and staff) will post recruitment ads and flyers on the WTV website and forum, as well as on other social media platforms. In addition, we will develop partnerships with providers, who serve diverse populations, including communities of color and lower SES. The JoinGroups.Com organization goes into underserved rural areas and establishes a health center to address medical and behavioral health needs, including in-person support groups for people with substance use problems. The Sixth Street Community Center serves a Latinx population. We will post recruitment advertisements on professional counseling member boards, such as the Association of Black Social Workers. All recruitment materials will direct interested individuals to the study page, so they can learn more about the study and complete an anonymous screening survey. We will not collect any identifying information during the screening process. If someone starts the screening survey but does not finish it, we will not be able to reach out to them and they will not be included in the screened category. We will track the number of incomplete screenings throughout the pilot study and where in the screening survey do people drop off. If they screen eligible, they will be directed to click the consent form link. If they screen ineligible, they will be directed to click a link to learn more about WTV and joining the business as usual peer support online forum. They will also be provided the study number if they have any questions and want to speak to a study staff person. If someone calls into the study to be screened over the phone, we will answer any questions, then refer them to the link located on the study's landing page to complete screening and the consent form.

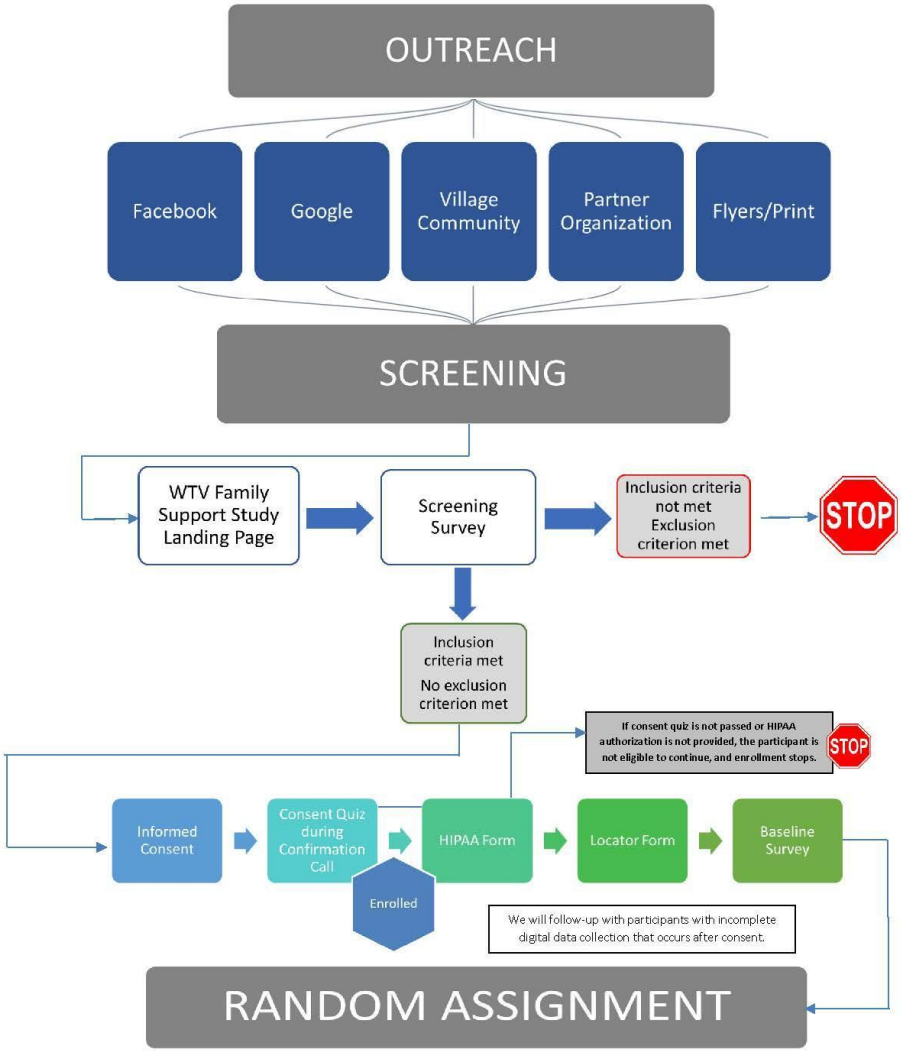
After completing informed consent, participants will be asked to call the research study phone number to complete a consent quiz and to confirm enrollment. They will have the option of calling the number to speak with a study staff person or completing an online request contact form. The brief contact form will ask for a participant's phone number and email address and best time period to contact them. The goal is to speak with participants within one business day after completing informed consent. These calls will be completed by study staff, including the research assistant, senior project manager, and intervention staff, if needed. During the

confirmation call, study staff will administer the brief consent quiz and provide information on next steps, if the participant answers 100% of the questions correct. If the person does not answer 100% of the questions correctly, the study staff person will review the consent form with the participant and re-administer the consent quiz. Participants will have up to three times to pass the consent quiz. If they do not pass the third time, they will be informed that they are not eligible for the study.

After administering the consent quiz during the confirmation call, study staff will answer questions, review next steps, and clarify expectations. If a potential participant did not pass the consent quiz, study staff will be able to review the appropriate consent form sections and to re-administer the consent quiz. After completing the confirmation call, all eligible study participants will be considered enrolled into the study. Study staff will send via email secure Survey Gizmo links with the HIPAA authorization form, locator form and baseline survey. The HIPAA authorization form will now have an option for "I'm not sure." If someone selects the not sure option, they will be directed to call the study number to discuss their concerns or ask questions before moving forward in the enrollment process. Participants must agree to the HIPAA authorization to continue with the study. After agreeing to the HIPAA authorization, participants will click the next step link to complete the locator form. After completing the locator form, participants will click a link to complete the baseline survey. The brief locator form will request important contact information in order to locate participants for the follow-up survey and to re-engage with research and intervention activities, if needed. For participants who report they share their email address with someone else, we will ask them if they are sure it is okay for us to send information to this email address. If they say No or Prefer not to answer, they will be asked if they have a secondary email address they want to use. If someone does not complete the locator form or baseline survey, study staff will reach out to the participants to encourage them to complete these required activities. All participants will have one week to complete the enrollment process. Randomization will occur after completing the baseline survey. We will use block randomization to assign a group of three participants to each condition. We will wait till we have at least people randomized to Program A to begin the program. Participants will be informed of their assigned group after completing their baseline survey. WTV will notify participants of their randomly assigned program and the appropriate next steps for their specific program assignment. This change will allow us to conduct block random assignment computed by Dr. Kirby and to allow us to equal number of people in each group throughout the study recruitment period. We will program Survey Gizmo to send the research team an automatic email when someone completes the baseline survey.

When Program A reaches approximately nine participants, we will form the next group assigned to Program A. We will follow-up participants who have incomplete digital data collection that occurs after consent for up to two times.

Figure A: Recruitment and Enrollment Flowchart



Recruitment activities will be conducted after IRB approval through March 31, 2020 or until we recruit up to 84 eligible CSOs, 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:

a. Recruitment channels
    i. Participants will be recruited through the following methods as needed:
        1. WTV Promotions (e.g., website callouts, emails, social media posts and 1:1 message) to existing and future WTV members.
        2. Engagement of the membership group to suggest a friend and make a referral if they know anyone who fits the participant description.
        3. Reaching out to existing partners who provide services to patients with OUD.
            a. Sixth Street Community Center
            b. Tempest
            c. Rebel For A Change
            d. Best Day Ever
            e. Center for Motivation and Change

f. JoinGroups.Com (medication-assisted treatment (MAT) for opioid addiction)

4. Develop recruitment strategies to increase diversification of study participants
    a. Promote research study on the following professional counseling member websites:
        i. Association of Black Psychologists (ABPsi)
        ii. National Association of Black Social Workers (NABSW)
    b. Develop new partnerships with providers who serve more diverse populations, including communities of color and lower SES
5. Targeted digital and local advertising efforts.
    a. Facebook
    b. Instagram
    c. Google

3.3 Describe how prospective participants will be screened. 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.

As discussed above, we plan to utilize wide-ranging requirement strategies to reach our target sample size. While WTV is located in New York City, participants may live across the United States. When a prospective participant responds to a recruitment message, flyer or referral, they will be directed to visit the We The Village Family Support 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 SurveyGizmo tool.

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, such as reporting "other type of drug used by their loved one." 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.

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

We will retain all the information we received as part of the screening process. During the screening process, we will collect information on prospective participant's year of birth, US residency, access to a computer or smart phone, their own substance use disorder diagnosis, type of relationship with IP, frequency of face-to-face interactions with their IP, perceptions of their IP's opioid use, IP's symptoms of opioid use or misuse, the types of substances used by IP, current treatment plan for their IP, and their ability to commit the time and resources to the study. 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.

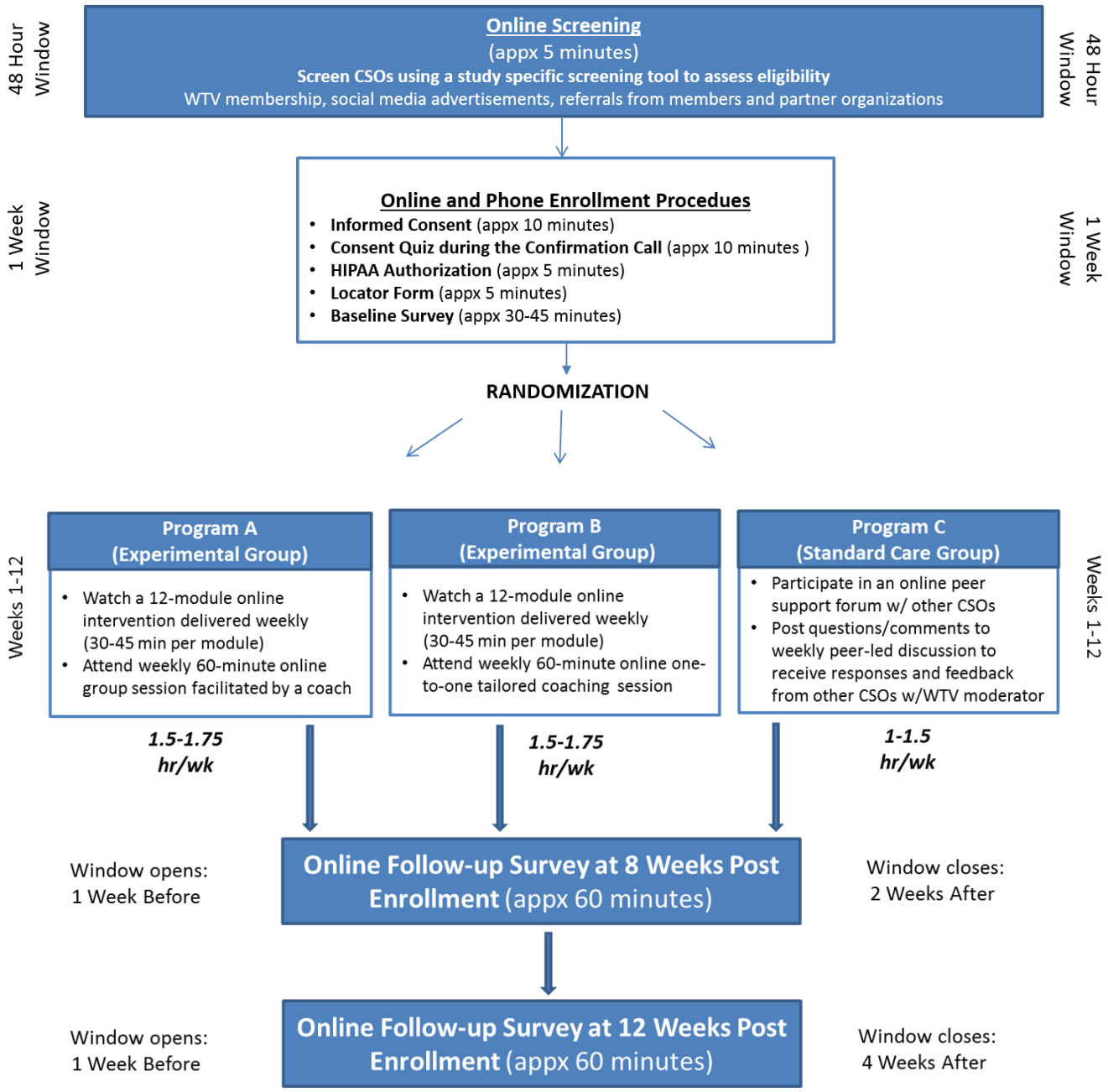
A study phone number and email address will be listed on the study landing page for prospective participants if they experience technical difficulties or have questions. If a prospective participant's answers do not make them clearly eligible or ineligible, they will be encouraged to call, or email the study team, most likely the Research Assistant, for additional information. We will attempt to communicate with participants within one business day. The Research Assistant will re-screen participants without collecting any identifying information to determine eligibility. If the person is eligible, they will be re-directed to the study landing page 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 the We The Village community.

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.

Study procedures are outlined in the figure below. After screening eligible participants complete online enrollment, which includes providing informed consent, passing a consent quiz during the confirmation call by study staff (research assistant), agreeing to the HIPAA authorization form, and completion of the locator form and baseline survey. Participants are then randomized into one of three groups.

Participants assigned to the PEER group (Program C) will participate in an online peer support forum with other CSOs. Members of the forum post questions or comments to weekly peer-led discussions and receive responses and feedback from other CSO forum members. Members typically express concerns regarding their IP's wellbeing and ask other members to share any strategies they have employed when dealing with their IPs.


48 Hour Window
Online Screening
(appx 5 minutes)
Screen CSOs using a study specific screening tool to assess eligibility
WTV membership, social media advertisements, referrals from members and partner organizations
48 Hour Window
1 Week Window
Online and Phone Enrollment Procedues
Informed Consent (appx 10 minutes)
Consent Quiz during the Confirmation Call (appx 10 minutes)
HIPAA Authorization (appx 5 minutes)
Locator Form (appx 5 minutes)
Baseline Survey (appx 30-45 minutes)
1 Week Window
RANDOMIZATION
Weeks 1-12
Program A (Experimental Group)
Watch a 12-module online intervention delivered weekly (30-45 min per module)
Attend weekly 60-minute online group session facilitated by a coach
Program B (Experimental Group)
Watch a 12-module online intervention delivered weekly (30-45 min per module)
Attend weekly 60-minute online one-to-one tailored coaching session
Program C (Standard Care Group)
Participate in an online peer support forum w/ other CSOs
Post questions/comments to weekly peer-led discussion to receive responses and feedback from other CSOs w/WTV moderator
Weeks 1-12
1.5-1.75 hr/wk
1.5-1.75 hr/wk
1-1.5 hr/wk
Window opens: 1 Week Before
Online Follow-up Survey at 8 Weeks Post Enrollment (appx 60 minutes)
Window closes: 2 Weeks After
Window opens: 1 Week Before
Online Follow-up Survey at 12 Weeks Post Enrollment (appx 60 minutes)
Window closes: 4 Weeks After

Interactions typically, are based either in 12-Step strategies members have learned (usually through Al-Anon or Nar-Anon Family Groups or Family Training Workshops provided by treatment programs) or in CRAFT skills learned (usually from treatment programs or other We The Village members). A staff member from We The Village monitors forum interactions to ensure members are interacting respectfully. This individual also will report any adverse or severe adverse events that members mention online.

Participant assigned to the CRAFT-A (Program A) and CRAFT-C (Program B) groups will have access to a 12-module on-line CRAFT intervention and asked to complete one module weekly for 12 weeks. Modules introduce CRAFT concepts and provide workbooks to assist participants in learning and applying the concepts. The modules include: 1) Introduction to CRAFT; 2) Communication Training; 3) Functional Analysis of Drug Using; 4) Positive Reinforcement; 5) Withdrawing Reinforcement; 6) Allowing Natural Consequences; 7) Problem-solving; 8) Life Enrichment; 9) Suggesting Treatment; 10) Recovery and Relapse; 11) Relationship; and 12) Recap of Skills. CRAFT-A participants also attend a weekly 60-minute online group sessions facilitated by a CRAFT-certified coach. CRAFT-C participants attend a weekly 60-minute individualized on-on-one coaching session with a CRAFT-certified coach. During weekly group or individual sessions concepts are briefly reviewed, questions are answered, and skills are practiced through role-plays of common situations. One-on-one sessions involve role-plays that are tailored to the participants' specific circumstances.

Counselors must complete their CRAFT training and certification prior to implementing Program A and Program B. In addition, CRAFT counselors must complete CITI training as limited personnel.

<table>
<tr><th colspan="3">STUDY ACTIVITIES BY PROGRAM</th></tr>
<tr><th colspan="2">Experimental Programs</th><th>Standard Care Program</th></tr>
<tr><th colspan="2">Program A & Program B</th><th>Program C</th></tr>
<tr><td colspan="2">● Commit 1½ to 1¾ hours a week</td><td>● Commit 1 to 1½ hours a week</td></tr>
<tr><td colspan="2">● Watch a 12-module online support program delivered weekly</td><td>● Join a private online support forum for people with a loved one with an opioid use problem</td></tr>
<tr><td colspan="2">● Each module will be 30 to 45 minutes in length</td><td>● Gain access to knowledge and experiences of fellow CSOs shared in peer-led forum discussions</td></tr>
<tr><td colspan="2">● Attend weekly 60-minute online sessions facilitated by a CRAFT coach via Zoom or phone</td><td>● Post your own questions specific to your current situation and receive support from peers and WTV moderators</td></tr>
<tr><td colspan="2">● Review content from the weekly module</td><td>● Share your knowledge and experience to answer fellow CSOs' questions and to support others through their journey</td></tr>
<tr><td colspan="2">● Participate in a Question and Answer segment</td><td></td></tr>
<tr><td colspan="2">● Practice content with role-plays</td><td></td></tr>
<tr><th>Program A</th><th>Program B</th><th>Program C</th></tr>
<tr><td>● Weekly sessions are in a small group with WTV coach and 3 to 8 study participants using Zoom
● Weekly sessions follow a specific course outline and schedule</td><td>● Weekly sessions are one-to-one with WTV coach using Zoom
● Weekly sessions are tailored to the individual study participant</td><td>● Discussions are self-initiated and ongoing
● Engagement can occur at any time of the day or night
● Benefit from the extensive database of shared peer experiences</td></tr>
</table>

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.

Data collected directly from participants:
Similar to screening and consent procedures, data collection for baseline, 8-week, and 12-week post enrollment follow-up surveys will be self-administered using Survey Gizmo software since participants may be located anywhere across the country. Participants will be directed to a separate link to complete the locator form and baseline survey after they complete the following steps:

1. Provide informed consent
2. Pass the consent quiz
3. Speak with a study staff person during the confirmation call
4. Agree to HIPAA authorization form

We will include a message that informs participants of the time estimate for completing the baseline survey, as well as the content of the baseline survey. They will be told that their contact information will be stored separately from the rest of the survey and never be directly connected to their survey answers. The baseline survey consists of socio-demographic questions, such as gender, age, race/ethnicity, and other standardized socio-demographic measures adapted from the GPRA instrument and the National Survey on Drug Use and Health. The questions in the 8-week and 12-week follow-up surveys will ask the same questions. The 8-week follow-up survey will enable the research team to assess changes in the lives of participants in an earlier phase of the intervention, with the 12-week assessing program impact at a later stage of the study.

	Behavior / Domain	**Measure**	**Timepoints**
1.	Socio-demographic questions	Measures adapted from GPRA and the National Survey on Drug Use and Health will include age, gender identity, race, ethnicity, sexual identity, and SES	Baseline only
2.	Treatment entry	Revised Supplemental Services Form	Baseline, 8-Week &12-Week Post Enrollment
3.	Relationship happiness	Relationship Happiness Scale	Baseline, 8-Week &12-Week Post Enrollment
4.	Missed work	SAS-SR – Work, Housekeeping, School sections (sections: A, B, C) only.	Baseline, 8-Week &12-Week Post Enrollment
5.	Depression, Anxiety, Anger	POMS	Baseline, 8-Week &12-Week Post Enrollment
	Physical illness	SF12 Health Survey	Baseline, 8-Week &12-Week Post Enrollment
6.	Learning CRAFT	Revised Family Training Survey	Baseline, 8-Week &12-Week Post Enrollment
7.	User satisfaction	Usefulness and Usability Survey	8-Week and 12-Week Post Enrollment only

Revised measures have been adapted specifically for CSOs with IPs with an OUP, as appropriate. In addition, we added questions specific to the impact of COVID-19 on the CSO, the CSO's contact with the IP, and IP's ability to access treatment and to receive quality treatment due to COVID-19 restrictions. The IP's treatment entry is the study's primary outcome and we need to understand the impact of COVID-19 on our participants' IPs gaining and receiving treatment to assess the study's impact on a primary outcome.

Participants may be contacted through email, text, calls, letters, and social media direct messaging. In addition, we will ask participants to give us the names and contact information for two people who can reach them if all other contact methods fail. Participants will be able to provide the messages we can send and/or leave, as well as any instructions they wish for us to follow when attempting to contact them or the contacts they shared with us.

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 the CSO's IP.

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.

Participants may be removed from the study for the following reasons:

a. They engage in hostile behavior with other participants during online interactions
b. They break the confidentiality and share personal information of other participants

Participants will be notified of their removal from the study by the Principal Investigator, Calum Handley. The PI will call the participant to explain the reason for their removal. In addition, a formal letter will be sent to participants. 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.

Removed participants' data will be deleted and will not be used for analysis and dissemination. 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 <u>compensation</u> that will be given to participants for the completion of research-related activities. Include the monetary value and type of compensation per activity.

Participants will be asked to complete surveys at three time points—baseline, 8-weeks, and 12-weeks post enrollment. They will receive a $20.00 incentive for completing each survey, a total of $60.00. The incentive will be in the form of a $20.00 Amazon gift card that will be emailed to the participant within two business days of completing each survey. We expect participants may receive their incentives sooner, but we want to allow time to communicate the completion of a survey between PHMC R&E Group and WTV. PHMC R&E Group is

responsible for all data collection activities and WTV is responsible for sending incentive payments to participants.

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. We specify no reimbursements will be given to participants in the consent form.

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	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 Survey Gizmo after completing the consent form. In addition, all participants will be emailed a copy of the PDF informed consent form with the box agreeing to join the study checked off and with their name typed into the "I agree" section.
☐ 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).

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 next step after informed consent is to administer the Consent Quiz during the Confirmation Call with all participants who agreed to participate. Participants will be informed that their enrollment is not final until they speak with a study staff person to complete the quiz and call with study staff. We will attempt to return phone calls and emails within one business day.

The final step in enrollment is for participants to agree to HIPAA authorization (See Appendix C). The HIPAA form will be sent to participants after passing they pass the Consent Quiz during the Confirmation Call.

With the addition of the 8-week follow-up interview and the need to get the Consent Addendum from all participants, WTV coaches will mention the Consent Addendum email to the participants in the Program A and Program B conditions during a scheduled session. For participants in the Group C condition, WTV will post a message on the community forum regarding the Consent Addendum. Scripts of these messages are included in Attachment 1. The research staff will send out the Survey Gizmo link with the Consent Addendum in a brief email message. Please refer to Attachment 1. Communication with participants for the messages that WTV and the research staff will use for contacting participants to notify them of reading and agreeing to the Consent Addendum.

We will send participants, who agree to the Consent Addendum, an electronic version of the Consent Addendum for their records. Program staff and research staff will reach out to participants who did not respond to our request to review the consent addendum. We will contact them via phone, text, and email as appropriate given the permissions they allowed on the contact form at baseline (Attachment 1).

If a participant selects, "I do not agree to complete the 8-week follow-up survey but agree to continue participating in this research study" in the consent addendum, we will not complete the 8-week follow-up survey and we will only send them the 12-week follow-up survey. If someone selects, "I am not sure," they will be instructed to call research staff to ask their questions or to get their concerns addressed. If someone selects, "I do not agree to complete the 8-week follow-up survey and do not agree to continue participating in this research study, they will receive a follow-up question asking them to provide a reason for not continuing with the research study. This will help us document reasons for withdrawal. In addition, if we do not receive a response from any contact attempts to review and to agree to the consent addendum, we will not complete the 8-week follow-up survey and we will honor the original consent form. We will not complete the consent quiz with participants for the Consent Addendum.

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

We will use a multiple-choice Consent Quiz to test participant's understanding of the information presented in the informed consent form. We will implement the following protocol to ensure participants comprehend the basic elements of the study information presented in the consent form:

a. The quiz will be administered during the Confirmation Call by a study staff person over the phone
b. Participants must take the quiz
c. Participants will be required to have 100% correct responses
d. If a participant does not pass (100%) of the consent quiz, we will re-administer the consent quiz after reviewing the consent form with them over the phone.
e. Participants will be given up to three opportunities to pass the consent quiz

f. If participants are not able to pass the consent quiz after three attempts, they will be informed that they are not eligible for the study and they will be invited to join WTV's standard online program outside of the study.
g. All participants will be provided an opportunity to ask questions or to receive additional information about WTV.

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 18 years old.

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. 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 by key study staff.
2. 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, and to provide $20.00 gift card incentive payment for completing a survey. This file will not be connected to study data.
3. Data collected as part of the online intervention 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.
4. When contacting participants for study-related purposes, staff will follow a locating and contact protocol that will decrease the chances someone will be identified as a research subject.

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. Data collected in the study will be kept strictly confidential and will not be shared with anyone outside of the research team. 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.
2. 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.
3. Participant enrollment spreadsheets will be sent via encrypted emails to WTV.

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 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. For those participating in intervention 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 a group. WTV agreed to purchase the higher-level membership account that is HIPAA compliant.
6. Participants will be visible to one another during the CRAFT sessions; however, their visibility is similar to attending an in-person group-level intervention session. Zoom sessions will not be recorded.
7. Counselors will record intervention fidelity using an intervention activity checklist. The checklists will not have a participant's name on them. They will only have their ID numbers.
8. 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.
9. All study staff will be required to undergo training in confidentiality procedures (including HIPAA regulations) which review 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.

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. 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.
5. Identifying data will be kept for a period of five years after the end of the pilot study then deleted. The information will be retained for this period so that we can ensure pilot study participants do not enroll in a future full research trial, if funded.
6. 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):

☐ 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
☐ 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):
☐ 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. If the following risks occur, we anticipate the magnitude to be low because of the protections we have put in place to protect identity and the access to study staff to discuss concerns.

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.

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 measures. Participants will be allowed to refuse to answer any question without penalty. **Discomfort associated with the treatment intervention** - The level of distress associated with 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. We have not encountered any instances of significant emotional upset from research activities with individuals who have participated in our previous CRAFT and self-help studies. 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.

3. **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 or as someone with a loved one with an opioid use problem. 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 intervention and research activities when they have enough time and privacy to participate, and using unique user names when participating in online study activities. In addition, participants will be informed of the importance of not sharing another person's information. The likelihood of this occurring is small.

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. CSOs who become pregnant during the study will be able to continue. The proposed study is a behavioral health 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.

Participants may not receive direct benefits from this study; however, the study uses teaching approaches when delivered face-to-face have been shown to help people interact with their loved ones using healthier strategies. In addition, participants may feel more supported by engaging with other CSOs or by interacting with their coach, depending on their assigned group. Current WTV members have reported increased level of happiness, support, and healthy behaviors.

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 treatment intervention such that the participant decides to stop their participation, reports of new diagnoses of

depression, anxiety, or panic attacks. In addition, we will document reports from the CSO of domestic or intimate partner violence that may occur during their time in the study. We plan to collect reportable AEs that occur for the participant.

Non-reportable AEs:
Clinically insignificant events are not considered AE's. 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 not related to drug use (e.g., back pain). As per the definition of AEs, only significant worsening of psychiatric 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. Although we do not believe the study procedures or intervention places participants at increased risk for clinical worsening, we will review and report events of clinical worsening that leads to a psychiatric hospitalization of the participant. We plan to collect reportable SAEs that occur from the participant. These events are not anticipated to occur on a regular basis, if at all, for participants.

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*):
Although we do not believe the study procedures or intervention places participants at increased risk for clinical worsening, we will review and report events of clinical worsening that leads to a psychiatric hospitalization. We plan to collect reportable SAEs that occur for the CSO from the CSO participants. These events are not anticipated to occur on a regular basis, if at all.

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 or monitor online conversations 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 Co-I will monitor the WTV forum and meet regularly with CRAFT counselors 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 assistant will document information related to AEs and SAEs shared when contacting participants. Also, the WTV team monitor online comments and interactions and will report any AEs or SAEs reported there to the PHMC team.

All adverse and serious adverse events occurring during the study are documented on a form, reviewed and signed by Dr. Kimberly Kirby and the PI, Calum Handley, 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.
☒ PHMC's DSMB conducted the initial review on November 15, 2019.
☐ 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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