UNIVERSITY OF WASHINGTON
STUDENT CLINICIAN CONSENT FORM
UW ALACRITY Center Project 001: Building Capacity

Researchers:

Gino Aisenberg, PhD	Associate Professor, Principal Investigator	University of Washington, School of Social Work	(206) 616-9365
Patricia Areán, PhD	Professor, UW ALACRITY Center Director	University of Washington, Department of Psychiatry & Behavioral Sciences	(206) 221-8692

Researchers' Statement

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in the study or not. Please read the form carefully. You may ask questions about the purpose of the research, what we would ask you to do, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions, you can decide if you want to be in the study or not. This process is called "informed consent." We will give you a copy of this form for your records.

You are being asked to take part in this study because you are a BASW student at Heritage University who is enrolled in a training to learn a brief manualized treatment for depression. A member of the study team will explain the study to you.

PURPOSE OF THE STUDY

Researchers from the University of Washington ALACRITY Center (UWAC) want to learn about the best strategies for training clinicians in delivering telephone-based psychotherapy in rural primary care settings. Students will learn telephone-based cognitive behavioral therapy (tCBT) and deliver this manualized intervention with depressed patient participants under clinical supervision.

STUDY PROCEDURES

Ten to twelve students will participate in this study over the course of two cohorts. One cohort will be enrolled in the Fall of 2019 and the second in the Fall of 2020. The first cohort of five to six students will be trained in tCBT that is enhanced with an intelligent tutoring system (ITS), a computerized training program designed to teach clinical skills. The second cohort of 5-6 students will be randomized to either ITS-enhanced tCBT training or an active comparator combined with tCBT training. The tCBT training curriculum will be delivered by Dr. Gino Aisenberg, an Associate Professor of Social Work and principal investigator of this study.

If you agree to participate, the following procedures will occur:

- First, you will be asked to complete a brief demographics questionnaire about your background (e.g. age, education, experience working in the mental health field, etc).
- Second, you will be trained in tCBT through workshops/coursework, roleplays, and supervision. tCBT is a manualized treatment for depression that consists of eight sessions delivered over 10 to 12 weeks. Each session is designed for delivery in 35 - 40 minutes and includes: structured assessment of depressive symptoms (5 min); review of prior session content (5 min); debriefing previous homework assignment (5-10 min); introduction of new material, including in-session examples and exercises (15-20 min); description of the new homework assignment (5-10 min); and a motivational assessment/enhancement exercise focused on the homework assignment (5 min). The four in-person workshops (5 hours each; 20 hours over Fall semester) consist of manual and process review. Roleplays will be done over the telephone with a partner. These will be audio recorded and submitted to a study investigator for supervision and evaluation of student clinician adherence to the tCBT delivery protocol. You will have biweekly (every other week) group supervision via telephone (1 hour each).
- Third, you may use an intelligent tutoring system (ITS) to supplement your tCBT training. The ITS is an online training program to teach basic clinical skills relevant to tCBT and other structured psychotherapies. There are seven ITS content modules: Empathy, Reflection, Cultural Responsiveness, Agenda-Setting, Redirection, Assigning Homework, and Reviewing Homework. The ITS questions simulate a psychotherapy interaction and asks students to make decisions about what they would say or do during a psychotherapy session.
    - Students in Fall 2019 will use the intelligent tutoring system (ITS) to supplement the in-person training. Students in Fall 2020 will be randomized to use either the ITS system or an alternative training activity.
    - You will use your personal devices (e.g., smartphone, tablets, or computers with internet access) to complete ITS training modules on a weekly basis during their tCBT training (i.e., course homework).
    - Each student will spend 10-15 minutes up to 5 times a week on each ITS module. In total this equates out to 50-75 minutes of ITS training for homework each week.

- Fourth, you will complete a standardized roleplay with a study trainer at the completion of your Fall semester training. These roleplays will simulate delivery of a tCBT session(s) with a mock patient. This roleplay will be audio recorded and evaluated for skill and adherence to the tCBT manual.
- During the Spring semester practicum, you will administer the intervention over eight telephone sessions with approximately 5 patients with depression at the Yakima Valley Farm Workers Clinic.
    - You will administer the PHQ-9 to the patient at each session and use this to review patient progress; you will also enter these data into the study database (RedCap) and the patient's electronic health record.
    - You will audio record your sessions with patients for review by study investigators and external raters to assess your adherence to tCBT and to allow for feedback and supervision. You will also complete a checklist of how well you adhered to the tCBT protocol after each session.
    - You will only be assigned study participants who have provided consent to have their therapy sessions audio recorded. Your audio sessions will be randomly selected for review by an external rater and kept in our database for retention purposes. No personally identifying information will be attached to study data or audio recordings.

Study data and audio recordings will be labeled with a unique study identification number. The link between personal identifiers will be destroyed after the records retention period required by state and/or federal law. Audio recordings will be stored in an electronic format and will destroyed after the records retention period required by state and/or federal law.

The following assessments will be included in participation:

- Students will be asked to complete a brief 5-minute demographics questionnaire at the beginning of tCBT training via REDCap or hardcopy
- Students will complete two hour-long interviews about their impressions of training, the intervention, and working with patients. These interviews will be conducted virtually using Zoom teleconference technology. They will occur at the end of training (approximately November) and again at the end of practicum (approximately May)
    - Students will also complete self-report questionnaires at this time to measure their impressions of tCBT and ITS, and to assess therapist comfort with delivering tCBT. All self-report questionnaires will be completed via REDCap or hardcopy and should take 15-20 minutes to complete.
- Students will also be asked to complete a brief 5-minute questionnaire about the tCBT intervention at two additional timepoints during training and practicum via REDCap or hardcopy.
- All interview questions and questionnaires are voluntary, and you may refuse to answer any questions.

National Institute of Mental Health Data Archive

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying depression to collect and share de-identified information with each other. A data repository is a large database where information from many studies is stored and managed. We may collect information from you to create a unique ID code that cannot be linked to your identity. This information includes your legal name at birth, your date of birth, gender and city where you were born. De-identified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about depression more quickly than before.

During and after the study, the researchers may send de-identified information about your training and delivery of tCBT with patients. Other researchers nationwide can then file an application with the NIMH to obtain access to your de-identified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers around the world treat future children and adults depression so that they have better outcomes. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available on-line at http://dataarchive.nimh.gov.

☐ I wish to share my information using NDA.

☐ I do not want to share my information using NDA.

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Printed name of subject Signature of subject

PARTICIPANT INCENTIVE

Training and Practicum Experience: You are eligible to receive up to $1500 for completion of the tCBT training and delivery of treatment protocol ($750 for completion of training in the fall semester and $750 for completion of practicum experience in the spring semester).

Assessments: You are eligible to receive $50 for each of the two completed interviews (pre- and post-intervention delivery), for a total of $100.

RISKS, STRESS, OR DISCOMFORT

There is a slight risk of loss of confidentiality. A breach of confidentiality may result in psychological or social harm (embarrassment, guilt, stress). To ensure participant confidentiality, the information about you will be numbered and linked to your name only on a master list that is password protected. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings. Study records are kept in a locked room in a locked cabinet or in a secure, password protected data system.

No personal information will be attached to study data or audio recordings of therapy sessions. Your study data and audio recordings will be labeled with a unique study identification number. The link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law. Study data and audio recordings are used to develop new versions of the tCBT training. . These data are kept on a secure server which requires multiple passwords to access.

ALTERNATIVES TO TAKING PART IN THIS STUDY

You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you.

BENEFITS OF THE STUDY

Students may benefit from participating in this study as they will be equipped to deliver a manualized depression care intervention. Also, all students will receive instruction in culturally responsive practice, assessment of suicidal ideation, and comorbid disorders. In addition, they will also benefit from quality supervision at their practicum sites and will receive first hand training and experience as case managers in primary care settings. Students who complete the specialized curriculum and training program will have a competitive advantage in applying for advance standing within MSW programs and be able to complete their MSW program of study in one year resulting in substantial tuition savings.

SOURCE OF FUNDING

The study team and/or the University of Washington is receiving financial support from the National Institute of Mental Health.

CONFIDENTIALITY OF RESEARCH INFORMATION

All of the information you provide will be confidential. The information about you will be numbered and linked to your name on a master list. We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research;
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly;
- the federal Food and Drug Administration (FDA), if required by the FDA;
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others.

Government or university staff sometimes reviews studies such as this one to make sure they are being done safely and legally. If a review of this study takes place, your records may be examined. The reviewers will protect your privacy. The study records will not be used to put you at legal risk of harm.

The State of Washington mandates that we must report physical abuse of a child, elder or dependent adult; the abandonment; isolation, neglect, or financial abuse of an elder; and/or instances in which a in which a person indicates that they have plans to harm themselves or others.

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

OTHER INFORMATION

You may refuse to participate, and you are free to withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Gino Aisenberg, PhD, at (206) 616-9365. If you have questions about my rights as a research subject, you can call the Human Subjects Division at (206) 543-0098 or collect at (206) 221-5940.

The UW does not normally provide compensation for harm except through its discretionary program for medical injury. However, the law may allow you to seek other compensation if the harm is the fault of the researchers. You do not waive any right to seek payment by participating in this study.

CONSENT

This study has been explained to me. I volunteer to take part in this research. I have had a chance to ask questions. If I have questions later about the research, or if I have been harmed by participating in this study, I can contact one of the researchers listed on the first page of this consent form. I will receive a copy of this consent form.

Printed name of subject	Signature of subject	Date

Printed name of study staff obtaining consent	Signature	Date

Copies to: Researcher
Subject