DDBT Adapted Problem Solving Treatment for Primary Care (PST-NA)

NCT03514394

12/21/2020

IRB APPROVAL OF MODIFICATION

December 21, 2020

Dear Patricia A Arean:

On 12/21/2020, University of Washington IRB Committee J reviewed the following application:

Type of Review:	Modification / Update
Title of Study:	UW ALACRITY Center for Psychosocial Interventions Research, DDBT Adapted Problem Solving Treatment for Primary Care (Project 002)
Investigator:	Patricia A Arean
STUDY ID:	STUDY00004236
MOD ID:	MOD00008487
Funding:	Name: National Institute of Mental Health (NIMH), Grant Office ID: A124242, Funding Source ID: 1P50MH115837 – 01
IND, IDE, or HDE:	None

IRB Approval

Under FWA #00006878, the IRB approved modifications to your research. The expiration of the current IRB approval period remains 2/6/2021.

- COVID NOTE: Researchers must comply with current infection control requirements and complete a self-assessment that activities fit within allowable research as described on the HSD website.
- Your modification(s) to the research qualified for expedited review ("minimal risk"; Categories 5 and "minor change").
- This approval applies to study-wide and UW-specific materials only. You will receive separate notifications about any site modification approvals. You are responsible for ensuring that all site investigators receive the updated information and materials.

Determinations, waivers, and regulations
The IRB made the determinations and waivers listed in the table below for the modification(s).

Requirement	Determination or Waiver
Consent	Waived for use of medical records and for patients receiving therapy from clinicians in study
Documentation of consent	Waived for Phase 3 procedures
HIPAA Authorization	Waived for use of medical records

Location of documents
Use the revised consent forms that were approved by the IRB. They can be downloaded from the Final column under the **Documents tab** in Zipline.

Thank you for your commitment to ethical and responsible research. We wish you great success!

Sincerely,

Jenny Maki
IRB Reliance Administrator
makij2@uw.edu, 206-543-4798

UNIVERSITY OF WASHINGTON
Clinician Participant Information Sheet
UW ALACRITY Center for Psychosocial Interventions Research, Project 002: Improving Usability

Researchers:

Study Team	**For general study questions**		**alacrity@uw.edu**
Patricia Areán, PhD	Professor, Principal Investigator	University of Washington, Department of Psychiatry & Behavioral Sciences	(206) 221-8692
Carmen Gonzalez, PhD	Assistant Professor, Co-Principal Investigator	University of Washington, Department of Communications	(206) 543-2660
Debra Kaysen, PhD	Professor, Co-Investigator	Stanford University, Department of Psychiatry & Behavioral Sciences	

Researchers' statement

We are asking you to be in a research study. The purpose of this information sheet 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.

PURPOSE OF THE STUDY

The purpose of this study is to work with community clinicians to evaluate a brief psychotherapy for use in primary care clinics to addresses common mental health problems presented by patients in these settings.

STUDY PROCEDURES

Researchers from the University of Washington ALACRITY Center (UWAC) are looking to evaluate a modified task-sharing version of Behavioral Activation (BA) that is flexible, easy to learn and remember for therapists and care managers, and addresses the challenges faced by clinic populations. This modified task-sharing version of BA was recently co-designed by University of Washington (UW) researchers and Bighorn Valley Health Center (BVHC) therapists and care managers. To evaluate this modified model, we are recruiting therapists and care managers from BVHC who work with underserved patient populations to use the model with patients in their clinic. If you decide to participate in this phase of the study, the following will occur:

- You will complete a full BA task-sharing training starting in January 2021. The training structure will consist of:
    - Up to 6 synchronous sessions via Zoom (about 1 hour each)
    - Asynchronous BA training material (ie. videos, readings, etc.) to be completed in between synchronous sessions
- For therapists, the training content will include:
    - Review of BA and BA for PTSD
    - Overview of differences between BA and CBT, EMDR, DBT
    - Strategies to overcome case-barriers related to action plans/exposure plans
- For care managers, the training content will include:
    - Overview of BA
    - How to support action planning
    - Identifying flags for when to step up care
- You will be paid $50 for each of the 6 synchronous training sessions you attend
- You will be asked to complete pre-trial usability questionnaires regarding the BA task-sharing model, for which you will be paid $25
- After the BA task-sharing training is complete, you will be asked to begin using the model with patients in your clinic (target of 10 patients per clinic)
- You will be asked to use a self-report checklist of task-sharing BA components with each patient to ensure that you are adhering to the model
- UW study staff (clinicians) will be available on an as-needed basis for consultation on using the modified BA model with your patients
- You will be asked to complete post-trial usability questionnaires regarding the BA task-sharing model, for which you will be paid $25
- You may be asked to complete an exit interview directly after the trial to discuss your experience using the BA task-sharing model, for which you would be paid $50. This interview may be video recorded.

You will be asked to complete a 3-month follow up interview to report if/how you are still using the BA task-sharing model, for which you will be paid $50. This interview may be video recorded.

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 and will be kept until the study ends and data analysis is complete. 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.

Your personal information will NOT be attached to any audio or video recordings of semi-structured interviews. Recordings are used to develop new versions of BA and will not be

shared with other researchers. These recordings are kept on a secure server which requires two passwords to access. Recordings will be destroyed at the end of the study.

There will be no risks to your employment at the clinic regardless of whether you decide to participate in the study or not.

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

There may be no direct benefit to you from participating in this study. However, the study may identify effective psychotherapies for late life depression that can be used by community clinicians.

SOURCE OF FUNDING

The study team and/or the University of Washington receive 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.

Your personal information may be given out if required by law. All of the information you provide will be confidential. However, if we learn that you intend to harm yourself or others, we must report that to the authorities.

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.

We have a Certificate of Confidentiality from the National Institutes of Mental 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.

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.

You will be paid $50 per hour for your study participation.

RESEARCH-RELATED INJURY

If you think you have been harmed from being in this research, contact Patricia Arean, PhD, at 206-221-8692.

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.

Subject's statement

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. If I have questions about my rights as a research subject, I can call the Human Subjects Division at (206) 543-0098 or call collect at (206) 221-5940. I will receive a copy of this consent form.