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

NCT03514394

12/21/2020

INSTRUCTIONS

- **If you are requesting a determination** about whether your activity is human subjects research or qualifies for exempt status, you may skip all questions except those marked with a ( ). For example (**1.1**) must be answered.
- **Answer all questions**. If a question is not applicable to your research or if you believe you have already answered a question elsewhere in the application, state "NA" (and if applicable, refer to the question where you provided the information). If you do not answer a question, the IRB does not know whether the question was overlooked or whether it is not applicable. This may result in unnecessary "back and forth" for clarification. Use non-technical language as much as possible.
- To check a box, place an "X" in the box. To fill in a text box, make sure your cursor is within the gray text box bar before typing or pasting text.
- The word "you" refers to the researcher and all members of the research team, unless otherwise specified.
- For collaborative research, describe only the information that is relevant to you unless you are requesting that the UW IRB provide the review and oversight for your collaborators as well.
- You may reference other documents (such as a grant application) if they provide the requested information in non-technical language. Be sure to provide the document name, page(s), and specific sections, and upload it to ***Zipline***. Also, describe any changes that may have occurred since the document was written (for example, changes that you've made during or after the grant review process). In some cases, you may need to provide additional details in the answer space as well as referencing a document.

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1 OVERVIEW

Study Title: UW ALACRITY Center for Psychosocial Interventions Research, R34 Project 002

1.1 Home institution. Identify the institution through which the lead researcher listed on the IRB application will conduct the research. Provide any helpful explanatory information.

In general, the home institution is the institution (1) that provides the researcher's paycheck and that considers him/her to be a paid employee, or (2) at which the researcher is a matriculated student. Scholars, faculty, fellows, and students who are visiting the UW and who are the lead researcher: identify your home institution and describe the purpose and duration of your UW visit, as well as the UW department/center with which you are affiliated while at the UW.

Note that many UW clinical faculty members are paid employees of non-UW institutions.

*The UW IRB provides IRB review and oversight for only those researchers who meet the criteria described in the **POLICY: Use of the UW IRB.***

University of Washington

1.2 Consultation history. Have you consulted with anyone at HSD about this study?

It is not necessary to obtain advance consultation. If you have: answering this question will help ensure that the IRB is aware of and considers the advice and guidance you were provided.

[ ] **No**
[x] **Yes** → If yes, briefly describe the consultation: approximate date, with whom, and method (e.g., by email, phone call, in-person meeting).

Emails and phone calls with Amanda Guyton; email with Theresa Naluai-Cecchini in Feb 2020. Emails with HSD Rely (Jenny Maki) in Nov. 2020 to discuss this modification and subsequent need for a reliance on UW IRB.

1.3 Similar and/or related studies. Are there any related IRB applications that provide context for the proposed activities?

Examples of studies for which there is likely to be a related IRB application: Using samples or data collected by another study; recruiting subjects from a registry established by a colleague's research activity; conducting Phase 2 of a multi-part project, or conducting a continuation of another study; serving as the data coordinating center for a multi-site study that includes a UW site.

Providing this information (if relevant) may significantly improve the efficiency and consistency of the IRB's review.

[x] **No**
[ ] **Yes** → If yes, briefly describe the other studies or applications and how they relate to the proposed activities. If the other applications were reviewed by the UW IRB, please also provide: the UW IRB number, the study title, and the lead researcher's name.

1.4 Externally-imposed urgency or time deadlines. Are there any externally-imposed deadlines or urgency that affect your proposed activity?

HSD recognizes that everyone would like their IRB applications to be reviewed as quickly as possible. To ensure fairness, it is HSD policy to review applications in the order in which they are received. However, HSD will assign a higher priority to research with externally-imposed urgency that is beyond the control of the researcher. Researchers are encouraged to communicate as soon as possible with their HSD staff contact person when there is an urgent situation (in other words, before submitting the IRB application). Examples: a researcher plans to test an experimental vaccine that has just been developed for a newly emerging epidemic; a researcher has an unexpected opportunity to collect data from students when the end of the school year is only four weeks away.

HSD may ask for documentation of the externally-imposed urgency. A higher priority should not be requested to compensate for a researcher's failure to prepare an IRB application in a timely manner. Note that IRB review requires a certain minimum amount of time; without sufficient time, the IRB may not be able to review and approve an application by a deadline.

[ ] **No**

[x] **Yes** → If yes, briefly describe the urgency or deadline as well as the reason for it.

We have received a Just-in-Time award and must submit IRB approval and other documentation

1.5 Objectives Using lay language, describe the purpose, specific aims, or objectives that will be met by this specific project. If hypotheses are being tested, describe them. You will be asked to describe the specific procedures in a later section.

If your application involves the use of a HUD "humanitarian" device: describe whether the use is for "on-label" clinical patient care, "off-label" clinical patient care, and/or research (collecting safety and/or effectiveness data).

The UW ALACRITY Center purpose is to address critical problems in the implementation of evidence-based psychosocial interventions (EBPIs) for underserved communities as they are delivered in primary care medicine settings. Per a recent IOM report on psychosocial intervention standards, access to EBPIs is hampered by (1) poor clinician training, (2) intervention design complexity, and (3) insufficient support to sustain quality of care. We will attempt to solve these problems by creating a team of researchers from human centered design, implementation science, psychosocial, health services research, and research methods.

The Center represents a unique partnership between the School of Medicine's Departments of Psychiatry/Behavioral Sciences and Family Medicine, the Department of Computer Science and Engineering, the Department of Communications, and the School of Social Work. The Center also bridges UW's many resources: CoMotion (UW's center for health technology innovation), the Institute for Translational Health Sciences (the UW CTSA), the AIMS Center (UW implementation and training center for collaborative care), and the WWAMI-region Practice Research Network (WPRN, a collaborative group of primary care practices through the states of Washington, Wyoming, Alaska, Montana and Idaho to facilitate innovative community-based research).

The Administrative Core will serve as the communication hub between center cores, our two advisory boards, and will oversee the solicitation and selection of R03 level proof of concept studies. The Methods Core (MC) will provide research infrastructure to the projects. Each project will use our Discover, Design, Build and Test framework to address clinician capacity, intervention usability and intervention sustainability. The MC will also compile data from these projects to create a Typology of EBPI Targets and a Matrix of EBPI Modifications that will be shared with other researchers within and outside of UW through our online research community.

The three R-34 research projects will collect a common core of outcomes to determine the impact of modifying EBPI targets on clinicians' quality delivery of care and patient-reported outcomes. The first R34 project proposes to improve clinician EPBI capacity by designing and building an Intelligent Tutor System based on adaptive training. The second R34 project will partner with the WPRN to simplify problem-solving therapy (PST), using user-centered design principles. The third R34 project will partner with the Washington Behavioral Health Integration Program (BHIP) to develop an electronic health record-supported behavioral health module and registry to support sustained clinician skill in delivering PST in primary care. All three projects, and future R03s, will test the effects modification targets of implementation outcomes (time to training, clinician skill drift), system usability, EBPI system burden, system acceptability, and patient-reported outcomes.

Psychosocial interventions are the preferred mode of treatment for people seeking treatment for depression , particularly among underserved communities, such as racial and ethnic minorities and those living in low-income communities, yet, very few people gain access to evidence-based psychosocial treatments because too few clinicians are trained to deliver them, they tend to be too complex to delivered in settings like primary care medicine, and there are too few supports to clinicians to deliver these interventions to high quality. The UW ALACRITY Center will attempt to address these issues by creating a novel framework informed by experts in human centered design technology, education, and implementation science. This team will develop and test three new solutions for addressing problems in the clinician capacity, intervention usability and sustainability of psychosocial interventions delivered in primary care medicine, and will support 8 new, proof of concept projects over the 4-year timeline.

This application focuses on the second (002) R34 project.

High quality delivery of evidence-based psychosocial interventions (EBPIs) in primary care medicine is a function of many variables, including clinician training and ready access to EBPI decision support. Importantly, quality is also driven by the clinician's ability to implement the therapeutic elements of EBPIs to fidelity and with competence. Even when clinicians undergo rigorous training, and find the intervention components useful in care, clinicians significantly drift from the original protocol because the processes, structure and elements of care frequently clash with clinician productivity and the shifting needs of the patient populations they serve. Clinicians in low resource settings like federally qualified health centers (FQHCs) report that while elements of EBPIs are important, their design is cumbersome, complex, overwhelming, inflexible, and minimize the nonspecific factors clinicians feel are crucial for quality delivery of care. In short, EBPIs demonstrate low usability (i.e., the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use. Although many implementation science (IS) frameworks do address the importance of EBPI characteristics, adapting and modifying EBPIs to enhance usability has not been a focus. User centered design (UCD) approaches, which have been successful in creating hardware and software tools that are accessible and compelling to use, have the potential to modify EBPIs so that they are accessible and compelling to clinicians.

We hypothesize that UCD-driven modifications to EBPI usability will result in enhanced clinician ability to deliver EBPI elements competently (target), and that better competence results in better patient-reported outcomes. We will modify Behavioral Activation (BA) because it is the EBPI often used in primary care settings.

To prepare for a larger trial to test hypotheses regarding the impact of EBPI usability on uptake, fidelity and competence, the aims of Project 002 R34 are:

Aim 1: Discover Phase (3 months). Using iterative and participatory methods, we will interview up to 15 clinicians from FHQCs affiliated with the WWAMI region Practice Research Network (WPRN, a collaborative group of primary care practices through the states of Washington, Wyoming, Alaska, Montana and Idaho to facilitate innovative community-based research), and observe them in routine practice to identify usability challenges. Contribution to the Center: Data from this phase will be used to inform the Typology of EBPI Targets.

Aim 2: Design/Build Phase (6 months) After identification of potential targets, the research team will work via Zoom teleconferencing with the original clinicians from the discover phase and 0-5 new clinicians to engage in a rapid cycle of iterative prototype development and testing (e.g., storyboarding, paper prototypes) of BA modifications. The build of these modifications will include the development of intervention prototypes for user testing and refinement with input from these care managers. Contribution to the Center: Data from this phase will be used to inform the Matrix of EBPI Modifications.

Aim 3: **Test Phase (15 months).** We will test and compare the BA modification (modBA) to usual care in a small non-randomized trial. We will assign all provider teams (therapist & care manager(s)) in the clinic to use modBA with 10 patients per team for a total of 40 patients. We will then compare patient outcomes for those receiving modBA vs. 40 patients receiving usual clinic care. **H1**: Modifications developed in the Design/Build phase for targets identified in the Discover Phase will result in better usability (System Usability and User Burden Scales) compared to usual care.
H2: modBA will be more effective than usual care on improving clinical outcomes of functional disability (Sheehan Disability Scale [SDS]), change in depression symptoms over time (PHQ-9 total score), and change in anxiety symptoms over time (GAD-7 total score).

1.6 Study design. Provide a one-sentence description of the general study design and/or type of methodology.

Your answer will help HSD in assigning applications to reviewers and in managing workload. Examples: a longitudinal observational study; a double-blind, placebo-controlled randomized study; ethnographic interviews; web scraping from a convenience sample of blogs; medical record review; coordinating center for a multi-site study.

The study design is a Discover, Design & Build, and Test model. We will work with clinicians to identify ways to improve usability of BA in clinic practice, and to design a new, modified BA intervention. When complete, we will test the modified BA model against usual care in a small pilot study.

1.7 Intent. Check all the descriptors that apply to your activity. You must place an "X" in at least one box.

This question is essential for ensuring that your application is correctly reviewed. Please read each option carefully.

Descriptor
☐ 1. Class project or other activity whose purpose is to provide an educational experience for the researcher (for example, to learn about the process or methods of doing research).
☐ 2. Part of an institution, organization, or program's own internal operational monitoring.
☐ 3. Improve the quality of service provided by a specific institution, organization, or program.

☐ 4. Designed to expand the knowledge base of a scientific discipline or other scholarly field of study, and produce results that:
- Are expected to be applicable to a larger population beyond the site of data collection or the specific subjects studied, or
- Are intended to be used to develop, test, or support theories, principles, and statements of relationships, or to inform policy beyond the study.

☐ 5. Focus directly on the specific individuals about whom the information or biospecimens are collected through oral history, journalism, biography, or historical scholarship activities, to provide an accurate and evidence-based portrayal of the individuals.

☒ 6. A quality improvement or program improvement activity conducted to improve the implementation (delivery or quality) of an accepted practice, or to collect data about the implementation of the practice for clinical, practical, or administrative purposes. This does not include the evaluation of the efficacy of different accepted practices, or a comparison of their efficacy.

☐ 7. Public health surveillance activities conducted, requested, or authorized by a public health authority for the sole purpose of identifying or investigating potential public health signals or timely awareness and priority setting during a situation that threatens public health.

☒ 8. Preliminary, exploratory, or research development activities (such as pilot and feasibility studies, or reliability/validation testing of a questionnaire)

☐ 9. Expanded access use of a drug or device not yet approved for this purpose

☐ 10. Use of a Humanitarian Use Device

☐ 11. Other. Explain:

1.8 Background, experience, and preliminary work. Answer this question **only** if your proposed activity has one or more of the following characteristics. The purpose of this question is to provide the IRB with information that is relevant to its risk/benefit analysis.
- Involves more than minimal risk (physical or non-physical)
- Is a clinical trial, or
- Involves having the subjects use a drug, biological, botanical, nutritional supplement, or medical device.

"Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

a. Background. Provide the rationale and the scientific or scholarly background for your proposed activity, based on existing literature (or clinical knowledge). Describe the gaps in current knowledge that your project is intended to address.

This should be a plain language description. Do not provide scholarly citations. Limit your answer to less than one page, or refer to an attached document with background information that is no more than three pages long.

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support. Importantly, quality is also driven by the clinician's ability to implement the therapeutic elements of EBPIs to fidelity and with competence. Even when clinicians undergo rigorous training, and find the intervention components useful in care, clinicians significantly drift from the original protocol because the processes, structure and elements of care frequently clash with clinician productivity and the shifting needs of the patient populations they serve. Clinicians in low resource settings like federally qualified health centers (FQHCs) report that while elements of EBPIs are important, their design is cumbersome, complex, overwhelming, inflexible, and minimize the nonspecific factors clinicians feel are crucial for quality delivery of care. In short, EBPIs demonstrate low usability (i.e., the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use. Although many implementation science (IS) frameworks do address the importance of EBPI characteristics, adapting and modifying EBPIs to enhance usability has not been a focus. User centered design (UCD) approaches, which have been successful in creating hardware and software tools that are accessible and compelling to use, have the potential to modify EBPIs so that they are accessible and compelling to clinicians.

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b. Experience and preliminary work. Briefly describe experience or preliminary work or data (if any) that you or your team have that supports the feasibility and/or safety of this study.

It is not necessary to summarize all discussion that has led to the development of the study protocol. The IRB is interested only in short summaries about experiences or preliminary work that suggest the study is feasible and that risks are reasonable relative to the benefits. Examples: You have already conducted a Phase 1 study of an experimental drug which supports the Phase 2 study you are now proposing to do; you have already done a small pilot study showing that the reading skills intervention you plan to use is feasible in an after-school program with classroom aides; you have experience with the type of surgery that is required to implant the study device; you have a study coordinator who is experienced in working with subjects who have significant cognitive impairment.

Team Experience: This multidisciplinary team is comprised of experts in EBPIs (Areán, Kaysen), and Communications (Gonzalez). Drs. Hoeft (qualitative research) and Munson (UCD expert) will serve as our design/build incubator experts. Expertise in EBPIs is needed on the team to ensure that the integrity of therapeutic elements remain intact. Dr. Areán is an expert in PST-PC. We anticipate, based on 15 years of working with clinicians in primary care medicine, that methods for addressing anxiety and trauma exposure will be a likely usability feature clinicians will identify. Dr. Kaysen is an expert in Cognitive Processing Therapy and Exposure Therapy. Communications expertise is needed for the development of intervention materials that are understandable and appealing to clinicians. Additionally, identification of key talking points that are appealing to clinicians and highlight the collaborative effort of the modification to PST requires expertise in communication methods. Dr. Gonzalez is an expert in the use of communications methods, including social media formats for raising health awareness in underserved communities. An innovation in her field will be the use of these methods for raising clinician awareness and subsequent adoption of EBPI elements.

Preliminary Work: Dr. Areán has been the lead PST-PC trainer for the UW AIMS Center (an implementation and training center for collaborative care) for 15 years. In uncovering the challenges in training and sustained use of PST-PC among clinicians, important usability problems with PST-PC have been highlighted, specifically: (1) too many steps in a typical session; (2) not enough time to

"get to know" the patient/not enough time to get through the process of PST-PC in each session; (3) too tiring to deliver on days when clinicians see PST-PC patients back to back; (4) focusing on problems was not synergistic with clinic mandates to use strength-based interventions; (5) difficulty using PST-PC to address common problems, such as lack of motivation, affect regulation, profound pessimism, trauma exposure, and access to basic needs in the face of poverty (food, shelter, access to health care, safety); (6) insufficient support to know when adding other EBPI elements or eliminating PST-PC elements was appropriate or in violation of protocol; (7) over-insistence by PST-PC trainers to have clinicians structure sessions and use of forms; and (8) perception that PST-PC was developed for research settings.

1.9 Supplements. Check all boxes that apply, to identify Supplements you should complete and upload to the **Supporting Documents** SmartForm in ***Zipline***.

This section is here instead of at the end of the form to reduce the risk of duplicating information in this IRB Protocol form that you will need to provide in these Supplements.

Check all That Apply	Type of Research	Supplement Name
☐	**Department of Defense** The research involves Department of Defense funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Defense
☐	**Department of Energy** The research involves Department of Energy funding, facilities, data, or personnel.	*ZIPLINE* SUPPLEMENT: Department of Energy
☐	**Drug, biologic, botanical, supplement** Procedures involve the use of any drug, biologic, botanical or supplement, even if the item is not the focus of your research	*ZIPLINE* SUPPLEMENT: Drugs
☐	**Emergency exception to informed consent** Research that requires this special consent waiver for research involving more than minimal risk	*ZIPLINE* SUPPLEMENT: Exception from Informed Consent for Emergency Research (EFIC)
☐	**Genomic data sharing** Genomic data are being collected and will be deposited in an external database (such as the NIH dbGaP database) for sharing with other researchers, and you are asking the UW to provide the required certification or to ensure that the consent forms can be certified	*ZIPLINE* SUPPLEMENT: Genomic Data Sharing
☐	**Medical device** Procedures involve the use of any medical device, even if the device is not the focus of your research, except when the device is FDA-approved and is being used through a clinical facility in the manner for which it is approved	*ZIPLINE* SUPPLEMENT: Devices
X	**Multi-site study** (You are asking the UW IRB to review one or more sites in a multi-site study.)	*ZIPLINE* SUPPLEMENT: Participating Site in Multi-Site Research
☐	**Participant results sharing** Individual research results will be shared with subjects.	*ZIPLINE* SUPPLEMENT: Participant Results Sharing

☐ None of the above

2 PARTICIPANTS

2.1 Participants. Describe the general characteristics of the subject populations or groups, including age range, gender, health status, and any other relevant characteristics.

Discover and Design/Build Phases: We will recruit up to 15 behavioral health clinicians and care managers from the partnering FQHC. For the Test Phase, we will recruit up to 11 clinicians and care managers and 80 patient participants. Patient participants must be 18 years or older and suffering from mild to moderate depression.

2.2 Inclusion and exclusion criteria.

a. Inclusion criteria. Describe the specific criteria you will use to decide who will be included in your study from among interested or potential subjects. Define any technical terms in lay language.

- Clinicians – must deliver behavioral treatment as part of standard clinical workflow and work at the partnering FQHC
- Participants – 18 years or older suffering from mild to moderate unipolar depression as measured by PHQ-9 score between 10-20, and the capacity to provide written consent for research assessment. (Phases 2 and 3)

b. Exclusion criteria. Describe the specific criteria you will use to decide who will be excluded from your study from subjects who meet the inclusion criteria listed above. Define any technical terms in lay language.

Clinicians who do not speak English are excluded from all phases of the study. Patient participants in Phases 2 and 3 who have 1) Intent or plan to attempt suicide in the near future; 2) history or presence of psychiatric diagnoses other than unipolar, non-psychotic major depression or generalized anxiety disorder will be excluded.

2.3 Prisoners. IRB approval is required in order to include prisoners in research, even when prisoners are not an intended target population.

a. Will you recruit or obtain data from individuals that you know to be prisoners?

For records reviews: if the records do not indicate prisoner status and prisoners are not a target population, select "No". See the WORKSHEET: Prisoners for the definition of "prisoner".

☒ **No**
☐ **Yes** → If yes, answer the following questions (i – iv).

i. Describe the type of prisoners, and which prisons/jails:

ii. One concern about prisoner research is whether the effect of participation on prisoners' general living conditions, medical care, quality of food, amenities, and opportunity for earnings in prison will be so great that it will make it difficult for prisoners to adequately consider the research risks. What will you do to reduce the chances of this?

iii. Describe what you will do to make sure that (a) your recruitment and subject selection procedures will be fair to all eligible prisoners and (b) prison authorities or other prisoners will not be able to arbitrarily prevent or require particular prisoners from participating.

iv. If your research will involve prisoners in federal facilities or in state/local facilities outside of Washington State: check the box below to provide your assurance that you will (a) not encourage or facilitate the use of a prisoner's participation in the research to influence parole decisions, and (b) clearly inform each prisoner in advance (for example, in a consent form) that participation in the research will have no effect on his or her parole.

☐ **Confirmed**

b. Is your research likely to have subjects who become prisoners while participating in your study?

For example, a longitudinal study of youth with drug problems is likely to have subjects who will be prisoners at some point during the study.

☒ **No**
☐ **Yes** → If yes, if a subject becomes a prisoner while participating in your study, will you continue the study procedures and/or data collection while the subject is a prisoner?

☐ **No**
☐ **Yes** → If yes, describe the procedures and/or data collection you will continue with prisoner subjects

2.4 Protected populations. IRB approval is required for the use of the subject populations listed here. Check the boxes for any of these populations that you will purposefully include in your research. (In other words, being a part of the population is an inclusion criterion for your study.)

The WORKSHEETS describe the criteria for approval but do not need to be completed and should not be submitted.

Population	Worksheet
☐ Fetuses in utero	WORKSHEET: Pregnant Women
☐ Neonates of uncertain viability	WORKSHEET: Neonates
☐ Non-viable neonates	WORKSHEET: Neonates
☐ Pregnant women	WORKSHEET: Pregnant Women

a. If you check any of the boxes above, use this space to provide any information you think may be relevant for the IRB to consider.

N/A

2.5 Native Americans or non U.S. indigenous populations. Will you actively recruit from Native American or non-U.S. indigenous populations through a tribe, tribe-focused organization, or similar community-based organization?

Indigenous people are defined in international or national legislation as having a set of specific rights based on their historical ties to a particular territory and their cultural or historical distinctiveness from other populations that are often politically dominant.

Examples: a reservation school or health clinic; recruiting during a tribal community gathering

[x] **No**
[ ] **Yes** → If yes, name the tribe, tribal-focused organization, or similar community based organization. The UW IRB expects that you will obtain tribal/indigenous approval before beginning your research.

2.6 Third party subjects. Will you collect private identifiable information about *other individuals* from your subjects? Common examples include: collecting medical history information or contact information about family members, friends, co-workers.

"Identifiable" means any direct or indirect identifier that, alone or in combination, would allow you or another member of your research team to readily identify the person. For example, suppose that you are studying immigration history. If you ask your subjects several questions about their grandparents but you do not obtain names or other information that would allow you to readily identify the grandparents, then you are not collecting private identifiable information about the grandparents.

[x] **No**
[ ] **Yes** → If yes, these individuals are considered human subjects in your study. Describe them and what data you will collect about them.

N/A

2.7 Number of subjects. Can you predict or describe the maximum number of subjects (or subject units) you need to complete your study, for each subject group?

Subject units mean units within a group. For most research studies, a group will consist of individuals. However, the unit of interest in some research is not the individual. Examples:

- *Dyads such as caregiver-and-Alzheimer's patient, or parent and child*
- *Families*
- *Other units, such as student-parent-teacher*

Subject group means categories of subjects that are meaningful for your research. Some research has only one subject group – for example, all UW students taking Introductory Psychology. Some common ways in which subjects are grouped include:

- *By intervention – for example, an intervention group and a control group.*
- *By subject population or setting – for example, urban versus rural families*
- *By age – for example, children who are 6, 10, or 14 years old.*

The IRB reviews the number of subjects you plan to study in the context of risks and benefits. You may submit a Modification to increase this number at any time after you receive IRB approval. If the IRB determines that your research involves no more than minimal risk: you may exceed the approved number and it will not be considered non-compliance. If your research involves more than minimal risk: exceeding the approved number will be considered non-compliance.

[ ] **No** → If no, provide your rationale in the box below. Also, provide any information you can about the scope/size of the research. You do not need to complete the table.

Example: you may not be able to predict the number of subjects who will complete an online survey advertised through Craigslist, but you can state that you will post your survey for two weeks and the number who respond is the number who will be in your study.

[x] **Yes** → If yes, for each subject group, use the table below to provide your estimate of the maximum desired number of individuals (or other subject unit, such as families) who will complete the research.

Group name/description	Maximum desired number of individuals (or other subject unit, such as families) who will complete the research **For clinical trials: provide numbers for your site and for the study-wide total number*
Behavioral health clinicians/support staff (Phases 1 & 2)	15
Behavioral health clinicians/support staff (Phase 3)	13
Patient Participants Phase 3	80

3 NON-UW RESEARCH SETTING

Complete this section only if your research will take place outside of UW and Harborview

3.1 Reason for sites. Describe the reason(s) why you selected the sites where you will conduct the research.

The UW ALACRITY Center goal is to improve clinician capacity, EBPI usability and sustained quality of interventions in low-resource settings. Thus, clinician and patient participants will be recruited clinics in Wyoming and Montana (from the WWAMI-region Practice Research Network). The community health centers provide services to a large percentage of Medicaid and Medicare patients as well as ethnic minorities.

3.2 Local context. Culturally-appropriate procedures and an understanding of local context are an important part of protecting subjects. Describe any site-specific cultural issues, customs, beliefs, or values that may affect your research or how it is conducted.

Examples: It would be culturally inappropriate in some international settings for a woman to be directly contacted by a male researcher; instead, the researcher may need to ask a male family member for permission before the woman can be approached. It may be appropriate to obtain permission from community leaders prior to obtaining consent from individual members of a group.

This federal site maintains an international list of human research standards and requirements:
http://www.hhs.gov/ohrp/international/index.html

No specific culturally-appropriate needs have been identified; however, we will work with local clinicians in well-established clinics in Montana who are aware of local norms.

3.3 Site-specific laws. Describe any local laws that may affect your research (especially the research design and consent procedures). The most common examples are laws about:

- **Specimens** – for example, some countries will not allow biospecimens to be taken out of the country.
- **Age of consent** – laws about when an individual is considered old enough to be able to provide consent vary across states, and across countries.
- **Legally authorized representative** – laws about who can serve as a legally authorized representative (and who has priority when more than one person is available) vary across states and countries.
- **Use of healthcare records** – many states (including Washington State) have laws that are similar to the federal HIPAA law but that have additional requirements.

There are no additional site-specific laws to consider.

3.4 Site-specific administrative or ethical requirements. Describe local administrative or ethical requirements that affect your research.

Example: A school district may require you to obtain permission from the head district office as well as school principals before approaching teachers or students; a factory in China may allow you to interview factory workers but not allow you to pay them.

None.

4 RECRUITING and SCREENING PARTICIPANTS

4.1 Recruiting and Screening. Describe how you will identify, recruit, and screen subjects. Include information about: how, when, where, and in what setting. Identify who (by position or role, not name) will approach and recruit subjects, and who will screen them for eligibility.

Phases 1 & 2: Behavioral health clinicians and support staff will be recruited with help from the partnering clinic. We partnered with Big Horn Valley Health Care (BHVHC) at the time of the grant submission and offered a letter of support in partnership for this project (awarded May 2018). BHVHC previously worked with the UW Department of Psychiatry/AIMS Center and has since joined the WPRN. BHVHC will help identify clinicians who will voluntarily participate in interviews, co-design, and training (Phase 3)
Phase 3: . Up to eleven clinicians will be recruited from Bighorn Valley Health Center (BVHC). The clinic will help identify clinicians who will voluntarily participate in training and testing for the pilot phase. Patient participants will be identified/screened based on depression symptoms pulled from their EHR.

4.2 Recruitment materials.

a. What materials (if any) will you use to recruit and screen subjects?

Examples: talking points for phone or in-person conversations; video or audio presentations; websites; social media messages; written materials such as letters, flyers for posting, brochures, or printed advertisements; questionnaires filled out by potential subjects.

We request flexibility in the approval of recruitment letters and phone scripts in all 3 phases so that minor edits to these instruments can be made without submitting the materials for IRB review. We confirm that any changes that will result in the collection of new personal identifying information and/or study data beyond the scope of the research as reviewed and approved by the IRB in the initial application and subsequent modifications will be submitted for review and approval by the IRB.

Phase 1 & 2: We will recruit clinicians via informational letters about the study and talking points for phone scripts.

Phase 3: Clinician participants will be recruited based on past participation in the Design phase of this study. Some new clinician participants will also be recruited for Phase 3 based on recommendation of these past participants who completed the Design phase and work in the same clinic. Participants will be recruited by email.

Patient Participants: Patients will be identified through electronic health records with a PHQ-9 score between 10-20. Patients will only be contacted and recruited if they are chosen to complete exit interviews. For those identified for exit interviews, they will be approached by BVHC staff either in person or via email, the study will be briefly explained to them, and then they will be asked if theyare willing to complete an exit interview. For those willing, their contact info will be provided to UW study staff to reach out for further explanation and consent.

Note that site champions will complete CITI Human Subjects Protection training and will be trained by study staff regarding appropriate procedures for recruitment.We will make it clear to site champions that the consequences of coercing patients into study participation will be removal from the study protocol.

b. Upload descriptions of each type of material (or the materials themselves) to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline***. If you will send letters to the subjects, the letter should include a statement about how you obtained the subject's name, contact information, and any other subject-specific information (such as a health condition) that is mentioned in the letter.

HSD encourages researchers to consider uploading descriptions of most recruitment and screening materials instead of the materials themselves. The goal is to provide the researchers with the flexibility to change some information on the materials without submitting a Modification for IRB approval of the changes. Examples:

- *You could provide a list of talking points that will be used for phone or in-person conversations instead of a script.*
- *For the description of a flyer, you might include the information that it will provide the study phone number and the name of a study contact person (without providing the actual phone number or name). In doing so, you would not need to submit a Modification if/when the study phone number or contact person changes. Also, instead of listing the inclusion/exclusion criteria, you might state that the flyer will list one or a few of the major inclusion/exclusion criteria.*
- *For the description of a video or a website, you might include a description of the possible visual elements and a list of the content (e.g., study phone number; study contact person; top three inclusion/exclusion criteria; payment of $50; study name; UW researcher).*

4.3 Relationship with participant population. Do any members of the study team have an existing relationship with the study population(s)?

Examples: a study team member may have a dual role with the study population (for example, being their clinical care provider, teacher, laboratory directory or tribal leader in addition to recruiting them for his/her research).

[x] **No**
[ ] **Yes** → If yes, describe the nature of the relationship.

4.4 Payment to participants. Describe any payment you will provide, including:

The IRB expects the consent process or study information provided to the subjects to include information about the number and amount of payments, and especially the time when subjects can expect to receive payment. One of the most frequent complaints received by HSD is from subjects who expected to receive cash or a check on the day that they completed a study and who were angry or disappointed when payment took 6-8 weeks to reach them.

Do not include a description of any expenses that will be reimbursed.

- Clinician /clinic staff participants will be paid $50 per hour worked during all 3 phases of the study.Checks will be issued within 2 weeks of receiving an invoice from the clinician. Clinicians may invoice monthly.
- Patient participants will be paid $25 for the completion of exit interviews. Payment will be in the form of check, cash card, Tango gift card, and/or an electronic Amazon gift code and will be sent within 2 weeks of survey completion.

4.5 Non-monetary compensation. Describe any non-monetary compensation you will provide. Example: extra credit for students; a toy for a child. If you will be offering class credit to students, you must provide (and describe) an alternate way for the students to earn the extra credit without participating in your research.

N/A

4.6 Will you access or obtain data or specimens for recruiting and screening procedures prior to enrollment?

Examples: names and contact information; the information gathered from records that were screened; results of screening questionnaires or screening blood tests; Protected Health Information (PHI) from screening medical records to identify possible subjects.

[ ] **No** → If no, skip the rest of this section; go to question **5.1**.

[x] **Yes** → If yes, describe any data and/or specimens (including PHI) you will access or obtain for recruiting and screening and whether you will retain it as part of the study data.

For Phase 3 (pilot testing): Staff (site champion) at the partnering clinic will identify potential patient participants through electronic health records (those aged 18 or older and with a PHQ-9 score between 10-20).. We will retain PHQ-9 scores as part of the study data.
.

4.7 Consent for recruiting and screening. Will you obtain consent for any of the recruiting and screening procedures? (Section 8: Consent of Adults asks about consent for the main study procedures).

"Consent" includes: consent from individuals for their own participation; parental permission; assent from children; consent from a legally authorized representative for adult individuals who are unable to provide consent.

Examples:

- *For a study in which names and contact information will be obtained from a registry: the registry should have consent from the registry participants to release their names and contact information to researchers.*
- *For a study in which possible subjects are identified by screening records: there will be no consent process.*
- *For a study in which individuals respond to an announcement and call into a study phone line: the study team person talking to the individual may obtain non-written consent to ask eligibility questions over the phone.*

[x] **No** → If no, skip the rest of this section; go to question **5.1**.

☐ **Yes** → If yes, describe the consent process.

a. Documentation of consent. Will you obtain a written or verifiable electronic signature from the subject on a consent form to document consent for all of the **recruiting and screening procedures**?

☐ **No** → If no, describe the information you will provide during the consent process and for which procedures.

☐ **Yes** → If yes, upload the consent form to the **Consent Forms and Recruitment Materials** page of ***Zipline***.

5 PROCEDURES

5.1 Study procedures. Using lay language, provide a complete description of the study procedures, including the sequence, intervention or manipulation (if any), drug dosing information (if any), use of records, time required, and setting/location. If it is available and you think it would be helpful to the IRB: Upload a study flow sheet or table to the **Supporting Documents** SmartForm in ***Zipline***.

*For studies comparing standards of care: It is important to accurately identify the research procedures. See UW IRB **POLICY: Risks of Harm from Standard Care** and the draft guidance from the federal Office of Human Research Protections, **"Guidance on Disclosing Reasonably Foreseeable Risks in Research Evaluating Standards of Care";** October 20, 2014.*

Phase 1 – Discovery : Behavioral Health Clinicians:

Interviews:
We will conduct semi-structured interviews with up to 15 behavioral health clinicians and care managers, both in-person and using Zoom.com technology. The interview will interrogate challenges they face in implementing evidence-based psychosocial interventions (EBPIs) that are related to (1) workflow, (2) patients they see, (3) EBPI processes, and (4) any other challenges they may face.

Questions will be tied to 3 content areas:

- The seven common problems with usability: (1) too many steps in a typical session; (2) not enough time to "get to know" the patient/not enough time to get through the process of a structured psychotherapy in each session; (3) too tiring to deliver on days when clinicians see patients back to back; (4) focusing on problems was not synergistic with clinic mandates to use strength-based interventions; (5) difficulty using EBPI to address common problems, such as lack of motivation, affect regulation, profound pessimism, trauma exposure, and access to basic needs in the face of poverty (food, shelter, access to health care, safety); (6) insufficient support to know when adding other EBPI elements or eliminating elements was appropriate or in violation of protocol; and, (7) over insistence by previouls trainers or supervisors to have clinicians structure sessions and use of forms.

- Consolidated Framework for Implementation (CFIR) constructs related to Intervention and Individual Characteristics. The CFIR outlines five major domains: (1) intervention characteristics, including core components and adaptable, peripheral elements; (2) outer setting,

the broader economic, political, social context in which an organization exists; (3) inner setting, the immediate organizational context in which implementation occurs, including shared receptivity to change; (4) individual characteristics of practitioners and implementation team members, such as personal and professional values, interests, and affiliations; and (5) the implementation process, the steps and modes by which active change is undertaken.

- We will also ask about modifications they have made to the intervention to accommodate those challenges, and if they are no longer using EBPIs, why. This interview will also cover process action research (PAR) driven questions about what they value about their work with their patients, what they feel is missing when using EBPIs, and suggestions for how it could be improved, given their clinical context and patient population.

Each clinician participant will be reimbursed $50.00 per hour for their time. Clinicians will invoice the study for their hours monthly and may expect payment within 2 weeks of invoice receipt.

Contextual Evaluation**:**
We will conduct two WPRN clinic site visits. We will shadow one-to-two clinicians over the course of his or her day and make further observations about the clinician's workflow, to gather more impressions about how EBPIs, and Behavioral Activation specifically, could be modified to fit into the clinicians' daily routine, workflow with other clinic staff (e.g., care managers), and observations of clinic and environment. Observations will be conducted by research staff members central to the UW ALACRITY core,. The data collection will be guided by the Consolidated Framework for Implementation Research (see above), and will include observations of inner and outer settings and how they potentially influence the use of EBPI. No identifiable information about the patients will be recorded during these observational procedures and the researchers will not interact with patients for research purposes.

For clinic patients whose clinician will be observed, information about shadowing and its purpose will be provided. We will ask patient permission from these patients for a UW reviewer to sit in on their session to observe the clinician. Patients will be told this is completely voluntary and may decline session observation. Only one UWAC team member will sit in on patient sessions.

Phase 2 – Design & Build:

Clinicians recruited for Phase 1 will also be invited to participate in Phase 2 of the study.

Co-Design Workshop**:**
Up to 15 clinicians, care managers, and other clinic staff, including those from Phase I, will participate in a co-design workshop for Behavioral Activation treatment. This workshop will serve as an introduction or refresher of BA principles, including and core elements of treatment. The workshop will be conducted remotely via Zoom due to restrictions from COVID-19.

During this co-design workshop, we will conduct a focus group with the clinicians, care managers, and clinic staff to ask their general impressions of BA and any concerns or thoughts they have about materials, the language in the materials, and how they think they could incorporate or modify BA to fit their workflow.

We will ask permission to video record this co-design workshop for two purposes:

1) Data review and coding, and
2) Editing to create a video for public dissemination on our website, www.uwalacrity.org and other web-based presence (e.g., our YouTube channel) as a learning tool for other researchers interesting in redesigning interventions. We will ask participants to sign a UW video release for this purpose.

User Testing

Based on learning from the co-design workshop, we will ask clinicians and care managers to practice elements of BA that arise from the workshop. For example, if we learn that clinicians do not routinely use activity charts with patients (a core element of BA), we may ask them to try using activity charts with their clinic patients for a week in order to give us feedback on the usability or burden of such components. (NOTE: we do not need patient data at this point [Phase 2], so we are not including patients as participants in this phase.) Our researchers will solicit feedback from clinicians in iterative rounds of interviews to query these barriers and opportunities.

We will develop initial prototypes of modifications to BA treatment components, including addressing modifications to clinician and care manager workflow to deliver elements of BA. Prototypes may include workflow diagrams and storyboards represent
ing the modification, materials and manuals. These prototypes be shared via email and/or during Zoom calls for clinicians/care managers to interact with and give further feedback for additional modification.

We will iteratively improve designs through usability testing with the clinicians and care managers. For example, if the *Discover* phase finds that the BA process needs to include no more than 3 steps, we may take the following steps:

1. The design team will create (for example) 3 different ways a BA component (such as activity charting) could be condensed, modified, or distributed differently in a workflow. These different processes will be depicted in electronic story boards.
2. The story boards will be shown to the clinicians with accompanying intervention materials (manuals, etc.). During the presentation, clinicians will be asked for their assessment of perceived usability (ease of learning, potential for use in clinic, perceived burden, and acceptability) for each iteration. These assessments will be both quantitative (System Usability Scale) and qualitative (Think Aloud). Quantitative data will be stored in the REDCap database, as will audio recordings of the Think Aloud Assessment.
3. Designers will then create a new version of the modification using information from all three storyboard assessments. The next version will be assessed using the processes described in step 2. This will continue until we reach a SUS scale score of .80. A final prototype will undergo initial feasibility evaluation in pilot field deployments with each clinician using the prototype with one depressed patient, with a PHQ-9 score between 10-20 (recruited from their WPRN clinic). Once we have completed the redesign of the EBPI so that it (1) meets needs of its clinicians and patients (i.e., is useful), and (2) is easy to use and understand (i.e., is usable), we will move to the *Test* phase (Phase 3) of this study.

Phase 3 Testing

We will conduct a pilot study comparing the modified EBPI to usual care at Bighorn Valley Health Center (BVHC). The EBPI itself (Behavioral Activation) will not change for the patients, but rather we will modify how Therapists and Care Managers at BVHC are sharing the tasks involved in Behavioral Activation. The modifications will also help guide Therapists and Care Managers as they decide how and

when to use BA in specific clinical situations. The Therapists and Care Managers of some clinics in the BVHC network have already implemented this modified approach, and the goal is to have all clinics in the network learn and use the model. The Therapists and Care Managers will receive additional training and guidance from the study team to achieve this modification, but the patients' clinical care visits will not change. During the additional training, UW and Stanford study staff members will provide consultation on BVHC patient cases in order to provide support for any cases where BVHC clinicians are having difficulty using BA. During these discussions, no staff from the UW or Stanford team will ever know any identifiable information about the patients. However, both UW and Stanford staff members will have access to clinician participants' identifiable information from training/support activities with the clinicians. We will use pre-existing clinic measures to collect patient outcome data for patients whose providers are using the modified BA model. We will also collect patient outcomes using the same pre-existing clinic measures for patients whose providers are providing usual care. We will then compare outcome data for each type of care. A total of 11 clinicians and 80 patients will be recruited for Phase 3.

Clinician Procedures:

Clinician training in BA**.** UW team staff will train clinicians in modified Behavioral Activation elements per the protocol used by the AIMS Center, which includes training in basic brief treatment skills, therapeutic elements of the intervention and therapy process. The training will also include modifications developed via clinician/research staff co-design in Phase 2.

Note: These modifications will be developed in Phase 2, and new materials will be submitted to the IRB prior to beginning Phase 3.

Training will be followed by simulated case training. Once clinicians finish the training and begin using the modified BA with patients, we will use a self-report checklist and open-ended questions regarding the use of modified BA to measure clinicians' adherence to the model.

Two types of data will be collected, clinician assessment of intervention usability, and clinician ability to learn the intervention and maintain competency. To measure intervention usability, clinicians will complete the AIM, FIM, IAM, the User Burden Scale and the System Usability Scale, which are core measures for this Center. These measures will be administered both pre- and post-. Clinicians may also be asked to complete exit interviews regarding their experience using the BA task-sharing model. These interviews may be video-recorded (with clinician consent) for later review.

To measure sustained competency**,** clinicians will use a self-report checklist of task-sharing BA components with each patient to ensure they are adhering to the model. Clinicians will also complete qualitative questions regarding model adherence at the end of the study.

We will conduct 3-month follow up interviews with clinicians to ask if they are still using the task sharing model, if they are using all aspects of the model, and if they have made any modifications to the model. These interviews may be video-recorded (with clinician consent) for later review.

Clinician procedures are summarized here:

- Complete updated consent form
- Complete full BA task-sharing training starting in January 2020

    - 6 synchronous sessions (about 1 hour each)
    - Complete asynchronous material in between sessions
    - Staff will be paid $50 for each of the 6 synchronous sessions they attend
- Complete pre-trial usability questionnaires re: BA task-sharing model, for which they will be paid $25
- After BA task-sharing training is complete, begin using the model with clinic patients (target of 10 patients per clinic)
- Use a self-report checklist of task-sharing BA components with each patient to ensure they are adhering to the model
- Complete post-trial usability questionnaires re: BA task-sharing model, for which they will be paid $25
- Possibly complete exit interviews re: their experience using the BA task-sharing model, for which they would be paid $50. These interviews may be video-recorded (with clinician consent) for later review.
- Complete a 3-month follow up interview to report if/how they are still using the modified BA model, for which they will be paid $50. These interviews may be video-recorded (with clinician consent) for later review.

Patient Procedures

Patient eligibility.

Patient participants will be identified through each clinic's electronic health record. Participants must be 18 years old or older, suffering from mild to moderate depression. The site champion will identify potential participants from their electronic health records (EHRs) who score between 10 and 20 on the PHQ-9. Patient procedures include:

- Up to 40 patients who are already receiving care at BVHC will receive care via the BA task-sharing model
- We will also include a sample of up to 40 other patients who are already receiving care at BVHC (but not yet receiving care via the modified BA model) who will continue to receive their usual care
- Patients will complete weekly PHQ and GAD (already being collected by BVHC as part of usual care). This includes both the patients who are receiving care via the BA task-sharing model and those who are receiving care without the model
- We will collect historic patient data (PHQ and GAD, already collected by BVHC and agreed to by patients) for all patient participants. This includes both the patients who are receiving care via the BA task-sharing model and those who are receiving care without the model.
- We will collect 3-month follow up patient data (PHQ and GAD, already collected by BVHC and agreed to by patients) for all patient participants. This includes both the patients who are receiving care via the BA task-sharing model and those who are receiving care without the model.
- We will ask up to 10 patients who received care via the BA task-sharing model to complete exit interviews to give their perspective on the care they received. Patients will be consented for these

interviews, as we will then be asking patients to complete research activities that are beyond activities already completed during their usual care. Patients will be paid $25 for the exit interviews.

5.2 **Data variables.** Describe the specific data you will obtain (including a description of the most sensitive items). If you would prefer, you may upload a list of the data variables to the **Supporting Documents** SmartForm instead of describing the variables below.

Clinician Data:

Phase 1 & 2 qualitative clinician interviews:

We request flexibility in qualitative interviewing questions with clinicians during Phase 1 and 2 which will include:

- common problems clinicians experience or anticipate in **usability** of EBPIs such as: (1) too many steps in a typical session; (2) not enough time to "get to know" the patient/not enough time to get through the process of EBPI in each session; (3) too tiring to deliver on days when clinicians see patients back to back; (4) focusing on problems was not synergistic with clinic mandates to use strength-based interventions; (5) difficulty using EBPIs to address common problems, such as lack of motivation, affect regulation, profound pessimism, trauma exposure, and access to basic needs in the face of poverty (food, shelter, access to health care, safety); (6) insufficient support to know when adding other EBPI elements or eliminating EBPI elements was appropriate or in violation of protocol; and, (7) over insistence by trainers or supervisors to have clinicians structure sessions and use of forms.
- Implementation domains to include (1) intervention characteristics, including core components and adaptable, peripheral elements; (2) outer setting, the broader economic, political, social context in which an organization exists; (3) inner setting, the immediate organizational context in which implementation occurs, including shared receptivity to change; (4) individual characteristics of practitioners and implementation team members, such as personal and professional values, interests, and affiliations; and (5) the implementation process, the steps and modes by which active change is undertaken.
- Questions about what clinicians value about their work with their patients, what they feel is missing when using EBPIs, and suggestions for how it could be improved, given their clinical context and patient population.

Phase 3

Clinician Participants:

Clinician Training:

Adherence Scale (checklist) – to be developed in Phase 2

Intervention Usability:
AIM (already uploaded to Zipline in "Assessments" pdf)
IAM(already uploaded to Zipline in "Assessments" pdf)
FIM (already uploaded to Zipline in "Assessments" pdf)
User Burden Scale
System Usability Scale
Qualitative adherence questions
Qualitative adherence/modification questions (at 3-month follow up)

Demographic Survey

Patient Participants:
Demographic info (EHR)
Process measures (eg. how long have patients been in treatment, how frequently do they have visits, etc.) – (EHR)
9-Item Patient Health Questionnaire (PHQ-9) – (EHR)
7-Item Generalized Anxiety Disorder (GAD-7) – (EHR)
Qualitative treatment experience questions

5.3 Data sources. For all types of data that you will access or collect for this research: Identify whether you are obtaining the data from the subjects (or subjects' specimens) or whether you are obtaining the data from some other source (and identify the source).

If you have already provided this information in Question 5.1, you do not need to repeat the information here.

We will obtain clinician data from the subjects. We will obtain all patient data from their EHR except for patients who agree to complete exit interviews. For those patients, data will also be collected directly from the subject.

5.4 Retrospective/prospective. For all types of data and specimens that you will access or collect for this research: do all data and specimens to be used in the research exist (for example, in subjects' medical records) at the time this application is being submitted for initial review?

- [x] **No**
- [ ] **Yes**

Include any necessary comments or explanation below (Note that for most studies this can be left blank):

5.5 Identifiability of data and specimens. Answer these questions carefully and completely. This will allow HSD to accurately determine the type of review that is required and to assist you in identifying relevant compliance requirements. Review the following definitions before answering the questions:

__Access__ means to view or perceive data, but not to possess or record it. See, in contrast, the definition of "obtain".
__Identifiable__ means that the identity of an individual is or may be readily (1) ascertained by the researcher or any other member of the study team from specific data variables or from a combination of data variables, or (2) associated with the information.
__Direct identifiers__ are direct links between a subject and data/specimens. Examples include (but are not limited to): name, date of birth, medical record number, email or IP address, pathology or surgery accession number, student number, or a collection of your data that is (when taken together) identifiable.
__Indirect identifiers__ are information that links between direct identifiers and data/specimens. Examples: a subject code or pseudonym.
__Key__ refers to a single place where direct identifiers and indirect identifiers are linked together so that, for example, coded data can be identified as relating to a specific person. Example: a master list that contains the data code and the identifiers linked to the codes.
__Obtain__ means to possess or record in any fashion (writing, electronic document, video, email, voice recording, etc.) for research purposes and to retain for any length of time. This is different from __accessing__, which means to view or perceive data.

a. Will you or any members of your team have <u>access</u> to any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

Names and contact information, medical record identifiers from the screening steps, video and audio recordings of clinicians and clinic staff during Phase 2 co-design workshop/focus group.

[ ] **No** → If no, select the reason(s) why you (and all members of your team) will not have access to direct or indirect identifiers.

- [ ] There will be no identifiers.
- [ ] Identifiers or the key have been (or will have been) destroyed before you have access.
- [ ] You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

  You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.
- [ ] There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.
- [ ] There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

b. Will you <u>obtain</u> any direct or indirect identifiers?

[x] **Yes** → If yes, describe which identifiers and for which data/specimens.

Names and contact information; video and audio recordings of clinicians and clinic staff during Phase 2 co-design workshop/focus group & Phase 3 trial. In Phase 3, BVHC staff members will obtain name, date of birth, and medical record

number for patients they work with as part of their usual workflow and will be able to link these identifiers to all patient data (PHQ, GAD, demographics, process measures). However, all patient data will be de-identified to the UW and Stanford study team unless a patient agrees to complete an exit interview. In this case, UW would obtain names and contact information for those patients.

☐ **No** → If no, select the reason(s) why you (and all members of your team) will not obtain direct or indirect identifiers.

☐ There will be no identifiers.

☐ Identifiers or the key have been (or will have been) destroyed before you have access.

☐ You have (or will have) entered into an agreement with the holder of the identifiers (or key) that prohibits the release of the identifiers (or key) to you under any circumstances.

You should be able to produce this agreement for IRB upon request. Examples: a Data Use Agreement, Repository Gatekeeping form, or documented email.

☐ There are written policies and procedures for the repository/database/data management center that prohibit the release of the identifiers (or identifying link). This includes situations involving an Honest Broker.

☐ There are other legal requirements prohibiting the release of the identifiers or key to you. Describe them below.

c. If you obtain any identifiers, indicate how the identifiers will be stored (and for which data). NOTE: Do not describe your data security plan here – we will ask for that information in section 9.6.

☒ You will store the identifiers with the data. Describe the data to which this applies:

Names and contact information will be stored in REDCap on UW secured servers. Video and audio recordings of clinicians and clinic staff will be stored on secure project database (OneDrive) accessible only to Center researchers; these recordings will be moved to study REDCap at least quarterly.

☒ You will store identifiers and study data separately but you will maintain a link between the identifiers and the study data (for example, through the use of a code). Describe the data to which this applies:

For patients whose identifiers will be obtained by UW (only patients who complete exit interviews), patient identifiers will be coded and linked to a master list stored in REDCap. At BVHC, identifiers for all patients will not be stored separately, but will be stored as usual in BVHC's secure electronic health record system.

☐ You will store identifiers separately from the study data, with no link between the identifiers and the study data. Describe the data to which this applies:

d. Research collaboration. Will individuals who provide you with coded information or specimens for your research also collaborate on other activities for this research? If yes, identify the activities and provide the name of the collaborator's institution/organization.

Examples include but are not limited to: (1) study, interpretation, or analysis of the data that results from the coded information or specimens; and (2) authorship on presentations or manuscripts related to this work.

N/A

5.6 Newborn dried blood spots. Will you use newborn dried bloodspots collected in the United States on or after March 18, 2015?

[x] **No**
[ ] **Yes** → If yes, is this research supported by any federal funding (including any fellowship or career development award that provides salary support)?

  [ ] **No**
  [ ] **Yes** → If yes, describe how you will ensure that the bloodspots were collected with parental permission (in compliance with a 2015 law that applies to federal-funded research).

5.7 Protected Health Information (PHI). Will you access, obtain, use, or disclose a participant's identifiable PHI for any reason (for example, to identify or screen potential subjects, to obtain study data or specimens, for study follow-up) that does not involve the creation or obtaining of a Limited Data Set?

PHI is individually-identifiable healthcare record information or clinical specimens from an organization considered a "covered entity" by federal HIPAA regulations, in any form or media, whether electronic, paper, or oral. ***If you will use UW Medical Records, you must answer yes to this question.***

[ ] **No** → If no, skip the rest of this question; go to question **5.8**
[x] **Yes** → If yes, answer all of the questions below.

a. Describe the PHI you will access or obtain, and the reason for obtaining it. *Be specific.*

- BVHC will access all patient participants' medical records for screening purposes and during usual care. BVHC will have access to patient names and contact information as well as all data listed below. BVHC already accesses this PHI outside of the study.
- UW will access names and contact information for the purpose of contacting the patients for exit interviews..
- The following will be collected from patients' EHR for purposes of evaluating efficacy of care being provided. BVHC will access the PHI via EHR and then de-identify the data before sending to UW and Stanford:
  - 9-Item Patient Health Questionnaire (PHQ-9)
  - 7-Item Generalized Anxiety Disorder (GAD-7)
  - Patient process measures (eg. how long have patients been in treatment, how frequently do they have visits, etc.)
  - Patient demographic info

b. Is any of the PHI located in Washington State?

[X] **No**
[ ] **Yes**

c. Describe how you will access or obtain the PHI. *Be specific.*

PHI will be obtained from the participants or by Electronic Health Record (EHR). Contact information will be collected by BVHC and will only be given to UW/Stanford study staff with patient permission. PHQ-9, GAD-7, process measures, and demographics will be obtained via EHR by BVHC and will be de-identified before being sent to UW/Stanford.

d. For which PHI will you obtain HIPAA authorization from the subjects by having them sign a HIPAA Authorization form, before obtaining and using the PHI?

None

Confirm by checking the box that you will use the UW Medicine HIPAA Authorization form maintained on the HSD website if you will access, obtain, use, or disclose UW Medicine PHI.

☐ **Confirmed**

e. For which PHI will you NOT obtain HIPAA authorization from the subjects?

- Names and contact information for the purpose of contacting the patients for exit interviews..
- The following will be collected from patients' EHR for purposes of evaluating efficacy of care being provided. BVHC will access the PHI via EHR and then de-identify the data before sending to UW and Stanford:
  - 9-Item Patient Health Questionnaire (PHQ-9)
  - 7-Item Generalized Anxiety Disorder (GAD-7)
  - Patient process measures (eg. how long have patients been in treatment, how frequently do they have visits, etc.)
  - Patient demographic info

Provide the following assurances by checking the boxes.

☒ The PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of PHI would be permitted.

☐ You will fulfill the HIPAA "accounting for disclosures" requirement. See UW Medicine Privacy Policy #25. THIS IS ONLY FOR UW RECORDS.

☒ There will be reasonable safeguards to protect against identifying, directly or indirectly, any patient in any report of the research.

5.8 Genomic data sharing. Will you obtain or generate genomic data (as defined at http://osp.od.nih.gov/scientific-sharing/genomic-data-sharing-faqs/)?

☒ **No**

☐ **Yes** → If yes, answer the question below.

a. Do you plan to send genomic data from this research to a national database (for example, NIH's dbGaP database)?

☐ **No**

☐ **Yes** → If yes, complete the ***ZIPLINE* SUPPLEMENT Genomic Data Sharing** and upload it to the **Supporting Documents** SmartForm of ***Zipline***.

5.9 Whole genome sequencing. For research involving biospecimens: Will the research include whole genome sequencing?

Whole genome sequencing is sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen.

[x] **No**
[ ] **Yes**

5.10 Data and specimen sharing/banking. Are you likely to share some or all of the data, specimens, or subject contact information with other researchers or a repository/database for research purposes not related to this study, or to bank them for your own future unspecified research uses? **You are strongly encouraged to consider the broadest possible future plans you might have, and whether you will obtain consent now from the subjects for future sharing or unspecified uses.** Answer **YES** even if you will only share information without identifiers. Answer **NO** if you are unlikely to do any sharing, or if your only sharing will be through the NIH Genomic Data Sharing described in question 5.8.

Many federal grants and contracts now require data or specimen sharing as a condition of funding, and many journals require data sharing as a condition of publication. "Sharing" may include: informal arrangements to share your banked data/specimens with other investigators; establishing a repository from which you formally share with others through written agreements; or sending your data/specimens to a third party repository/archive/entity such as the Social Science Open Access Repository (SSOAR), or the UCLA Ethnomusicology Archive.

[ ] **No**
[x] **Yes** → If yes, answer all of the questions below.

a. Describe what will be stored, including whether any direct or indirect (e.g., subject codes) identifiers will be stored.

NIMH requires that data from this study related to depression be uploaded to the National Institute of Mental Health Data Archive.

b. Describe what will be shared, including whether direct identifiers will be shared and (for specimens) what data will be released with the specimens.

Data will be de-identified, using a unique study ID. Data to be shared includes patient participant assessment data such as the PHQ-9 and the GAD-7.

c. Who will oversee and/or manage the sharing?

The UWAC study coordinator and Methods Core faculty will oversee and manage the data sharing with NIMH.

d. Describe the possible future uses, including limitations or restrictions (if any) on future uses or users. As stated above, consider the broadest possible uses.

Examples: data will be used only for cardiovascular research; data will not be used for research on population origins.

Researchers throughout the U.S. may file an application to NIMH to obtain de-identified study data for research purposes.

e. Consent. Will you obtain consent now from subjects for the banking and/or future sharing?

[X] **No**
[ ] **Yes** → If yes, be sure to include the information about this consent process in the consent form (if there is one) and in your answers to the consent questions in Section 8.

f. Withdrawal. Will subjects be able to withdraw their data/specimens from banking or sharing?

[X] **No**
[ ] **Yes** → If yes, describe how, and whether there are any limitations on withdrawal.

Example: data can be withdrawn from the repository but cannot be retrieved after they are released.

Participants may change their mind about sharing their data, and data sharing will stop. However, NDA cannot take back information that has already been shared.

g. Agreements for sharing or release. Confirm by checking the box that you will comply with UW (and, if applicable, UW Medicine) policies that require a formal agreement between you and the recipient for release of data or specimens to individuals or entities other than federal databases.

Data Use Agreements or Gatekeeping forms are used for data; Material Transfer Agreements are used for specimens (or specimens plus data. Do not attach your template agreement forms; the IRB neither reviews nor approves them

[x] **Confirmed**

5.11 Communication with subjects during the study. Describe the types of communication (if any) you will have with already-enrolled subjects during the study. Provide a description instead of the actual materials themselves.

Examples: email, texts, phone, or letter reminders about appointments or about returning study materials such as a questionnaire; requests to confirm contact information.

Communication with clinician participants regarding the scheduling of trainings and interviews via email, text, phone or letters.

5.12 Future contact with subjects. Do you plan to retain any contact information you obtain for your subjects so that they can be contacted in the future?

[ ] **No**
[X] **Yes** → If yes, describe the purpose of the future contact, and whether use of the contact information will be limited to your team; if not, describe who else could be provided with the contact information. Describe your criteria for approving requests for the information.

Examples: inform subjects about other studies; ask subjects for additional information or medical record access that is not currently part of the study proposed in this application; obtain another sample.

Clinicians and clinic staff from Phase I will be contacted and invited to participate in all subsequent phases of this study.

5.13 Alternatives to participation. Are there any alternative procedures or treatments that might be advantageous to the subjects?

If there are no alternative procedures or treatments, select "No". Examples of advantageous alternatives: earning extra class credit in some time-equivalent way other than research participation; obtaining supportive care or a standard clinical treatment from a health care provider instead of participating in research with an experimental drug.

[x] **No**
[ ] **Yes** → If yes, describe the alternatives.

5.14 Upload to the Supporting Documents SmartForm of ***Zipline*** all data collection forms (if any) that will be directly used by or with the subjects, and any scripts/talking points you will use to collect the data. Do not include data collection forms that will be used to abstract data from other sources (such as medical or academic records, or video recordings.

- ***Examples****: survey, questionnaires, subject logs or diaries, focus group questions.*
- ***NOTE:*** *Sometimes the IRB can approve the general content of surveys and other data collection instruments rather than the specific form itself. This prevents the need to submit a modification request for future minor changes that do not add new topics or increase the sensitivity of the questions. To request this general approval, use the text box below to identify the questionnaires/surveys/ etc. for which you are seeking this more general approval. Then briefly describe the scope of the topics you will cover and the most personal and sensitive questions. The HSD staff person who screens this application will let you know whether this is sufficient or whether you will need to provide more information.*
- ***For materials that cannot be uploaded****: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*
- ***For data that will be gathered in an evolving way****: This refers to data collection/questions that are not pre-determined but rather are shaped during interactions with participants in response to observations and responses made during those interactions. If this applies to your research, provide a description of the process by which you will establish the data collection/questions as you interact with subjects, how you will document your data collection/questions, the topics you plan to address, the most sensitive type of information you will plan to gather, and the limitations (if any) on topics you will raise or pursue.*

Use this text box (if desired) to provide

- Short written descriptions of materials that cannot be uploaded, such as URLs
- A description of the process you will use for data that will be gathered in an evolving way.
- The general content of questionnaires, surveys and similar instruments for which you are seeking general approval. (See the **NOTE** bullet point in the instructions above.)

The study team requests approval for the general content of the following questionnaires instead of the exact questionnaires, as they are not yet finalized:

- **Clinician adherence scale/checklist:** We will use this self-report checklist to measure how closely clinicians are adhering to the modified Behavioral Activation (BA) model. This checklist will include the aspects of BA listed below and will ask clinicians to check off whether they have been using each aspect or not. The checklist may also include comment boxes for clinicians to add notes explaining why they did or didn't use a particular aspect. BA aspects for checklist will include:
  - Set an agenda
  - Help patient set goals
  - Identify barriers to setting goals, including: Avoidance, Negativity Bias, Affect Regulation, Distraction, Apathy, Reward Processing Dysfunction, Substance Use
  - Use learned strategies to address barriers with patient

- **Clinician qualitative adherence/modification questions (at 3-month follow up):** We will conduct follow up interviews 3 months after the trial to ask if clinicians if/in what manner they are still using the modified BA model. We will ask open-ended questions like:
  - Are you still using the modified BA model?
  - Are you using all aspects of the model, or only some?
  - Have you made any modifications to the model?

- **Patient qualitative treatment experience questions:** We will conduct exit interviews with up to 10 patient participants to capture their perspective and satisfaction with the care their providers delivered via the modified BA model. We will ask questions like:

- Are you satisfied with the quality of care that you received?
- Do you feel that your Therapist and Care Manager worked well together?
- Do you feel like you would have received better care by working with just one or the other, rather than with both?

5.15 Send HSD a Confidentiality Agreement if you will obtain or use any private identifiable UW records without subject's written consent (for example, screening medical records or class grades to identify possible subjects).

The Confidentiality Agreement form must be completed, printed, signed, and mailed to the Human Subjects Division at Box 359470. Your IRB application cannot be approved until we receive the Confidentiality Agreement.

6 CHILDREN (MINORS) and PARENTAL PERMISSION

6.1 Involvement of minors. Does your research include minors (children)?

Minor or child means someone who has not yet attained the legal age for consent for the research procedures, as described in the applicable laws of the jurisdiction in which the research will be conducted. This may or may not be the same as the definition used by funding agencies such as the National Institutes of Health.

- In Washington State the generic age of consent is 18, meaning that anyone under the age of 18 is considered a child.
- There are some procedures for which the age of consent is much lower in Washington State.
- The generic age of consent may be different in other states, and in other countries.

[x] **No** → If no, go to Section 8.

[ ] **Yes** → If yes, provide the age range of the minor subjects for this study and the legal age for consent in your population(s). If there is more than one answer, explain.

[ ] **Don't know** →This means is it not possible to know the age of your subjects. For example, this may be true for some research involving social media, the Internet, or a dataset that you obtain from another researcher or from a government agency. Go to Section 8.

6.2 Parental permission. Parental permission means actively obtaining the permission of the parents. This is not the same as "passive" or "opt out" permission where it is assumed that parents are allowing their children to participate because they have been provided with information about the research and have not objected or returned a form indicating they don't want their children to participate.

a. Will you obtain parental permission for:

[ ] All of your research procedures → Go to question **6.2b.**

[ ] None of your research procedures → Use the table below to provide your justification, and skip question 6.2b.

☐ Some of your research procedures → Use the table below to identify the procedures for which you will not obtain written parental permission.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO parental permission[2]	Reason why you will not obtain parental permission	Will you inform them about the research?[3]	
			YES	NO
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐
			☐	☐

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*
2. *If you plan to obtain identifiable information or biospecimens without parent permission, any waiver granted by the IRB does not override parents' refusal to provide broad consent (for example, through the Northwest Biotrust).*
3. *Will you inform them about the research beforehand even though you are not obtaining active permission?*

b. Indicate by checking the appropriate box(es) your plan for obtaining parental permission

☐ Both parents, unless one parent is deceased, unknown, incompetent, or not reasonably available; or when only one parent has legal responsibility for the care and custody of the child

☐ One parent, even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.

This is all that is required for minimal risk research.

If you checked both boxes, explain:

6.3 Children who are wards. Will any of the children be wards of the State or any other agency, institution, or entity?

☐ **No**

☐ **Yes** → If yes, an advocate may need to be appointed for each child who is a ward. The advocate must be in addition to any other individual acting on behalf of the child as guardian or in loco parentis. The same individual can serve as advocate for all children who are wards.

Describe who will be the advocate(s). Your answer must address the following points:

- Background and experience
- Willingness to act in the best interests of the child for the duration of the research
- Independence of the research, research team, and any guardian organization

7 ASSENT OF CHILDREN (MINORS)

Go to Section 8 if your research does not involve children (minors).

7.1 Assent of children (minors). Though children do not have the legal capacity to "consent" to participate in research, they should be involved in the process if they are able to "assent" by having a study explained to them and/or by reading a simple form about the study, and then giving their verbal choice about whether they want to participate. They may also provide a written assent if they are older. See **WORKSHEET: Children** for circumstances in which a child's assent may be unnecessary or inappropriate.

a. Will you obtain assent for:

☐ All of your research procedures and child groups	→ Go to question **7.2.**
☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then skip to question 7.5.
☐ Some of your research procedures and child groups	→ Use the table below to identify the procedures for which you will not obtain assent.

Be sure to consider all research procedures and plans, including screening, future contact, and sharing/banking of data and specimens for future work.

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be obtained	Reason why you will not obtain assent

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

7.2 Assent process. Describe how you will obtain assent, for each child group. If your research involves children of different ages, answer separately for each group. If the children are non-English speakers, include a description of how you will ensure that they comprehend the information you provide.

7.3 Dissent or resistance. Describe how you will identify a child's objection or resistance to participation (including non-verbal indications) during the research, and what you will do in response.

7.4 Documentation of assent. Which of the following statements describes whether you will obtain documentation of assent?

☐ None of your research procedures and child groups	→ Use the table below to provide your justification, then go to question 7.4.a.
☐ All of your research procedures and child groups	→ Go to question **7.4.a**, do not complete the table
☐ Some of your research procedures and/or child groups	→ Complete the table below and then to go question 7.4.a

Children Group[1]	Describe the procedures or data/specimen collection (if any) for which assent will NOT be documented

Table footnotes

1. *If your answer is the same for all children groups or all procedures, you can collapse your answer across the groups and/or procedures.*

a. Describe how you will document assent. If the children are functionally illiterate or are not fluent in English, include a description of what you will do.

b. Upload all assent materials (talking points, videos, forms, etc.) to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***. Assent materials are not required to provide all of the standard elements of adult consent; the information should be appropriate to the age, population, and research procedures. The documents should be in Word, if possible.

7.5 Children who reach the legal age of consent during participation in longitudinal research.

Children who were enrolled at a young age and continue for many years: It is best practice to re-obtain assent (or to obtain it for the first time, if you did not at the beginning of their participation).
Children who reach the legal age of consent: You must obtain informed consent from the now-adult subject for (1) any ongoing interactions or interventions with the subjects, or (2) the continued analysis of specimens or data for which the subject's identify is readily identifiable to the researcher, unless the IRB waives this requirement.

a. Describe your plans (if any) to re-obtain assent from children.

b. Describe your plans (if any) to obtain consent for children who reach the legal age of consent.

- If you plan to obtain consent, describe what you will do about now-adult subjects whom you are unable to contact.
- If you do not plan to obtain consent or think that you will be unable to do so, explain why.

7.6 Other regulatory requirements. (This is for your information only; no answer or response is required.)
Researchers are responsible for determining whether their research conducted in schools, with student records, or over the Internet comply with permission, consent, and inspection requirements of the following federal regulations:

- PPRA – Protection of Pupil Rights Amendment
- FERPA – Family Education Rights and Privacy Act
- COPPA – Children's Online Privacy Protection Act

8 CONSENT OF ADULTS

Review the following definitions before answering the questions in this section.

CONSENT	is the process of informing potential subjects about the research and asking them whether they want to participate. It usually (but not always) includes an opportunity for subjects to ask questions. It does not necessarily include the signing of a consent form. This question is about the consent process.
CONSENT DOCUMENTATION	refers to how a subject's decision to participate in the research is documented. This is typically obtained by having the subject sign a consent form.
CONSENT FORM	is a document signed by subjects, by which they agree to participate in the research as described in the consent form and in the consent process.
ELEMENTS OF CONSENT	are specific information that is required to be provided to subjects.
PARENTAL PERMISSION	is the parent's active permission for the child to participate in the research. Parental permission is subject to the same requirements as consent, including written documentation of permission and required elements.
SHORT FORM CONSENT	is an alternative way of obtaining written documentation of consent that is most commonly used with individuals who are illiterate or whose language is one for which translated consent forms are not available.

	means there is IRB approval for not obtaining consent or for not including some of the elements of consent in the consent process.
WAIVER OF CONSENT	**NOTE**: If you plan to obtain identifiable information or identifiable biospecimens without consent, any waiver granted by the IRB does not override a subject's refusal to provide broad consent (for example, the Northwest Biotrust).
WAIVER OF DOCUMENTATION OF CONSENT	means that there is IRB approval for not obtaining written documentation of consent.

8.1 Groups Identify the groups to which your answers in this section apply.

[x] Adult subjects

[ ] Parents who are providing permission for their children to participate in research

→ *If you selected **PARENTS**, the word "consent" below should also be interpreted as applying to parental permission and "subjects" should also be interpreted as applying to the parents.*

8.2 The consent process. This series of questions is about whether you will obtain consent for all procedures except recruiting and screening and, if yes, how.

The issue of consent for recruiting and screening activities is addressed in question 4.6. You do not need to repeat your answer to question 4.6.

a. Are there any procedures for which you will not obtain consent?

[ ] **No**

[X] **Yes** → If yes, use the table below to identify the procedures for which you will not obtain consent. "All" is an acceptable answer for some studies.

Be sure to consider all research procedures and plans, including future contact, and sharing/banking of data and specimens for future work.

Group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO consent process	Reason why you will not obtain consent	Will you provide subjects with info about the research after they finish? YES	NO
Patients	We will not consent patients for collection of data from their EHR (PHQ-9, GAD-7, demographics, process measures). We also will not consent patients for clinical care sessions they will complete after their therapists start receiving coaching on the Phase 3 research intervention.	Obtaining consent would likely cause confusion and provide no useful information to the patients because the research will not affect the basic therapies chosen or the structures of their clinical visits. In addition, some clinics have already implemented this approach outside of the research study, so patients are already receiving this model of care	[ ]	[X]

	as part of their usual care prior to the research study.		
		☐	☐
		☐	☐
		☐	☐
		☐	☐

Table footnotes

1. *If your answer is the same for all groups you can collapse your answer across the groups and/or procedures.*

b. Describe the consent process**,** if you will obtain consent for any or all procedures, for any or all groups. Address groups and procedures separately if the consent processes are different.

Be sure to include:

- *The location/setting where consent will be obtained*
- *Who will obtain consent (refer to positions, roles, or titles, not names).*
- *Whether/how you will provide an opportunity for questions*
- *How you will provide an adequate opportunity for the subjects to consider all options*

Clinician Participant Consent – Phases 1-3
In all three phases of the study, clinicians will be consented. A member of the UWAC team will contact the clinicians, review study procedures, and answer any questions and concerns. In order to minimize potential coercion, the UWAC team staff will explain that study participation is completely voluntary, and that anyone who participates in the study may withdraw at any time with no loss of benefits.

Clinician Participant Consent – Phase 2
During the co-design workshop/focus group clinicians/clinic staff will be video recorded. A member of the UWAC team will notify the clinicians/clinical staff prior to the group and will obtain their verbal agreement prior to recording. It will be made clear that we may publish these recordings, including their face and/or voice. Participants will be provided with an Information Sheet for their records detailing this addition (see attached in Zipline). We will begin all recordings with an announcement that the conversation is now being recorded.

Clinician Participant Consent – Phase 3
Since all interactions between BVHC clinicians and UW study staff will be carried out remotely, clinician consent will also occur remotely. UW study staff will email a copy of the consent form to each clinician and ask them to review it. UW study staff will then meet with clinicians via Zoom prior to the first training session to review the form and obtain verbal consent from all clinicians before moving forward with the training. Clinicians will be given opportunities to ask any questions about the study throughout the entire consent process.

Patient Consent – Phase 1
During the contextual evaluation observation, clinicians will be shadowed throughout their day. Their patients will be provided details about the study and the observation by the site champion, who will

obtain verbal consent from the patient, to have a UWAC observer present for this session. In order to minimize potential coercion, the study champion will explain agreeing to session observation is completely voluntary, and that the patient may decline or change their mind at any time with no loss of benefits.

Patient Consent – Phase 3

Patients will only be consented if they are selected to complete exit interviews at the end of the study. Patients will be randomly selected to complete exit interviews. For patients who are selected, they will be approached by their provider at BVHC who will briefly describe the trial being conducted and model being used at the clinic. They will then ask patients if they would be willing to complete an interview with UW staff to provide feedback based their experience receiving care at BVHC via the modified BA model.

For patients who agree to complete an interview, BVHC will share their contact information with UW staff who will reach out to the patients and schedule a time to meet. UW staff will then consent patients over the phone or over Zoom and collect verbal consent. If consented over Zoom, UW staff will screen share so that the patient can follow along through the document. Staff will give patients opportunities to ask questions about the study throughout the consent process. Once patients have given verbal consent, UW staff will proceed with the interview. UW staff will also obtain verbal consent to record the interview.

c. Comprehension**.** Describe how you will ensure or test the subjects' understanding of the information during the consent process.

During the consent process, each section of the consent form will be verbally reviewed with the participant. Subjects will be given the opportunity to ask questions throughout this process; in addition, participants will be asked to answer questions about the study so that the study team is sure the subject understands what participation involves. Potential subjects will be given as much time as they need to consider their participation in the study.

d. Influence**.** Does your research involve any subject groups that might find it difficult to say "no" to your research because of the setting or their relationship with you, even if you don't pressure them to participate?

Examples: Student participants being recruited into their teacher's research; patients being recruited into their healthcare provider's research, study team members who are participants; outpatients recruited from an outpatient surgery waiting room just prior to their surgery.

[x] **No**

[ ] **Yes** → If yes, describe what you will do, for each of these subject groups, to reduce any effect of the setting or relationship on their decision.

Examples: a study coordinator will obtain consent instead of the subjects' physician; the researcher will not know which subjects agreed to participate; subjects will have two days to decide after hearing about the study.

e. Ongoing process. For research that involves multiple or continued interaction with subjects over time, describe the opportunities (if any) you will give subjects to ask questions or to change their minds about participating.

- Subjects are encouraged to ask questions or voice concerns throughout their participation in the study. Contact information is provided for the study team and for the Human Subjects Division.
- Subjects may discontinue participation at any time.

These items are in the consent form.

8.3 Written documentation of consent. Which of the statements below describe whether you will obtain documentation of consent? NOTE: This question does not apply to screening and recruiting procedures which have already been addressed in question 4.6.

Documentation of consent that is obtained electronically is not considered written consent unless it is obtained by a method that allows verification of the individual's signature. In other words, saying "yes" by email is rarely considered to be written documentation of consent

a. Are you obtaining written documentation of consent for:

[X] None of your research procedures	→ Use the table below to provide your justification then go to question **8.4.**
[ ] All of your research procedures	→ Do not complete the table; go to question **8.4.**
[ ] Some of your research procedures	→ Use the table below to identify the procedures for which you will not obtain written documentation of consent from your adult subjects.

Adult subject group[1]	Describe the procedures or data/specimen collection (if any) for which there will be NO documentation of consent	Will you provide them with a written statement describing the research (optional)? YES	NO
		[ ]	[ ]
Clinician Participants	We are requesting waiver of written documentation of consent for clinician activities in all phases of the study. We are requesting this waiver since these interviews are being conducted remotely and will reduce burden on clinician participants.	[x]	[ ]
Patient Participants	We are requesting waiver of written documentation of consent for patient exit interviews. We are requesting this waiver since these interviews are being conducted remotely and will reduce burden on patient participants.	[ ]	[x]
		[ ]	[ ]
		[ ]	[ ]

Table footnotes

1. *If your answer is the same for all adult groups or all procedures, you can collapse your answer across the groups and/or procedures.*

8.4 Non-English-speaking or -reading adult subjects. Will you enroll adult subjects who do not speak English or who lack fluency or literacy in English?

[x] **No**
[ ] **Yes** → If yes, describe the process you will use to ensure that the oral and written information provided to them during the consent process and throughout the study will be in a language readily understandable to them and (for written materials such as consent forms or questionnaires) at an appropriate reading/comprehension level.

a. Interpretation. Describe how you will provide interpretation and when. Also, describe the qualifications of the interpreter(s) – for example, background, experience, language proficiency in English and in the other language, certification, other credentials, familiarity with the research-related vocabulary in English and the target language.

b. Translations. Describe how you will obtain translations of all study materials (not just consent forms) and how you will ensure that the translations meet the UW IRB's requirement that translated documents will be linguistically accurate, at an appropriate reading level for the participant population, and culturally sensitive for the locale in which they will be used.

8.5 Barriers to written documentation of consent. There are many possible barriers to obtaining written documentation of consent. Consider, for example, individuals who are functionally illiterate; do not read English well; or have sensory or motor impairments that may impede the ability to read and sign a consent form.

a. Describe your plans (if any) for obtaining written documentation of consent from potential subjects who may have difficulty with the standard documentation process (that is, reading and signing a consent form). Skip this question if you are not obtaining written documentation of consent for any part of your research.

Examples of solutions: Translated consent forms; use of the Short Form consent process; reading the form to the person before they sign it; excluding individuals who cannot read and understand the consent form.

N/A

8.6 Deception. Will you deliberately withhold information or provide false information to any of the subjects? *Note: "Blinding" subjects to their study group/condition/arm is not considered to be deception.*

[x] **No**
[ ] **Yes** → If yes, describe what information and why.

Example: you may wish to deceive subjects about the purpose of the study.

a. Will you debrief the subjects later? (Note: this is not required.)

☐ **No**
☐ **Yes** → If yes, describe how you will debrief the subjects. Upload any debriefing materials, including talking points or a script, to the **Consent Form and Recruitment Materials** SmartForm of ***Zipline***.

8.7 Cognitively impaired adults, and other adults unable to consent. Do you plan to include such individuals in your research?

Examples: individuals with Traumatic Brain Injury (TBI) or dementia; individuals who are unconscious, or who are significantly intoxicated.

☒ **No** → If no, go to question **8.8**.
☐ **Yes** → If yes, answer the following questions.

a. Rationale. Provide your rationale for including this population in your research.

b. Capacity for consent / decision making capacity. Describe the process you will use to determine whether a cognitively impaired individual is capable of consent decision making with respect to your research protocol and setting.

b.1. If you will have repeated interactions with the impaired subjects over a time period when cognitive capacity could increase or diminish, also describe how (if at all) you will reassess decision-making capacity and obtain consent during that time.

c. Permission (surrogate consent). If you will include adults who cannot consent for themselves, describe your process for obtaining permission ("surrogate consent") from a legally authorized representative (LAR).

*For research conducted in Washington State, see the **SOP: Legally Authorized Representative** to learn which individuals meet the state definition of "legally authorized representative".*

d. Assent. Describe whether assent will be required of all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not (and why not). Describe any process you will use to obtain and document assent from the subjects.

e. Dissent or resistance. Describe how you will identify the subject's objection or resistance to participation (including non-verbal) during the research, and what you will do in response.

8.8 Consent-related materials. Upload to the **Consent Forms and Recruitment Materials** SmartForm of ***Zipline*** all consent scripts/talking points, consent forms, debriefing statements, Information Statements, Short Form consent forms, parental permission forms, and any other consent-related materials you will use.

- *Translations must be included. However, you are strongly encouraged to wait to provide them until you know that the IRB will approve the English versions.*
- *Combination forms: It may be appropriate to combine parental permission with consent, if parents are subjects as well as providing permission for the participation of their children. Similarly, a consent form may be appropriately considered an assent form for older children.*
- *For materials that cannot be uploaded: upload screenshots or written descriptions that are sufficient to enable the IRB to understand the types of data that will be collected and the nature of the experience for the participant. You may also provide URLs (website addresses) or written descriptions below. Examples of materials that usually cannot be uploaded: mobile apps; computer-administered test; licensed and restricted standardized tests.*

9 PRIVACY AND CONFIDENTIALITY

9.1 Privacy protections. Describe the steps you will take, if any, to address possible privacy concerns of subjects and potential subjects.

Privacy refers to the sense of being in control of access that others have to ourselves. This can be an issue with respect to recruiting, consenting, sensitivity of the data being collected, and the method of data collection.
Examples:

- *Many subjects will feel a violation of privacy if they receive a letter asking them to participate in a study because they have ____ medical condition, when their name, contact information, and medical condition were drawn from medical records without their consent. Example: the IRB expects that "cold call" recruitment letters will inform the subject about how their information was obtained.*
- *Recruiting subjects immediately prior to a sensitive or invasive procedures (e.g., in an outpatient surgery waiting room) will feel like an invasion of privacy to some individuals.*
- *Asking subjects about sensitive topics (e.g. details about sexual behavior) may feel like an invasion of privacy to some individuals.*

BVHC Privacy Protections

Patient participants will be identified by BVHC through the clinic's electronic health record (EHR) and patient data will also be pulled from their EHR. Only BVHC staff members who already have access will access a patient's EHR. BVHC will not move any identifiable information outside of their HIPAA compliant EHR for this study – only de-identified information – except for name and contact information of patients who have agreed to complete interviews with UW study staff. To send this identifiable information to UW, BVHC will upload it to a secure database (REDCap) for UW staff to access.

UW Privacy Protections

All patient data will be de-identified before being accessed by UW staff. UW staff will only receive patient names and contact information for patients who have already agreed to complete exit interviews. BVHC will upload this information to a secure database (REDCap) for UW staff to access. The data will remain stored in REDCap. All contacts made to recruit patient subjects for exit interviews will be kept confidential.

9.2 Identification of individuals in publications and presentations. Do you plan to use potentially identifiable information about subjects in publications and presentations, or is it possible that individual identities could be inferred from what you plan to publish or present?

[ ] **No**
[X] **Yes** → If yes, will you obtain subject consent for this use?
  [X] **Yes**
  [ ] **No** → If no, describe the steps you will take to protect subjects (or small groups of subjects) from being identifiable.

Clinicians/clinic staff attending the Phase 2 co-design workshop will be video recorded. They will be made aware of the requirement prior to group and it will be clear that we may publish these including, their face and/or voice.

9.3 State mandatory reporting. Each state has reporting laws that require some types of individuals to report some kinds of abuse, and medical conditions that are under public health surveillance. These include:

- Child abuse
- Abuse, abandonment, neglect, or financial exploitation of a vulnerable adult
- Sexual assault
- Serious physical assault
- Medical conditions subject to mandatory reporting (notification) for public health surveillance

Are you or a member of your research team likely to learn of any of the above events or circumstances while conducting your research **AND** feel obligated to report it to state authorities?

[ ] **No**
[x] **Yes** → If yes, the UW IRB expects you to inform subjects of this possibility in the consent form or during the consent process, unless you provide a rationale for not doing so:

From the consent form:
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.

9.4 Retention of identifiers and data. Check the box below to indicate your assurance that you will not destroy any identifiers (or links between identifiers and data/specimens) and data that are part of your research records until after the end of the applicable records retention requirements (e.g. Washington State; funding agency or sponsor; Food and Drug Administration) for your research. If you think it is important for your specific study to say something about destruction of identifiers (or links to identifiers) in your consent form, state something like "the link between your identifier and the research data will be destroyed after the records retention period required by state and/or federal law."

This question can be left blank for conversion applications (existing paper applications that are being "converted" into a Zipline application.)

See the "Research Data" sections of the following website for UW Records management for the Washington State research rectords retention schedules that apply in general to the UW (not involving UW Medicine data):
http://f2.washington.edu/fm/recmgt/gs/research?title=R

See the "Research Data and Records" information in Section 8 of this document for the retention schedules for UW Medicine Records: ***http://www.uwmedicine.org/about/Documents/UWM-Records-Retention-Schedule-v1.6.pdf***

[x] **Confirm**

9.5 Certificates of Confidentiality. Are you planning to obtain a federal Certificate of Confidentiality for your research data? *NOTE: Answer "No" if your study is NIH funded, because all NIH-funded studies automatically have a Certificate.*

x	**No**
	Yes

9.6 Data and specimen security protections. Identify your data classifications and the security protections you will provide, referring to the ***ZIPLINE* GUIDANCE: Data and Security Protections** for the minimum requirements for each data classification level. ***You cannot answer this question without reading this document. Data security protections should not conflict with records retention requirements.***

a. Which level of protections will you apply to your data and specimens? If you will use more than one level, describe which level will apply to which data and which specimens.

The highest level of data collected are at Level 4 (mental health diagnoses), but data will primarily be at Level 3 (e.g., symptom data, executive functioning, experiences of stress).

b. Use this space to provide additional information, details, or to describe protections that do not fit into one of the levels. If there are any protections within the level listed in 9.6.a which you will *not* follow, list those here.

Phase 1 and 2 data. Qualitative interviews regarding clinician experience with the training program will be conducted via interactive video and be video and/or audio recorded. The UWAC discovery team will have access to provider identifiers (e.g. provider name, phone number) for the purpose of scheduling interview. Voice recordings are considered identifying information and the transcriptionist will have access to this for purposes of creating a transcript for analysis. Video recording of the co-design workshop with clinicians may be edited and published by UWAC for dissemination as an educational tool of this type of methodology for other researchers interested in intervention adaptation.

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Data Synthesis and Confirmation of Findings

Recordings of interviews will be transcribed and entered into Dedoose or Atlas.ti, qualitative data analysis and research software, to organize data for coding by multiple coders. A codebook will be created to describe data codes and meaning of codes. Interviews may be coded by the qualitative interviewers, Dr. Areán, and other study research staff. Coding will be grounded in the CFIR constructs. As interviews are coded, the results will be reviewed by the coders to discuss findings, resolve discrepancies, and identify any new themes. The final product from this data synthesis will be an as-Is workflow diagram that describes the usability challenges with BA. As-is workflow diagrams allow for a pictorial representation of BA and identifies where bottlenecks, duplication of effort, and potential burdens and opportuniites lie. We will share these diagrams with the clinicians we interviewed for confirmation of accuracy of their experience. After the as-is diagrams are completed, we will then share them with the Community Practice Board (CPB) members for further information and confirmation. Confirmation and input from a larger number of representative clinicians may enhance the generalizability of our modification. Finally, data collected on the implementation challenges of BA through these sources will be used in the development of the Typology of EBPI Targets**.**

Protection of Confidentiality. All study staff will be trained by the UWAC Methods Core on the protection of participants' rights, especially in areas relevant to confidentiality. All staff will

acknowledge in writing that they will abide by the University's rules and procedures pertaining to the rights of participants, confidentiality, and data safety in general. They will acknowledge that any lapse could result in disciplinary action or termination. In addition, the proposed project will adhere to the following general rules of data safety: 1) all staff will sign a written commitment to maintain an atmosphere of confidentiality, which will include not discussing confidential study information with anyone outside the study team and not attempting to learn the identity of an individual participant; 2) all data will be marked only by a non-identifying ID number; 3) all identifying information (consent forms, contact information for follow-up interviews) will be kept separate from data gathered from participants and kept in password-protected files in password-protected computers or systems; 4) non-study personnel will at no time be permitted to view identifying information; 5) all electronic data containing identifiers will be maintained with password protection, 6) all participants must understand, agree, and sign a consent for before participating and will be provided a copy of the consent form with instructions about how to contact a university official responsible for research oversight with any questions or concerns; 7) strict adherence to a participant's right to withdraw or refuse to answer questions will be maintained; and 8) participants will be provided with a summary of study results upon verbal or written request. In addition, qualitative interviews will be scheduled ahead of time to facilitate participant privacy in case friends or family members (who may be unaware that the individual is participating in a study) may be curious as to why the participant is being contacted. We will train research assistants to tactfully avoid answering such questions.

Data Security. Consent forms will have the signature of the participant. Locator forms will contain the participant's name, study ID, clinic patient ID, current address and emails, as well as the addresses and telephone numbers of contacts. For survey data, each study participant will be given a unique, but non-identifying number. No names or other identifying information will appear in the data. Electronic copies of the research data will be kept on the password-protected server which is backed up nightly. Electronic copies of the questionnaire responses will be kept indefinitely to insure the ability to replicate analyses. Audio recordings will be transmitted to the transcriptionist via a HIPAA-compliant FTP server and recordings will be transcribed with removal of as much personally identifiable information as possible. Once the transcriptions are confirmed to be accurate, the audio recordings will be destroyed. Electronic copies of the transcriptions will only be available to members of the study team, and will be stored on a password-protected computer server that is housed in a locked facility with restricted access.

All data are stored on the study-specific REDCap database hosted at UW. This includes survey/assessment data, contact information for participants, audio and video recordings, transcripts, and interview summaries. Interview data (e.g., audio and video recordings, transcripts, and interview summaries) may also be stored on an internal OneDrive (hosted by UW) specific to the UWAC research team, and will be reconciled to REDCap at least quartlery by the study team.

10 RISK / BENEFIT ASSESSMENT

10.1 Anticipated risks. Describe the reasonably foreseeable risks of harm, discomforts, and hazards to the subjects and others of the research procedures. For each harm, discomfort, or hazard:

- Describe the magnitude, probability, duration, and/or reversibility of the harm, discomfort, or hazard, AND
- Describe how you will manage or reduce the risks. Do not describe data security protections here, these are already described in Question 9.6.

- *Consider possible physical, psychological, social, legal, and economic harms, including possible negative effects on financial standing, employability, insurability, educational advancement or reputation. For example, a breach of confidentiality might have these effects.*
- *Examples of "others": embryo, fetus, or nursing child; family members; a specific group.*
- *Do not include the risks of non-research procedures that are already being performed.*
- *If the study design specifies that subjects will be assigned to a specific condition or intervention, then the condition or intervention is a research procedure - even if it is a standard of care.*
- *Examples of mitigation strategies: inclusion/exclusion criteria; applying appropriate data security measures to prevent unauthorized access to individually identifiable data; coding data; taking blood samples to monitor something that indicates drug toxicity.*
- *As with all questions on this application, you may refer to uploaded documents.*

The primary risk of participating in this proposed study is loss of confidentiality due to the inadvertent release of sensitive information. Another potential risk is respondent burden during the online research surveys and Zoom interviews for both clinician and patient participants. Based on our prior use of the survey instruments and qualitative interviews, we do not expect the assessments to present substantial burden to respondents. Online surveys will take no more than 20 minutes and Zoom interviews will take no more than 60 minutes. If respondents become fatigued or distressed during their assessment, they can complete it later or choose not to complete it. Based on the prior experience with similar studies examining depressive symptoms, we believe that the instances of participants becoming emotionally distressed due to the survey process will be minimal.

Clinician participants may experience personal distress while providing psychotherapy to depressed individuals. Consulting clinicians are also available on an as-needed basis for unanticipated consultation.

10.2 Reproductive risks. Are there any risks of the study procedures to men and women (who are subjects, or partner of subjects) related to pregnancy, fertility, lactation or effects on a fetus or neonate?

Examples: direct teratogenic effects; possible germline effects; effects on fertility; effects on a woman's ability to continue a pregnancy; effects on future pregnancies.

[x] **No** → If no go to question 10.3

[ ] **Yes** → If yes, answer the following questions:

a. Risks. Describe the magnitude, probability, duration and/or reversibility of the risks.

b. Steps to minimize risk. Describe the specific steps you will take to minimize the magnitude, probability, or duration of these risks.

Examples: inform the subjects about the risks and how to minimize them; require a pregnancy test before and during the study; require subjects to use contraception; advise subjects about banking of sperm and ova.

If you will require the use of contraception: describe the allowable methods and the time period when contraception must be used.

c. Pregnancy. Describe what you will do if a subject (or a subject's partner) becomes pregnant

For example; will you require the subject to immediately notify you, so that you can discontinue or modify the study procedures, discuss the risks, and/or provide referrals or counseling?

10.3 Unforeseeable risks. Are there any research procedures that may have risks that are currently unforeseeable?

Example: using a drug that hasn't been used before in this subject population.

[ ] **No**
[x] **Yes** → If yes, identify the procedures.

It is possible, during treatment sessions, for patients to present with suicidal intentions. Clinicians will follow clinic and state policies for assessing, reporting and managing risk of harm.

10.4 Subjects who will be under regional or general anesthesiology. Will any research procedures occur while subjects-patients are under general or regional anesthesia, or during the 3 hours preceding general or regional anesthesia (supplied for non-research reasons)?

[x] **No**
[ ] **Yes** → If yes, check all the boxes that apply.

- [ ] Administration of any drug for research purposes
- [ ] Inserting an intra-venous (central or peripheral) or intra-arterial line for research purposes
- [ ] Obtaining samples of blood, urine, bone marrow or cerebrospinal fluid for research purposes
- [ ] Obtaining a research sample from tissue or organs that would not otherwise be removed during surgery
- [ ] Administration of a radio-isotope for research purposes**
- [ ] Implantation of an experimental device
- [ ] Other manipulations or procedures performed solely for research purposes (e.g., experimental liver dialysis, experimental brain stimulation)

If you checked any of the boxes:
You must provide the name and institutional affiliation of a physician anesthesiologist who is a member of your research team or who will serve as a safety consultant about the interactions between your research procedures and the general or regional anesthesia of the subject-patients. If your procedures will be performed at a UW Medicine facility or affiliate, the anesthesiologist must be a UW faculty member.

*** If you checked the box about radio-isotopes: you are responsible for informing in advance all appropriate clinical personnel (e.g., nurses, technicians, anesthesiologists, surgeons) about the administration and use of the radio-isotope, to ensure that any personal safety issues (e.g., pregnancy) can be appropriately addressed. This is a condition of IRB approval.*

10.5 Data and Safety Monitoring. A Data and Safety Monitoring Plan (DSMP) is required for clinical trials (as defined by NIH). If required for your research, upload your DSMP to the **Supporting Documents** SmartForm in ***Zipline***. If it is embedded in another document you are uploading (for example, a Study Protocol, use the text box below to name the document that has the DSMP.

DSMP is uploaded to the Supporting Documents SmartForm

10.6 Un-blinding. If this is a double-blinded or single-blinded study in which the participant and/or you do not know the group to which the participant is assigned: describe the circumstances under which un-blinding would be necessary, and to whom the un-blinded information would be provided.

N/A

10.7 Withdrawal of participants. If applicable, describe the anticipated circumstances under which participants will be withdrawn from the research without their consent. Also, describe any procedures for orderly withdrawal of a participant, regardless of the reason, including whether it will involve partial withdrawal from procedures and any intervention but continued data collection or long-term follow-up.

The study researcher may stop a participant from taking part in this study at any time if he or she believes it is in the participant's best interest, or if the study is stopped. Should a subject become acutely suicidal and require hospitalization or more specialized treatment, they will be withdrawn from the study. Information concerning study withdrawal is included the consent form.

10.8 Anticipated direct benefits to participants. If there are any direct research-related benefits that some or all individual participants are likely to experience from taking part in the research, describe them below:

Do not include benefits to society or others, and do not include subject payment (if any). Examples: medical benefits such as laboratory tests (if subjects receive the results); psychological resources made available to participants; training or education that is provided.

Patient participants may experience an improvement in their depressive symptoms. Clinician participants will receive training and possibly certification in BA psychotherapy.

10.9 Individual subjects findings.

a. Is it likely that your research will unintentionally discover a previously unknown condition such as a disease, suicidal intentions, or genetic predisposition?

☐ **No**
☒ **Yes** → If yes, explain whether and how you would share the information with the subject.

From the consent form:
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 patient indicates that they have plans to harm themselves or others. These instances represent exceptions to confidentiality for participation in this research study. Organizations that may look at and/or copy your research records for research, quality assurance, and data analysis include:

- The University of Washington
- The National Institute for Mental Health (NIMH)

b. Do you plan to share the individual results of any of your study procedures or findings with the subjects – such as genetic test results, laboratory tests, etc.?

You should answer YES if your consent form says anything about sharing individual information with subjects.

☒ **No**
☐ **Yes** → If yes, complete and upload the **SUPPLEMENT: Participant Results Sharing** to the **Supporting Documents** SmartForm of ***Zipline***

10.10 Commercial products or patents. Is it possible that a commercial product or patent could result from this study?

☒ **No**
☐ **Yes** → If yes, describe whether subjects might receive any remuneration/compensation and, if yes, how the amount will be determined.

11 ECONOMIC BURDEN TO PARTICIPANTS

11.1 Financial responsibility for research-related injuries. Answer this question only if the lead researcher is not a UW student, staff member, or faculty member whose primary paid appointment is at the UW.

Describe who will be financially responsible for research-related injuries experienced by subjects, and any limitations. Describe the process (if any) by which participants may obtain treatment/compensation.

N/A

11.2 Costs to subjects. Describe any research-related costs for which subjects and/or their health insurance may be responsible (examples might include: CT scan required for research eligibility screening; co-pays; surgical costs when a subject is randomized to a specific procedure; cost of a device; travel and parking expenses that will not be reimbursed).

N/A

11.3 Reimbursement for costs. Describe any costs to subjects that will be reimbursed (such as travel expenses).

N/A.

12 RESOURCES

12.1 Faculty Advisor. (For researchers who are students, fellows, or post-docs.) Provide the following information about your faculty advisor.

- Advisor's name
- Your relationship with your advisor (for example: graduate advisor; course instructor)
- Your plans for communication/consultation with your advisor about progress, problems, and changes.

N/A

12.2 Study team communication. Describe how you will ensure that each study team member is adequately trained and informed about the research procedures and requirements (including any changes) as well as their research-related duties and functions.

☐ **There is no study team.**

The study team and staff are seasoned researchers from the University of Washington and Stanford University. We will work with our collaborators via protocol meetings, and study kick-off to ensure staff are trained and comfortable in their roles. We hold regular team/site meetings to discuss all study matters. All study staff have completed CITI Human Subjects Protections training and training in Good Clinical Practices. Study PIs and coordinators are available to handle questions or concerns.

13 OTHER APPROVALS, PERMISSIONS, and REGULATORY ISSUES

13.1 Other regulatory approvals. Identify any other regulatory approvals that are required for this research, by checking applicable boxes

Do not attach the approvals unless requested by the IRB.

Approval	Research for which this is required
☐ Radiation Safety	Procedures involving the use of radioactive materials or an ionizing radiation producing machine radiation, if they are conducted for research rather than clinical purposes. Approvals need to be attached to the Supporting Documents page in ***Zipline***.
☐ Institutional Biosafety	Procedures involving the transfer/administration of recombinant DNA, DNA/RNA derived from recombinant DNA, or synthetic DNA.
☐ RDRC	Procedures involving a radioactive drug or biological product that is not approved by the FDA for the research purpose and that is being used without an IND, for basic science research (not to determine safety and effectiveness, or for immediate therapeutic or diagnostic purposes).
☐ ESCRO	Procedures involving the use of some types of human embryonic stem cells.

13.2 Approvals and permissions. Identify any other approvals or permissions that will be obtained. For example: from a school, external site/organization, funding agency, employee union, UW Medicine clinical unit.

Do not attach the approvals and permissions unless requested by the IRB.

N/A

13.3 Financial Conflict of Interest. Does any member of the team have a Financial Conflict of Interest (FCOI) in this research, as defined by UW policy GIM 10?

[x] **No**

[ ] **Yes** → If yes, upload the Conflict Management Plan for every team member who has a FCOI with respect to this research, to the **Supporting Documents** page of ***Zipline***. If it is not yet available, use the text box to describe whether the Significant Financial Interest has been disclosed already to the UW Office of Research.

PROJECT SUMMARY. Evidence-based psychosocial interventions are rarely used in part because of their design complexity. Although many implementation frameworks do address the importance of EBPI characteristics, adapting and modifying EBPIs to enhance usability has not been a focus. User-centered design (UCD) approaches, which have been successful in creating hardware and software tools that are accessible and compelling to use, have the potential to modify EBPIs so that they are accessible and compelling to clinicians. We hypothesize that UCD driven modifications to EBPI usability (target mechanism) will result in enhanced clinician ability to deliver EBPI elements competently, and that better competence results in better patient reported outcomes. We will modify Behavioral Activation (BA), an EBPI often used in primary care, to function as a Task Sharing model between clinicians and care managers. Our specific aims are to (1) identify usability problems clinicians and care managers encounter with BA (2) create a clinician- and care manager-driven modification of BA and (3) compare the modified Task Sharing version of BA to usual care on usability, clinician competence, and patient reported outcomes.

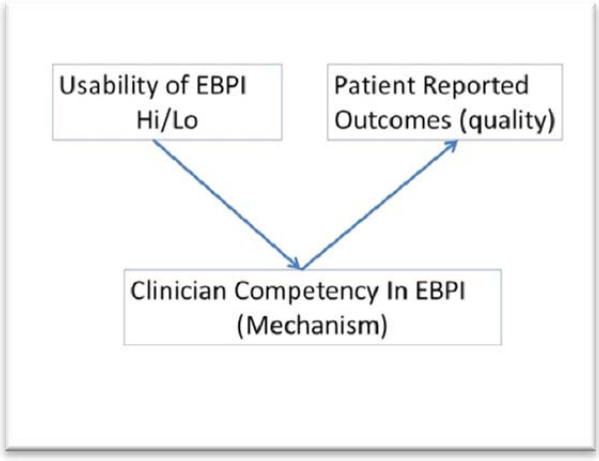
SPECIFIC AIMS. High quality delivery of evidence-based psychosocial interventions (EBPIs) in primary care medicine is a function of many variables, including clinician training (UWAC Study 1) and ready access to EBPI decision support (UWAC Study 3)[1-3]. Importantly, quality is also driven by the clinician's ability to implement the therapeutic elements of EBPIs to fidelity and with competence[4,5]. Even when clinicians undergo rigorous training, and find the intervention components useful in care, clinicians significantly drift from the original protocol[6,7] because the processes, structure and elements of care frequently clash with clinician productivity and the shifting needs of the patient populations they serve[8]. Clinicians in low resource settings like federally qualified health centers (FQHCs) report that while elements of EBPIs are important, their design is cumbersome, complex, overwhelming, inflexible, and minimize the nonspecific factors clinicians feel are crucial for quality delivery of care.[3,8,9]. In short, EBPIs demonstrate low usability (i.e., the extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use[10]. Although many implementation science (IS) frameworks do address the importance of EBPI characteristics, adapting and modifying EBPIs to enhance usability has not been a focus[9]. User-centered design (UCD) approaches, which have been successful in creating hardware and software tools that are accessible and compelling to use, have the potential to modify EBPIs so that they are accessible and compelling to clinicians. We hypothesize that UCD-driven modifications to EBPI usability will result in enhanced clinician ability to deliver EBPI elements competently (target), and that better competence results in better patient-reported outcomes (mediation, Fig. 1). We will modify Behavioral Activation (BA) because it is the EBPI often used in primary care settings. To prepare for a larger trial to test hypotheses regarding the impact of EBPI usability on uptake, fidelity and competence, the aims of this R34 are:

Aim 1: Discover Phase (3 months). Using iterative and participatory methods, we will interview 10 clinicians from FHQCs affiliated with the WWAMI region Practice Research Network (WPRN, a collaborative group of primary care practices through the states of Washington, Wyoming, Alaska, Montana and Idaho to facilitate innovative community-based research), and observe them using PST-PC to identify usability challenges. Contribution to the Center: Data from this phase will be used to inform the Typology of EBPI Targets.

Aim 2: Design/Build Phase (6 months) After identification of potential targets, the research team will work with the original 10 clinicians to engage in a rapid cycle of iterative prototype development and testing (e.g., storyboarding, paper prototypes) of BA modifications. The build of these modifications will include the development of intervention prototypes for user testing and refinement with input from these care managers. Contribution to the Center: Data from this phase will be used to inform the Matrix of EBPI Modifications.

Aim 3: **Test Phase (15 months).** We will test and compare the BA modification (Task Sharing) to usual care in a small non-randomized trial. We will assign all provider teams (therapist & care manager(s)) in the clinic to use Task Sharing with their patients. We will then compare patient outcomes for those receiving Task Sharing vs. patients receiving usual clinic care. H1: Modifications developed in the Design/Build phase for targets identified in the Discover Phase will result in better usability (System Usability and User Burden Scales) compared to usual care. H2: Task Sharing will be more effective than usual care on improving clinical outcomes of functional disability (Sheehan Disability Scale [SDS]), change in depression symptoms over time (PHQ-9 total score), and change in anxiety symptoms over time (GAD-7 total score).

This study directly addresses IOM report recommendation 3-1: conduct research on psychosocial intervention elements and NIMH SP 4.1 Improve efficiency and effectiveness of existing mental health services.



SIGNIFICANCE

1. Depression is a ubiquitous yet treatable illness in low-resourced populations. Depression is *the leading cause of disability in the US and worldwide*, affecting 17% of Americans (approximately 22 million people) across all age and ethnic and racial groups.[12-15] Depression and anxiety is also associated with *excess mortality*.[16] Psychosocial interventions are effective in the treatment of depression,[17-23] and are the preferred treatments for many people suffering from these disorders, particularly ethnic minority populations, and those living in rural areas.[24-32].[33-38] Effect sizes of EBPIs are moderately large across adult age groups (Cohen's *d* = .81 in older adults and .78 in younger adults),[39] with negligible differences compared to antidepressant medications (another effective depression intervention).[40,41]. Behavioral Activation (BA) is a core component of **Problem-Solving Treatment for Primary Care** (PST-PC[11]), an example of an EBPI that is designed specifically for primary care medicine and is one of the most effective and among the most widely used psychotherapies for mild to moderate depression in primary care settings.[42-45] . PST-PC has been studied in over *100 randomized clinical trials* around the globe, dating as far back as 1986.[46] It has been translated into Spanish and Chinese,[47,48] and studied in all age groups,[49,50] from children to older adults. PST-PC has been found to be effective in primary care settings[45] and with underrepresented populations,[51] and is as good as other evidence-based psychotherapies (e.g., CBT),[40] more effective than usual care psychotherapy,[45] and has lower drop-out rates than other psychotherapies.[52]

2. Few primary care patients have access to EBPIs, despite EBPI effectiveness and patient preferences[53,54]. Access to EBPIs is complicated by a number of cultural, geographical, system and provider factors (e.g., stigma, travel distance, variable employment, waiting lists, limited workforce). While there have been successful attempts to overcome access barriers[55-66], research has shown that increasing access to mental health care does not always result in positive outcomes or guarantee quality of care[67-69]. Poor quality of care is driven by many factors, but most importantly by clinician adoption and use of EBPIs. To illustrate the point on the importance of clinician adoption of EBPIs in quality of care, we compare two large-scale studies that were focused on increasing access to depression treatment in older adults seen in primary care. In the first study[70] of over 1800 older adults, clinicians underwent rigorous training and were regularly supervised in the delivery of PST-PC. In the second study[71] of over 2000 older adults, clinicians were offered the opportunity to be trained in EBPIs (PST-PC, cognitive behavioral therapy [CBT]), but clinicians were not mandated to use any of these EBPIs, apart from a Brief Treatment for Alcohol Misuse (which was mandated). In the first study, not only was there better access to EBPIs among low-income and minority adults, but participants had better clinical outcomes[72,73]. In the second study, access to care was also improved, but patient outcomes were not[67], except for patients receiving the mandated EBPI[74]. It is important to highlight here that mandates alone do not ensure greater access to EBPIs. Although clinicians in the first study were supported in the use of PST-PC, only 20% of participants were offered the EBPI, even though 50% of participants surveyed said they preferred psychosocial treatment over medications[75].

3. Reasons why clinicians do not use EBPIs. Several factors are associated with poor adoption of EBPIs, including insufficient leadership and support to use them, attitudes clinicians have about research-supported treatment, and the historic disconnect between intervention developers and their end users[9,76,77]. Recent research, however, has uncovered an important component of clinician adoption and use of EBPIs is intervention usability. In the context of EBPIs,[9] usability is a function of (1) learnability of the EBPI; (2) the time, effort and cost of using the EBPI; (3) memorability of the EBPI elements and ability to apply them with minimal guidance; (4) ease of recovery from misapplications of EBPI content; (5) reputation of the EBPI in terms of its acceptability and value compared to other interventions; (6) amount of cognitive load the EBPI places on the clinician, in the form of task structure and number of steps required to implement it in a given session and across sessions; and (7) flexibility of the EBPI to be implemented in different contexts. Qualitative research exploring the reasons for poor EBPI adoption among community clinicians has confirmed these seven usability challenges when implementing EBPIs in their settings. According to Chung et al[8], clinicians report feeling overwhelmed by the complexity of most EBPIs (learnability, memorability and cognitive load), report that the design and implementation of the EBPI often clashes with the need to be productive (time, effort and cost) as well as the need to address changing needs of their patients (flexibility), and that most EBPIs were designed for academic settings, not community practice (reputation). In a large-scale analysis of clinician attitudes toward different types of EBPIs pre- and post-training, clinician ratings of intervention appeal (e.g., "If I received training in a therapy or intervention that was new to me, I would adopt it if it 'made sense' to me.") trumped perceived burden and complexity in EBPI adoption[78].

4. User-centered design (UCD) as a solution to improving adoption and use of EBPIs. From the perspective of user-centered design fields, the challenges clinicians face in the use of EBPIs are symptoms of

a poorly designed tool. User-centered design (UCD) is a framework whereby usability, user characteristics, the user environment, tasks and workflow of the intervention are given extensive attention at each stage of the design (see Methods Core for more detailed explanation of the framework). The primary difference between UCD approaches and approaches typically used by intervention developers is that UCD modifies the intervention around clinician capabilities, how they want to work with patients, and what they need the intervention to do, rather than forcing the users to change their behavior to accommodate the intervention. The clinician becomes a driver and partner in the modification at each step of the process, including designing the interventions and objectives within the context they will use it, as well as helping to design the granular details of tasks, task organization, and task flow. UCD is a central process in our Discover, Design/Build and Test Framework (DDBT; see Methods Core). However, to ensure that modifications driven by UCD processes do not unintentionally eliminate the therapeutic elements of an EBPI, the intervention expert must also be involved in the process. The point of the DDBT framework (and the use of UCD methods) is not to create new interventions, but to make existing EBPI core elements more acceptable and easier to use.

The purpose of this study is to test whether modifications to BA created with UCD-based clinician input throughout the process will result in a more usable version of BA, whether better usability results in better fidelity and competency to BA elements, and whether usability will result in better patient outcomes through enhanced clinician ability to adhere to, and competently deliver, treatment (target mechanism of action) (Fig. 1).

5. Impact. Although the main goal of this pilot study is to prepare for a future RCT that will definitively answer pertinent questions about the usability of EBPIs relative to fidelity/competence to therapeutic elements and subsequently quality of care, the results from this pilot still have the potential to make an impact on implementation and intervention science. This study will be part of the larger Center mission to begin creating a Typology of EBPI Targets for future intervention modification and potentially novel psychosocial interventions. It will also serve to inform the Center mission of identifying best methodology for EBPI modification (Matrix of EBPI Modifications). Although our R34 is focused on BA, the principles and findings from this study have the potential to inform the modification of other EBPIs.

INNOVATION

The main innovation from this project will be the implementation of UCD methods to the modification of EBPIs. Although the field has been aware of the complexities involved in supporting the adoption, use, and fidelity to EBPIs in public sector settings, the field has yet to interrogate how EBPIs – as they are designed by scientists – interacts with frontline clinicians in real-world practice, and whether clinician-informed modifications will indeed impact adoption, use and fidelity to EBPI elements.

APPROACH

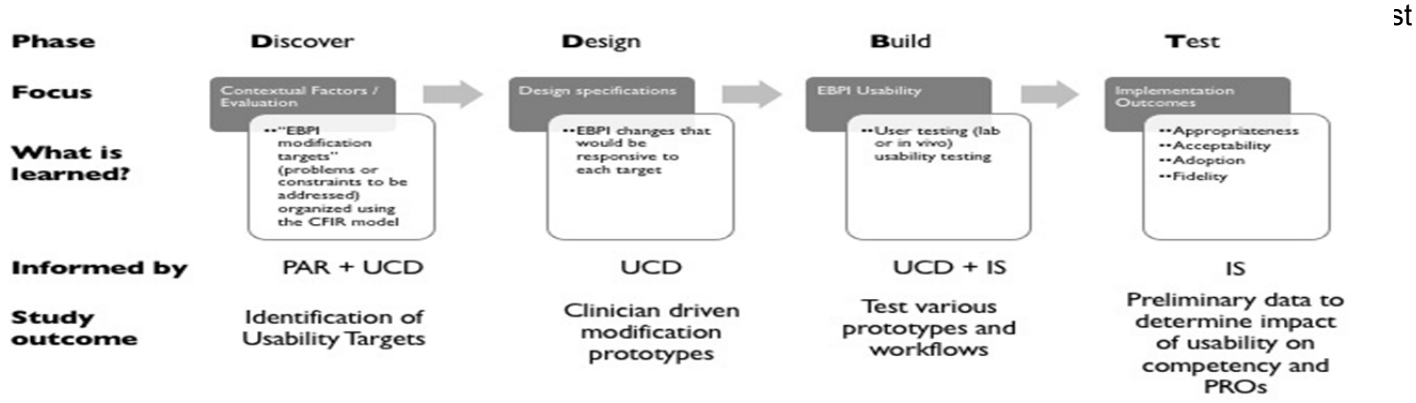
Team Expertise. This multidisciplinary team is comprised of experts in EBPIs (Areán, Kaysen), and Communications (Gonzalez). Drs. Hoeft (qualitative research) and Munson (UCD expert) will serve as our design/build incubator experts. Expertise in EBPIs is needed on the team to ensure that the integrity of therapeutic elements remain intact. Dr. Areán is an expert in PST-PC, of which BA is a core component. We anticipate, based on 15 years of working with clinicians in primary care medicine, that methods for addressing anxiety and trauma exposure will be a likely usability feature clinicians will identify. Dr. Kaysen is an expert in Cognitive Processing Therapy and Exposure Therapy. Communications expertise is needed for the development of intervention materials that are understandable and appealing to clinicians. Additionally, identification of key talking points that are appealing to clinicians and highlight the collaborative effort of the modification to PST requires expertise in communication methods. Dr. Gonzalez is an expert in the use of communications methods, including social media formats for raising health awareness in underserved communities. An innovation in her field will be the use of these methods for raising clinician awareness and subsequent adoption of EBPI elements.

Problem-Solving Therapy for Primary Care. PST-PC consists of up to 10 weekly sessions, with 6 sessions considered an adequate dose.[45,79-82] In the first session the clinician provides an overview of the therapy, helps the patient create a list of problems to work on, and then shows the consumer how to use the PST process. All problems, solutions and action plans are identified and developed by the consumer, making this a consumer-centered intervention. In this process, the consumer identifies a problem area (Step 1), picks and explores a specific problem (Step 2), sets goals for the week (Step 3), considers alternative methods for meeting goals (Step 4) and selects an action plan (Step 5). Between sessions, the consumer implements action plans (Step 6) and in the next session, evaluates the success of the plan (Step 7). The process is applied to another

problem, until consumers become competent in solving problems on their own (maximum 10 weeks). As patients learn to use this model on their own, clinicians switch to a supportive stance. We elected to modify BA, not only because of its presence in primary care medicine, but because is a core component of PST-PC, and clinicians trained in PST-PC show almost immediate drift from the protocol[83], which appears to be driven by clinician concerns about intervention fit and ability to complete the PST-PC protocol in the window of time they have with their client[7]
(see preliminary study below).

Preliminary Studies. Dr. Areán has been the lead PST-PC trainer for the UW AIMS Center (an implementation and training center for collaborative care) for 15 years. In uncovering the challenges in training and sustained use of PST-PC among clinicians, important usability problems with PST-PC have been highlighted, specifically: (1) too many steps in a typical session; (2) not enough time to "get to know" the patient/not enough time to get through the process of PST-PC in each session; (3) too tiring to deliver on days when clinicians see PST-PC patients back to back; (4) focusing on problems was not synergistic with clinic mandates to use strength-based interventions; (5) difficulty using PST-PC to address common problems, such as lack of motivation, affect regulation, profound pessimism, trauma exposure, and access to basic needs in the face of poverty (food, shelter, access to health care, safety); (6) insufficient support to know when adding other EBPI elements or eliminating PST-PC elements was appropriate or in violation of protocol; (7) over-insistence by PST-PC trainers to have clinicians structure sessions and use of forms; and (8) perception that PST-PC was developed for research settings.

Study Overview. To accomplish the aims of the study, this project will be broken down into 3 phases that are



Phase (Aim 3; see Fig.2). For phases 1 and 2, we will identify 15 representative clinicians working in FQHCs partnering with the AIMS Center and in the WWAMI region Practice and Research Network (WPRN). For phase 3, we will work with the Wyoming Family Practice Center in Casper, WY, a community health center that provides integrated mental health care to over 25,000 patients yearly (40% are on Medicaid or Medicare; see letter of support) to identify 6 representative clinicians and 30 patient participants, ≥18 years old with a PHQ9 of 10-20. The study will be conducted over a 2.5 year period during Y02 through Y04. Steps 1 and 2 will be conducted in the first 9 months of the study and Step 3 in the last 15 months (See timeline).

Phase 1/Aim 1: Discovery (3 months). The purpose of this phase is to uncover usability problems clinicians experience when implementing BA. Drs. Areán and Hoeft will be responsible for data collection and synthesis in this phase. As is detailed in the **Methods Core**, discovery data collection involves the identification of end-user needs (PAR process), contextual evaluation (IS process), and user testing (UCD process).

Clinician End Users. We will work with 10 PST-PC clinicians and 5 PST-PC naïve clinicians identified through the AIMS Center and through the WPRN. Previously certified clinicians need not be currently using PST-PC. The inclusion of untrained clinicians and previously certified clinicians who have abandoned PST-PC (or modified it for their use) is important to ensure we have a breadth of perspectives from different end-user types. Including naïve clinicians allows us to evaluate first impressions of PST-PC usability.

Identification of user needs. We will conduct semi-structured interviews with the 10 clinicians who were certified in PST-PC previously, using Zoom.com technology. The interview will interrogate challenges they face in implementing PST-PC that are related to (1) workflow, (2) patients they see, (3) PST-PC processes, and (4) any other challenges they may face. Questions will be tied to the seven common problems with usability (see Background Part 3) and CFIR constructs related to Intervention and Individual Characteristics (see **Methods**

Core). We will also ask about modifications they have made to the intervention to accommodate those challenges, and if they are no longer using PST, why. This interview will also cover PAR driven questions about what they value about their work with their patients, what they feel is missing when using PST-PC, and suggestions for how it could be improved, given their clinical context and patient population. Each clinician participant will be reimbursed $50.00 for their time.

Contextual evaluation. We will conduct two WPRN site visits. We will shadow a clinician over the course of his or her day and make further observations about the clinician's workflow, to gather more impressions about how PST-PC could be modified to fit into the clinicians' daily routine, and observations of clinic and environment. Observations will be guided by the Consolidated Framework for Implementation Research (CFIR; see **Methods Core**), and will include observations of inner and outer settings and how they potentially influence the use of PST-PC.

User-Testing. All 15 of our clinicians will participate in BA training; for previously trained clinicians, the training will serve as a refresher of BA principles, and for BA naïve clinicians, they will be introduced to basic and core elements of BA. After the training, we will conduct a focus group with the naïve clinicians to ask their general impressions of BA and any concerns or thoughts they have about materials, the language in the materials, and how they think BA may or may not influence their workflow. Each clinician will then participate in a "think-aloud" exercise where the clinician uses BA with Drs. Areán and Kaysen, who will play standardized simulated cases typically used for BA training. However, unlike simulated case training, where trainers provide corrective feedback, they will be instructed to verbalize what they are experiencing and thinking while engaged in the role play. As an example, a clinician who is struggling with the BA form may give impressions about what it is like to have their attention split between the form and the patient. The training and think-aloud exercise will be conducted on-line through the UWAC data portal and Zoom (see **Methods Core**). Think-aloud interaction will be recorded using Zoom.

Data Synthesis and Confirmation of Findings. Recordings of interviews will be transcribed and entered into Atlas.ti, a qualitative data analysis and research software, to organize data for coding by multiple coders. A codebook will be created to describe data codes and meaning of codes. Interviews will be coded by the qualitative interviewer and Dr. Areán. Coding will be grounded in the CFIR constructs. As interviews are coded, the results will be reviewed by the coders to discuss findings, resolve discrepancies, and identify any new themes. The final product from this data synthesis will be an **as-Is workflow diagram** that describes the usability challenges with BA. As-is workflow diagrams allow for a pictorial representation of BA and identifies where bottlenecks, duplication of effort, and potential burdens lie. We will share these diagrams with the clinicians we interviewed for confirmation of accuracy of their experience using BA. After the as-is diagrams are completed, we will then share them with the Community Practice Board (CPB) members (**see Admin Core**) for further information and confirmation. Confirmation and input from a larger number of representative clinicians may enhance the generalizability of our modification. Finally, data collected on the implementation challenges of BA through these sources will be given to the Methods Core directors for use in the development of the Typology of EBPI Targets**.**

Phase 2/Aim 2 Design and Build Phase (6 months). The next step in the process will be to create initial prototypes of modifications to BA, based on the findings in the *Discover* phase. The Methods Core designer, working in consultation with Drs. Munson and Gonzalez, will create 3-5 initial prototypes. The process, described in the **Methods Core**, involves the same clinicians who participated in the *Discover* phase and has them work with the designer to create initial prototypes. In this context, prototypes will include work flow diagrams and storyboards representing the modification, materials and manuals. These prototypes will then be shared in our remote prototyping portal for clinicians to interact with and give further feedback for additional modification. Although we are not anticipating technology-based solutions, some modifications may include the use of technology to support intervention usability. We will iteratively improve designs through usability testing (e.g., with 5 participants per design iteration). For example, if the *Discover* phase finds that the BA process needs to include no more than 3 steps, they following iterative design process using the remote prototyping portal would occur as follows:

1. The design team will create 3 different ways BA steps could be condensed. These different processes will be depicted in electronic story boards.
2. The story boards will be shown to the clinicians with accompanying intervention materials (manuals etc). During the presentation, clinicians will be asked for their assessment of perceived usability (easy

of learning, potential for use in clinic, perceived burden, acceptability) for each iteration. These assessments will be both quantitative (System Usability Scale) and qualitative (Think Aloud). Quantitative data will be recorded on UWAC data portal, as will audio recordings of the Think Aloud Assessment.

3. Designers will then create a new version of the modification using information from all three storyboard assessments. The next version will be assessed using the processes described in step 2. This will continue until we reach a SUS scale score of .80.

A final prototype will undergo initial feasibility evaluation in pilot field deployments with each clinician using the prototype with one patient. Once we have completed the redesign of BA so that it (1) meets needs of its clinicians and patients (i.e., is useful), and (2) is easy to use and understand (i.e., is usable), we will move to the *Test* phase of this study.

Phase 3/Aim 3: Test phase (15 months). We will conduct a pilot study comparing the modified version of BA to usual care. Therapists will be randomized to either modified BA, and will use their assigned intervention with 5 patients.

Patient eligibility. Patient participants will be identified through each clinic's electronic health record. Participants must be 18 years old or older, suffering from mild to moderate depression. The site champion will identify potential participants from their electronic health records (EHRs) who score between 10 and 20 on the PHQ-9 and will contact potentially eligible patients to conduct a preliminary screening for eligibility, provide a brief description of the study and obtain informed consent.

Clinician training in modified BA. Dr. Areán and Dr. Kaysen will train clinicians in the modified BA. We will follow the protocol developed by the AIMS Center, which includes training in basic brief treatment skills, therapeutic elements of the intervention and therapy process. This is followed by simulated case training.

Clinician data collection. Two types of data will be collected, clinician assessment of intervention usability, and clinician ability to learn the intervention and maintain competency. To measure **intervention usability**, clinicians will complete the ALFA-Q Acceptability Scale, the User Burden Scale and the System Usability Scale, which are core measures for this Center (see **Methods Core** for description of scales). **Learnability** of the interventions will be measured in number of role plays needed to reach competency during training. To measure **sustained competency,** clinicians will collect audio recordings of patient sessions for review by experts. Drs. Areán and Kaysen will conduct these reviews using each intervention's adherence scale. Sustained competency will defined by (1) time to first session rated < 4 ("good") and (2) number of sessions rated < 4 ("good") once certified. Clinicians will not be given feedback on session performance.

Patient data collection. We will use the UWAC data portal, which will be based on the UWAC Data portal[84] designed specifically for research on mobile depression interventions to confirm eligibility, complete the consent process, and conduct baseline and outcomes assessment (see Methods Core for further details.) For qualitative interviews, we will use Zoom.com, a secure teleconferencing service with HIPAA-compliant data security features and the capacity to record sessions. Patients can participate either by phone or video. Participants will receive $20 for completing each of 2 (baseline and post-treatment) assessments. Patient data will be collected before treatment initiation and after treatment ends. Patients will complete a demographic survey to determine gender, age, race/ethnicity, income categories, and educational level. Patients will complete a series of brief clinical measures to determine the presence of a depressive disorder and if there are any important comorbidities. The *Sheehan Disability Scale(SDS)* [85,86] is a brief analog scale measuring functioning in work, social, and health domains, using visual-spatial, numeric and verbal anchors. The scale has been validated in medical and psychiatric populations with a variety of psychiatric diagnoses.[85,86]**.** The *9-item Patient Health Questionnaire*[87] *(*PHQ-9) consists of 9 DSM depression symptoms and one disability item. It has been found to have excellent sensitivity to change over time (sensitivity = .88, sensitivity = .80).[88]

Data analysis. Aim 3 focuses on pilot feasibility data to inform a larger (future) clinical trial comparing modified BA to usual care. Thus, analyses do not focus on hypothesis-driven inferential statistics but rather on descriptive statistics, graphical summaries, and basic effect sizes. **H1: Usability**. Differences in clinician-reported usability

between modified BA and usual care will be plotted using a dotplot and tested using a *t*-test using the SUS and UBS as dependent variables. **H2: Fidelity/Competence:** A similar strategy (dotplot, *t*-test) will be used with number of hours to reach certification. Number of sessions with fidelity scores <4 ("good") will be summarized as proportions, both by clinician and by treatment. Between-treatment differences will be tested with a 2-sample proportion test. (Future analyses with larger sample size will use a generalized linear mixed model approach to account for the nested data[89,90].) H3: **Patient Reported Outcomes.** Histograms and kernel density estimates will be plotted by treatment condition to explore differences on depression outcomes (PHQ-9 total score) and overall daily functioning (SDS). Descriptive statistics (*M* and *SD*) will also be examined by clinician and by treatment, using Cohen's *d* as an effect size summary. A *t*-test will be used to examine treatment differences in patient outcomes. Of ultimate interest is whether the modified treatment has its impact on patient outcomes through enhanced usability and clinician fidelity. We will use graphical summaries of the data to explore the relationships that are consistent with mediation (e.g., correlation of usability with patient outcomes [b pathway], and treatment differences on patient outcomes with fidelity partialed out [c' pathway']). The primary focus here is whether the data and relationships appear consistent with mediation, as opposed to a formal test, which will be dramatically under-powered.

Power and Sample Size. Sample sizes for Aims 1 and 2 were based on estimates from the UCD literature on necessary number of participants to capture critical design information, where the recommendation is 5-10 end users. As Aim 3 is focused on gathering information (feasibility, recruitment and retention rates, response and attrition rates, etc.) for a future R01 application, the sample size was set primarily for practical reasons and used estimated effect sizes, rather than being driven by hypothesis testing.

Timeline. This study will begin in Y02 of the Center. The *Discover* phase activities will be completed in 3 months. The *Design/Build* phase will be completed in 6 months. The *Test* phase will take a total of 12 months, of which identification and training of clinicians in the two interventions will take approximately 2 months, and patient recruitment and data collection will take 10 months. Data analysis will take 3 months.

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