PracticeGround: Transforming Training and Delivery of Mental Health EBPs

NCT02314624 | Patient Informed Consent Form | October 18, 2017

National Institute of Mental Health, Rockville, Maryland, United States

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	PracticeGround: Transforming Training and Delivery of Mental Health EBPs

This consent form contains important information to help you decide whether to participate in a research study.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

Evidence-Based Practice Institute, LLC
CONSENT TO PARTICIPATE IN RESEARCH
[RCT OMNIBUS CONSENT – Patient Version]

1. General Information

TITLE:	PracticeGround: Transforming Training and Delivery of Mental Health EBPs
PROTOCOL NO.:	2 R44 MH093993-02A1
SPONSOR:	National Institute of Mental Health Rockville, Maryland United States
PRINCIPAL INVESTIGATOR:	Linda Dimeff, PhD 3303 South Irving Street Seattle, Washington 98144
CO-INVESTIGATOR:	Kelly Koerner, Ph.D. 3303 South Irving Street Seattle, Washington 98144
SITE(S):	Evidence-Based Practice Institute, LLC 3303 South Irving Street Seattle, Washington 98144 United States
STUDY-RELATED PHONE NUMBER(S):	Linda Dimeff, PhD Principal Investigator (206) 384-7371 Angela Kelley Brimer, MS Research Coordinator (206) 455-7934

2. Study Description

You are being invited to participate in a 12-week research study. Your participation is completely voluntary. You do not have to participate if you do not want to. Your decision to participate may affect whether and when you receive treatment at the clinic and/or by your treatment provider. You are encouraged to speak with your clinic or therapist about this.

Study description:
The purpose of this research project is to learn whether computers can be used to help therapists treat patients experiencing depression. We are particularly interested in whether it is helpful in reducing a patient's depression and how patients feel about the use of computers to aid in their care.

This study compares two different approaches in the treatment of depression. One approach is called "standard care". This approach involves a therapist applying their usual treatment strategies and approach to treating your depression. In most cases, computers are not used. The other treatment condition is called the "computer-assisted therapy" (CAT). The CAT condition involves the use of a new computer tool called "WILLOW" that was designed to help therapists deliver evidence-based treatment approaches for specific mental health problems. For depressed patients, WILLOW includes an evidence-based cognitive behavioral treatment called Behavioral Activation as well as other tools to track your treatment progress as you proceed. WILLOW is designed to aid therapists in applying procedures that may be new to them. Your therapist may be new to using a computer during therapy and may just be learning Behavioral Activation. The ultimate goal of this research is to determine whether use of software tools help improve treatment outcomes. Your therapist or a therapist you may be assigned to has agreed to participate in this research study and has been assigned to either the standard care condition or the CAT condition. If you agree to participate in this study, the treatment approach you will receive will depend on which approach your therapist is assigned to. You will not get to choose your treatment condition.

If you choose to participate, you will be asked to meet with a member of our research staff over the phone at four different time points over the 12-week research period. These meetings will occur at the start of treatment (“baseline”), then again after 4 weeks, 8 weeks, and finally at 12 weeks. Each meeting will take between 45 and 60 minutes to complete and will involve answering questions about your mood, your satisfaction with the treatment you are receiving, and specific ways in which your therapist is helping you. Your baseline meeting will include two parts: the first before your first study therapy session, and the second right after your first study therapy session. We anticipate the first part of this meeting will take approximately 45 minutes and the second part about 5-10 minutes.

All meetings will take place over the phone and online. Beginning in Week 4, each remaining meeting will include a short (10-15 minute) telephone interview with a member of our research team. In the interview, we will ask for a description of the therapeutic approaches and strategies used by your therapist. The information you provide during your interview and while completing the surveys will be used for research purposes only; it will <u>not</u> be shared with your therapist or treatment team. Participation in this study should not impact any other aspects of your treatment. Involvement in this research project is separate from your involvement in therapy. This means that if you choose to end your treatment, you can still participate in the research study for the 12 weeks. Also, should you choose to end your involvement in the research, this may not impact your treatment. Additionally, while the research lasts for 12 weeks, this does not mean that your engagement at your clinic will terminate in 12 weeks. Because the research procedures are conducted separately from the clinic itself, we encourage you to talk with your therapist or another representative of the clinic about what you can expect following completion of this 12-week research study.

If you have any additional questions after reading through this form, you may call 206-455-7934 to speak with Evidence-Based Practice Institute research staff.

3. Study Procedures

What will I be asked to do if I participate in the study?

1. You have been referred to this study because you have been identified as someone who has low mood and who struggles with depression. For that reason, should you choose to participate in this research, your therapist will engage in a therapy for your depression. Research therapists have been randomly assigned to one of the two conditions and you will be assigned to a research therapist who will provide either standard treatment or computer-assisted therapy. If you are assigned to a therapist in the standard treatment condition, your therapist will treat your depression using his or her preferred method for treating depression. If you are assigned to a therapist in the computer-assisted therapy condition, your therapist will use a computer-assisted therapy tool (described below) with you to help deliver your care.

2. We will ask you to provide permission for our research staff to communicate with your therapist about your study participation, your progress in therapy, how you and your therapist are doing together, and specific therapeutic approaches your therapist is using in his or her work with you.

3. Involvement in this study does not require you to change your use of psychiatric medications; if you currently do not take psychiatric medications, we do not require that you take any as part of this study; if you are currently prescribed psychiatric medications by your treatment professional, we do not require that you limit or discontinue your use of those medications. The decision of whether to use psychiatric medications and which medications to use, if any, is left entirely up to you and your physician to decide.

4. You will be asked to complete four study meetings over the course of your participation in this study. You will be asked to complete a set of surveys online at the start of treatment ("baseline"), and then asked to complete a brief interview and a set of surveys online at four weeks, at eight weeks, and at twelve weeks. Each meeting will take between 45 and 60 minutes to complete and will be completed online and over the phone. Surveys will include questions about your mood, satisfaction with treatment, and specific ways in which your therapist is helping you with your depression. The phone interview with a member of our research team will be approximately 15 minutes in length. An example online survey question may include: "In the past two weeks, how often have you been bothered by any of the following problems? [Little interest or pleasure in doing things], [Feeling tired or having low energy]." Interview examples about your therapy may include: "Please describe a typical session you would have with your therapist", "What were the common ingredients of your sessions?"

   These meetings will be scheduled at a time that is most convenient for you. In the event that you are having difficulty completing your surveys at home, we may request that your therapist offer to provide assistance. This may include having you complete the surveys at his/her office.

5. As compensation for your time and potential inconvenience involved in completing the study procedures, you will receive $40 for completing each of your Week 4 and Week 8 interview and surveys, and $60 for completing your Week 12 interview and surveys, for a total of $140 if you complete all study procedures.

6. Each set of surveys you complete within one week of the scheduled appointment will earn you an additional chance to win a tablet in a raffle that will occur at the end of the study. For example, if you complete all four sets of surveys on time, you will earn four chances to win the tablet in the raffle drawing. You also will receive and extra raffle ticket for completing the second part of the baseline surveys.

What Can You Expect if Your Therapist is Using WILLOW?

1. We expect that patients assigned to computer-assisted therapy condition will allow their therapists to use WILLOW, the new software program, as a primary means of treating their depression. This includes using the computer in session to learn and apply Behavioral Activation, an evidence-based treatment for depression, as well as other evidence-based behavioral treatment procedures included in WILLOW. WILLOW is designed to aid therapists in applying a treatment that is new to them. Your therapist may be new to using a computer during therapy and may just be learning Behavioral Activation.

2. WILLOW will encourage and may at times guide you and your therapist in the use of these specific scientifically validated treatments and procedures; this may be in the form of bullet points on a computer screen, video recordings, and/or worksheets and handouts. As a part of you and your therapist's use of WILLOW, your therapist may also use WILLOW to track agenda topics in session, as well as have you complete one or more brief (3 to 5 minute) questionnaires using WILLOW, to assess your mood (e.g., depression, anxiety, and stress) on a weekly basis. This will likely include: 1) having you complete one or more online measures of your mood on a weekly basis in WILLOW (please note that you would complete these measures <u>in addition</u> to the four sets of surveys you will be asked to complete as a part of the study), and 2) having your therapist use a computer (desktop, laptop or tablet) at different points during your treatment together.

   The first time you log into WILLOW you will be prompted to agree to the Terms of Use. Using WILLOW means you also agree to the Privacy Policy and Site Terms. These three documents can be found upon your first log in to WILLOW or by clicking links on the bottom of each page within WILLOW. They can also be found by clicking links on the bottom of each page within WILLOW. As described in these documents, WILLOW is designed to passively collect information such as your homework and measure assignments in WILLOW, how frequently you logged into WILLOW and may contain clinical outcome or progress monitoring data. This data may be used in our analysis to help explain and qualify our outcomes.

3. If you and your therapist decide to continue treatment after the end of the 12-week study, you may continue to use WILLOW, if you and your therapist like, for up to an additional six months. Ongoing use of WILLOW will only be available for those research participants who complete the twelve-week research study.

Your treatment and your participation in our study are separate activities. While the period of the research trial is 12 weeks, this does not mean you must quit treatment in 12 weeks or that you are obligated to continue for 12 weeks. You will still be encouraged to complete the surveys at each time point even if you are no longer receiving therapy by that time. If more treatment is indicated or requested after the 12-week period, it will be up to your participating clinic and/or therapist to determine whether to continue to provide treatment or to provide referrals. Referrals may include information for other treatment providers and clinics. We encourage you to have a conversation with your therapist and clinic now about what will happen after your study participation ends.

If you have any questions, please feel free to contact the research staff at the Evidence-Based Practice Institute at 206-455-7934.

4. Risks and Minimizing Risks

What risks will I face by participating in this study?
While therapy itself can be stressful and painful, participation in this study is not designed or expected to create any stress or discomfort. Nonetheless, some people may feel some degree of discomfort. For some, it may be uncomfortable answering questionnaires about their low mood. Others may feel uncomfortable speaking with a member of the research team about their treatment. Finally, there is a possibility that your confidentiality could be breached.

For those assigned to receive the computer-assisted therapy, there may be some additional risk. It is possible that using a computer with your therapist during therapy for the first time and early on during therapy may feel awkward and/ or uncomfortable. Another risk in the computer-assisted therapy condition is that the tool is designed to aid therapists in applying a treatment that is new to them. It is possible, therefore, that your therapist may be uncomfortable or unskillful in providing this new treatment. A final possible source of discomfort may be receiving an evidence-based treatment that targets your problems in a very particular, structured way, as opposed to the traditional, more unstructured talk-therapy.

You are under no obligation to participate in the study at all. To ensure that participation is indeed completely voluntary, we have informed clinic intake staff and your therapist on multiple occasions that participation in this study is and must remain completely voluntary. To lessen the anxiety that assessment procedures can cause, we have purposely designed the procedure to allow you to complete the assessments in the comfort of your own home. Additionally, you may refuse participation in any part of the study or not answer a specific question or questions during the research assessments without impacting your treatment or study involvement. You may also discontinue your participation in this study at any time, without in any way jeopardizing your treatment.

For those receiving computer-assisted therapy, we have provided you with very specific information about the computer-assisted therapy tool and about what to expect. To lessen the anxiety that using a computer-assisted therapy tool for the first time may cause, we have provided instruction to your therapist about how to walk you through the tool so you understand exactly how it is used. You are also free to provide feedback to your therapist about how you prefer that they use (or don't use) WILLOW with you. Additionally, you may refuse to use WILLOW altogether if you find that its use is causing you too much discomfort.

Finally, we will implement a number of strategies to guard against a breach of confidentiality. Specifically, information collected from you and your therapist will be coded with an identification number that is used to identify you. We will keep the link between your name and your identification number and all study data in a secured, locked file cabinet, on a secure, password-protected computer, and/or in a secured online data storage system.

Passively collected data about your usage of WILLOW is linked to your account email within the WILLOW database, which can then be connected back to your name. However, access to the WILLOW database is restricted to a few HIPAA-certified members of the WILLOW product and development team. All servers that transmit and store data within WILLOW are secure, HIPAA compliant, and encrypted.

You have the right to not answer a question or withdraw from the study for any reason at any time if you choose, without penalty. You may contact the Dr. Dimeff or Dr. Koerner at any time if you have any concerns or are feeling discomfort due to study participation.

5. Benefits

Will I receive any benefit from my participation in this study?
There is no direct benefit to you for participating in this study. One possible benefit is that you will be contributing to the body of scientific knowledge about different strategies to improve mental health outcomes and decrease human suffering.

Financial disclosure
The Principal Investigator, Linda Dimeff, PhD, and co-Investigator Kelly Koerner, PhD, own the company that will commercialize the software developed through this research, and will receive annual compensation. Please feel free to contact us with any further questions you might have about this matter. You may ask to see a Financial Conflict of Interest statement for both Drs. Dimeff and Koerner as part of this informed consent process.

Are participants paid or given anything for being in the study?
You will receive $40 for completing the Week 4 interview and surveys, $40 for completing the Week 8 interview and surveys, and $60 for completing the Week 12 interview and surveys. You will be paid a maximum of $140 for your participation in this 12-week study. You will be mailed a check within 30 days of completing each meeting. If receiving a check is difficult or provides hassle to you, we can instead send your compensation by email using Amazon gift cards or Target gift cards. Contact our research staff if you prefer this method of compensation.

You can also earn chances to receive a tablet computer by completing your assessments within one-week of the scheduled appointments. For example, if you complete all study meetings and surveys on time (within one week of the original scheduled appointment), you will receive five chances to win.

6. Study Costs

Will I be charged anything for participating in this study?
You will not be responsible for any of the costs associated with taking part in this study. You will, however, be responsible for costs associated with the therapy you obtain. This is because the research study is completely separate from your therapy. By now, your therapist has probably already discussed the fee for their professional services. If not, we would encourage you to speak directly with your therapist.

7. Confidentiality

What happens to the information collected?
You will be given an ID number and all the data you provide will be identified only with that ID number, not with your name or any other information that will identify you. This applies to both survey data collected outside of WILLOW and data we collect from WILLOW. WILLOW collects information passively as you and your therapist use it, including information about your homework and measure assignments, how frequently you logged into WILLOW, and therapy activities that you and your therapist completed. This information is linked to your account email within the WILLOW database, which can then be connected back to your name. However, access to the WILLOW database is restricted to a few HIPAA-certified members of the WILLOW product and development team. All servers that transmit and store data within WILLOW are secure, HIPAA compliant, and encrypted. In order to participate in the study, we will ask you to provide permission for us to use your data stored within WILLOW as part of this study.

We will also ask for your permission to exchange records with your treatment provider. Information we obtain from and disclose to your provider will only be related to the study (e.g., how many sessions did you attend? Did you and your provider use any form of technology to help with your treatment?), the theoretical orientation of the treatment you received from your therapist (e.g., eclectic therapy, client-centered therapy, cognitive-behavioral therapy, dialectical behavior therapy, etc.), and the specific kinds of therapeutic activities provided to you by your therapist (e.g., empty chair technique, use of homework, assigned specific worksheets to help you in therapy, gathered information about your progress, asked you to describe your dreams, assigned specify activities for you to do). The purpose or need for such disclosure is for coordination of treatment and research. The confidentiality of the requested information is protected by federal confidentiality laws and these laws prohibit making any further disclosure of this information without your specific written consent, or as otherwise permitted by state law. You can withdraw this consent at any time, but doing so excludes disclosures that have already been made based on initial consent. If you have questions or concerns about this or how this information will be used, please contact us right away or discuss with your provider.

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. When we present the research findings to others or publish our results in scientific journals or at scientific conferences, the findings will be presented without any identifying information on the participants. The Behavioral Health Research Collective (BHRC) IRB or appropriate federal agencies like the Office for Human Research Protections, Department of Health and Human Services (DHHS) agencies, or the study sponsor (the NIMH) may review your records. These agencies oversee this research to make sure we are conducting it ethically and safely. We are required to get your permission to release your study records for research or oversight purposes to these groups overseeing the study.

Study data, as well as the record linking your name to research data through the ID number, will be stored in a secured, locked file cabinet, on a secure, password-protected computer, and/ or in a secured online data storage system. The link between participant name and subject ID number will destroyed after six years. After the record is destroyed there will be no way to link your name to your responses. The data in the computer will be referenced by code number only and will be retained indefinitely.

8. Alternatives

Are there alternatives to participating in the study?
If you do not want to participate, you are free to not sign this consent form or withdraw from the study at any time.

9. Voluntary Participation and Withdrawal

What happens if I decide not to be in this study?
Your participation in this study is voluntary. You may decide not to participate or end your participation at any time. Your decision will not result in any penalty and will not impact your ability to receive therapy from your mental health provider.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

10. Questions

Who do I contact for questions about this study?
For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Linda Dimeff, PhD
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
(206) 384-7371

Kelly Koerner, PhD
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
(206) 265-2507

Who do I contact for questions about my rights or complaints about my participation as a research participant?
If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Behavioral Health Research Collective (BHRC) IRB
Attn: Chair: Travis L. Osborne, PhD
1200 5th Ave, Suite 800
Seattle WA, 98101
(206) 374-0109

BHRC IRB is a group of people who perform independent review of research. BHRC IRB will not be able to answer some study-specific questions, such as questions about appointment times.

However, you may contact BHRC IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

11. Signatures

Research Participant's Consent to Participate in Research:
In order to participate in the study, please provide your permission for us to exchange records with your treatment provider. Information we obtain from and disclose to your provider will only be related to the study. You can revoke this consent at any time, but doing so excludes disclosures that we have already made based on initial consent.

☐ **Consent to <u>obtain</u> records and information:** I authorize my therapist, who is also participating in this study, to release (disclose) my diagnostic and treatment records regarding my treatment while participating in the study to the team conducting the research (the Evidence-Based Practice Institute, LLC).

☐ **Consent to <u>disclose</u> records and information:** I authorize the Evidence-Based Practice Institute, LLC to release (disclose) study data (such as diagnostic summary, treatment plan, course of treatment, and information about study participation) to my therapist, who is also participating in this study, for the purpose of coordination of treatment and research.

We will also collect your study-related data from WILLOW. To participate in the study, please provide permission for us to use this data.

☐ **Consent to obtain data from WILLOW**: I authorize the Evidence-Based Practice Institute, LLC to access and use the data collected within WILLOW during my participation in the research study.

By signing the line below, I am voluntarily agreeing to take part in this study. I am aware that if I choose to take part in this study, I may withdraw at any time. I am not giving up any of my legal rights by signing this form. By signing and dating below, I indicate that I have read this entire consent form, including the risks and benefits, and have had all of my questions answered, and that I am 18 years of age or older. I freely consent to be in this research study.

I authorize the release of my records for research or regulatory purposes to the sponsor (NIMH), DHHS agencies, and BHRC IRB.

☐ **Overall Consent:** I consent to participate in this study.

_____ _____
Printed Name of Participant Date

_____
Signature

PracticeGround: Transforming Training and Delivery of Mental Health EBPs

NCT02314624 | Therapist Informed Consent Form & Addendum | October 18, 2017

National Institute of Mental Health, Rockville, Maryland, United States

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	PracticeGround: Transforming Training and Delivery of Mental Health EBPs

This consent form contains important information to help you decide whether to participate in a research study.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

<u>Please read this consent form carefully.</u>

Evidence-Based Practice Institute, LLC
CONSENT TO PARTICIPATE IN RESEARCH
[RCT OMNIBUS CONSENT – Therapist Version]

1. General Information

TITLE:	PracticeGround: Transforming Training and Delivery of Mental Health EBPs
PROTOCOL NO.:	2 R44 MH093993-02A1
SPONSOR:	National Institute of Mental Health Rockville, Maryland United States
PRINCIPAL INVESTIGATOR:	Linda Dimeff, PhD 3303 South Irving Street Seattle, Washington 98144
CO-INVESTIGATOR:	Kelly Koerner, PhD 3303 South Irving Street Seattle, Washington 98144
SITE(S):	Evidence-Based Practice Institute, LLC 3303 South Irving Street Seattle, Washington 98144 United States
STUDY-RELATED PHONE NUMBER(S):	Linda Dimeff, PhD Principal Investigator (206) 384-7371 Angela Kelley Brimer, MS Research Coordinator (206) 455-7934

2. Study Description

You are being invited to participate as a research therapist in a randomized controlled trial (RCT). Study participation as a research therapist is only available to those who are already employed or contracted at a specific clinic that has agreed to participate as a research site.

You have already expressed your provisional interest in serving as a research therapist in this study. The intent of this informed consent process is to ensure that you are fully informed of all relevant aspects of the project before deciding whether you wish to participate.

Your participation is completely voluntary. If you do not wish to participate, you are under no obligation to do so. Your decision will not impact in any way the terms of your employment at your mental health clinic or any other organization associated with this research project.

Study Description:
The purpose of this research is to test a computer-assisted therapy tool called WILLOW. We are particularly interested in learning how computers can be used to assist therapists to treat patients experiencing depression. We will also want to gather data from you and your patients about how they are progressing in treatment, how satisfied they are with the treatment they are receiving, and their clinical response to treatment for depression. A further goal for this study is to assess your wellbeing, use of progress monitoring with your patients, and your attitude towards progress monitoring.

This study involves two conditions: a computer-assisted therapy condition (i.e., WILLOW) and a standard therapy condition. Both conditions involve treating patients who are experiencing depression and who want treatment. You are expected to have no less than two and no more than five research patients over the course of this six-month study.

If You Are Randomly Assigned to Standard Therapy:
Research therapists assigned to the standard therapy condition will be expected to treat patients using their usual approach to treating persons with depression.

If You Are Randomly Assigned to WILLOW:
Therapists assigned to the Computer-Assisted Therapy condition will be expected to use WILLOW in each session with their assigned research patients. WILLOW is a HIPAA-compliant, software tool that incorporates clinical interventions and scientifically validated procedures to help improve patient outcomes. Additionally, WILLOW allows therapists and patients to track clinical outcomes. WILLOW also provides clinical support and feedback to therapists to improve their delivery of evidence-based procedures.

If you are assigned to the WILLOW condition, you will be asked to use WILLOW to track your patient's mood and other symptoms on a weekly basis using a brief three to five minute questionnaire. WILLOW may encourage you to use specific treatment procedures to address your patient's problems. These may include learning these procedures and treatment tasks, like Behavioral Activation for Depression, either with your patient or before they arrive for their session. You may be encouraged to use other WILLOW resources such as videos describing specific treatment procedures and/or handouts that correspond to the patient's problem.

To ensure your readiness to use WILLOW with depressed patients, therapists assigned to the WILLOW condition will have to first learn *how* to use WILLOW. Your training may include online tutorials and online or in-person trainings in WILLOW. We will also provide you a checklist of tasks and workflows in WILLOW for you to familiarize yourself with. We estimate that training in how to use WILLOW will not exceed three hours, but may be less for you. Once you believe you know how to use WILLOW easily and efficiently, we will establish a one-hour virtual online meeting with you to evaluate your use of WILLOW. You will be asked to demonstrate (verbally over the phone or online using screen sharing) that you know how perform various tasks in WILLOW that we consider to be essential to your ability to use the tool effectively with a patient. The tasks included in this "Feature Review" will match the study guide we provide you at the start of training. You may take the WILLOW Feature Review up to three times to demonstrate proficiency before becoming ineligible to participate in the research study. Research patients will only be assigned to you once you have reached proficiency. You will receive $100 after passing the test. If you participated in the pilot RCT study and already passed the Feature Review, you will not be required to take it again.

For All Research Therapists:
We will ask that before beginning study therapy sessions, you conduct your usual intake session to gather clinically relevant information about your patient and their goals for treatment. Research therapists will also be required to verify that a prospective research patient meets study criteria. Research therapists will be required to contact the EBPI study staff after this initial session to let EBPI know when your first study therapy session (most likely, your second meeting with the patient) is scheduled. The overall study is of limited duration (approximately six months total). The total study length for each therapist-patient dyad is twelve weeks; the count of twelve weeks will start upon your first study therapy session using WILLOW or your usual treatment methods after the Intake session.

After providing consent, you will be asked to complete a baseline assessment that asks about your beliefs and opinions about using computers in therapy, progress monitoring with patients, and your views on evidence-based treatments. This initial online baseline assessment will take approximately 30 minutes. For each research patient you treat, we will also ask you to complete an assessment at Week 4, Week 8, and Week 12 of your study therapy sessions. The Week 4 and Week 8 assessments will involve a brief (15 minute) phone interview with a member of the research team during which you will be asked questions about your experience in the study, how many sessions your patient has attended, what you do in a typical therapy session with your study patient, and what barriers (if any) that you have run into. You will then be asked to complete some survey measures online. We expect the total time required for you to complete these assessments will be approximately 45 minutes. You will receive $50 for each of these mid-study assessments. The final assessment at The Week 12 assessment will include a longer telephone interview (approximately 30 minutes) with a member of our research team to better understand your therapeutic approach used in treating your patient’s depression and the exact number of sessions your patient attended. You will then be asked to complete some survey measures online. The estimated total length of this Week 12 assessment is 60 minutes. You will receive $60 for your time.

While we define this as a twelve-week study for each of your research patients, you are not required by this study to limit or extend the length of treatment you provide. In some cases, you and your patient may choose to discontinue treatment before the study is over. In this case, we request that you continue to complete your study assessments even if you have discontinued treatment. In other cases, more treatment may be indicated or requested after the twelve-week study period. If so, it is up to you and/or

your clinic to determine whether to continue providing treatment or to instead provide referrals to other providers.

If you have any additional questions after reading through this form, you may call 206-455-7934 to speak with Evidence-Based Practice Institute research staff.

3. Study Procedures

If you agree to be in this study, the following will happen:

1. You will be assigned to one of two conditions: computer-assisted therapy (i.e., WILLOW) or standard therapy.

2. You will be asked to complete an initial baseline assessment shortly after agreeing to participate in this study. This online assessment will take approximately 30-45 minutes to complete. Items will assess your beliefs about using computers and other technology in therapy as well as your views about and use of evidence-based treatments and progress monitoring.

3. Over the duration of the study, you are expected to treat between two and five research patients. The rate that you receive research patients to treat and how many you treat will depend on both your own availability and the availability of research patients. The research patients will be recruited from patients already seeking treatment at your clinic. You will also be expected to learn how to use computer-assisted therapy, if you are assigned to that condition. Once you are eligible to approach your patients about participation in the study (after passing the Feature Review if assigned to the computer-assisted therapy condition or after study orientation for the standard therapy condition), you will be given six weeks to provide your first patient referral to the study. If after six weeks you are unable to find patients on your caseload interested and/or appropriate for this study, research staff will contact you to discuss ending your participation in the study or provide additional support if you would like to continue with your participation.

4. For each of your research patients, you will be asked to complete an assessment 4- and 8-weeks into your study therapy sessions. These 30-45-minute mid-study assessments will involve a brief phone interview that will assess your patient's progress, your use of WILLOW (if applicable), what you do in a typical therapy session with your study patient, and what barriers (if any) that you have experienced with respect to implementing aspects of this research. You will then be asked to complete some survey measures online that assess your current wellbeing, your rapport with the patient, what materials you've used in therapy sessions, and your views and use of evidence-based practices and progress monitoring. You will receive $50 for each mid-study assessment completed.

5. You will also be asked to complete a final assessment for each research patient, 12 weeks into your study therapy sessions. This 60-minute assessment will involve a telephone interview (approximately 30 minutes) to better understand your patient's progress and your overall approach to his/her care. We will also ask you to provide information about the exact number of sessions you conducted with your study patient. You will then be asked to complete some survey measures online (approximately 30 minutes) about the therapy you provided to your patient, your beliefs about use of technology in therapy, your views about and use of evidence-based practices and progress monitoring, and your opinion about your patient's progress in treatment. You will receive $60 for each post-study assessment you complete.

6. Throughout the 12-week trial, the research staff may contact you to ask whether you need any assistance with respect to your involvement in this research. This may be to assess your availability to take on a new research patient, your experience with approaching patients about this study, and/or to inquire about your use of WILLOW (if applicable). You will also always be able to reach out to us for support by emailing research@ebpi.org or calling at 206-455-7934

7. Involvement in this research does not restrict, limit, or require that your patient use anti-depressants or other medications for the treatment of their depression and other mental health problems. We will, however, ask for information about what medications have been prescribed to your patient during the study period and which medications your patient is taking at the time of the assessment.

8. You will earn a raffle ticket for each assessment that you complete within one week of the originally scheduled appointment time. These tickets will be entered into a drawing for a tablet at the end of the study.

9. Research therapists from both conditions who treat at least one study patient and complete all of their assessments will receive free access to WILLOW for 12 months following their final assessment.

For Therapists Assigned to WILLOW:

1. You will be asked to use WILLOW to help you treat your patients' depression. In order to do so, you will be required to learn how to use it. We will provide you with tutorial videos and other materials, as well as customer service support. Using WILLOW will likely include: selecting and assigning specific measures for your patient to fill out on a weekly or periodic basis to allow you to track their mood and other symptoms; using a computer (desktop, tablet, laptop) in session with your patient; using WILLOW to learn how to do the therapy tasks associated with delivering Behavioral Activation (either before you arrive to session and/or during session using a Just-in-Time Training tool); and assigning treatment-specific homework.

2. Before using WILLOW with a research patient, you will need to demonstrate your ability to proficiently use WILLOW. This mastery test or Feature Review will be conducted with a research staff member either over the phone or online using a screen sharing service. It is expected to take approximately one hour during which you will be asked to demonstrate your ability to easily perform core tasks using WILLOW. The tasks included in the Feature Review will match the study guide we will provide you at the start of training. If you are unable to perform a specific task, the research staff will show you how it is done and answer remaining questions you may have and you will need to schedule a re-take of the test. You may retake the test up to two more times before becoming ineligible to participate. You may only start using WILLOW with research patients once you have reached proficiency. You will receive $100 after passing the Feature Review. If you participated in the pilot RCT and already passed the Feature Review, you will not be required to take it again.

   As a user of WILLOW, you will be required to review and accept the conditions for use of WILLOW. The first time you log into WILLOW, you will be prompted to agree to the Terms of Use. Using WILLOW means you also agree to the Privacy Policy and Site Terms. These three documents can be found upon your first login to WILLOW or by clicking links on the bottom of each page within WILLOW. As described in these documents, WILLOW is designed to passively collect information on how it is being used. It will collect data on things like the number of patients with which you use the

software, the number of sessions for which it is used, what features of the tool were used, how frequently each was used, and may contain clinical outcome or progress monitoring data. This data may be used in our analysis to help explain our study outcomes. This data will continue to be collected, as it is with all users, if you choose to use WILLOW after your study participation is completed. Your de-identified data will be aggregated with the anonymous data of other users into a data repository for data analysis and clinical research to better understand behavioral health problems and improve behavioral health care.

3. WILLOW therapists are free to continue to use WILLOW with your research participants after their 12-week study trial for as long as you have access to the tool. WILLOW therapists may also choose to use WILLOW with non-research patients during and after the study for as long as you have access to the tool.

If you have any questions, please feel free to contact the research staff at the Evidence-Based Practice Institute at 206-455.7934.

4. Risks and Minimizing Risks

What risks will I face by participating in this study?
Participation in this study is not designed or expected to create any stress or discomfort. However, participation may cause a degree of stress or discomfort for some individuals. One possibility is that your supervisor may put pressure on you to participate in this study, thereby reducing your ability to make a free choice about whether or not to participate. For those assigned to the computer-assisted therapy condition, you may feel uncomfortable learning a new way of providing therapy, particularly when asked to use a computer during therapy sessions. Additionally, you may feel uncomfortable delivering a therapy you are learning while providing it. Another possible source of discomfort may be providing an evidence-based treatment that targets the patient's problems in a very particular, structured way, as opposed to the traditional, more unstructured talk therapy. Finally, there is a possibility that your confidentiality will be breached. These risks are addressed below.

You are under no obligation to participate in this study at all. To ensure that participation is indeed completely voluntary and that therapists are not pressured to participate by agency/ program directors or supervisors, we have taken several precautions. First, we have informed them on multiple occasions that participation in this study must be completely voluntary. Second, we will not disclose to your employer whether you remain an active research therapist or have opted to withdraw from the study. Any identifiable treatment outcome data from patient participants will be collected by research staff only and will not be available to any clinic managers or supervisors. Neither your decision to participate in the study, nor the treatment outcomes of patients, will have any impact on your employment.

To lessen discomfort from the study procedures themselves, we will take several other precautions. You have the right to not answer a specific question or questions during the research assessments and to refuse to participate in any part of the study. You may also discontinue your participation in this study at any time, without penalty. If assigned to the computer-assisted therapy condition, you may access and review the Behavioral Activation content at any time, including (if you so choose) to prepare for upcoming therapy sessions or to learn the Behavioral Activation content in advance of upcoming therapy sessions.

Finally, we will implement a number of strategies to guard against a breach of confidentiality. Specifically, information collected from you and your patient will be coded with an identification number that is used to identify you. We will keep the link between your name and your identification number and all study data in a secured, locked file cabinet, on a secure, password-protected computer, and/or in a secured online data storage system.

Passively collected data about your usage of WILLOW is linked to your account email within the WILLOW database, which can then be connected back to your name. However, access to the WILLOW database is restricted to a limited number of HIPAA-certified members of the WILLOW product and development team. All servers that transmit and store data within WILLOW are secure, HIPAA compliant, and encrypted.

You may contact the Principal Investigator, Dr. Linda Dimeff, or co-Investigator, Dr. Kelly Koerner, at any time if you have any concerns or are feeling discomfort due to study participation.

5. Benefits

Will I receive any benefit from my participation in this study?
There may be no direct benefit to you from participating in this study. All therapists who treat at least one study patient and complete all of their assessments will eventually receive access to WILLOW. Because WILLOW includes ways to learn new treatments, you will have the opportunity to expand your professional knowledge base, if you so choose.

All participants will potentially benefit from participating in scientific research that is intended to help improve therapeutic processes and procedures for those suffering from mental illness.

Financial disclosure
The Principal Investigator, Linda Dimeff, PhD, and co-Investigator, Kelly Koerner, PhD own the company that will commercialize the software developed through this research, and will receive annual compensation. Please feel free to contact us with any further questions you might have about this matter. You may ask to see a Financial Conflict of Interest statement for both Drs. Dimeff and Koerner as part of this informed consent process.

Are participants paid or given anything for being in the study?
You will receive $50 for completing each of the Week 4 and Week 8 assessments for each study patient, and $60 for each Week 12 assessment you complete. Thus, you can earn up to $160 per research patient. You will be mailed a check within 30 days of completing an assessment. If receiving a check is difficult or provides hassle to you, we can instead send your compensation by email using Amazon gift cards or Target gift cards. Contact our research staff if you prefer this method of compensation.

Every time you complete an assessment within a week of the scheduled due date, you will also earn a raffle ticket for a chance to win a tablet. Additionally, all research therapists who treat at least one patient who also enrolls in the study will receive access to WILLOW for 12 months free of charge upon completion of the study.

For those in the WILLOW condition, you will also receive $100 when you pass the Feature Review as compensation for your time in learning how to use WILLOW.

6. Study Costs

Will I be charged anything for participating in this study?
You will not be responsible for any of the costs associated with taking part in this study.

7. Confidentiality

What happens to the information collected?
You will be given an ID number and all the data you provide will be identified only with that ID number, not with your name or any other information that will identify you. This applies to assessment data collected outside of WILLOW.

All information collected about you during the course of this study will be kept confidential to the extent permitted by law. When we present the research findings to others or publish our results in scientific journals or at scientific conferences, the findings will be presented without any identifying information on the participants. The Behavioral Health Research Collective (BHRC) IRB or appropriate federal agencies like the Office for Human Research Protections or the study sponsor (the NIMH) may review your records.

Study data, as well as the record linking your name to research data through the ID number, will be stored in a secured, locked file cabinet, on a secure, password-protected computer, and/or in a secured online data storage system. The link between participant name and subject ID number will be destroyed after six years. After the record is destroyed, there will be no way to link your name to your responses. The data in the computer will be referenced by code number only and will be retained indefinitely. Data collected by WILLOW will be stored within WILLOW indefinitely and may be used in the future, for other purposes, in a deidentified, aggregated manner consistent with our Terms of Use, Site Terms, and Privacy Policy.

8. Alternatives

Are there alternatives to participating in the study?
If you do not want to participate, you are free to not sign this consent form or withdraw from the study at any time.

9. Voluntary Participation and Withdrawal

What happens if I decide not to be in this study?

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Your supervisor will not be informed of your decision.

Your participation in this study may be stopped at any time by the study staff or the sponsor without your consent for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

10. Questions

Who do I contact for questions about this study?
For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Linda Dimeff, PhD
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
206-384-7371

Angela Kelley Brimer, MS
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
206-455-7934

Who do I contact for questions about my rights or complaints about my participation as a research participant?
If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Behavioral Health Research Collective (BHRC) IRB
Attn: Chair: Travis L. Osborne, PhD
1200 5th Ave, Suite 800
Seattle WA, 98101
(206) 374-0109

BHRC IRB is a group of people who perform independent review of research. BHRC IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact BHRC IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

11. Signatures

Research Participant's Consent to Participate in Research:
By signing the line below, I am voluntarily agreeing to take part in this study. I am aware that if I choose to take part in this study, I may withdraw at any time. I am not giving up any of my legal rights by signing this form. By signing and dating below, I indicate that I have read this entire consent form, including the risks and benefits, and have had all of my questions answered, and that I am 18 years of age or older. I freely consent to be in this research study.

I authorize the release of my records for research or regulatory purposes to the sponsor (NIMH), DHHS agencies, and BHRC IRB.

_____ _____
Printed Name of Participant Date

_____
Signature

Evidence-Based Practice Institute, LLC
ADDENDUM CONSENT TO PARTICIPATE IN RESEARCH
[RCT CONSENT ADDENDUM – Therapist Version]

1. General Information

TITLE: PracticeGround: Transforming Training and Delivery of Mental Health EBPs

PROTOCOL NO.: 2 R44 MH093993-02A1

SPONSOR: National Institute of Mental Health
Rockville, Maryland
United States

PRINCIPAL INVESTIGATOR: Linda Dimeff, PhD
3303 South Irving Street
Seattle, Washington 98144

CO-INVESTIGATOR: Kelly Koerner, PhD
3303 South Irving Street
Seattle, Washington 98144

SITE(S): Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle, Washington 98144
United States

STUDY-RELATED PHONE NUMBER(S): Linda Dimeff, PhD
Principal Investigator
(206) 384-7371

Angela Kelley Brimer, MS
Research Coordinator
(206) 455-7934

2. Additional Study Compensation Information

You are currently taking part in the above-named research study. The purpose of this document is to provide you with additional information regarding study compensation at your clinic. Your clinic director has stipulated that therapist participant payment go directly to the clinic and not to you individually. Your clinic has agreed to allow you to complete all study assessments during your work hours. Your clinic has indicated that the funds it receives for your completion of the assessments and other research activities will be placed in a special training and education fund that will benefit all department employees, regardless of whether they participated in the research activities.

By participating in the study and signing this addendum, you agree to allow EBPI to redirect payments from you personally to the training and education fund.

Will therapist participants from my clinic be given anything for being in the study?
You will receive entry into a raffle for a chance to win a tablet every time you complete an assessment within one week of the scheduled due date. Additionally, all research therapists who treat at least one patient in the study will receive access to WILLOW for one year free of charge upon completion of the study.

If you have any questions, please feel free to contact the research staff at the Evidence-Based Practice Institute at 206-455-7934.

3. Questions

Who do I contact for questions about this study?

For more information about the study or the study procedures or treatments, or to withdraw from the study, contact:

Linda Dimeff, PhD
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
206-384-7371

Angela Kelley Brimer, MS
Evidence-Based Practice Institute, LLC
3303 South Irving Street
Seattle WA, 98144
206-455-7934

Who do I contact for questions about my rights or complaints about my participation as a research participant?

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may contact:

Behavioral Health Research Collective (BHRC) IRB
Attn: Chair: Travis L. Osborne, PhD
1200 5th Ave, Suite 800, Seattle WA, 98101
(206) 374-0109

BHRC IRB is a group of people who perform independent review of research. BHRC IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact BHRC IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

4. Signatures

Research Participant's Consent to Addendum:

By signing the line below, I am voluntarily agreeing to take part in this study and agreeing to accept the changes in payment as outlined in this addendum. I am aware that if I choose to take part in this study, I may withdraw at any time. I am not giving up any of my legal rights by signing this form. By signing and dating below, I indicate that I have read this entire consent addendum form and have had all of my questions answered. I freely consent to the changes outlined in this addendum.

Please indicate if you accept the changes or not by choosing one of the following options and signing below:

☐ I accept the changes in payment as outlined in this consent form addendum.

☐ I do not accept the changes in payment as outlined in this consent form addendum.

_____ _____
Printed Name of Participant Date

_____
Signature