

PracticeGround: Transforming Training and Delivery of Mental Health EBPs

NCT02314624 | Patient Protocol | October 18, 2017

Patient Study Process overview

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PI Cell Phone Numbers:

Linda Dimeff: 206-384-7371

Kelly Koerner: 206-265-2507

Step 1: Set Up Time for Initial Phone Call

1. Review clinic procedures and notes in the [Summative Tracking DB](#). Ensure they are associated with a clinic and make note of their referring provider (if indicated). If needed, find out the patient's medical record number from the referring clinic and log this in the tracking database along with the patient's name.
2. Open the [Eligibility Screen DB](#). Ensure the client is entered into the Client Referral tab.
3. Call the patient to let them know about the study and gauge their interest in participation.
4. Open the [Eligibility Screen on SurveyMonkey](#) in case patient prefers to complete screen with you over the phone.

Voice-mail Script:

Hi! This is _____ from Evidence-Based Practice Institute. I'm calling to tell you more about the research study you talked with the folks at <>Agency<> about. I would love to talk more with you about the study! I will also send you more information by email after I leave this message. Please reply to that email or call me at (phone #) when you have a few minutes to talk. Thank you!

If they call you back or pick up

Hello _____. My name is _____ and I'm calling from Evidence-Based Practice Institute. I'm calling to tell you more about the study and see if you might be interested in participating. I expect this call will take about 15 minutes. Is now a good time to talk?

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If it is, proceed.

If not, schedule a time to call back later. Log call time and date in the Pilot RCT Calendar.

We at the Evidence-Based Practice Institute are conducting a research study to test two different approaches to the treatment of depression. We have developed a new software system called WILLOW that assists therapists in providing treatment for depression. We are interested in learning whether computers can be used to help therapists treat patients experiencing depression, whether it is helpful in reducing a patient's depression, and how patients feel about the use of computers to help in their care.

This study compares two different approaches to the treatment of depression. One approach is called "standard care" which involves a therapist applying their usual treatment strategies to treat your depression. In most cases, computers are not used. The other treatment condition is called "computer-assisted therapy" which involves the use of the new computer tool we developed that was designed to help therapists deliver evidence based treatment. If you are eligible and decide to participate, we will ask that you meet weekly with your research therapist for 12 weeks. Over the course of the study, we will ask that you complete 4 sets of study surveys online and over the phone. You will earn up to \$140 for your participation in the study.

Does this sound like something you might be interested in?

If no, thank them for their time and hang up.

If yes, proceed to the next section.

Awesome! Do you have any questions for me?

Great! The next step would be for you to complete a survey to see if you meet the requirements for the study. I expect the survey to take about 15 minutes. Would you like to complete this survey over the phone with me now or would you prefer to complete it online on your own? If I send you the survey after we hang up, will you have time to complete it today?

If patient prefers to complete survey over the phone:

Read each set of instructions and the following questions to the patient verbatim. Click their answers in SurveyMonkey as you go.

Once all questions are answered:

1. [Thank participant, let them know we will follow up soon about eligibility and next steps.](#)

If patient prefers to complete survey online:

Great! I will send you an email shortly that contains the link to the survey and we ask that you complete it within the next two days. After you complete the survey, we will contact you again to talk with you about next steps.

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Thank you so much for your interest in our research. Please don't hesitate to contact us if you have any questions as you are filling out the survey. Have a great day!

Step 2: Review Screen

1. Check Survey Monkey for screen if it is your folder day
 - a. **Screen:**
https://www.surveymonkey.com/collect/?sm=rdfeMF4WmHZAwsLTT7mCDtxNhHMMd_2B_2BgRbeMWz3R_2Bz1Oyx9qXYlgLMacO5axHRWS
 - b. Click on **Exports** on the left hand side of the screen
 - c. Click **Export All** and choose **All Responses Data** in the dropdown
 - d. Select .XLS for format
 - e. In the **Cells**: dropdown menu choose "Numerical Value"
 - f. Click the **Export** button
 - g. When it finishes loading, click the drop down arrow and select download.
 - h. Open the zip file
 - i. Go to excel folder and select Sheet_1
 - j. Copy and paste answers into 'PatientScreen.ALL' tab in the [Eligibility Screen DB](#)
 - k. Score PHQ-9 to ensure patient meets criteria for depression (Total score = 11+). See column AQ in 'PatientScreen.ALL' tab in the [Eligibility Screen DB](#) for total score.
 - l. Determine if patient is eligible or not.
 - i. If eligible: copy/paste information into 'Eligible.Patients' tab in [Eligibility Screen DB](#)
 - ii. If unsure: consult with Angela on how to follow up
 - m. Review screen for any skipped questions or those you need to follow-up on. Note these as follow-up items during phone call.
 - n. Review 'Patient Referrals Received' tab in the [Eligibility Screen DB](#)
 - i. If they are not listed in the list, look to see what clinic they are from in the screen to ensure they are being treated at one of our participating clinics
 - o. **Make note if they gave us permission to contact their therapist and/or clinic**

If patient is ineligible:

1. Send ineligible email
2. If we have permission to contact therapist and/or clinic, call to inform the clinic that patient is ineligible to participate

If patient passes screen or unsure:

1. Flag any questions and consult with Angela on how to answer.

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2. Create a cover sheet for the patient with contact information and keep notes of all interaction with the patient in the log.
3. Call and Email Patient for clarification of eligibility and/or Informed Consent

Voicemail Script if Eligible:

Hi this is _____ from Evidence-Based Practice Institute. I'm calling to let you know that you are eligible to participate in our study! The next step to enroll in this study is to read and sign the consent form and take your first set of study surveys. I will send you more information about this process via email after I leave this message. Please reply to that email or call me at (phone #) to schedule a time for these next steps. Thank you!

Voicemail Script if Follow-up Needed to Determine Eligibility:

Hi this is _____ from Evidence-Based Practice Institute. I'm calling to talk with you more about your participation in our study. We just have a couple of questions about the answers you provided in the online questionnaire. I will also send you an email after leaving this voicemail message. Please reply to that email or call me back at (phone #) at your earliest convenience. Thank you!

1. If they call you back
 - a. And it is a good time for you to talk: Go through the script below
 - b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Research Calendar
 - c. Log the call in the cover sheet
2. If they pick up, use the script below in Step 2.

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### **Step 3: Patient Informed Consent Call**

Hi, is this \_\_\_\_\_?

Hello \_\_\_\_\_, my name is \_\_\_\_\_ and I'm calling from Evidence-Based Practice Institute. I am calling to let you know that based on the answers you provided on the online survey, you are eligible to participate in the study! The next steps for your participation in this study is for me to tell you more about the details of the study and then there are a couple of things for you to complete online. I expect this entire process to take about 1-1.5 hours. Is now a good time for this or would you like to schedule another day this week or early next week for this?

**If it is, proceed to the next section.**

**If not, schedule a time to call back later.**

Great! I want to start off by telling you a little bit about the study. We are studying different treatments for depression. This study will compare two approaches to treating depression –

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standard therapy and computer-assisted therapy aided by our newly developed software called WILLOW. If you decide to participate in this study, you will be asked to meet with a therapist for 12 weeks. Your therapist has already been assigned to one of the two study conditions [let them know what condition they were assigned], which means you are also in the [standard care, WILLOW] condition with them.

**<<for RA: if not yet assigned to therapist, describe both conditions. If assigned to therapist and we know their condition, describe only the condition they are assigned to unless they want to hear about both conditions.>>**

### **Describe CAU:**

Since you are assigned to a therapist in the standard therapy condition, you will receive their standard therapy for treating depression. This means your therapist will be using their usual method for treating depression with you. This condition is sometimes called “care as usual”. If you have any questions about the specifics of your sessions and therapy, please direct those to your therapist.

### **Describe WILLOW:**

Since you are assigned to a therapist in the computer-assisted therapy condition, your therapist will be using WILLOW to help provide you treatment for your depression. In this condition, your therapist will be using WILLOW to help provide an evidence-based treatment known as Behavioral Activation. WILLOW also includes a number of videos, worksheets, and discussion guides your therapist may choose to use.

Do you have any questions so far?

**If there are no questions, move on to the next section**

### **Describe Surveys:**

Four times during the 12-week study you will be asked to complete some questionnaires online.

- The first time will be today after we finish with our call. I will be sending you the links to our online consent form and also the link to the first set of surveys for you to do.
- As a kind of addendum to today's surveys, I'll also be sending you a link to a really quick survey for you to do after your next session.

### **Ask them the date for the next session and record in coversheet**

- If you're able to complete your first set of surveys today [before next session], then I'll go ahead and send you that link to the quick survey for you to do.
- Now, the next three times we'll ask for you to complete surveys will be at Weeks 4, 8, and 12 during your participation. These will take between 45-60 minutes to complete and will involve a 10-15 minute phone call with a member of our research team and then an online survey that will take about 30 minutes answering questions about your mood, your satisfaction with the treatment you are receiving, and questions about your experience with your therapy and therapist.

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The information you provide during this study will be used for research purposes only; it will not be shared with your therapist or treatment team. Your treatment and your participation in our study are separate but parallel activities. You are doing them at the same time but there will not necessarily be any cross over between the two EXCEPT for during the research appointments I just described to you where we'll ask about how sessions are going and what type of activities you do in session, etc. Everything you do for the research will be either on the phone or on SurveyMonkey, where the surveys are located. Everything else <>for WILLOW patient participants specify measures, videos, worksheets, etc in WILLOW>> would be for your therapy separate from the research. If you ever need clarification, please ask your provider or contact us.

As you know, the length of research-based treatment is 12 weeks. After the 12-week period, you and your therapist or clinic will decide what your next steps for treatment will be. If you have questions about this, we encourage you to talk with your therapist or clinic before enrolling in the study. While the research trial is 12 weeks, this does not mean you must quit treatment after 12 weeks or that you are obligated to continue treatment for 12 weeks. If more treatment is needed after the 12-week period, you will work with your therapist and the clinic to decide how to proceed. If you decide to stop treatment before the 12 weeks of your study participation are over, we ask that you still complete the online surveys and phone calls, regardless of whether or not you are still receiving treatment from your study therapist.

As compensation for your study participation and time involved in completing the online surveys and phone calls, you will receive \$40 for each of your Week 4 and Week 8 surveys, and \$60 for your Week 12 survey, for a total of \$140 if you complete all study procedures. The payment will be coming from Chase Bank so be sure to keep an eye out for envelopes from Chase when the time comes.

Since completing your surveys in a timely manner is really important to the research, each survey and phone call you complete within one week of the scheduled appointment date will qualify you to earn a chance to win a tablet in a raffle drawing that will happen 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.

Do you have any questions about the study so far?

**If there are no questions, move on to the next section**

Participation in this study is completely voluntary. You can decline at any time if you are not interested in participating.

Now that you know a more about the study, are you still interested in participating? Do you have any questions?

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**If yes, continue with the script**

**If no, thank them for considering the study and end call**

**Describe next steps:**

Okay, I'd like to summarize the next steps for us now. I will send you the link to our online consent form for you to complete after this call.

- It will review the information we just discussed and also provide you with more details about participating in this study.
- The survey will also include more information about The Health Insurance Portability and Accountability Act (HIPAA)

After you're done with the consent form, the survey will direct you back to the email I'll be sending to you in a minute. There will be another link in the email that will take you to the first set of surveys. We expect that they will take about 30-45 minutes to complete. This survey will ask for your study ID, if you have something to write on I can provide that right now? Or I can text it to you if that's better for you. Which do you prefer?

**Make sure to text or read aloud the study ID to the patient.**

If you have any questions or if you experience any difficulty with the survey system, please call or email us immediately. We're here to help! Once you have completed the surveys, please call or text or email me back at my direct line you'll find in the email I will send you to record the completion of that survey. I will also ask for the date of your next therapy session. After this, we will let your therapist and/or clinic know you are ready to schedule your first study session. After your first visit with your therapist, we will call you to schedule your next three study assessments and also send you the link to one final survey to complete as part of your first bundle of survey measures.

Do you have any final questions for me? Excellent! I will now email you the link to the consent form and your first set of surveys. Thank you for talking with me today. If you have any questions or concerns as you are reviewing the consent form or completing the surveys, please don't hesitate to contact me and remember to give me a call when you're finished with the surveys. Thank you!

**Action items while participant completes baseline surveys:**

1. Check the debrief items at the end of the survey
2. If participant reports a score of 5 or greater on items 3a, 3b, or 4b **call them** and do [mood induction protocol](#) (see [flowchart](#) for the coping skills)
3. If they do not answer leave a voicemail (script below)

**Voicemail Text (if patient does not answer when research team calls):**

Hi \_\_\_\_\_, this is \_\_\_\_\_ from Evidence-Based Practice Institute. Thank you for completing the research study surveys. I see that you reported you are feeling like harming yourself or someone else. It's not uncommon for people who are completing an assessment like this one to notice a drop in their mood. Please contact me right away by calling xxx-xxx-xxxx. If

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there are things that you have found helpful to do in situations like this or if you and your therapist have identified something that is helpful for you to try, we will ask that you do these now. We can also suggest other activities to try that may help improve your mood. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes. Thank you again for completing this assessment. I look forward to hearing back from you.

### 4. Follow up with email text

Dear XXX,

Thank you for completing the research study surveys today. I would like to talk with you about some of your answers on the last survey. Please contact me right away by calling xxx-xxx-xxxx. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes.

Thank you again for completing these surveys today. I look forward to hearing back from you.

Kind Regards,

Xxx

### 5. If participant does not respond soon, call and email their provider

#### **When participant calls you back after completing consent and baseline:**

1. Thank participant for completing the Consent process and baseline surveys; let participant know you will be sending them a copy of their Consent Form and HIPAA authorization via email shortly.
2. Proceed through debrief protocol if needed
3. Collect date of next therapy session and schedule assessments if they know.

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Step 4: Action Steps after Informed Consent Call

1. Send the patient a link to the consent form/HIPAA authorization/baseline surveys in an email.
 - a. Study IDs = first three digits of therapist Study ID and fourth digit the number of patient assigned to the therapist.
Example: This patient is the third study patient the therapist is treating. The therapist ID is 117. → Patient ID = 1173
 - b. If patient hasn't yet been assigned to a therapist, they will be numbered in consecutive order, starting with 3001
2. Log that the phone call has been completed in the cover sheet and that the consent form and baseline are pending
3. Log that the phone call has been completed and the consent and baseline have been sent in the [Participant Tracking DB](#)

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4. Check back in two hours if you haven't heard back from patient to see if they filled out the consent form and baseline assessment on survey monkey.
 - a. If they have not completed the consent form or baseline, call and email the participant to check in; reschedule as needed.
5. When they complete the consent form, check to make sure all answers are filled in the consent form and that they agree to participate in the study. Make note if they answer No to any of the authorization questions and discuss at next Research Meeting
6. Log the consent completion into the database and cover sheet
7. Log the Baseline completion into the database and cover sheet
8. **If we have permission to discuss study participation with Therapist/Clinic**, let the Therapist and/or clinic know the patient is enrolled in the study and ready to start their study therapy sessions and request they let us know when the client's first session will be (call and email; do not include patient name in email). **If we do not have permission to discuss study participation with Therapist/Clinic**, ask patient to let their therapist/clinic know they are ready to start their study therapy sessions and request they let us know when their first session will be.
9. **Send patient copy of their consent form and HIPAA auth**
 - a. In SurveyMonkey copy everything under "Collect" until the end of the consent form section and paste it to the end of the Consent Form template
 - b. In SurveyMonkey copy what's under "Collect" (through time spent) and the HIPAA section and paste to the end of the HIPAA authorization template
 - c. Save both as PDFs with following naming conventions:
Lastname,FirstInitial.FullRCT.PatientConsentForm
Lastname,FirstInitial.FullRCT.PatientHIPAA

(Use full first name if last name is same as someone else's)

Step 5: Collect dates from Therapist

NOTE: check Clinic details in [Participant Tracking DB](#). Some clinics will have already completed this session prior to informing client of study. In which case the below is irrelevant because it should already have been done before this point.

1. Record the client's care start date in the Tracking DB under the patient and therapist tabs
2. Record when the client's first session with their research therapist will be (the "Welcome/Get to Know You" Session).
3. Contact therapist after the Welcome/Get to Know You Session
 - a. Did the client attend this session?
 - b. Is the client eligible / appropriate for the study?
 - c. When is the first Study Therapy Session?
4. Record information in [Participant Tracking DB](#)
5. If eligible, continue to Step 6

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6. If ineligible, discontinue client's participation
 - a. Log that the patient is ineligible in the tracking database and move cover sheet to the "Ineligible" folder.

Step 6: Scheduling Call

1. Make scheduling call as soon as you can, script below
2. If the patient doesn't answer the call, send scheduling email and leave the voicemail below.
3. Call back/email every 2 days until you reach patient.

Voicemail Script:

Hi _____, this is _____ from Evidence-Based Practice Institute. We wanted to reach out to you in order to schedule your 4, 8, and 12 week study surveys. At your earliest convenience, please give us a call back at (Phone#)_____. Thanks!

4. If they call you back
 - a. And it is a good time for you to talk: Go through the script below
 - b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Pilot RCT Calendar
 - c. Log the call in the cover sheet

If they pick up, use the script below:

Call Script:

Hi _____, this is _____ from Evidence-Based Practice Institute. Thanks again for your participation! I am calling today to schedule your study surveys. Is now a good time to talk?

We have three appointments to schedule. Each appointment will be about 45-60 minutes. We will have a quick chat on the phone then send you a link to the online surveys for you to complete. The first appointment will be 4 weeks from now, during the week of (Month, Date). Do you have a day or time that works best for you? And now your 8 week set of surveys: during the week of (Month, Date). Do you want to try to schedule for (Day) again? Great! Now your final set of surveys during the week of (Month, Date).

[say this part only if their next session date hasn't already passed], I will send you an email after your next therapy session that includes a link to a quick online survey. We are interested in learning more about your thoughts about your first therapy session and will ask that you complete it within one day of your session. I expect the survey will take only about 5 minutes to complete.

Do you have any questions for me before we hang up? Great! I will send you an email listing these appointment times after we get off the phone. Have a good day!

Step 7: Logging Scheduling Call into Tracking DB

1. After the scheduling call, send patient the email confirming the scheduled times.
 - a. Log that you scheduled the patient in cover sheet/[Participant Tracking DB](#).
2. Log that the phone call has been completed in the patient cover sheet and change the file name to include the date of their next study step (MSSS/Scheduling).
3. Add the scheduled times to the [Participant Tracking DB](#) and Research Calendar.
4. Add the date you completed the scheduling call in the tracking database.
5. Put cover sheet into the [Pending Folder](#).

On Fridays, take these extra steps:

- o Check all other daily folders for any stragglers (cover sheets that are not in the proper folder). Follow up as needed and place participant in appropriate folder
- o Review the Pending folder and look at each tracking sheet to determine what is needed for each participant. Sort them accordingly.
- o Move all of the participants in the Friday folder to either the pending folder, if everything is complete, or into daily folders for next week, depending on what action steps are required for that participant during the week
- o Send a reminder email to all patients that have assessments next week.

Step 8: Mental Health Services Satisfaction Survey (MSSS)

1. After the patient's first study session using WILLOW or CAU (after welcome/get to know you session), send email with link to MSSS.
2. Log the date that you sent the MSSS in cover sheet and [Participant Tracking DB](#)
3. Check every day for completion, needs to be completed within **one week**, send daily reminders (alternating phone and email)
4. Log completion date in cover sheet and [Participant Tracking DB](#)

Step 9: Assessment Calls

1. Open the [Semi-Structured Interview Template](#), Save As 'SSID.PatientSemiStructuredInterviewWeekX' in the [Interview Notes folder on Box](#).
2. Call participant at scheduled time, script below.
3. If the patient doesn't answer the call, send email and leave the voicemail below.
 - a. Alternate calling/emailing every day for the next few days until you reach the patient

1st Contact Voicemail Script:

Hi _____, this is _____ from Evidence-Based Practice Institute. I have that we are scheduled for your <4, 8, or 12> week study survey. I'll call back in a few minutes, but if you get this before, please call me back at (Phone#). Thanks!

<Call back in 10 minutes>

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2nd Contact Voicemail Script:

Hi _____, this is _____ from Evidence-Based Practice Institute. It looks like we missed you for your <4, 8, or 12> week study surveys. At your earliest convenience, please give us a call back at (Phone#)_____. Thanks!

1. If they call you back
 - a. And it is a good time for you to talk: Go through the script below
 - b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Research Calendar
 - c. Log the call in the cover sheet

If they pick up, use the script below:

Call Script:

Hi _____, this is _____ from the Evidence-Based Practice Institute. Thanks again for your participation! I am calling today for your <4, 8, or 12> week study surveys. Is now still a good time to talk?

Great! Today involves two steps. First, we'll talk for a few minutes here on the phone. I just have a few questions for you and welcome any other feedback about your experience in the study so far. Then, I will send you an email with a link to complete your surveys online. Once you have completed the surveys, I'll ask that you call me back so that we can talk for a few more minutes before we end for the day. Do you have any questions before we get started?

Wonderful! First, I want to thank you for the time you have invested into our study and your important contributions. We'd like to ask you several questions about your experience.

<<Administer Semi-Structured Interview, taking detailed notes during conversation >>

Thank you for answering those questions! Is there anything else I should note about your experience in the study? Thank you.

Now I will now send you an email with the link to your surveys for today. Please let me know when you get it.

Great! We anticipate these surveys will take 30-45 minutes to complete. The survey will ask you to enter your Study ID and you'll find this in the email. Please call me back as soon as you complete the surveys to record your completion. I included my phone number in the email that you can use to call my directly. Thanks! Talk soon!

- After the call, send patient the email with link to assessment surveys.

Log that you sent the email in cover sheet/[Participant Tracking DB](#)

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Action steps while participant completes surveys:

1. Check the debrief items at the end of the survey
2. If participant reports a score of 5 or greater on items 3a, 3b, or 4b call them and do [mood induction protocol](#) (see [flowchart](#) for the coping skills)
3. If they do not answer leave a voicemail (script below)

VoiceMail Text (if patient does not answer when research team calls):

Hi _____, this is _____ from Evidence-Based Practice Institute. Thank you for completing the research study surveys. I see that you reported you are feeling like harming yourself or someone else. It's not uncommon for people who are completing an assessment like this one to notice a drop in their mood. Please contact me right away by calling xxx-xxx-xxxx. If there are things that you have found helpful to do in situations like this or if you and your therapist have identified something that is helpful for you to try, we will ask that you do these now. We can also suggest other activities to try that may help improve your mood. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes. Thank you again for completing this assessment. I look forward to hearing back from you.

4. Follow up with email text

Dear XXX,

Thank you for completing the research study surveys today. I would like to talk with you about some of your answers on the last survey. Please contact me right away by calling xxx-xxx-xxxx. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes.

Thank you again for completing these surveys today. I look forward to hearing back from you.

Kind Regards,

Xxx

If participant does not respond soon, call and email their provider

When Patient calls back:

<<[administer debrief protocol](#) if needed– RA fills out protocol on SurveyMonkey while talking with the patient>>

Thanks for answering those questions! We are all done for today. Our next study appointment is scheduled for **Day, Date at Time**. I look forward to talking with you then! Please also feel free to contact us before then if you have any questions. Thank you!

- Log that the phone call has been completed in the patient cover sheet and change the file name to include the date of their next assessment.
- Log call in the [Participant Tracking DB](#).

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- Log date surveys complete in cover sheet and [Participant Tracking DB](#)
- Put cover sheet into the [Pending Folder](#).

If 12-week assessment, take these extra steps:

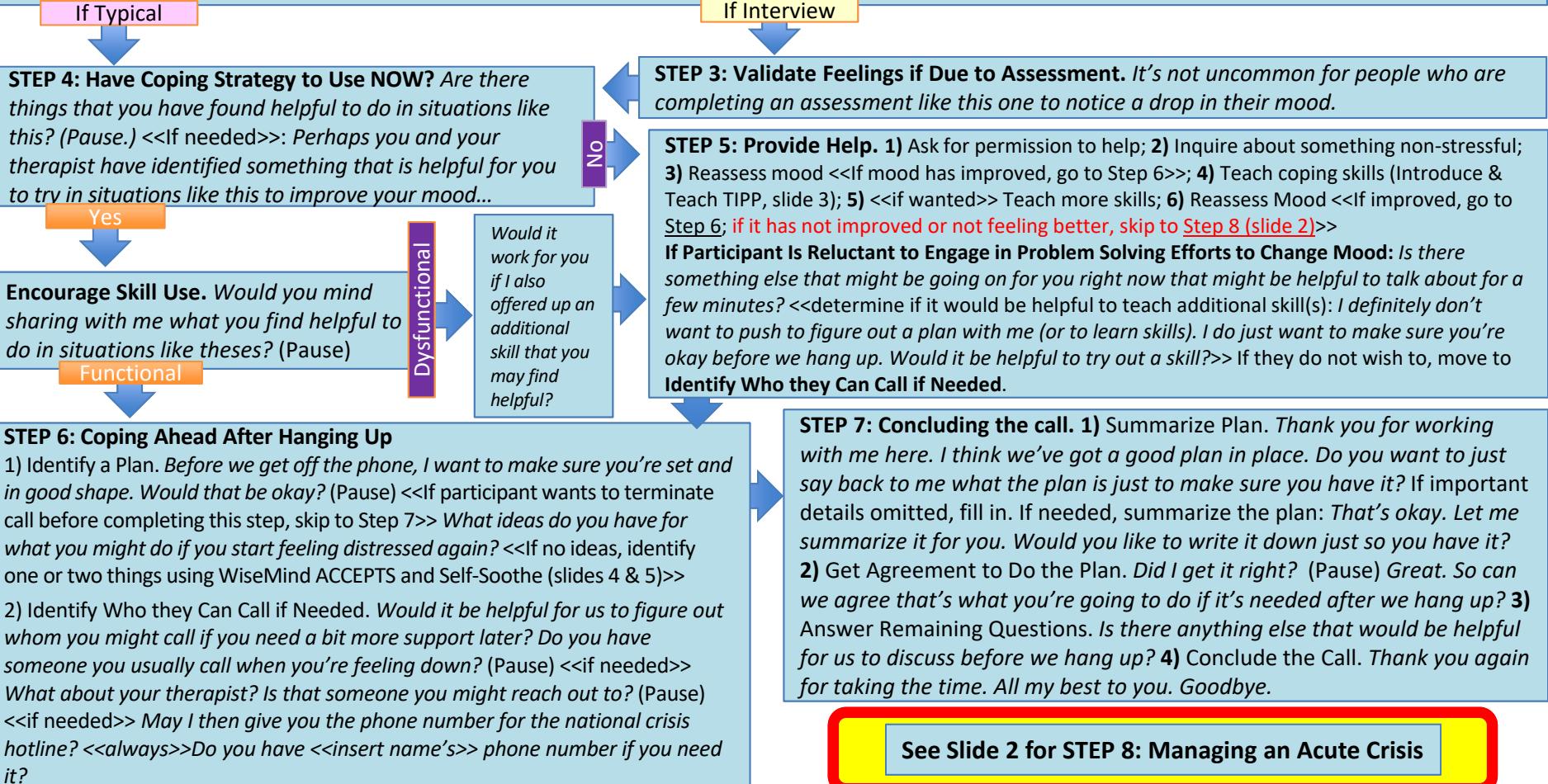
- Let participant know this is their last study assessment and that their participation will end after they complete this final set of surveys
- Discuss raffle (how many raffle tickets they earned) and that we will let the winners know by email and phone. Drawing will take place once all participants have completed the study.
- Put cover sheet into the [Completed Folder](#).

Transition from Assessment to Mood Induction

STEP 1: Orient to Mood Induction [if patient reports a score of 5+ on items 3a, 3b, 4b]. You mentioned on that mood rating that you are feeling <<insert what person endorsed, e.g., "like using drugs" or "like killing yourself" or "like harming someone else">>. I just want to make sure that you're in good shape before we hang up. Would it be okay with you if we take a few moments to see if we can get your mood up a bit before we hang up?

If really distressed, use/discuss Acute Skills, slides 3-7

STEP 2: Distress Due to Assessment? Is how you're feeling now like how you often feel, or does it feel worse than typical, maybe because of going through the study processes?



Survey Monkey Link to Debrief Protocol: <https://www.surveymonkey.com/r/3LV2HS8>

STEP 8: Managing an Acute Crisis:

For use when participant is extremely upset and/or you are uncertain about how to proceed.



Validate Person's Plan & Desire to Help.

I can tell you are still having a hard time. I want to make sure that you are okay and safe after we hang up.

<<Go to STEP 5 (slide 1), "Teach Additional Coping Skills">>

If you haven't yet taught TIPP, introduce and teach now or practice a different TIPP skill if you have already covered some skills previously.

Acute Skills (really distressed)

- Cold water/Ice pack on face
- Paced Breathing and other

TIPP Skills (slide 2).

Linda: 206-384-7371

Emergency / Crisis Situation.

If participant seems unresponsive or not willing to seek help, call
Linda Dimeff 206-384-7371 or **Kelly Koerner 206-265-2507**.

State to participant: *I am very worried about you and I'd like to get help from my supervisor who is a clinical psychologist if you don't mind. May I briefly put you on hold while I attempt to reach her? If I can reach her, I'll tell her a bit about what we discussed and I'll have her join the line with us. Is that okay with you?*



Inform Clinic of Event.

Discuss event with Linda or Angela so they can contact clinic emergency contact to inform them of the event. The clinic contact will decide how next to proceed with client and therapist as determined by clinic-specific protocols.

TIPP Skills:

T

TEMPERATURE CHANGE:

Immerse your face in Ice or Cold Water. Taking a hot bath or shower may also be effective.

*Fill a sink with cold water and add some ice. If you don't have ice, be creative. Add a pack of cold peas or something icy that will lower the temperature of the water even more. If you don't have a sink, fill a big mixing bowl. Now you're going to hold your breath and dunk your face and head in for as long as you can hold your breath. Then come up, exhale, inhale and dunk again. Repeat as many times as you need to until you feel quite a bit calmer. *DO NOT USE THE ICE TECHNIQUE IF YOU HAVE A HEART CONDITION OR HAVE HAD A HEART ATTACK**

I

INTENSE PHYSICAL EXERCISE:

Running around the block, doing jumping jacks, turning on a song and dancing around for a little while...all of these things can use up some of the energy that is fueling distress.

P

PACED BREATHING:

Breathe in and out normally, slightly lengthening the out breath. Starting with 9 and decreasing to 0, label each of the out breaths with a number, *i.e. In.. Out (9).... In.. Out (8).... In.. Out (7)....* If you notice your mind wandering, gently bring your attention back to the counting of the breaths. Try to focus on the numbers and breathing, and nothing else. When you reach zero, start counting down again. This time don't start with the number 9; start with the number 8. Work your way down to 0 again. When you reach 0, continue starting the counts again, each time decreasing the starting number by one, until you have reached zero again. When you have finished, if you need to, start again at 9, and repeat until you are feeling more regulated.

P

PROGRESSIVE MUSCLE RELAXATION:

There are many ways of doing progressive relaxation, but in a nutshell, you are going through your body and mindfully relaxing one area at a time. If your distress is very high, you may want to squeeze all the muscles in each area very tightly for a few seconds and then release. Don't forget your face! Scrunch it up tightly, and release. Don't give up on it if it doesn't work once - try it a few times. You can also find guided progressive relaxation videos on YouTube.

SELF SOOTHE:

Think of soothing each of your Five Senses

VISION:

Buy one beautiful flower, make one space in a room pretty, light a candle and watch the flame. Set a pretty place at the table, using your best things for a meal. Go to a museum with beautiful art. Go sit in the lobby of a beautiful old hotel. Look at nature around you. Go out in the middle of the night and watch the stars. Walk in a pretty part of the town. Fix your nails so they look pretty. Look at beautiful pictures in a book. Go to a ballet or other dance performance, or watch one on TV. Be mindful of each sight that passes in front of you, not lingering on any.

HEARING:

Listen to beautiful or soothing music, or to invigorating and exciting music. Pay attention to sounds of nature like waves, birds rainfall, rustling leaves. Sing your favorite songs, hum a soothing tune, learn to play an instrument. Call 800 or other information numbers to hear a human voice. Be mindful of any sounds that come your way, letting them go in one ear and out the other.

SMELL:

Use your favorite perfume or lotions, or try them on in the store, spray fragrance in the air, light a scented candle. Put lemon oil on your furniture. Put potpourris in a bowl in your room. Boil cinnamon, bake cookies, cake or bread. Smell the roses. Walk in a wooded area and mindfully breathe in the fresh smells of nature.

TASTE:

Have a good meal, have a favorite soothing drink, such as herbal tea or hot chocolate (but no alcohol). Treat yourself to a dessert. Put whipped cream on your coffee. Sample flavors at an ice cream store. Suck on a piece of peppermint candy. Chew your favorite gum. Get a little bit of special food you don't usually spend the money on, such as fresh squeezed orange juice or organic vegetables. Really taste the food you eat, eating one thing mindfully and focusing on its taste.

TOUCH:

Experience whatever you are touching, notice that the touch is soothing. Take a bubble bath, put clean sheets on the bed, pet your dog or cat, have a massage, soak your feet, put creamy lotion on your whole body. Put a cold compress on your forehead, sink into a really comfortable chair in a hotel lobby or in your home, put on a silky blouse, dress, or scarf. Try on fur-lined gloves. Brush your hair for a long time. Hug someone.

A
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DISTRACT: *Wise Mind ACCEPTS*

ACTIVITIES:

Activities helps you to feel better, and as you feel better and productive, your self esteem rises and endorphin's are released. Do something physical like exercise, hobbies, cleaning, go to a community event, call or visit a friend, go walking, work, play, participate in sports, go out to a meal, have decaf coffee or tea, go fishing, chop wood, do gardening, play pinball. Do whatever works for you.

CONTRIBUTING:

Contribute to someone, do volunteer work; give something to someone else, make something nice for someone else, do a surprising, thoughtful thing.

COMPARISONS:

Watch disaster movies, watch soap operas, visit an ER waiting room, or a hospital waiting room, compare yourself to people coping the same as you or less well than you.

EMOTIONS

(Opposite Emotions): Be sure what you do will create the opposite emotion to what you are feeling. You could watch comedies like "I Love Lucy" or "Carol Burnett" or watch emotional movies or listen to emotional music. Read emotional books or stories.

PUSHING AWAY

(use this skill last - as a tuning out): Push the situation away by leaving it for a while, leave the situation mentally. Build an imaginary wall between yourself and the situation or push the situation away by blocking it out of your mind. Censor ruminating. Refuse to think about the painful aspects of the situation. Put the pain on a shelf. Box it up and put it away for a while.

THOUGHTS

(other thoughts): Count to 10; count colors in a painting or tree or out the window. Do anything, work puzzles, watch TV, read.

SENSATIONS

(other intense sensations): Hold ice in your hand, squeeze a rubber ball very hard, take a hot shower, listen to loud music, sex, snap a rubber band on your wrist, suck on a lemon.

IMPROVE THE MOMENT

IMAGERY:

Imagine very relaxing scenes or soldiers fighting and winning. Imagine a secret room within yourself, seeing how it is decorated. Go into the room whenever you feel threatened. Close the door on anything that can hurt you. Imagine everything going well. Imagine coping well. Make up a fantasy world that is calming and beautiful and let your mind go with it. Imagine hurtful emotions draining out of you like water out of a pipe.

MEANING:

(create a track record of endurance) Find or create some purpose, meaning or value in physical or emotional pain. Remember, listen to, or read about spiritual values. Focus on whatever positive aspects of a painful situation you can find. Repeat them over and over in your mind. Make lemonade out of lemons.

PRAYER:

(walk & talk out loud or kneel and pray to your higher power, to God, Goddess, whoever) Open your heart to a supreme being with great wisdom, whatever that means to you. It could be God or your own wise mind for instance. Ask for the strength to bear the pain in this moment. Turn things over to God or a higher being.

RELAXATION:

Find humor and laugh. Try relaxing each large muscle group, starting with your hands and arms, going to the top of your head, and then working down. Listen to a relaxation tape, exercise hard, take a hot bath, or sit in a hot tub. Drink hot milk, massage your neck and scalp, or your calves and feet, get in a tub filled with very cold or hot water and stay in it as long as you can tolerate. Breathe deeply, half-smile, change your facial expression

ONE THING IN THE MOMENT:

Focus your entire attention on just what you are doing right now. Keep yourself in the very moment you are in in the present. Focus your entire attention on physical sensations that accompany nonjudgmental tasks. (e.g. walking, washing, doing dishes, cleaning, fixing). Be aware of how your body moves during each task. Do awareness exercises.

VACATION:

Give yourself a brief vacation. For instance, from 2 p.m. to 4 p.m., get in bed and pull the covers over your head for 20 minutes. Rent a motel room at the beach or in the woods for a day or two. Unplug your phone for a day, or let your answering machine screen your calls. Take a 1 hour breather from work that needs to be done. Look at a magazine, bundle up in a chair, eat slowly. Allow yourself to be a kid again - take a break from adulthood.

ENCOURAGEMENT:

Cheer lead yourself. Repeat over and over: "I can stand it. This won't last forever. I will make it out of this. I'm doing the best I can. I can do it. I am OK."

THINKING OF PROS & CONS

Make a list of the **pros and cons** of tolerating the distress.

Make another list of the **pros and cons** of not tolerating the distress - that is, of coping by doing something impulsive.

Focus on long-term goals, the light at the end of the tunnel. Remember times when your discomfort has ended.

Think of the positive consequences of tolerating the distress. Imagine in your mind how good you will feel if you achieve your goals, if you don't act impulsively.

Think of all of the negative consequences of not tolerating your current distress. Remember what has happened in the past when you have acted impulsively to escape the moment.

Ask yourself, "*Will this event that is distressing me going to matter in 5 years?*"

WILLOW RCT
Mood Assessment and Debrief Protocol

**Adapted from Linehan's
Suicide Risk/Distress Assessment Protocol**

PURPOSE:

While the risk is deemed low, the intent of this Mood Induction Protocol is to ensure that research patients are not at imminent risk to harm or kill self following completion of a study assessment.

PROCEDURE:

Before concluding each assessment, the patient will complete the Mood Assessment online. If the patient reports a score of 5 or greater on items 3a, 3b, 4b, they will receive a message from the survey system. This message will include validation of their experience and suggestions for improving their mood through the use of behavioral skills. Specific changes are detailed below.

MOOD ASSESSMENT:

1. Feedback on their experience during this assessment and other experiences they have had with the study (i.e., other assessments -- how did this one compare? How was it different? What made the difference?). Describe.

2. ____ On a scale of 0 to 7, what is your level of stress right now?

Low 0 1 2 3 4 5 6 7 High

- 3a. ____ On a scale of 1 to 7, what is your urge to harm yourself now?

Low 0 1 2 3 4 5 6 7 High

- 3b. ____ On a scale of 1 to 7, what is your intent to kill yourself right now?

Low 0 1 2 3 4 5 6 7 High

4. ____ On a scale of 1 to 7, what is your urge to use drugs or alcohol right now?

Low 0 1 2 3 4 5 6 7 High

- 4a. ____ On a scale of 1 to 7, how angry are you (i.e., what is your level of anger right now)?

Low 0 1 2 3 4 5 6 7 High

- 4b. ____ On a scale of 1 to 7, what is your intent to physically hurt another person right now?

Low 0 1 2 3 4 5 6 7 High

If the patient endorses a score of 5 or greater on items 3a, 3b, 4b, they receive the following message:

You reported that you are feeling like harming yourself or someone else. It's not uncommon for people who are completing an assessment like this one to notice a drop in their mood. Please contact us right away by calling Julie (XXX-XXX-XXXX) or Angela (XXX-XXX-XXXX). If there are things that you have found helpful to do in situations like this or if you and your therapist have identified something that is helpful for you to try, we will ask that you do these now. We can also suggest other activities to try that may help improve your mood. You may also consider calling your therapist, your clinic where you receive services, or call the National Suicide Prevention Lifeline at 1-800-273-8255 or go to <http://www.suicidepreventionlifeline.org/> for other helpful information. If this is a clinical emergency, please call 911 right away.

Transition from Assessment to Mood Induction

For use when participant scores 5+ on items 3a, 3b, and/or 4b.

If the patient endorses a score of 5 or greater on items 3a, 3b, 4b, Research Assistant will call and email participant to go through the protocol below (see Steps 1-8). If the Research Assistant is unable to reach the participant, they will call and email the patient's provider.

Voicemail Text (if patient does not answer when research team calls):

Hi _____, this is _____ from Evidence-Based Practice Institute. Thank you for completing the research study surveys. I see that you reported you are feeling like harming yourself or someone else. It's not uncommon for people who are completing an assessment like this one to notice a drop in their mood. Please contact me right away by calling xxx-xxx-xxxx. If there are things that you have found helpful to do in situations like this or if you and your therapist have identified something that is helpful for you to try, we will ask that you do these now. We can also suggest other activities to try that may help improve your mood. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes. Thank you again for completing this assessment. I look forward to hearing back from you.

Email Text:

Dear _____,

Thank you for completing the research study surveys today. I would like to talk with you about some of your answers on the last survey. Please contact me right away by calling xxx-xxx-xxxx. Our study procedures also require that we contact your therapist unless we hear back from you in the next few minutes.

Thank you again for completing these surveys today. I look forward to hearing back from you.

Kind Regards,

xxx

STEP 1: ORIENT TO MOOD INDUCTION / ELICIT PERMISSION

You mentioned on a mood rating that you are feeling <<insert what person endorsed, "like harming yourself" or "like killing yourself" or "like harming someone else">>. I just want to make sure that you're in good shape before we hang up. Would it be okay with you if we take a few moments to see if we can get your mood up a bit before we hang up?

STEP 2: DUE TO ASSESSMENT?

Is how you're feeling now like how you often feel, or does it feel worse than typical, maybe because of going through the study processes?

Unusual	Go to Step 3: VALIDATE
Typical	Go to Step 4: ASSESS/OFFER SKILLS

STEP 3: VALIDATE IF DUE TO ASSESSMENTS

It's not uncommon for people who are completing an assessment like this one to notice a drop in their mood.

STEP 4: HAVE COPING STRATEGY THEY CAN USE NOW?

Assess Skills. *Are there things that you have found helpful to do in situations like this? (Pause for participant's response. If needed, then): Perhaps you and your therapist have identified something that is helpful for you to try in situations like this to improve your mood...*

If No Skills Named: Go to Step 5.

If Skills Named, Encourage Their Use: *Would you mind sharing with me what you find helpful to do in situations like these? (Listen to strategies. Are they functional behaviors that you could image doing yourself or recommending to a loved one to try? If yes, then encourage their use. Before moving off this step and moving to Step 6, make sure the plan they identify can actually be implemented. If solution proposed is dysfunctional or potentially harmful e.g., I'm going to smoke a bowl of pot, then consider saying): Would it work for you if I also offered up an additional skill that you may find helpful? (Then proceed to Step 5).*

STEP 5: PROVIDE HELP

Ask Permission: *Would it be okay with you if I offered some suggestions that may help improve your mood?*

Inquire About Something Non-Stressful: *How about if we start by you telling me something about your life that is pleasant or positive. (Pause for participant's response. If participant pauses a while or indicates that nothing comes to mind, then ask follow up): It may be that there's nothing particularly pleasant or enjoyable happening in your life right now. How about instead telling me something that's ordinary and not stressful in your life right now. [Listen with interest; ask simple, casual questions about what participant has said that draws him/her out a bit more, just as you might at a public social event. In other words, if you would not ask your question to an acquaintance in a public setting, if is probably NOT a good follow up question].*

Reassess Mood: *How are you feeling now? (Pause for participant's response. If clarification is needed, then ask following): Do you feel that your mood has improved from where it was? [If mood has improved, go to Step 6. If it has not, continue on].*

Teach Additional Coping Skills: *Could I offer you some coping strategies? These are behavioral skills that you may find useful to also help improve your mood. I'd like to teach you a couple that may be helpful to you. Is that okay? (Pause for participant's response then proceed): There is a set of skills called TIPP that I'd like to introduce you to. Each letter stands for a different skill. I'll tell you what they are and then we can figure out which one or two you'd like to try. The T stands for Temperature... (Orient participant to TIPP skills individually at a high level. Make sure to mention that if participant has any heart problems or concerns, skip the T and move to the others. Once reviewed ask the following question): Which of these skills would you like to try first? (Pause for participant's response. Proceed with teaching and practicing the skill selected, then ask): How are you feeling now? Would you like to learn and practice another? (Assess participant's mood and interest in learning another. It may be the case that participant's mood has improved AND they still*

wish to learn a new skill. If this is the case, teach them another skill. If participant is not feeling better, skip to Step 8).

If Participant Is Reluctant to Engage in Problem Solving Efforts to Change Mood: (Ask participant): *Is there something else that might be going on for you right now that might be helpful to talk about for a few minutes?* (If there is, just thoughtfully listen for a few moments. When the conversation winds down naturally, state): *I am really glad we talked about that. How are you feeling now?* (Listen with ear to determining whether it would be helpful to teach a skill or two. If it would be helpful, ask participant if he/she would like to learn some skills that may be helpful to them): *I definitely don't want to push to figure out a plan with me (or to learn skills). I do just want to make sure you're okay before we hang up. Would it be helpful to try out a skill?* (If they do not wish to, move to **Identify Who they Can Call if Needed**.

STEP 6: COPING AHEAD AFTER HANGING UP

Identify a Plan. *Before we get off the phone, I want to make sure you're set and in good shape. Would that be okay?* (Pause for participant to respond. If participant wants to terminate call before completing this step, skip to Step xx. Otherwise proceed): *What ideas do you have for what you might if you start feeling distressed again?* (Elicit one or two ideas from participant [If no ideas, identify one or two things person can do to distract themselves. Use Crisis Survival Handouts for WiseMind ACCEPTS and Self-Soothe if need to generate ideas].

Identify Who they Can Call if Needed. *Would it be helpful for us to figure out whom you might call if you need a bit more support later? Do you have someone you usually call when you're feeling down?* (Pause for participant's response. Help generate ideas of who the best person might be to reach out to in their social support network. If there is no one or if participant is hesitant to contact someone in network, then proceed with following): *What about your therapist? Is that someone you might reach out to?* (Pause for participant's response. If unable/unwilling to call therapist but a contact is needed, proceed with): *May I then give you the phone number for the national crisis hotline?* (Before proceeding, make sure participant has phone number for person/organization they agree to call): *Do you have <<insert name's>> phone number if you need it?*

STEP 7: CONCLUDING THE CALL

Summarize the Plan. *Thank you for working with me here. I think we've got a good plan in place. Do you want to just say back to me what the plan is just to make sure you have it? <<If person has it, move to **Get Agreement to DO the Plan** section. If person omitted important details, fill them in. If person doesn't have plan, summarize the plan: That's okay. Let me summarize it for you. Would you like to write it down just so you have it? <If yes, pause to provide participant with opportunity to get writing materials>.*

Get Agreement to Do the Plan. *Did I get it right?* (Pause for response from participant). Great. So can we agree that's what you're going to do if it's needed after we hang up?

Answer Remaining Questions. *Is there anything else that would be helpful for us to discuss before we hang up?*

Conclude the Call. *Thank you again for taking the time. All my best to you. Goodbye.*

STEP 8: MANAGING AN ACUTE CRISIS - For use when participant is extremely upset and/or you are uncertain about how to proceed.

Validate Person's Pain & Desire to Help. *I can tell you are still having a hard time. I want to make sure that you are okay and safe after we hang up.* (If you haven't yet taught TIPP, go to Step 5, "Teach Additional Coping Skills" and teach TIPP or practice a different TIPP skill.

Emergency / Crisis Situation. (If participant seems unresponsive or not willing to seek help, then call Linda Dimeff 206-384-7371 or Kelly Koerner 206-265-2507. State to participant): *I am very worried about you and I'd like to get help from my supervisor who is a clinical psychologist if you don't mind. May I briefly put you on hold while I attempt to reach her? If I can reach her, I'll tell her a bit about what we discussed and I'll have her join the line with us. Is that okay with you?*

PracticeGround: Transforming Training and Delivery of Mental Health EBPs

NCT02314624 | Therapist Protocol | October 18, 2017

Therapist Study Process Overview

1. [Study Staff Reviews Screen](#)
2. [Informed Consent Phone Call](#)
3. [Send Consent Survey](#)
4. [Logging Consent & Randomization Info](#)
5. [Randomization](#)
6. [Warm Phone Call & Baseline Survey](#)
7. [Orientation Call](#)
8. [Feature Review \(WILLOW Condition Only\)](#)
9. Ready to Accept Study Patients
10. Post-Orientation Call Tracking
11. Post-Intake Steps
12. [Scheduling Call](#)
13. Week 4 & 8 Assessments
14. Week 12 Assessment
15. After 6 weeks & no study referrals yet
16. End of Study Procedure

Step 1: Review Screen

1. Check Survey Monkey for screen if it is your folder day
 - a. Click on **Exports** on the left hand side of the screen
 - b. Click **Export All** and choose **All Responses Data** in the dropdown
 - c. Select .XLS for format
 - d. In the **Cells:** dropdown menu choose “Numerical Value”
 - e. Click the **Export** button
 - f. When it finishes loading, click the drop down arrow and select download.
 - g. Open the zip file
 - h. Go to excel folder and select Sheet_1
 - i. Copy and paste answers into ‘TherapistScreen.ALL’ tab in [Therapist Screen Database](#)
 - j. Determine if therapist is eligible or not.
 - i. If eligible: copy/paste information into ‘Eligible’ tab in [Therapist Screen Database](#)
 - ii. If unsure: consult with Angela on how to follow up
 - k. Review screen for any skipped questions or those you need to follow-up on. Note these as follow-up items during phone call.

If therapist is ineligible:

1. Send ineligible email

WILLOW Full RCT Therapist Protocol

If therapist passes screen or unsure:

1. Flag any questions and consult with Angela on how to answer.
2. Create a cover sheet for the therapist with contact information and keep notes of all interaction with the therapist in the log. Save as FirstName,LI-CoverSheet
3. Call and Email Therapist for clarification of eligibility and/or Informed Consent

Voicemail Script if Eligible:

Hi this is _____ from the Depression Treatment Study. I'm calling to let you know that you are eligible to participate in our study! The next step to enroll in this study is to read and sign the consent form. I will send you more information about this process via email after I leave this message. If you have any questions or if I can be of any assistance, please reply to that email or call me at (phone #). Thank you!

Voicemail Script if Follow-up Needed to Determine Eligibility:

Hi this is _____ from the Depression Treatment Study. I'm calling to talk with you more about your participation in the study. We just have a couple of questions about answers you provided in the online questionnaire. I will also send you an email after leaving this voicemail message. Please reply to that email or call me back at (phone #) at your earliest convenience. Thank you!

1. If they call you back
 - a. And it is a good time for you to talk: Go through the script below
 - b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Pilot RCT Calendar
 - c. Log the call in the cover sheet
2. If they pick up, use the script below in Step 2.

Step 2: Informed Consent Phone Call

1. Open up the [online screen](#) in SurveyMonkey to have it ready in case you need to review answers.
2. Open the [therapist screen database](#). Make note of the items that need follow up.
3. Contact every 2 days until you reach them, alternating email and phone.

Call Script:

Hi, is this _____?

Hello _____. My name is _____ and I'm calling from the Depression Treatment Study. I am excited to say that based on the answers you provided in the screen, you are eligible to

WILLOW Full RCT Therapist Protocol

participate in the study! I would like to tell you more about our study and the next steps for participation. I expect this call will take about 15 minutes. Is this a good time to talk?

If it is, proceed.

If not, schedule a time to call back later. Log call time and date in the Pilot RCT Calendar.

We at the Evidence Based Practice Institute have developed new software system called WILLOW that assists therapists in delivering evidence-based practices. This tool has the capability to be flexibly integrated into therapy sessions based on your personal style of delivering treatment. Using WILLOW is like having a treatment expert in the room, ensuring that you are being guided by best practices:

- It provides the tools, resources, and guidance to help therapists of all experience levels deliver evidence-based therapies.
- It has a built-in progress monitoring system allowing you to easily assign, score, and view a variety of measures to better understand how your patient is progressing.
- It provides a flexible, session-to-session tracking system that will make organizing your session notes and treatment plan a lot easier.

These are just a few of the features you can find in WILLOW.

We will be comparing the use of WILLOW to standard care for the treatment of depression. Half of the participants in this study will be assigned to use WILLOW and the other half will be asked to provide the therapy they normally would to treat depression.

Do you have any questions so far?

If no, proceed to the next section.

If yes, refer to the FAQ section for assistance.

Now, to give you a sense of what will happen in our study,

- All participation in this study is voluntary and you can choose to withdraw from it at any time.
- You will be randomized to one of two conditions: the WILLOW condition or standard care condition.
- If you are randomized to the WILLOW condition, you will be asked to use a computer in session to guide you through conducting Behavioral Activation for the treatment of depression.
- If you are randomized to the standard care condition, you will be asked to conduct treatment as you normally would.
- In both cases, we will ask that you meet with 2-5 research patients for 12 weeks each. You can choose to treat as many study patients as your schedule allows. Patients that

WILLOW Full RCT Therapist Protocol

are enrolled in the study with you will need to be new patients to your clinic and must not have received treatment from you previously.

- You can still use WILLOW with your patients who are not involved in the research study.
- Participants in both conditions will be asked to complete one online survey before starting the study (baseline) and another set of online surveys with a brief telephone interview after 4, 8 and 12 weeks for each research patient they treat. You will be compensated \$50 for each 4 week and 8 week survey, and \$60 for each 12 week survey you complete.
- You will be eligible to obtain free access to WILLOW for 12 months after the completion of your participation, which involves successfully recruiting at least 1 study patient and completing all assessments for that patient.

Does this sound like something you would be interested in?

If no, thank them for their time and hang up.

If yes, proceed to the next section.

Awesome! The next step would be for you to read and sign a consent form.

The entire process takes about 15-20 minutes. I will send you an email shortly that contains the link to the consent form and we ask that you complete it within the next two days. After completing the consent form, we will randomize you to either the WILLOW condition or the standard care condition and follow up with orientation brief call to explain the next steps.

Do you have any last questions for me?

Thank you so much for your interest in our research. Please don't hesitate to contact us if you have any questions as you are reviewing the consent form. Have a great day!

Step 3: Send Consent Survey

1. Send therapist consent survey email
2. Log date consent sent in the [Summative Tracking DB](#)
3. Log call in coversheet, including answers to any follow-up questions you had when confirming eligibility, and any concerns they brought up and how they were/will be addressed
4. Check SurveyMonkey for consents every day
5. Every 2 days, follow up with those who expressed interest but haven't completed consent, alternating phone calls and emails
 - a. Log contacts with them in coversheet



Step 4: Logging Consent & Randomization Info

1. Check daily to see if the completed their consent/baseline
2. Create a Word Doc of their consent and HIPAA to send with their baseline email
 - a. Open up the Consent & Consent Addendum templates
 - b. Go to the therapist consent form on SurveyMonkey
 - c. Make sure you are on the “Individual Responses” tab.
 - d. Copy and paste the information underneath the word “Complete” in the grey text box into the bottom of the consent template.
 - e. Copy and paste all of the pages of questions and responses between (but not including) the Contact Info Page and the HIPAA into the consent form template
 - f. Rename the template by replacing the word “Template” in the title with (Therapist last name and first initial)
(example: !Template.Pilot-TherapistConsentForm → Brimer,A-Pilot.TherapistConsentForm)
 - g. Save document as PDF
 - h. Open up the Signed HIPAA template
Make sure you are on the “Individual Responses” tab.
 - i. Copy and Paste the information underneath the word “Complete” in the grey text box into the bottom of the HIPAA template.
 - j. Copy and paste the HIPAA page questions and answers at the bottom of the HIPAA template
 - k. Rename the template by replacing the word “Template” in the title with (Therapist initials)
(example: !Template.Pilot-TherapistHIPAA → Brimer,A-Pilot.TherapistHIPAA)
 - l. Save document as PDF
3. Log the date they completed the consent in the [Summative Tracking DB](#)
4. Assign the therapist a study ID and record it in the SSID column in the [Summative Tracking DB](#)
5. Record the randomization categories for the participant in the ‘Randomization’ tab in the [Summative Tracking DB](#).

Step 5: Randomization

1. Check that the randomization information is entered into the ‘Randomization’ tab in the [Summative Tracking DB](#)
2. Email Angela (or person responsible for randomizing) to request they randomize the participant
3. To Randomize:
 - a. Open Minim Py
 - b. Enter in the randomization categories

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- c. Record the Date Randomized, UI number, and Condition in the 'Randomization' tab in the Summative Tracking DB
- d. Email Research Assistant once participant is randomized

Step 6: Therapist Warm Phone Call & Baseline Survey

1. If they don't pick up, leave a voicemail and send appropriate email, script below.
2. Call them back every 2 days until you reach them.

Voicemail Script:

Hi this is _____ from the Depression Treatment Study. Sorry we missed you. Thanks so much for submitting your consent form and enrolling in our study! We would love to schedule a time to tell you more about the study and the next steps of your participation. We are eager to get started and I hope to schedule a time to talk with you soon. Please give us a call back at (phone #) when you have 10-15 minutes for a quick call or let us know when a good time for us to call you back would be.

3. If they call you back
 - a. And it is a good time for you to talk: Go through the script below
 - b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Pilot RCT Calendar
 - c. Log the call in the cover sheet
4. If they pick up, use the script below:

Warm Call & Baseline Script:

<<customize as needed for pilot therapists>>

Hi, this is _____ and I'm calling from the Depression Treatment Study. Thank you for completing our consent form and enrolling in the the study! We would like to briefly review the study procedures and let you know what the next steps are for your participation. Is this a good time to talk?

If it is, proceed.

If not, schedule a time to call back later. [Log the call in the tracking sheet, update the date of the call in both tracking sheet and database, and enter this new date into the calendar]

We are super excited that you decided to participate in this study! As a reminder, this study will compare how clients respond to different ways of delivering treatment for depression. You have been randomly assigned to the **[Standard Care or WILLOW]** condition.

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<<For pilot therapists enrolling again: *You will still be assigned to [Standard Care or WILLOW] condition*>>

This means that we will ask you to treat 2-5 study patients over the next 4-6 months, depending on when your study patients are enrolled in the study, for 12 weeks each using **[your usual method of treating depression or WILLOW]**. We'll provide more information about your study condition after you complete the first set of study surveys. For now, we just wanted to make sure you will be available to participate in the study for 4-6 months and have room on your caseload for 2-5 study patients over this time. Does this sound doable?

If no, troubleshoot: is there any assistance we can provide to help you with this? What is needed for you to be able to treat study patients?

If yes, Great! We're so happy this will work for you!

The next step for your participation is to complete the first set of surveys. These are set up online and I will send you a link to access the surveys after our call today with instruction about how to log in to complete them. The email address I have on file is [email address]. Will this be the best email address to send the surveys to? We'll ask that you complete the surveys within 48 hours. Is this doable? Ideally, we would love if you were able to log in to complete the surveys after our call today. Is this possible? If not, when can we expect you will be able to complete the surveys by?

Once you complete the baseline survey, we will give you a call to tell you more about the study and review the study procedures in depth. Let's schedule a time for us to talk. I expect this call to take approximately 20-30 minutes. What day and time in the next week or so would work best for you? Remember, we need to have your first set of surveys completed by this time.
[Schedule call, record on cover sheet, in tracking DB, and add to calendar]

We will ask that you complete three additional study assessments for each study patient you treat. These will take place at weeks 4, 8, and 12 of your patient's study treatment. We've worked to keep the study assessments as convenient as possible. Surveys at Weeks 4 and 8 will consist of a brief phone interview lasting approximately 10-15 minutes and then an online survey that may take about 15-20 minutes. You will be compensated \$50 for each week 4 and 8 survey you complete. The Week 12 assessment will consist of a phone interview that will last about 30 minutes and the online survey that will take another 30 minutes. You will be compensated \$60 for each week 12 survey you complete. During your final study assessment, you will be asked to provide information about the exact number of sessions you conducted with each of your study patients. In order to help you track these assessments, we will provide you with a session tracking sheet for your convenience.

<<for pilot therapists make sure to point out that we will not be doing amazon giftcards anymore, both for therapists and patients>>

If WILLOW Condition:

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<<if therapist did pilot, then they do not need to do the feature review. Skip to last paragraph>>
After our next call, we will provide you access to WILLOW and the training resources. We will also work with you to come up with a tailored training plan to meet your learning style and needs so that you can feel prepared to use WILLOW in-session. Once you have explored WILLOW and understand how to use it, we will schedule a WILLOW Feature Review with one of our study staff and ask that you demonstrate some of the WILLOW features to us. (Don't worry, you can retake the feature review up to 2 times and we will provide you with a study guide!). You'll receive \$100 for passing this review. After you complete the feature review, you will be ready for your first study patient to use WILLOW with.

Again, we will review the study procedures in depth during our next call, but do you have any questions about this right now?

Wonderful! Thanks so much for taking the time to talk with me today. I will send you an email right after we hang up that includes a copy of your signed consent form for your records and the link to the baseline assessment. Remember, we will need you to complete the surveys within the next 48 hours. If you have any questions as you are completing the surveys, please contact us immediately. We're here to help! I look forward to talking with you again on **[day, date, time that you scheduled orientation call]**!

2. Send therapist the Baseline Survey email and attach their signed consent form and HIPAA authorization
 - a. Make sure to attach their signed HIPAA and Consent form.
 - b. Check every day
 - c. Send reminder email if Baseline surveys are not completed within 48 hours, baseline must be done before orientation call
3. Record all scheduling information in Summative Tracking DB, including when orientation call is scheduled, when BL surveys were sent

Step 7: Therapist Orientation Call

1. If they don't pick up, leave a voicemail and send appropriate email, script below.
2. Call them back every 2 days until you reach them.

Voicemail Script:

Hi this is _____ from the Depression Treatment Study. Sorry we missed you. I had in my calendar that we were scheduled to speak today, Day, Date at Time. If you receive this message in the next few minutes, please give me a call back at (phone #). Otherwise, we would love to reschedule a time to review the study procedures and the next steps for your participation. We are eager to get started and I hope to talk with you soon. Please give us a call back at (phone #)

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when you have 15-20 minutes to talk or let us know when a good time for us to call you back would be.

3. If they call you back

- a. And it is a good time for you to talk: Go through the script below
- b. And it is not a good time for you to talk: Schedule a time you can call them back.
 - i. Log call time and date in the Pilot RCT Calendar
- c. Log the call in the cover sheet

4. If they pick up, use the script below:

Calling Script:

Hi, this is _____ and I'm calling from the Depression Treatment Study. Thank you for completing our baseline survey! We would like to tell you more about our study procedures at this time. Is this a good time to talk?

If it is, proceed.

If not, schedule a time to call back later. [Log the call in the tracking sheet, update the date of the call in both tracking sheet and database, and enter this new date into the calendar]

In this study, we're comparing how clients respond to different ways of delivering treatment for depression. As you know, you have been randomly assigned to the **[Standard Care or WILLOW]** condition.

We'll ask that you meet weekly with two or more study patients for 12 weeks each. We expect that you will first conduct a welcome/intake/get to know you session with the study patient to introduce the study to them and gauge if they would be a good fit. This does not count toward the 12 weeks. While the clients have gone through our screening process, we ask that you use your clinical judgment during this session to assess if the client is appropriate for the study or not. If your client is experiencing active mania or psychosis, meets criteria for alcohol or other drug abuse/dependence, is at imminent risk of suicide, or reports the occurrence of self-harm or self-injury in the past 30 days they should not be participating in this study. If you find your client meets any of the exclusion criteria, please let study staff know right away. We will work with you to discontinue the patient's participation in the study. It is up to you and your clinic if you decide to continue seeing the client outside of the study or if they should be assigned to another clinician. We will contact you after this initial session to verify that your client meets study criteria and will also at that time schedule your study assessments.

If assigned to Standard Care:

During your participation in this study, your clinic will assign you new study patients with depression. We ask that you treat them for depression as you would normally for 12 weeks. The patients will all be consenting study participants. They will complete study assessments at the same time points as you and will also receive payment for their participation. <<For Navos

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Therapists: compensation for your participation will be sent to your clinic, where it will be put towards a special training and education fund that will benefit all department employees. >> It is up to you and your clinic how to proceed with the patient after the 12 weeks of therapy. Your clinic administrators should have already discussed this with you, but if they have not, please check in with them about your procedures. It may be that you continue to see your client as needed after the research study, your patient may be placed back on the waitlist, or they may be assigned to a therapist as they normally would at intake. Please make sure to contact your clinic administrators to ensure you are clear how to proceed with your patient after the study. Any questions about your study condition so far?

If assigned to WILLOW: <<skip to next paragraph for pilot WILLOW therapists>>

How much do you know about WILLOW? (Tailor description based on this)

Describe WILLOW:

WILLOW is a comprehensive software system that is specifically designed for therapists to deliver evidence-based therapies. WILLOW is a tool designed by therapists for therapists with tons of input from therapists and patients.

WILLOW has two main domains—

- Progress monitoring: assign measures to patients, patients complete measures in their own WILLOW account on their own time, responses are automatically scored and appear in graphs on a therapist dashboard.
 - Do you currently use progress monitoring?
- Just-in-time-training (JITT): use it before session to prepare as well as in session with your patient to guide you through delivery of Behavioral Activation for depression. Included in this module are tools (videos, bullet points, worksheets, discussion questions); designed to be used by everyone from therapists who have limited knowledge of the treatment to learn to deliver it, to experienced therapists who want to have the tools at their fingertips

As I will explain in more detail in just a moment, we will provide you with WILLOW training resources so you are confident and competent in your use of WILLOW.

Any questions so far?

During your participation in this study, you will get new study patients with depression who were assigned to you by your clinic or who you recruit yourself. We ask that you treat them for depression using WILLOW for 12 weeks. The patients will all be consenting study participants. They will complete study assessments at the same time points as you and will also receive payment for their participation. <<For Navos Therapists: compensation for your participation will be sent to your clinic, where it will be put towards a special training and education fund that will benefit all department employees. >> It is up to you and your clinic how to proceed with the patient after the 12 weeks of therapy. Your clinic administrators should have already discussed this with you, but if they have not, please check in with them about your procedures.

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It may be that you continue to see your client as needed after the research study, your patient may be placed back on the waitlist, or they may be assigned to a therapist as they normally would at intake. Please make sure to contact your study liaison to ensure you are clear how to proceed with your patient after the study.

We'll ask that you use WILLOW to deliver Behavioral Activation (BA), starting the session following this welcome/get to know you session. You will be encouraged to use your clinical judgment to respond to anything that comes up outside of the domain of your patient's depression. We ask that you use the BA module in WILLOW every week with your patient, both to prepare before session as needed, as well as in session and in real time, to guide your delivery of Behavioral Activation. The WILLOW module includes worksheets, handouts, scripts, videos, and checklists. You can use your clinical expertise to determine how best to use these resources. WILLOW will also assist you in collaboratively setting and tracking agendas, goals, and homework. WILLOW also has a notes feature that you are free to use as you see fit and as best integrates with your clinic's existing requirements and tools for session notes.

We'll also ask that you use WILLOW's progress monitoring features to track your patient's mood on a weekly basis by assigning them one or more brief (2-5 minute) questionnaires that they complete outside of session. These features will be clearer once you get in and start using WILLOW.

FAQ:

What if I don't have access to WILLOW one week?

What if a crisis comes up and we don't get to BA that week - WILLOW is flexible – use your clinical judgment.

In addition to using it with your study patients, you can also choose to use WILLOW with your other patients who are not participating in the study. With those patients you can choose to use it however you like, whether you use the Behavioral Activation content or just the progress-monitoring feature. This means you can create WILLOW accounts for them or just print resources from WILLOW to use with them.

After your last study patient has completed their 12-trial for the research, you will then be given free So to be eligible to receive the free 12-month access to WILLOW after the research study, you must complete the study procedures for at least 1 study patient.

We just covered a lot of information! Do you have any questions so far?

Describe surveys (for both conditions):

We will ask for your feedback at various points in the study:

- **Describe Study surveys (for both conditions):** You have already completed your first set of surveys online. You will also be asked to complete surveys during Weeks 4, 8, and 12 for

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each of your patients. Surveys at Weeks 4 and 8 will consist of a brief phone interview and online survey. The phone interview will last approximately 10-15 minutes. You will be provided with a \$50 check that will be mailed to you for each week 4 and 8 survey you complete.

- The Week 12 surveys also consist of a phone interview and online survey. The phone interview will last about 30 minutes and the online survey will take another 30 minutes. You will be provided with a \$60 check for each week 12 survey you complete.
 - During your final study assessment, you will be asked to provide information about the exact number of sessions you conducted with each of your study patients.
 - In order to help you track these assessments, we will provide you with a session tracking sheet for your convenience.
- The checks will be coming from Chase Bank so be sure to keep your eyes out for an envelope from Chase when the time comes. It does often look like junk mail so we want to make sure that you're aware and not throwing those away.

If your patient exits therapy before the 12-week study trial is over, that is okay. Neither the patient nor the therapist will be removed from the study. If this happens with any of your patients, we will still ask both you and your patient complete your post surveys and you will be paid in full upon completion of the surveys. Similarly, if any sessions are skipped or rescheduled, we will still ask you both to complete the assessments as planned.

After the week 12 survey is completed, you and your clinic will decide the next steps for the patient and if more treatment is indicated or requested, whether or not you continue with the patient outside of the study or if they will be assigned to a non-research therapist.

Do you have any questions at this point?

Describe goal of Full RCT (for both conditions):

- To give you an overview, the purpose of this full randomized controlled trial (RCT) is to test WILLOW, our computer-assisted therapy tool, and how it can be used to assist therapists to treat their patients who are experiencing depression. Additionally, we will also assess the wellbeing of both you and your patient. .

Any questions?

Describe Next Steps:

For CAU Condition Only: Skip to Step 9

<<For pilot WILLOW therapists briefly note:

- The account activation link no longer expires, but please ask your research patients to try to complete the activation as soon as possible.
- Email reminders for measures are sent the day before the due date and there is no email reminder for homework items you manually entered in WILLOW.

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- New feature: RCI, reliable change index, that tells you whether the change in score for a particular measure is significant.
- Your patients using WILLOW (either research patients or non-research patients) can login to WILLOW anytime to complete measures or homework, once they have activated their account, and do not need to wait for an email to prompt them.
- If they are experiencing technical difficulties, please direct them to contact our customer support (customersupport@willow.technology). They can also use the green Feedback & Support tab in WILLOW to contact us.

Skip to Step 9 or schedule a refresher review if needed: Now, how are you feeling about using WILLOW? Do you feel that you would need another review with me to refresh your memory?>>

For WILLOW Condition Only <<schedule on join.me or on WebEx if network security blocks don't allow join.me Great! The next step would be for us to send you the WILLOW training materials and instructions for accessing the system. I will also send you the study guide that will help you focus your getting to know WILLOW and prepare for the feature review. It has all of the questions and answers to those questions that I would ask you during the Feature Review so you can use that to prepare. The Feature Review will be a 1 hour online appointment we'll do on a screensharing program called Join.me. You can retake the review as many times as needed, but I don't expect that you will need to since we will provide the study guide. After you 'successfully' complete the feature review, we will provide you with a \$100 check. You will then be ready to accept your first study patient to use WILLOW with.

But before we schedule that I have some tips that might help you plan how you will get to know WILLOW. We have found that it works best if you block out two 1-hour blocks of time your schedule in the next week or so to do a solo exploration of WILLOW. Would you be able to do that? We can also give you a quick, 15 minute check-in call to answer any questions you may have while you're looking at WILLOW. Would you like to schedule that now, or would you prefer I check in later to see if you would like to have that quick phone call?

Record next steps – phone call or check in email as determined by therapist

Finally, let's schedule your one-hour feature review. We can do it as soon as the week of **month, day**. What time and day will work best for you during that week?

Great! I will send you the meeting information shortly after this call. It will include information about how to log into the screen sharing system. If you have any questions or technical difficulties, please contact us immediately. My colleague, Julie, conducts the feature review and so will log in with you on Day, Date at Time.

Any questions or concerns before we end this call?

Great! I will put you down for ____ at ____ pm/am.

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1. Schedule join.me call, send to research@ebpi.org and julie@ebpi.org
2. From your own calendar create a calendar invitation that is a duplicate of the one sent by join.me – send this calendar invitation to Julie and the therapist
3. Let Julie know it was scheduled.
4. Record information in Summative Tracking DB

Check-in call Script

Hi ____

This is ____ from the depression treatment study. Is this a good time to talk? How much time do you have to talk?

Ok great. I'll keep track of that.

Did you have a chance to look over Willow? Do you have any questions so far?

Ok great! Would **[Date]** at **[Time]** still be a good time for your feature review?
Awesome! Looking forward to speaking with you then.

~~~~~

## Step 8: Feature Review (WILLOW Condition Only)

1. Send a reminder email to therapist the day before the scheduled feature review including the study guide *without* answers and join.me information
2. 15 minutes before call, log into the join.me meeting

### PROCEDURE:

Before starting the Pilot RCT, WILLOW therapists will receive individualized instruction and/or access to instructional tutorials from the EBPI research team in how to use WILLOW. WILLOW therapists will be required to demonstrate competencies in the following areas before beginning WILLOW use with a depressed patient. Competencies will be assessed during a virtual screen-share demonstration session that is expected to last approximately one hour. The test will be scheduled at the research therapist's convenience, and may be retaken as often as necessary until the participant is fully able to demonstrate competencies with all stated items. WILLOW therapists will be paid a \$100 Amazon gift card upon passing their competency test to compensate them for their time.

### INSTRUCTIONS:

<<SCRIPT>>: *Thank you for making this time today to demonstrate your ability to complete the various WILLOW tasks. As you know, we want to make sure you have had all the training and*

## WILLOW Full RCT Therapist Protocol

*support you need in order to use WILLOW thoroughly in treating your depressed patients. We have identified a number of essential tasks we call WILLOW Core Competencies that are necessary for you to use WILLOW well. In just a moment, I will ask you to perform a specific core competency. Because you will need to be able to use WILLOW efficiently with actual patients, I will be gauging your readiness based on your ability to correctly perform each task. Please keep in mind that I'm reviewing your familiarity and understanding of WILLOW, not your clinical skills. If you realize that you made a mistake in executing a task, you can repeat the task until you pass it before moving on to the next one. If you pass, terrific. If you don't, that is okay. I will just show you how to complete the task and we'll consider this as part of your training. Our goal is to make sure you are ready to go and have the training you need. We can redo this test as many times as needed until you pass with flying colors. Please do not have your study guide with answers open while we are going through the feature review.*

*Do you have any questions before we get started?*

### **Task 1: WILLOW Orientation & Client onboarding**

*RA: Please start by pretending you are talking with one of your patients. You have already completed the intake session and confirmed that the patient is a good fit for WILLOW.*

- A. *RA: Please provide me a brief, motivating orientation to WILLOW. Assume I am depressed and somewhat reluctant.*
  - Properly describes WILLOW as helping track outcomes**
  - Properly describes WILLOW as useful for guiding the delivery of an evidence based treatment**
  - Mentions why a tool like WILLOW is useful**
  - **Bonus Points: Deciding measures and when, make a plan with patient of what they would do and how the treatment will incorporate WILLOW features and tools**
- B. *RA: Explain to the client what they will have to do to get access to WILLOW after you create their account.*
  - Mentions email with account activation link**
  - Mentions that the email could be sent to junk mail**
  - -

**RA Prompt:** Can you be more specific? What parts of the process of activating the account is required in order to use WILLOW?

- *The account activation does not expire, but please prompt your patients to try and complete the activation process as soon as possible. The account activation process begins after your client clicks the link/button in the email and includes setting up 3 security questions, creating their password, and consenting to the Terms of Use for WILLOW. They must consent to the Terms of Use to be able to use WILLOW.*

## WILLOW Full RCT Therapist Protocol

C. RA: Explain the WILLOW patient portal to the client (what they do in WILLOW outside of session, what to expect to see).

- Mentions measures
- Mentions due dates
- Mentions homework
- Mentions homework progress reporting using the slide bar

RA Prompt: What would your client use their account for?

- Clients/patients would login between the sessions you have together
- WILLOW is accessible from any web accessible device (i.e., smart phone, tablet, laptop, desktop)
- If your client/patient hasn't completed their measures yet, a reminder email is sent out to them a day before the due date. BUT they do not need to wait for the email reminder, they can login to WILLOW at any time to do their homework and measures.

D. RA: Show me how you would find out where your patient is in the activation process.

- Goes to bottom of Patient Information page

E. RA: Imagine your client told you they never received the activation link. What would you do?

- Check junk mail
- Goes to bottom of Patient Information page and clicks Resend Account Activation Email

RA Prompt: Is there anything your client can do? Is there anything you would ask them to do first before you resend the activation link?

F. RA: Your client clicked the activation link but it showed an error message or the activation expired. What would you do?

- Click Resend Account Activation Email on patient information page

RA Prompt: This is a similar situation to the last question – your client is not able to start the activation process. What can you do from your therapist portal to restart the process for them?

### Task 2: Patient Setup

RA: Please set up an account for a fictitious client, one with whom you have already had an intake session and whom you confirmed would be a good fit for the study and for using WILLOW.

#### A. Patient Information

RA: For this you can use "practicex.xx@example.com" [replace xxx with today's date and write this into the chat so that the therapist may copy/paste into WILLOW]. Feel free to enter fake information into the other required fields

- Enters information for all required fields (email, nickname, DOB)

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### B. Problems

RA: Assume this patient suffers from depression.

- Clicks checkbox for Depression**

### C. Protocol

RA: Please select Behavioral Activation as the protocol that you will use to treat this patient. And make sure to pair it with the problem you just indicated on the last page.

Click Save & Add Measures when you're done.

- Clicks checkbox for BA**
- Pairs with Depression**

### D. Measures

RA: Please select measures for this patient, including all the measures WILLOW recommends when treating depression with Behavioral Activation. Select another measure, not related to depression, and assign it on a 4-week basis.

Click Save & Add Measures when you're done.

- Selects BADS-SF, DASS-21, and PHQ-9S (recommended based on protocols)**
- Sets start dates**
- Selects another measure from Other Measures list**
- Sets frequency to 4 weeks**
- Sets start date for the other measure**

### E. Messages

RA: Assume that the patient would like to receive email reminders to complete measures. How would you do that?

- Checkmark to Send Reminder emails to patient**

### F. Treatment plan

RA: Now go to your treatment plan page. Please add diagnoses and goals.

Say you just remembered that your patient also indicated that they sometimes struggle with anger. You don't know if this is an actual problem yet, but you want to track it so you assign a measure. Go ahead and add a measure that assesses anger.

- Adds diagnosis/es**
- Adds goal(s)**
- Adds measure associated with sleep**
- Does these things from treatment plan page or the patient set up**

*You can add measures from the treatment plan page or you can go back to the measures page to add the measure. You can also add anger as a problem and then add the measure.*

### Task 3: Set up JITT sessions

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A. *RA: Now we're going to set up your Behavioral Activation agendas from the treatment plan page. Can you show me how you would use the expert recommendation to assign a standard course of BA with this patient? Go ahead and customize the first two Agendas in your playlist by deleting a therapy task, reordering therapy tasks, and adding a new one from the list of Therapy Tasks on the left.*

- Adds the agendas from the Expert Suggested Playlist**
- Customizes the first 2 agendas**
  - delete a therapy task**
  - Rearrange therapy tasks**
  - Adds a therapy task**

B. *RA: Now let's say you realize that you only have 8 weeks to treat your patient, but the expert playlist is 10 weeks long. Show me how you would delete two agendas.*

- Deletes 2 agendas**

*To clarify deleting agendas for the BA protocol specifically, agendas 4 through 9 in the expert suggested playlist all contain the exact same therapy tasks. So in this scenario where you want to delete 2 agendas to accommodate for the shorter amount of time your patient has for therapy, you would NOT delete the agendas at the very end of the list. Instead you would delete agendas from the middle – between 4 and 9- so that you can still conduct the end of therapy agenda items.*

C. RA: Imagine that you are at session 9, but you decide with your client that it would be beneficial to do the tasks again for another session, show me how you would add an extra agenda before session 10.

- Adds another agenda**
- Does this by using Expert Suggested Playlist or by manually adding a new agenda**

*[Make sure therapist is aware of both ways to add a new agenda]*

D. *RA: Demonstrate how you would review the newly created Agendas so you can review the content, before having to use it with your patient. Please also demonstrate how you would review the content from an agenda that is 2 weeks in the future and also how you would review the content 5 minutes before a patient arrives.*

- Reviews therapy tasks of newly created agenda (from Treatment Plan or JITT Library)**
- Reviews therapy tasks of agenda 2 weeks in the future (from Treatment Plan or JITT Library)**
- Reviews therapy tasks 5 minutes before session (from Treatment Plan, Dashboard, or JITT Library)**

RA Prompt: Can you show me where else you can view the therapy content?

*[Make sure to tell the therapist all the places they can review the agenda content]*

E.

### Task 4: Review data with patient

*RA: Imagine that your patient completed some progress measures since your last session. Using the Jane Doe practice patient, please review my outcome monitoring data with me.*

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*Please also demonstrate how you would edit a measure*

- Hovers over individual data points**
- Open chart/table view**
- Open Edit Measure view (click data point to view or navigate there from the Table view)**

RA Prompt: What are the different functions you can use with the graph? How can you view more detail about the data? Can you show me how to view the individual answers? How can you edit answers in the case where your patient accidentally entered the wrong answer?

*[Make sure Therapist know the different ways to Edit Measure]*

### **Task 5: Find a WILLOW tool (Activity Monitoring Worksheet)**

RA: Please demonstrate how to find the Activity Monitoring Worksheet

- Finds the Activity Monitoring Worksheet**

RA: You can find the Worksheets and other resources by going to the bottom of the JITT Library page or from the treatment plan (click Getting Started with Activity Monitoring and then Activity Monitoring Worksheet).

### **Task 6: Find the Bird's Eye View of Behavioral Activation.**

RA: Please navigate to the "Bird's Eye View" of BA.

- Navigates to the Bird's Eye View of BA from either the JITT Library page or the protocol page of the patient setup

### **Task 7: Custom agenda item**

RA: A custom agenda item is something that isn't already a part of the protocol that you are using. Please add a customized agenda item that you might do with a typical depressed client.

- Adds custom agenda item from Patient Dashboard**

RA: You can also add agenda items from the Treatment Plan page like you did for an earlier core competency. But you can only add custom agenda items from the Patient Dashboard.

### **Task 8: Use JITT tools and complete agenda items**

RA: Please demonstrate walking a patient through at least one of the BA therapy tasks on the agenda. Make sure to fully use all available resources. Mark this therapy task as complete when you've finished.

*Also check off all but 3 of the remaining JITT therapy task agenda items. What will happen to the therapy tasks that you did not complete during this session? [\*not a requirement to pass, but something they should know]*

### **Task 9: Homework**

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*RA: Please create a homework assignment for me, due a week from today, called Activity Monitoring. In the Description of the task, please add that the task should be done every day in a block fashion (morning, afternoon, evening).*

- Creates homework assignment as described**

*In order to minimize any confusion on your patient's end, please make sure to enter any instructions you might have for your patient because they will see only exactly what you enter in these fields and nothing more.*

### Task 10: Session note

*RA: Imagine that you finished a session with a client and now you want to create a session note. How would you do that?*

- Creates a session note**

*RA: the one field that must be filled out in the session notes is the Session Number because a future function in WILLOW will be determining whether the patient is on-track or off-track compared to other patients. You would need to fill in the Session Number in order for that function to work for the client.*

### Task 11: Clearing out completed items

*RA: Imagine you completed your third session with the patient, but were in a rush after the session and did not have a chance to get WILLOW up to date to reflect that. The patient just came in for their fourth session, and you need to quickly clear out past items and have the agenda be updated to the items for this session. Demonstrate how you would do this. [not required to "pass", but something the therapist should know how to do]*

*Creating a session note wipes out completed items from the dashboard so that items for the next session are available*

### Task 12: Log Out and Exit WILLOW

*RA: Please show me how you logout and exit WILLOW.*

- Logs out**

*[Script for therapists who pass]:*

*That's terrific. You have successfully navigated all the WILLOW Core Competencies. You are ready to go!*

*<<Follow the script in the WILLOW protocol for Therapists, starting from Step 9>>*

*[Process for therapists who do not pass]:*

*<<Provide supportive feedback. Emphasize that there is a lot to learn and that's why you are doing this. Convey that you are certain they pick it up; it just takes time>>.*

*<<Ask participant if they would like to go through a few areas now, or if they prefer to do a bit more on their own first. Be responsive to their request.>>*

*<<Before concluding the call, reschedule another time to complete the test.>>*

## Step 9: Ready to Accept Study Patients

**During orientation call for CAU condition and Pilot WILLOW therapists | After Feature Review for WILLOW condition**

You are now ready to receive patients!

After this call, I will send you an email with the link to access the study resource materials. This includes the patient flyer and a handout with information a Study Tracking Sheet that will help you track your study assessment schedule for each patient. It also includes space to record the date of your session with each of your research clients across the 12 weeks that you will meet with them for the study. We will ask you about the session dates in detail during your final assessment so please record the date of the therapy session for each patient each week or indicate if the session that week was skipped. **Please also be sure to record the Care Start Date and let us know what this date is.** The Care Start Date is the first date the patient received services at your clinic; the care start date is your patient's first face-to-face psychotherapy session and includes the intake session. We will be using this date in our study analyses so it is very important that we have this date on record.

Okay, now I'd like to summarize the referral process again so we're on the same page. You will get your new folks with depression who you think would be interested in participating in the study. Then, you will do the Welcome to WILLOW discussion with them and if they are interested in participating, please ask for their permission to share their contact information with the research team. If they say yes, you can either give me a call directly to convey their name, email, and phone number or you can complete our online referral form, which I will include in the email I'll be sending shortly. It is important that we do not share any of the patient's personal information via email. If they say no, that they do not want you to provide us with their contact information, you can give them my phone number or the patient flyer and they can call us directly. We will then take it from there to get them screened and enrolled. If after 6 weeks you are unable to find patients on your caseload who are interested and/or appropriate for the study, we will contact you to discuss ending your participation in the study or to provide additional support if you would like to continue with your participation.

Do you have any questions?

### **First Session (Both WILLOW and CAU)**

After the patients have been screened, you will schedule your session with the patient as you normally would. This first session will be the intake session during which you will do one last check to ensure the patient is eligible and appropriate for the study.

Exclusion criteria include:

- If the patient is experiencing active mania or psychosis
- If the patient meets criteria for alcohol or other drug abuse/dependence

## WILLOW Full RCT Therapist Protocol

- If the patient is deemed to be at imminent risk of suicide
- If the patient had an occurrence of self-harm or self-injury in the past 30 days

If the patient is deemed ineligible, you can have a conversation with your patient and your clinic about the next steps and let us know of the outcome.

If the patient is deemed eligible, please let us know and continue with therapy.

Do you have any questions?

A couple more things before we wrap up, It is important for our research that you keep track of your visits with each of your study. Please refrain from talking in detail about the research with others at your clinic who are participating in this study, especially if they are not in the same study condition as you are. *[explain if they are in CAU they should refrain from talking about the study with WILLOW therapists and vice versa]*.

Great, that's everything I had for you today! I will send you a follow up email reviewing some of the information we talked about. We are really excited to have you on board!

Thanks,  
Have a great day!

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## Step 10: Post-Orientation Call Tracking

6. Send [Ready](#) to Accept Study Patients email for CAU
7. Send [Ready to Accept Study Patients email](#) for WILLOW (make sure to include the tracking sheet, and WILLOW User Guide)
8. Log date orientation completed
9. Log call in coversheet, including answers to any follow-up questions you had when confirming eligibility, and any concerns they brought up and how they were/will be addressed.

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## Step 11: Post-Intake Steps

10. If the therapist doesn't get back to you within 24 hours of the intake session, send email to check if the patient was eligible or not.
11. Log the following info:
  - a. If patient showed up or not
  - b. Date rescheduled if patient didn't show up
  - c. Eligibility status
  - d. If patient is eligible, schedule ALL therapist assessments and record in Summative Tracking DB

## **Step 12: Scheduling Call**

1. Make scheduling call as soon as you can after first Tx session date, script below
2. If the therapist doesn't answer the call, send scheduling email and leave the voicemail below.
3. Call back/email every 2 days until you reach therapist.

### **VoiceMail Script:**

Hi \_\_\_\_\_, this is \_\_\_\_\_ from Evidence-Based Practice Institute. We wanted to check-in regarding your first session and to schedule your 4, 8, and 12 week study surveys. At your earliest convenience, please give us a call back at (Phone#)\_\_\_\_\_. Thanks!

4. If they call you back
  - a. And it is a good time for you to talk: Go through the script below
  - b. And it is not a good time for you to talk: Schedule a time you can call them back.
    - i. Log call time and date in the Pilot RCT Calendar
  - c. Log the call in the cover sheet

If they pick up, use the script below:

### **Call Script:**

Hi \_\_\_\_\_, this is \_\_\_\_\_ from Evidence-Based Practice Institute. Thanks again for your participation! I am calling today to schedule your study surveys. Is now a good time to talk?

In this call, I want to talk about your sessions with your patient \_\_\_\_\_. Since we cannot disclose your patient's name through email, if we need to talk about him/her I will use their study ID in place of their name which is \_\_\_\_\_.

Great! Firstly, I want to make sure we have the correct dates recorded for your patient. We have it that you completed your first session with the client, a Welcome/Get to know you, non-study session on DATE. In this session, you would have assessed to ensure that the client is appropriate for the study and could also be considered the intake session at some clinics. Is this date correct? (if not, correct date). Next, we have it that your first study session is DATE. Is this correct?

Fantastic! Thanks for reviewing that with us. Now we have three sets of surveys to schedule that will specifically focus on your participation in the study with your patient \_\_\_\_\_. The week 4 and 8 surveys will take about 20-30 minutes over the phone and the week 12 survey will take about an hour total. The first appointment will be 4 weeks from now, during the week of (Month, Date). Do you have a day or time that works best for you? And now your 8 week set of surveys: during the week of (Month, Date). Do you want to try to schedule for (Day) again? Great! Now your final set of surveys during the week of (Month, Date).

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I also want to clarify your patient's Care Start Date. The Care Start Date is the first date the patient received services at your clinic and includes the intake session. So if your client has been to your clinic before, their Care Start Date is whatever day they first came in to receive services at your clinic. The care start date is your patient's first face-to-face psychotherapy session. With that in mind, what is the Care Start Date of patient \_\_\_\_\_?

Do you have any questions for me before we hang up? Great! I will send you an email listing these appointment times after we get off the phone. Have a good day!

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### On Fridays, take these extra steps:

- Check all other daily folders for any stragglers (cover sheets that are not in the proper folder). Follow up as needed and place participant in appropriate folder
- Review the Pending folder and look at each tracking sheet to determine what is needed for each participant. Sort them accordingly.
- Move all of the participants in the Friday folder to either the pending folder, if everything is complete, or into daily folders for next week, depending on what action steps are required for that participant during the week.
- Send a reminder email to all therapists that have their assessment next week

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### Step 13: Week 4 & 8 Assessments

1. Prepare Semi-Structured Interview notes form:
  - Open [interview notes template](#), save as 'SSID.4WeekSemi-StructuredInterview\_p#' or 'SSID.8WeekSemi-StructuredInterview\_p#'

#### Call Script:

Hi \_\_\_\_\_, this is \_\_\_\_\_ from Evidence-Based Practice Institute. Thanks again for your participation! I am calling today for your <<4 week or 8 week>> study assessment. Is now still a good time to talk? Great! I expect this call will take about 20-30 minutes to complete.

Remember, during this time we'll be talking only about your experience in the study you're your client <<NAME, SSID>>.

Any questions before we begin?

First, I want to personally thank you for the time you have invested into our study and your important contributions. We'd like to ask you several questions about your experience.

<<Administer Semi-Structured Interview, taking detailed notes during conversation >>

## WILLOW Full RCT Therapist Protocol

<<If needed, remind WILLOW therapists that they can they can use WILLOW with non-research clients (i.e., create WILLOW account) and that the patients can login to WILLOW at any time to complete their measures>>

Thank you for answering those questions! Is there anything else I should note about your experience in the study? Thank you.

Thank you so much for answering those questions! Now, I will send you the link to the Week \_\_\_ surveys for you to complete when you have a moment after our call today. You will need to enter your study ID and the study ID of your client. They are xxxx and xxxxx, I have included these in the email. If you run into any problems, please give me a call directly.

Our next study call is scheduled for Day, Date, Time. We'll send you a reminder the week before your next call. Thank you!

## Step 14: Week 12 Assessment

1. Prepare Semi-Structured Interview notes form:
  - o Open [interview notes template](#), save as 'SSID.4WeekSemi-StructuredInterview' or 'SSID.8WeekSemi-StructuredInterview'

### Call Script:

Hi \_\_\_\_\_, this is \_\_\_\_\_ from Evidence-Based Practice Institute. Thanks again for your participation! I am calling today for your 12 week study assessment. Is now still a good time to talk? Great! I expect this call will take about 30 minutes to complete.

1. Administer Semi-Structured Interview, taking detailed notes during conversation
  - <<If needed, remind WILLOW therapists that they can they can use WILLOW with non-research clients (i.e., create WILLOW account) and that the patients can login to WILLOW at any time to complete their measures>>
  - o Send link to Week 12 surveys via email

Thank you so much for answering those questions! I have just sent you the link to the Week 12 surveys. You will need to enter your study ID and the study ID of your patient. They are xxxx and xxxxx, I have included these in the email. This is your final appointment for this patient! Once you are completed with the survey, I will go ahead and process your payment which will be a \$60 check. Do you have any final questions for me before I let you go to do the survey? Thank you!

## **Step 15: After 6 weeks and no patient referral**

1. Call provider to discuss either discontinuing participation or how we can provide additional support if they would like to continue with participation

## **Step 16: End of Study Procedures**

1. Create WILLOW accounts for CAU therapists at the end of study and provide them the WILLOW training materials we give all new therapists, because CAU therapists will get free access to WILLOW for 12 months if they successfully recruited 1 study patient.
2. When the therapist's last patient completes their participation, log the date of completion as the start date and 12 months after that date as the end date in the following log for both WILLOW and CAU therapists.