The Ohio State University Consent to Participate in Research

Study Title:	Cognitive Behavioral Therapy for Depression: Helping Clients Learn New Skills
Researcher:	Daniel R. Strunk, Ph.D.
Sponsor:	The Ohio State University

Study Consent Form

This is a consent form for research participation. It contains important information about this study and what to expect if you decide to participate.

Your participation is voluntary.

Please consider the information carefully. Feel free to ask questions before making your decision whether or not to participate.

Purpose: The purpose of this study is to improve our understanding of how cognitive behavioral therapy (CBT) for depression achieves its effects and how this therapy might be improved. Participants in this study will be randomized to one of two forms of CBT: CBT as usual or skill-enhanced CBT. In many ways, the two treatments are similar. Both involve working individually with a therapist using core elements of CBT. The difference is that skill-enhanced CBT includes some additional emphasis on strategies intended to help clients develop facility with these skills. Beyond comparing these two approaches, we also hope to learn more what clients get out of CBT, what strategies are most useful to different patients, and what helps patients continue to do well after treatment ends.

Procedures/Tasks: After an initial screening, potential participants are presented with this consent form. If you consent to participate, you will be asked to complete an online survey followed by a virtual interview (i.e., an interview over the internet). Following that interview, study personnel will be able to determine if you are eligible for the study. If you are eligible, you will be randomized to one of the two forms of CBT in the study.

During the treatment phase of the study, you will participate in individual cognitive behavioral therapy for 12 weeks. In light of COVID-19 considerations, all study participation will occur online, with therapy being provided through videoconferencing software. Due to state licensing laws, you must be physically located in the state of Ohio to participate in these services. For your safety, your therapist will need information for at least one emergency contact.

Your therapist will be a psychology trainee (a graduate student) who is supervised by a licensed psychologist (Daniel R. Strunk). Supervision is provided in an effort to achieve the

highest quality of care possible. Dr. Strunk meets with all psychology trainees on a regular basis to review the progress of therapeutic work. This is one reason your sessions will be video-recorded, to aid in the supervision process and ensure that a high quality of care is being provided. Another reason for video-recording these sessions is to allow us to assess how the treatments were provided as part of the study and to evaluate how these treatments achieve their effects. More information on how session recordings are protected and stored is provided in the Confidentiality section below.

In addition to your therapy sessions, the tasks we will ask you to complete if you choose to take part in this study are questionnaires and interviews. The information we collect will assess some basic descriptive information about you and your mental health. Assessments will also cover topics such as your specific symptoms and functioning, your personality, the way you think about various situations, and strategies you may use to regulate your emotions.

You will be asked to complete questionnaires online, both before and after your therapy sessions and on several additional occasions as you progress through treatment. These additional assessment will occur at three times throughout the study (i.e., just prior to your intake interview, 4 weeks after you begin treatment, and at end of treatment).

We ask that you maintain your appointment schedule, participate in therapy, and work toward the treatment goals that you will develop with your therapist. If you miss sessions recurrently, your therapist may discuss this with you, and after several missed sessions, you could be considered to have dropped out of the study.

Duration: Cognitive behavioral therapy will be provided for 12 weeks. For the first four weeks, sessions will occur twice a week. In the following 4 weeks, sessions can occur either weekly or twice-weekly as determined by you and your therapist. For the last four weeks, sessions will occur weekly. Each session is approximately 50 minutes. If you cannot attend your scheduled appointment, please contact your therapist at least 24 hours prior to your appointment to cancel. After your 12-week course of treatment, you will be invited to respond to a series of follow-up questionnaires (provided you do not pursue an alternative course of treatment) once per month for 6 months. These questionnaires will take approximately 6 minutes each. You also have the option to participate in up to two booster sessions during this period.

You will also be asked to participate in an assessment before the start of treatment as well two additional assessments over the course of your treatment (i.e., 4 weeks after you begin treatment and end of treatment). The questionnaires and interviews will take varying amounts of time. An intake survey will take about 1 hour and 15 minutes. The intake assessment typically takes about 3.5 hours. Another assessment (lasting 70 minutes) will occur four weeks after initiating treatment. A post treatment assessment at the end of the 12-week course of treatment will take approximately 80 minutes. Depending on which condition you are assigned to, you may be asked to complete two additional one-hour assessments related to what you are learning in treatment. Apart from these lengthier assessments, you will be asked

to complete brief questionnaires before and after your therapy sessions (10 minutes before and 5 minutes after each session).

You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits: Some people experience a minimal degree of psychological stress in response to therapy and study questionnaires and interviews. This stress is unlikely to be any greater in intensity than the emotions that are generally experienced on a day-to-day basis. Some questions you are asked may be somewhat sensitive in that they require you to reflect on potentially negative thoughts, behaviors, or attitudes. If you are uncomfortable with any questions, you may refrain from answering them. In the event that you choose not to participate or do not qualify for the study, study personnel can provide you with information regarding other places where you could seek treatment.

Although we are using technology that has been approved by the University and has important security features, there is some risk of a breach of confidentiality when using the internet.

Participation in this study has a number of benefits. Most notably, your participation will be helping to advance our understanding of how cognitive behavioral therapy for depression achieves its effects.

Confidentiality: We will make efforts to keep what you disclose in therapy confidential, but there are some important limitation to note. Limits to confidentiality are as follows:

1. If you are in immediate danger of hurting yourself or another person, your therapist may alert others. (However, this does not mean that every time suicide is discussed in sessions your therapist will take outside action.)
2. If in the unusual circumstance that your therapist is court-ordered to disclose confidential information, he or she may do so.
3. Your therapist has the duty to report abuse and neglect of children, adults deemed incompetent, or physically/mentally disabled adults, such as those who are developmentally disabled.
4. Your therapist can disclose confidential information in accordance with state or federal laws, such as the requirement to report child abuse or neglect.
5. Your progress in therapy will be discussed by your therapist, other study personnel, and the principal investigator of the study, Daniel R. Strunk.

We will work to make sure that no one sees your online responses without approval. But, because we are using the Internet, there is a chance that someone could access your online responses without permission. In some cases, this information could be used to identify you.

Clinicians will take steps to protect your privacy by ensuring that they have a private and secure space when they connect with you for an internet session. We ask that you take steps to protect your privacy during these sessions as well, by finding a space that is private, quiet, and minimizes distractions. If you are using Wi-Fi, you are also advised to use a secure Wi-Fi network.

Also, there may be circumstances where your study related-information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law. Also, your records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Will my de-identified information be used or shared for future research?

Yes, it may be used or shared with other researchers without your additional informed consent.

Incentives: If you choose to participate in this study, you will be given the opportunity to participate in a course of cognitive behavioral therapy free of charge. You will be compensated for some assessments using Amazon gift cards. You can earn $2 per session for up to $32 total for responding to pre- and post-session questionnaires. For post treatment assessment, you can earn $15 for the assessment. For the monthly follow-up assessments occurring for six months following treatment, you can earn $5 per questionnaire for a maximum of $30. The maximum incentive per participant is $77. Again, all incentives will be provided as Amazon gift cards. Incentives will provided in two installments: the first will occur after your week 12 assessment and the second will occur at the conclusion of the 6-month follow up period.

In addition, lottery prizes will be offered as follows:
- A drawing for a $100 Amazon gift card, with participants earning a chance in this drawing for each session survey they submit.
- Another drawing for another $100 Amazon gift card, with participants earing a chance in this drawing for each monthly follow-up survey they submit.

By law, payments to participants are considered taxable income.

Participant Rights: You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of research participants.

Contacts and Questions: For questions, concerns, or complaints about the study, or you feel you have been harmed as a result of study participation, you may contact Dan Strunk at strunk.20@osu.edu or 614-688-4891.

For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact the Office of Responsible Research Practices at 1-800-678-6251 or hsconcerns@osu.edu.

Providing consent

I have read (or someone has read to me) this page and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study. I am not giving up any legal rights by agreeing to participate.

To print or save a copy of this page, select the print button on your web browser.

Please click below to proceed and participate in this study. If you do not wish to participate, please close out your browser window.