

The Ohio State University Consent to Participate in Research

Study Title: Incorporating Positive Affect into Cognitive Behavioral Therapies

Researchers: Jennifer S. Cheavens, Ph.D. & 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 examine different strategies for success in cognitive behavioral therapies. We are specifically testing the effect of adding a focus on promoting positive affect to the procedures of cognitive behavioral therapy for depression. Participants in this study will be randomized to one of two forms of CBT: CBT as usual or CBT with a positive affect focus. In many ways, the two treatments are similar. Both involve working individually with a therapist using core elements of CBT. The difference is that the version of CBT with a positive affect focus includes a set of strategies for promoting positive affect that have not generally been included in CBT. Beyond comparing these two approaches, we also hope to learn more about what clients get out of CBT and what strategies are most useful to different patients.

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 an interview that may be in-person or virtual (i.e., 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 described above.

During the treatment phase of the study, you will participate in individual cognitive behavioral therapy for 12 weeks. This therapy may be provided in-person at the Psychological Services Center at Ohio State University or online through videoconferencing software. To participate virtually, you will still need to be physically located in the state of Ohio. This is a requirement related to state licensing laws for psychology. For your safety, your therapist will need information for at least one emergency contact.

36 Your therapist will be a psychology trainee (a graduate student) who is supervised by a
37 licensed psychologist (Daniel R. Strunk). Supervision is provided in an effort to achieve the
38 highest quality of care possible. Dr. Strunk meets with all psychology trainees on a regular
39 basis to review the progress of therapeutic work. This is one reason your sessions will be
40 video-recorded, to aid in the supervision process and ensure that a high quality of care is
41 being provided. Another reason for video-recording sessions is to allow us to assess how the
42 treatments were provided as part of the study and to evaluate how these treatments achieve
43 their effects. More information on how session recordings are protected and stored is provided
44 in the Confidentiality section below.

45
46 In addition to your therapy sessions, the tasks we will ask you to complete if you choose to
47 participate in this study are questionnaires and interviews. The information we collect will
48 assess some basic descriptive information about you and your mental health. Assessments will
49 also cover topics such as your specific symptoms and functioning, your personality, the way
50 you think about various situations, and strategies you may use to regulate your emotions.

51
52 You will be asked to complete questionnaires online, both before and after your therapy
53 sessions and on several additional occasions as you progress through treatment. These
54 additional assessments will occur at three times throughout the study (i.e., just prior to your
55 intake interview, 4 weeks after you begin treatment, and at end of treatment).

56
57 We ask that you maintain your appointment schedule, participate in therapy, and work toward
58 the treatment goals that you will develop with your therapist. If you miss sessions recurrently,
59 your therapist may discuss this with you, and after several missed sessions, you could be
60 considered to have dropped out of the study and treatment.

61
62 **Duration:** Cognitive behavioral therapy will be provided for 12 weeks. For the first four
63 weeks, sessions will occur twice a week. In the following 4 weeks, sessions can occur either
64 weekly or twice-weekly as determined by you and your therapist. For the last four weeks,
65 sessions will occur weekly. Each session is approximately 50 minutes. If you cannot attend
66 your scheduled appointment, please contact your therapist at least 24 hours prior to your
67 appointment to cancel.

68
69 You will be asked to participate in an assessment before the start of treatment as well two
70 additional assessments over the course of your treatment (i.e., 4 weeks after you begin
71 treatment and at the end of treatment). The questionnaires and interviews will take varying
72 amounts of time. An intake survey will take about 1 hour and 15 minutes. The intake
73 assessment typically takes about 3.5 hours. Another more extensive set of questionnaires (that
74 we expect to take 60 minutes) will occur four weeks after initiating treatment. A post
75 treatment assessment at the end of the 12-week course of treatment will take approximately
76 80 minutes. Apart from these lengthier assessments, you will be asked to complete brief
77 questionnaires before and after your therapy sessions (10 minutes before and 5 minutes after
78 each session).

79

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

84
85 **Risks and Benefits:** Some people experience a minimal degree of psychological stress in
86 response to therapy and study questionnaires and interviews. This stress is unlikely to be any
87 greater in intensity than the emotions that are generally experienced on a day-to-day basis.
88 Some questions you are asked may be somewhat sensitive in that they require you to reflect
89 on potentially negative thoughts, behaviors, or attitudes. If you are uncomfortable with any
90 questions, you may refrain from answering them. In the event that you choose not to
91 participate or do not qualify for the study, study personnel can provide you with information
92 regarding other places where you could seek treatment.

93
94 Although we are using technology that has been approved by the University and has
95 important security features, there is some risk of a breach of confidentiality when using the
96 internet.

97
98 Participation in this study has a number of benefits. Most notably, your participation will be
99 helping to advance our understanding of ways that we might improve therapy for depression.

100
101 **Confidentiality:** We will make efforts to keep what you disclose in therapy confidential, but
102 there are some important limitation to note. Limits to confidentiality are as follows:

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

115
116 We will work to make sure that no one sees your online responses without approval. But,
117 because we are using the Internet, there is a chance that someone could access your online
118 responses without permission. In some cases, this information could be used to identify you.

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120 For those participating in sessions online. Clinicians will take steps to protect your privacy by
121 ensuring that they have a private and secure space when they connect with you for an internet
122 session. We ask that you take steps to protect your privacy during these sessions as well, by

123 finding a space that is private, quiet, and minimizes distractions. If you are using Wi-Fi, you
124 are also advised to use a secure Wi-Fi network.

125
126 Also, there may be circumstances where your study related-information must be released. For
127 example, personal information regarding your participation in this study may be disclosed if
128 required by state law. Also, your records may be reviewed by the following groups (as
129 applicable to the research):

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

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

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

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142 **Incentives:** If you choose to participate in this study, you will be given the opportunity to
143 participate in a course of cognitive behavioral therapy free of charge.

144

145 We will provide an honorarium in Amazon gift cards as a token of our appreciation for your
146 participation. You can earn \$5 per session for up to a maximum of \$80 for responding to pre-
147 and post-session questionnaires. For the week 4 questionnaires, you can earn \$10 for
148 participating. For the post treatment assessment, you can earn \$15 for participating.

149 Altogether, the maximum honorarium per participant is \$105. Again, all incentives will be
150 provided as Amazon gift cards. Incentives will be provided in one installment provided after
151 your week 12 assessment.

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153 By law, payments to participants are considered taxable income.

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

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

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

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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 / 614-688-4891 or Jen Cheavens at cheavens.1@osu.edu / (614) 247 – 6733.

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.