

The Ohio State University Consent to Participate in Research

Study Title: Incorporating Positive Affect into Cognitive Behavioral Therapies

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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 Dialectical Behavior Therapy (DBT). Participants in this study will be randomized to one of two forms of DBT: DBT as usual or DBT with a positive affect focus. In many ways, the two treatments are similar. Both involve working individually with a therapist using core elements of DBT. The difference is that the version of DBT with a positive affect focus includes a set of strategies for promoting positive affect that have not generally been included in DBT. Beyond comparing these two approaches, we also hope to learn more about what clients get out of DBT 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 DBT described above.

During the treatment phase of the study, you will participate in DBT for 24 weeks. DBT includes both individual and group sessions. Individual sessions last for about 50 minutes each and are provided weekly. Group sessions last for about 120 minutes and are also provided weekly. Sessions will occur in-person at the Psychological Services Center at Ohio State University. 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 (Jennifer S. Cheavens). Supervision is provided in an effort to achieve
38 the highest quality of care possible. Dr. Cheavens meets with all psychology trainees on a
39 regular basis to review the progress of therapeutic work. This is one reason your sessions will
40 be 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.

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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.

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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 four times throughout the study (i.e., just prior to your
55 intake interview, 4 weeks after beginning treatment, 12 weeks after beginning treatment, and
56 at end of treatment).

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

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63 **Duration:** DBT will be provided for 24 weeks. Individual and group sessions will occur
64 weekly, with individual sessions lasting 50 minutes and group sessions lasting 120 minutes. If
65 you cannot attend your scheduled appointment, please contact your therapist at least 24 hours
66 prior to your appointment to cancel.

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

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

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

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

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

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

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

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

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119 Because group sessions will be attended by multiple clients, there are special confidentiality
120 considerations in this context. While we ask other group participants to keep the discussion in
121 the group confidential, we cannot guarantee this. Please keep this in mind when choosing
122 what to share in the group setting.

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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 dialectical behavioral therapy free of charge.

We will provide an honorarium in Amazon gift cards as a token of our appreciation for your participation. You can earn \$5 per session for up to a maximum of \$80 for responding to pre- and post-session questionnaires. For the week 4 questionnaires, you can earn \$10 for participating. For the week 12 assessment and the post treatment assessments, you can earn \$15 each for participating. Altogether, the maximum honorarium per participant is \$120. Again, all incentives will be provided as Amazon gift cards. Incentives will be provided in one installment provided after your week 24 assessment.

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.

166 **Contacts and Questions:** For questions, concerns, or complaints about the study, or you feel
167 you have been harmed as a result of study participation, you may contact Jen Cheavens at
168 cheavens.1@osu.edu / (614) 247 – 6733 or Dan Strunk at strunk.20@osu.edu / 614-688-4891.

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

173

174 **Providing consent**

175

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

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

182

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

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