

# **INFORMED CONSENT**

## **The University of South Dakota**

**TITLE:** Living a Meaningful Life

**PROJECT DIRECTOR:** Christopher R. Berghoff, Ph.D.  
**PHONE #:** 605-658-3710

**STUDENT INVESTIGATORS:** Rachel Bock; Emily Kalantar; Mahsa Mojallal; Rebecca Sistad;  
Kyle Walters; Michael Webb

**Department:** Psychology

### **Invitation to be Part of a Research Study**

You are invited to participate in a research study. In order to participate, you must struggle with symptoms of depression, express interest in attending group therapy for problems with low mood, and consent to being videotaped as part of all research sessions. Taking part in this research project is voluntary. Please take time to read this entire form and ask questions before deciding whether to take part in this research project.

### **What is the study about and why are we doing it?**

The purpose of the study is to identify the effectiveness of Behavioral Activation Group Treatment for Depression, a group-delivered psychological therapy designed for individuals currently experiencing depressive symptoms. About 200 people will take part in this research.

### **What will happen if you take part in this study?**

If you agree to take part in this study, your participation will last approximately 11-14 weeks.

All study procedures occur out of the USD Department of Psychology Psychological Services Center and are completed in the South Dakota Union building. First, you will attend a 90-minute intake session, during which you will first complete informed consent (this document). Then, you will be asked to complete survey questions about your personal characteristics (e.g., employment; relationship status), mental health (e.g., depression, anxiety, stress, substance use), and other behaviors. The survey will be followed by a clinical interview, during which you will be asked questions about your mental health (e.g., depression, suicidal thoughts, thoughts of harming others, substance use, potentially illegal activity) and any associated problems in life you may be experiencing.

If you are eligible for the study based on the results of the survey and interview, you will be invited to participate in a 6-session group therapy. Each therapy session lasts 60 minutes. At times, sessions will be held once weekly for six consecutive weeks. At other times, sessions will be held twice weekly for three consecutive weeks. You will be allowed to choose the once or twice weekly schedule based upon current offerings. A portion of each session consists of completing surveys related to your symptoms and functioning. The remaining session time will be dedicated to covering content of the therapy. In general, the therapy is designed to help participants (a) identify current behavioral patterns that may influence depression symptoms, (b) identify personally important areas of life, and (c) increase activities that are personally important or enjoyable.

Finally, you will complete two 30-minute surveys, one 30-days and one 60-days following completion of your group therapy. You will be emailed links to an electronic version of the survey, which can be completed at your home. Alternatively, you may schedule sessions to take the surveys in our lab. Otherwise, we can mail you a copy of the surveys, along with stamped return envelopes, so that you can complete the survey at home and return them to the researcher through the US Postal Service.

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### **Your Participation in this Study is Voluntary**

It is totally up to you to decide to be in this research study. Participating in this study is voluntary. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to answer any questions you do not want to answer. If you decide to withdraw before this study is completed, you will retain all compensation previously earned and we will make use of any partial data that you have provided.

Your participation may be terminated by the principle investigator if, during the course of the study, you report active (past 14-day) suicidal ideation or behavior or indicate you have begun problematic use of substances. Your participation may also be terminated if you attend less than 4 out of the 6 sessions of group therapy.

You will be informed by the research investigators of this study of any significant new findings that develop during the study which may influence your willingness to continue to participate in the study. Your decision whether or not to participate will not affect your current or future relations with USD.

### **What other choices do you have if you don't take part in this study?**

If you choose not to participate in this study, several alternatives are available. First, you may participate in the group therapy even if you choose not to participate in this study or choose to withdraw your participation during the study. Second, you may receive free or reduced-fee individual and/or group therapy at several USD organizations, including the Student Counseling Center (605-658-3580), Psychological Services Center (605-658-3710), and the Counseling & School Psychological Services Center (605-658-5250). Third, you may receive individual and/or group therapy through several community-based organizations (referrals available upon request).

### **What risks might result from being in this study?**

There are some risks you might experience from being in this study. You may experience frustration that is often experienced when completing surveys and tasks. Some questions and tasks may be of a sensitive nature, and therefore you may become upset as a result.

Behavioral Activation has been researched as an individual, face-to-face treatment for depression in a wide range of populations. This research has suggested no negative effects of participating in the treatment. However, research has not evaluated this treatment in group settings. As such, potential negative effects are unknown. In addition, the researchers cannot guarantee that other participants in your group will keep your information confidential. This is a risk with all group therapy experiences. Confidentiality will be discussed at the start of each therapy session in an effort to minimize this risk.

Overall, these risks are not viewed as being in excess of "minimal risk". Nonetheless, if you become upset, you may stop participation at any time or choose not to answer a question. If you would like to talk to someone about your feelings regarding this study, you are encouraged to contact The University of South Dakota's Student Counseling Center at 605-658-3580, which provides counseling services to students at no charge, or The University of South Dakota's Psychological Services Center at 605-658-3720, which provides counseling services at a discounted rate to students and community members. You may also ask your group leader for additional mental health resources available on and/or off campus.

### **How could you benefit from this study?**

You may not benefit personally from being in this study. Research evaluating Behavioral Activation, the treatment being investigated in this study, consistently reports benefits to participants. However, the treatment has not been adequately evaluated in a group format. Also, not all people realize benefits after participating in the therapy. In sum, research suggests some individuals may benefit from being in this study, but we cannot guarantee you personally will have a favorable response. However, others may benefit from this study in the future, as the information found may help to improve understanding of the effects of group therapy on depression symptoms and quality of life outcomes.

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### How will we protect your information?

The records of this study will be kept confidential to the extent permitted by law. If we write a report or article about this study, we will describe the study results in a summarized manner so that you cannot be identified. Your study records may be reviewed by government agencies, Office of Human Subjects Protection and The University of South Dakota - Institutional Review Boards. In addition, this study is being conducted out of the USD Department of Psychology Psychological Services Center. As such, basic therapy records will be stored as part of patient files and may be reviewed by the Clinic Director and staff as needed to facilitate day-to-day operations of the clinic and ensure adequate psychological care is being provided. If you tell us something that makes us believe that you or others have been or may be physically harmed, we may report that information to the appropriate agencies.

Any other information that is obtained in connection with this study and that can be identified with you (for example, responses to survey questions) will remain confidential and will be disclosed only with your permission or as required by law. Confidentiality will be maintained through several means. Your name and any other information that can directly identify you will be stored separately from the data collected as part of the project. Electronic survey responses are collected through a fully secure, encrypted system on the study website and are stored in a password protected database accessible only to Dr. Berghoff and his research staff. However, given that some surveys can be completed from any computer (e.g., personal, work, school), we are unable to guarantee the security of the computer on which you choose to enter your responses. As a participant in our study, we want you to be aware that certain "key logging" software programs exist that can be used to track or capture data that you enter and/or websites that you visit.

When paper and pencil surveys are used, records of your responses are anonymized and entered into a secure database. Paper copies are stored in locked file cabinets located in the principle investigator's research lab, which is also kept locked when staff is not present. Second, electronic study data will be password protected, stored on secure servers, and accessible by Dr. Berghoff and his personnel only. All records that may link your personal information to your data will be destroyed upon the end of data collection. This means there will be no way to connect you to your survey responses.

There are additional limitations to confidentiality that arise due to the group-format of the treatment. Though your communications with your study therapist are protected by client-therapist privilege, others members of your group will have access to any information you share during therapy sessions. We are unable to guarantee fellow group members will maintain your confidentiality. In order to reduce the risk that other group members may disclose your personal information, each therapy session begins with a reminder that all stories heard during group should not be discussed outside of the therapy room. In order to protect the identity of non-participants during interview and therapy procedures, we ask you use first names only when referring to friends, family, co-workers, and others not involved in the research project.

All sessions of this study are videotaped, which allows the principle investigator to provide adequate supervision to study therapists. Only the principle investigator, their research staff, and study personnel will have access and rights to view these videos. Eligibility session video will be deleted within three years of the end of the research project. Therapy session video will be deleted on a rolling basis, no later than 6 months following termination of your therapy group. ***By providing your consent below, you also give consent to be videotaped during this study.***

### How will my information be used after the study?

After this study is complete, study data may be shared with other researchers for use in other studies or as may be needed as part of publishing our results without asking for your consent again. The information we share with these other investigators will not contain information that could directly identify you. There still may be a chance that someone could figure out that the information is about you.

**How will we compensate you for being part of the study?**

You will not be paid for participating in the study. However, you may be eligible to receive a \$10.00 Amazon.com or Walmart gift card (your choice) for providing valid responses to the 30- and 60-day follow-up surveys (\$20 total). You may choose to have your gift cards delivered electronically to your email address or mailed to your home through the postal service. You will have to provide some personal information to receive payment, including your full name and either a valid email or home mailing address. The personal information you provide will be temporarily linked to your survey responses. However, it will be stored in a secure, password protected database and will be deleted when we finish the study. Should you choose to withdraw from the study, your right to all compensation previously earned will be retained.

**What are the costs to you to be part of the study?**

You will not have any costs for being in this research study.

**Will you be compensated for an injury?**

If you require treatment because you were injured from participating in this study, the research study staff will assist you in obtaining appropriate medical treatment. You or your health plan/insurance will be billed for the cost of this treatment. There are no plans to offer any type of payment for injury. However, by signing this form, you have not given up any of your legal rights. In the same manner, the research study staff and any involved entities have not waived their defenses or immunities allowed under law.

If you feel you have suffered a research-related injury, please contact Dr. Berghoff at 605-658-3710.

**Contact Information for the Study Team and Questions about the Research**

The researcher conducting this study is Christopher R. Berghoff, PhD. You may ask any questions you have now. If you later have questions, concerns, or complaints about the research please contact Dr. Berghoff at 605-658-3710 during the day.

If you have questions regarding your rights as a research subject, you may contact The University of South Dakota - Office of Human Subjects Protection at (605) 658-3743. You may also call this number with problems, complaints, or concerns about the research. Please call this number if you cannot reach research staff, or you wish to talk with someone who is an informed individual who is independent of the research team.

**Your Consent**

Before agreeing to be part of the research, please be sure that you understand what the study is about. We will give you a copy of this document for your records and you can print a copy of the document for your records by visiting the study website, <https://www.mymindfuldays.com>. If you have any questions about the study later, you can contact the study team using the information provided above.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

Subject's Name: \_\_\_\_\_

\_\_\_\_\_  
Signature of Subject

\_\_\_\_\_  
Date

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