



## ActivaTeen App for Teens in Depression Treatment

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### **What is this study about?**

We are asking you to join a research study. This form will describe the research study to you. After reading the form, you can decide whether you want to be in the study. A research study is a way to learn more about something. We want to know how well an online app we designed improves a form of "talk" therapy, called Behavioral Activation (BA), depression treatment for teenagers. The app is called "ActivaTeen." We are interested to know how participating in this therapy and using the app influences your feelings and behavior.

Using the app and being in therapy might help you feel less depressed than not being in therapy. You and your family might learn about your depression. You might learn how to cope with depression. What we learn from this research may help other depressed teens in the future.

### **What will you be asked to do?**

If you join the study, you will start a therapy treatment called Behavioral Activation, or "BA". You may be put in a group that will only do BA depression treatment and use a part of the ActivaTeen app ("BA Only" group) or a group with the treatment with all features of the ActivaTeen app ("ActivaTeen+BA" group). Your BA sessions will be once a week for 12 weeks, or about 3 months. The BA sessions are recorded so that your study therapists can get feedback about their work.

We will ask you to do 3 online study visits with our research staff. Being in the study lasts about 6 months. You will meet with our staff at the study start, at the end of treatment around Month 3, and end of Month 6. Once you start, you will be asked to complete short surveys on your phone 5 times a day asking about how you feel and what you did. We will also send you online mid-treatment surveys 2 times at the end of Month 1 and end of Month 2.

All the study visits are done online on a Zoom video call. For each visit, we will ask you to fill out some surveys. Your surveys will ask you details about yourself, like how old you are, your gender, and your mental health. We will also ask for your opinion on the treatment you will be getting in the study.

Some study visits will also have short interviews with research staff. These interviews will be recorded. We will create written text of what was said and we will remove all information that could identify you.

### **How do we decide the groups?**

At the end of the first study visit, you will be assigned to either the ActivaTeen+BA group or the BA Only group. This decision is made by chance, like flipping a coin.

### **What is the ActivaTeen app?**

All teens who join the study will download the ActivaTeen app on Teams. All teens will use the app to complete brief reports 5 times daily on your feelings and behaviors during treatment. If you are assigned to the ActivaTeen+BA group, you will also have access to other ActivaTeen features like viewing your mood and activity reports, getting support for learning and using BA skills, chatting with other teens in the study, or sending messages to your study therapist. You can use it at any time during treatment.

### **Are there any risks with doing the study?**

Some survey questions may ask you about sensitive topics that could cause you to feel bad or stressed. You might not feel better or even feel worse during the treatment. The new ActivaTeen app might have errors or bugs that can frustrate you. When interacting with teens on the ActivaTeen app, there is a chance you might come across rude, offensive, hurtful, or threatening language from other teens in the study. The messages will be monitored by a moderator. It is possible the information you share with us is exposed, hacked, or leaked. If you become very uncomfortable during the study, you can tell us and we can stop the study.

### **What if you don't want to join?**

This study is totally voluntary meaning you can choose to join or not to join. The treatment you may be getting now will not be changed or affected if you decide not to join the study. You can continue treatment at Seattle Children's Hospital.

### **What if you want to stop being in this study, or if we decide you or should no longer participate?**

If you decide that you do not want to do the study anymore, you may stop at any time. If you decide you want to stop being in this study, please let the study team or your caregiver know.

If you misses 3 treatment sessions in a row or need more care than the study provides, we can choose to end your participation in the study. You might continue to feel depressed or feel worse if

you stop the treatment in the study. We want to make sure you have all the help you need to be cared for outside of the research. You will be offered help to match you with a therapist that works for you and your family.

Group Guidelines about behavior when using the ActivaTeen app will be shared before to using ActivaTeen. Teens who break the guidelines may be removed from the app and/or removed from the study.

### **How will my data be stored and used?**

Since you will be a part of a treatment study, it is important for us to open a medical record at Seattle Children's Hospital (if you do not already have one) and keep very general notes about your treatment.

We will make every effort to keep your personal information confidential and private. This means that we will not share what you tell us with people outside of the study or treatment team unless we learn about any of the safety issues listed below. If we learn about any of the listed issues, then we will need to tell someone about it to make sure you or others are safe. If this happens, we will do our best to tell you before sharing your information so we can decide on a plan together. Below are reasons that we may need to share your information with your caregiver or someone outside of the study or treatment team:

- If we learn that a child (under age 18) is being abused or neglected currently or has been abused or neglected in the past
- If we learn that you might hurt yourself or someone else

We won't tell anyone you were in the study. Your name will not be written on the surveys. Instead, you will be assigned a study ID number that will be put on all forms. We will save a link between your study ID number, your name, and study answers. This link will be saved in a password protected file on a secure research server.

Your name will be on this form and we will keep this form on a secure research server, away from your answers.

All data collected in this study will be made available to other researchers for future data analyses. We will share data with other researchers within and outside the University of Washington after they send us a written request. If the request is approved, the data released will be "anonymized" which means we will not give them information that would identify you (e.g., name, birthdate, address, contact information).

This study may be reviewed by government or university staff to make sure it is being done safely and legally. If this happens, your data may be examined. The reviewers will protect your privacy. The study information cannot be used to put you at legal risk of harm.

We have a Certificate of Confidentiality from the federal National Institutes of Health. This helps us protect your privacy. The Certificate means that we do not have to give out identifying information about you even if we are asked to by a court of law. We will use the Certificate to resist any demands for identifying information.

We can't use the Certificate to withhold your research information if you give your written consent to give it to an insurer, employer, or other person. Also, you or a member of your family can share information about yourself or your part in this research if you wish.

There are some limits to this protection. We will voluntarily provide the information to:

- a member of the federal government who needs it in order to audit or evaluate the research
- individuals at the University of Washington, the funding agency, and other groups involved in the research, if they need the information to make sure the research is being done correctly
- the Federal Food and Drug Administration (FDA), if required by the FDA
- state or local authorities, if we learn of child abuse, elder abuse, or the intent to harm yourself or others

### **What else should I know?**

As a thank you for being in the study, you will be given a \$40 gift card for each study visit you complete and \$15 for each of the mid-treatment surveys. You will also be paid up to \$60 total for filling out the short daily reports. The total amount for completing all parts of the study is \$210.

If you have questions later about the study, or if you feel that you have been hurt by participating in this study, you can contact one of the researchers listed at the top of this form. If you have questions about your rights as a research subject, you can call the UW Human Subjects Division at (206) 543-0098.

### **Contact Information:**

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