

## STATEMENT OF INFORMED CONSENT

**TITLE OF STUDY:** Phone app for grounding (de-escalation) of substance-abusing transition-age youth

**PRINCIPAL INVESTIGATOR:** Lisa M. Najavits, Ph.D. (617-299-1620)

**SPONSOR:** National Institutes on Health

### Introduction

You are being asked to participate in a research study titled, Phone app for grounding (de-escalation) of substance-abusing transition-age youth, being conducted by Lisa M. Najavits, Ph.D. It is important that you read the following explanation of the proposed procedures. This form describes the purpose, procedures, benefits, risks, discomforts, and precautions of the study. It also describes the alternative procedures that are available to you and your right to withdraw from the study at any time. A member of the study staff is available for you to ask questions and/or read through the consent with you and discuss all the information; you can contact our study team via email or phone (see the section at the end of this document titled, "**Whom to contact if you have questions about the study**" for our contact information). When you think you understand the study, you will then be asked if you agree to take part. If you agree, you will be asked to sign this consent form. Once you sign it, we will give you a signed and dated copy to keep and/or you can download one electronically by printing it from your computer screen or by contacting us for a copy that we can send to you. You may show this consent form to your family or trusted friends or your clinician or doctor before you sign it. You may want to discuss it with them to help you decide if you want to be part of the study.

### Purpose

The goal of this study is to evaluate a new investigational phone app that we are developing for young adults ages 18-25 who have a substance abuse problem. The phone app is designed for "grounding" (reducing negative feelings, and creating a feeling of calm). We are recruiting up to 350 young adults. This study is funded by the National Institutes of Health. The entire study will last about two years.

You are eligible for this study if you are age 18-25, outpatient, in a substance abuse program or have a substance abuse problem, and are willing to complete the tasks described below. Note that for study phase B, C, or D, you would also need to have a mobile phone so as to be able to use the phone app.

The checkmark(s) below indicate the part(s) that you could participate in, if you are eligible and if you choose to.

     *Study part A: First set of focus groups or interviews.* We will hold focus groups or individual interviews with up to 12 young adults to identify which app features and grounding techniques they like best.

\_\_\_ Study part B: Second set of focus groups or interviews—first version of the grounding app. We will hold focus groups or individual interviews with up to 12 young adults to try out the first version of the mobile phone app for Grounding using either a real version of the phone app and/or a paper model of it. The goal will be to give feedback about it, including which app features and grounding techniques they like best.

\_\_\_ Study part C: Using a Grounding app. In this part of the study, we will have two groups of young adults who will be assigned by chance (randomly) to either: (1) the *enhanced app condition* (which will be given access to the enhanced phone app, which is being tested to see if it is an appealing, interesting way to learn and use Grounding); or (2) the *basic app condition* (which will be given access to a phone app that provides basic information about Grounding). Our goal is to learn how helpful the enhanced phone app is versus the basic app. To be eligible for this study phase you need to have a mobile phone so that you can try out the phone app.

\_\_\_ Study part D: Final set of focus groups or interviews—final version of the enhanced grounding app. We will hold focus groups or individual interviews with up to 12 young adults to try out the final version of mobile phone app for Grounding using either a real version of the phone app and/or a paper model of it. The goal will be to give feedback about it, including which app features and grounding techniques they like best.

## **Procedures**

\_\_\_ Study part A: First set of focus groups or interviews. A member of our study team will conduct the focus groups /interviews either in person or over the phone or online and will ask a series of questions. The focus groups/interviews will be audio-recorded so that our team can listen to it later to identify important points that came up. The focus group/interview would last up to 1.5 hours. You would also be asked to fill out a measure to provide basic information about yourself (such as age, gender, how much you use a smartphone, etc.) The measure would be filled out either online or on paper or by phone.

\_\_\_ Study part B: Second set of focus groups or interviews—first version of the grounding app. This will be conducted exactly the same as described in Study Part A above.

\_\_\_ Study part C: Using a Grounding app.

To be eligible for this phase of the study you need to have a mobile phone so that you can download one of our study phone apps.

i. First, you would first go through an assessment that will include various measures that ask about your substance use and related problems, and other areas relevant to this project (such as your knowledge of Grounding). Some of the measures will be based on interview (which may be done by phone or in person), and other measures will be ones where you can write in your answers (which can be done online, on paper, or over the phone). The entire assessment will take up to 1.5 hours.

ii. Second, if you are found to be eligible for this project based on the assessment, you will be

assigned by chance (randomly) to one of the following two study conditions, and you will have a 50% chance of being assigned to each group: (1) the *enhanced app condition* (which will be given access to the enhanced phone app, which is designed to provide a very appealing, interesting way to learn and use Grounding); or (2) the *basic app condition* (who will be given access to a phone app that provides basic information about Grounding). Whichever study condition you are assigned to, you will receive a unique login and password so that you could download the app onto your smartphone. All participants will be given access to their app (enhanced or basic) for 6 weeks and only those 6 weeks. You will also be sent a automated text reminders to use app based on a schedule that you prefer.

iii. Finally, after your 6 weeks using the app you will be asked to complete an assessment that is like the one you did in the section “I” above. You will also be asked how much you liked the app and to answer questions about it. Your use of the app will also be automatically part of our database. This means that we will be able to identify how often you used the app and what parts of it you used.

\_\_\_ Study part D: Final set of focus groups or interviews—final version of the enhanced grounding app. This will be conducted exactly the same as described in Study Part A above.

### **Voluntary nature of this study**

Your participation in this study is voluntary. Your refusal to participate or your withdrawal from the study will involve no penalty or loss of benefits to which you are entitled. Throughout the study, you can refuse to answer any questions that make you feel uncomfortable or you choose not to answer. You may stop your participation at any time without affecting your ongoing medical care.

### **Discomforts or inconveniences of the study**

Foreseeable inconveniences/discomfort include answering questions that may feel sensitive to some people.

### **Risks of the study**

Participation in this study may involve some added risks or discomforts. These include:

1. It can be uncomfortable to provide your feedback and opinions to a member of our study team whom you have not met before. However, you can skip any questions that make you uncomfortable.
2. Loss of confidentiality is possible. A number of steps will be taken to minimize risk related to loss of confidentiality. To minimize that risk, we will use only a confidential participant identification number and unique initials to identify you; and will keep all study files locked, retain strict control over all of the information that we collect from all participants, including the audio recordings, the surveys you complete, and information from the phone app such as how much you used it. We will make sure that only our study team has access to information about you. Although unlikely, if you report any major distress or upset while participating in any aspect of this study, this will trigger us to contact your clinician and/or program with this information so that they can help provide clinical assistance to you.

In addition to the risks listed above, you may experience a previously unknown risk or side effect, but we consider this unlikely as this project is designed to create a calming phone app. Also, the assessments we will conduct are widely used and rarely if ever have negative impact.

### **Expected benefits of the study**

You may or may not benefit from participation in this study.

### **Confidentiality**

If you agree to join this study, the study team will ask you for some personal health information needed for the study. Personal health information is any information that could be used to identify you and, for clients in this study, also includes your name, address, date of birth, and information on your mental health diagnoses.

The survey information and app usage information that is collected for the study and is on computer will be kept on a password-protected computer indefinitely. Also you are encouraged to put a password on your phone. All audio recordings will be digital and will be coded using only your study identification number (no names or other identifying information); and will be stored on the study's password-protected computer at Treatment Innovations. These digital recordings will not be destroyed; they will be kept indefinitely.

All surveys and data will be handled by the study team. For all participants, your name will not be publicly disclosed at any time and you will not be identifiable in any publications or presentation that may arise from this research.

If you decide to leave the study, the information about you that was collected before you left the study will still be used. No new information will be collected without your permission. None of your research records and the information you provide in any way will be used for any purpose other than that which is described in this consent form.

While all efforts will be made to protect your privacy, you should understand that there are ethical and legal limits to confidentiality, and that there are some circumstances under which information that may identify you may be released. In particular, this may occur if you indicate or the research staff has reason to believe that you express a clear and credible threat or intention to do serious harm to yourself or to some other identifiable person. Under federal law and our professional ethics codes, the research staff would have an obligation to take all reasonable steps to protect both you and the intended victim. This usually involves notifying the other person but may involve notifying the police or others who could intervene to prevent harm from being done. In all cases, only the minimal necessary information would be released. A similar situation would exist if, during the research, you indicate that a child or elder in your care is being abused and/or neglected. There is a mandatory reporting law whereby the research staff would be required by state law to report admitted or suspected child or elder abuse and/or neglect to the Department of Social Services.

The study team places a high value on the privacy of its research participants and the confidentiality of the data collected in all of its research projects. In order to strictly protect

your confidentiality, all of your records will be kept in a locked file, under a code number and unique initials rather than your name; the records will be strictly maintained according to current legal requirements. All electronic information, including audio recordings, will be kept in a database using a code number rather than your name. Nothing shared will be traceable to participants as individuals. Only authorized personnel will have access to your electronic and other records.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, *except as explained below*.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects. You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse or neglect, elder abuse or neglect, or imminent physical harm to self or others that requires our study team to protect your health or safety.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

### **Costs**

There are no costs for participating in this study.

### **Payment**

If you participate in study parts A, B, and/or D, you will be paid \$20 for each. If you participate in study part C, you will be paid \$25 for the first assessment and \$35 for the second assessment (6 weeks later). All payments will be either cash, a check, or an electronic gift card (such as from amazon.com) sent to your smartphone. Payments will be given immediately after your participation for parts A, B, and/or D, and at the end of your participation (6 weeks) for part C.

The total you can receive in this study is \$110 (\$20 each for parts A, B and D; and \$60 for part C).

### **Research-Related Injury**

As mentioned above, the assessments we will conduct are widely used and rarely if ever have negative impact. Also, the phone apps in this study are designed to be calming. Nevertheless, every effort will be made to prevent any adverse reactions from occurring in the study. If you should experience any adverse reactions or injuries directly resulting from this research, we will do everything we can to manage the situation, in a timely manner, with the best possible care. If, during your assessment you have an adverse reaction (for example, becoming so upset that you are not safe), a trained clinician from our study team will intervene to protect your safety. This may include: arranging transport to a local emergency room for evaluation, contacting your individual clinician or psychopharmacologist, and/or talking with you to help you decide on the best plan of action. Please be aware, however, that there are no plans to provide medical care or financial compensation for any research-related or non-research-related medical injuries or adverse reactions.

In summary, if you become ill, injured or harmed during or as a result of taking part in this study, you will be referred to care. However, you will be responsible for the cost of this care. Signing this consent form does not waive your legal rights nor does it relieve the investigators, sponsors or involved institutions from their legal and professional responsibilities. You do not give up any of your legal rights by signing this consent form.

### **Alternatives to participating in this study**

As this is not a treatment study, your alternative is to not participate. If you choose not to participate in this study, you would simply not be providing your opinions and feedback. Your choice of whether or not to participate in this study will not alter any treatment you are receiving elsewhere. You can learn about Grounding using other methods than we provide in this study, for example, by searching YouTube for the term "grounding" or by searching for mobile apps with that term. Those methods are not known to be evidence-based, however, and use different methods than we are using in this study. .

### **New Findings**

You will be told of any significant new findings that come to light during the course of this study and that may relate to your wanting to stay in the study.

### **Right to refuse or withdraw**

You can ask any questions during the survey or interview at any time, and can refuse to answer any questions that make you feel uncomfortable. Your participation in this study is voluntary and you may decide to withdraw your consent and discontinue participation in this project at any time. However, once you provide any study data or taped interviews, you will not have the option to withdraw these.

### **Possible removal from the study**

Your participation in this study can be ended by the study team for any of the following reasons (even if you want to remain in the study):

1. If you are unable to keep your scheduled appointment to participate;
2. If the investigator decides that you should no longer be in the study;

3. If you show up for your scheduled appointments intoxicated;
4. If you represent a clear threat to study staff or others.
5. If the study is cancelled by the sponsor or the New England Independent Review Board.
6. If new information shows that the study is no longer in your best interest.
7. If you do not complete the required study assessments.
8. If we are unable to reach you.

### **Conflict of interest**

Dr. Najavits, the study investigator for this research, is developing the phone app for this project, which if successful may be sold in the future to individuals and/or treatment programs. She could thus potentially benefit financially from this project if it is successful. She is director and owner of Treatment Innovations, a limited liability company that received the grant from the National Institutes of Health, this study's sponsor.

### **Whom to contact in case of emergency**

If you experience an adverse reaction or a research-related injury during the course of the study, you should immediately contact the study Principal Investigator, Dr. Lisa Najavits at 617-299-1120 (office and cell number) at any time, including after hours. You can also call the study team at 617-299-1610, 617-299-1630, 617-299-1640, 617-299-1670 or 617-299-1640. You can also seek immediate care from a resource that is available 24/7 such as an emergency room, doctor on call, or other service. You can also seek care from your doctor or any other health professionals you choose throughout the course of the study.

### **Whom to contact if you have questions about the study**

Should you have any questions, concerns or complaints about the research in general, you may contact Dr. Najavits at 617-299-1610 (office and cell number) or a member of the study team at 617-299-1610, 617-299-1630, 617-299-1640, 617-299-1670, or email the study team at [info@treatment-innovations.org](mailto:info@treatment-innovations.org). If you have questions about your rights as a research subject, or other questions, concerns or complaints about the research, you can contact the New England IRB at 1-800-232-9570.

## **VOLUNTEER'S STATEMENT**

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. I may contact Dr. Najavits if I have any more questions about taking part in this study. Dr. Najavits and the company she is employed by are being paid by the sponsor for my participation in this study.

I understand that my participation in this research project is voluntary. I know that I may quit the study at any time without harming my future medical care and/or my employment or

losing any benefits to which I might be entitled. I also understand that the investigator in charge of this study may decide at any time that I should no longer participate in this study.

If I have any questions about my rights as a research subject in this study I may contact:

New England Independent Review Board  
Telephone: 1-800-232-9570

By signing this form, I have not waived any of my legal rights.

I have read and understand the above information. I agree to participate in this study. I understand that I will be given a copy of this signed and dated form for my own records.

\_\_\_\_\_  
Study Participant (signature)

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Participant's Name

\_\_\_\_\_  
Person who explained this study (signature)

\_\_\_\_\_  
Date

**At some future point after the study, we may want to contact you to see if you might be interested in a later follow-up study. Please initial here if you are willing for us to contact you after your involvement in the study \_\_\_\_.**