Medical University of South Carolina
STATEMENT OF RESEARCH

Bounce Back Now: Intervention to Facilitate Post-Disaster Recovery

A. PURPOSE AND BACKGROUND: You are being asked to volunteer in a research study sponsored by the National Institute of Mental Health. In all parts of the study, we are expecting to have 5,000 participants. The purpose of the project is to evaluate the benefits of different mental health resources that may be helpful to disaster survivors. This information will help us to improve treatment resources, including Bounce Back Now, an online, self-help intervention for disaster victims. The investigator in charge of this study is Dr. Kenneth Ruggiero, and this portion of the study is being conducted by faculty at the College of Nursing at the Medical University of South Carolina.

B. PROCEDURES: If you agree to participate in this project, the following will happen:

1. You will be randomly assigned into one of two conditions. You will not have the opportunity to choose which condition you receive. You will have an equal chance of being assigned to either condition (There is a 50/50 chance - like flipping a coin - you will be assigned to either group.)
2. If you are randomly assigned to Group A (the control condition), you will receive a comprehensive list of local, regional, and natural disaster resources for disaster survivors.
3. If you are assigned to Group B (the experimental condition), you will be given access to additional technology-based resources that can be accessed via your smartphone or any Internet-accessible device. These resources, including the Bounce Back Now self-help intervention, are designed to address the mental health needs of disaster survivors.
4. Regardless of whether you are randomly assigned to Groups A or B, you will be asked to complete an online assessment 3 months, 6 months, and one year from today. You will receive compensation after each of the three online assessments.

C. DURATION: Participation in the study includes the completion of three online assessments, which you will be asked to complete 3 months, 6 months, and 12 months from today. The questionnaires should take between 15-20 minutes to complete.

D. RISKS/DISCOMFORTS:

1. Breaches of confidentiality are a concern with components of any study. We have outlined several steps to maintain confidentiality, including only using study ID numbers to store and track data. You will not enter your name or other protected health information on the smartphone-based intervention, and the application’s data is stored on secure, encrypted servers. Nevertheless, if our protocol for maintaining confidentiality were broken, there is a risk of potential loss of confidentiality.
2. Although unlikely, there is the potential that you may experience distress when asked questions during the web-assessments about disaster, prior traumatic events you might have
experienced, and possible emotions you might have been feeling as the result. The study website, itself, is not a source of real time help, and it is not actively monitored on a continuous basis. Other factors, such as Wi-Fi access, may also further delay transmission of data. The website will, however, include a “Find Help Now” feature available at all times throughout the intervention, which will include direct links to resources you can contact (including a Disaster Distress Hotline and local referrals to trained counselors) should you experience more than minimal distress. We can also provide mental health referrals if necessary.

3. Randomization: You will be assigned to either the experimental or control condition by chance. These groups may differ in their effectiveness, and one condition may have more side effects than the other study treatment(s) or other available treatments.

4. Unknown Risks: The Bounce Back Now intervention may have unknown side effects. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

E. BENEFITS: Findings from studies similar to the one described here have suggested that many participants obtain positive benefits from their participation.

F. COSTS: You will not be charged for participation in the study.

G. PAYMENT TO PARTICIPANTS: Upon completion of each of the 3-month, 6-month, and 12-month assessments, you will receive Amazon gift codes in the amounts of $10, $15, and $25, respectively. This is a total of $65. You will not be required to enter any personal information to access these gift codes.

H. ALTERNATIVES: There are no alternatives other than to not participate in this research study.

I. NEW INFORMATION: If there are significant new findings during the course of the study, you will be notified.

J. CLINICAL TRIAL REGISTRY DATABANK: A description of this clinical trial will be available on [http://www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), as required by U.S. Law. This website 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.

K. CONFIDENTIALITY: Results of this research will be used for the purposes described in this study. Your responses will be kept confidential to the extent allowed by law. Only the investigators and appropriate professional consultants and staff will have access to any data collected by this project. Your name will not be recorded. All data will be referred to by identification number only. Data will be kept secure and separate from identifying information. The likelihood that these methods will not effectively protect the confidentiality of participants is considered to be extremely low.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research
that can be identified with you will remain confidential to the extent possible within State and Federal law. The investigators associated with this study, the sponsor, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event that you are injured as a result of participation in this study, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator’s instructions.

If I have any more questions about my participation in this study or study related injury, I may contact Dr. Kenneth Ruggiero (843-792-3687), Dr. Tatiana Davidson (843-792-6123) or Danna Lewsky (843-792-9054). If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study. I agree to participate in this study. I have been given a copy of this form for my own records.

By clicking “Yes” you are agreeing to participate in this study

- Yes, I agree to participating in this study
- No, I am not interested in participating in this study