Evaluation of a Novel Behavior Change Intervention for Posttraumatic Stress
Informed consent document
9/23/22

Permission to Take Part in a Human Research Study

Title of research study: Evaluation of a Novel Behavior Change Intervention for Posttraumatic Stress

Investigator: Carter Bedford, B.A.

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are over the age of 18, have experienced at least one traumatic life event, and report elevated symptoms of posttraumatic stress.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of the current randomized trial study is to evaluate a novel behavior change intervention for posttraumatic stress symptoms, as compared to a control condition.

How long will the research last and what will I need to do?

We expect that you will be in this research study for one month.

At your initial appointment, you will be asked to complete a battery of self-report measures and a randomly-assigned intervention. After the appointment, you will receive text messages asking you to complete a short 5-minute survey two times a week. Two weeks after the initial appointment you will receive an email with a link to a 30-minute survey. Finally, one month after your initial appointment, you will complete another battery of self-report measures.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

The risks to human subjects in the proposed study are minimal. Nevertheless, precautions will be taken to minimize any risks you may incur in the proposed study. Some individuals may experience slight discomfort describing their thoughts, feelings, and past experiences. These tasks should not be any more anxiety-provoking than situations commonly experienced in day-to-day life.

There are no long-term risks associated with these procedures. If it is determined that there is an immediate need for assistance, you will be referred to clinicians with whom you may speak about your discomfort or distress. You furthermore have the right to refuse or discontinue participation at any time. There may be uncommon or previously unknown risks. You should report any problems to a member of our research team.

More detailed information about the risks of this study can be found under ***"Is there any way being in this study could be bad for me? (Detailed Risks)"***

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include a decrease in trauma-related symptoms.

Additionally, information learned during this study may be used to benefit others in the future. Possible benefits to others include a decrease in trauma-related symptoms.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate or not to participate. Your alternative to participating in this research study is to not participate.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at abhcfsu@psy.fsu.edu.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at 850-644-7900 or humansubjects@fsu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 50 people here will be in this research study out of 50 people in the entire study nationally.

What happens if I say "yes" to being in this research?

Your initial appointment will be at the Department of Psychology at Florida State University.

At your initial appointment, you will first be asked to complete a battery of self-report measures, and then you will complete your assigned intervention. This study is a randomized trial study, meaning the treatment you get will be chosen by chance, like flipping a coin. Neither you nor the researcher will choose what treatment you get. You will have an equal chance of being given each treatment. You will not be told which treatment you are getting, however your researcher will know. The initial appointment is expected to take no longer than 1.5-2 hours.

After the initial appointment, you will receive text messages asking you to complete a short 5-minute survey two times a week.

Two weeks after the initial appointment, you will receive an email with a link to a 30-minute survey.

Finally, one month after your initial appointment, you will receive an email with a link to a 1-hour survey.

What happens if I say "yes," but I change my mind later?

You can leave the research at any time, it will not be held against you.

Is there any way being in this study could be bad for me? (Detailed Risks)

The risks to human subjects in the proposed study are minimal. Nevertheless, precautions will be taken to minimize any risks you may incur in the proposed study. Some individuals may experience slight discomfort describing their thoughts, feelings, and past experiences. These tasks should not be any more anxiety-provoking than situations commonly experienced in day-to-day life.

There are no long-term risks associated with these procedures. If it is determined that there is an immediate need for assistance, you will be referred to clinicians with whom you may speak about your discomfort or distress. You furthermore have the right to refuse or discontinue participation at any time. There may be uncommon or previously unknown risks. You should report any problems to a member of our research team.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.

If identifiers are removed from your identifiable private information or identifiable samples that are collected during this research, that information or those samples could be used for future research studies or distributed to another investigator for future research studies without your additional informed consent.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include technical difficulties or incomplete data.

What else do I need to know?

If you agree to take part in this research study, you can choose whether or not you would like to enter your name into a raffle to win one of two $150 Amazon gift cards as compensation for your participation. The winner will be determined using a random number generator after the study has concluded. If you choose to enter raffle and win, the gift card codes will be emailed to you.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	