

DOCUMENT TYPE: Informed Consent form

TITLE OF THE STUDY: A pilot randomized control trial of a conditioning paradigm to increase affinity for sacredness of life and decrease experiences of suicide-related thoughts and behaviors.

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Permission to Take Part in a Human Research Study

TITLE OF THE STUDY: A pilot randomized control trial of a conditioning paradigm to increase affinity for sacredness of life and decrease experiences of suicide-related thoughts and behaviors.

Principal Investigator: Anna Gai, Principal Investigator, Florida State University

Faculty Advisor: Thomas Joiner, Faculty Advisor, Florida State University

You are being invited to take part in a research study. Please find below information about this research for you to think about before you decide to take part. Ask us if you have any questions about this information or the research before you decide to take part.

What is this study about?

Researchers at Florida State University are studying a new online-based intervention designed to increase the affinity towards the sacredness of life. Researchers are interested in finding out how this intervention works and if it is an acceptable intervention. You are invited to take part in the study because you have a history of suicide-related thoughts and behaviors and/or symptoms of depression. You are one of 200 persons to take part in this study. Your involvement in the study is expected to last 2 months.

This work was in part supported by the Military Suicide Research Consortium (MSRC), funded by the Office of the Assistant Secretary of Defense for Health Affairs under Award No. (W81XWH-16-2-0004). Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the MSRC or the Department of Defense.

What will happen during this research?

If you agree to be in this research, your participation will include:

- **Baseline Questionnaires:** *Approximately 45 minutes one time.*
 - You will complete a set of self-report questionnaires online that will ask about demographic characteristics, your experiences with suicide-related thoughts and behaviors, your perception on the sacredness of life, experiences with spirituality and religiosity. You will also complete two short (5 – 10 minutes) behavioral tasks online.
- **Weekly Behavioral Tasks:** *Approximately 15 – 30 minutes once a week.*
 - Once a week, you will receive an email with study instructions and a reminder to complete online behavioral tasks. These behavioral tasks are one of two different themes and are delivered based on random assignment. The theme completed during the initial week will continue for the remaining weeks. For two of these weeks, you will be asked to complete a series of questionnaires following the behavioral tasks that will reassess your experiences with suicide-related thoughts and behaviors, perception of sacredness of life, and experiences with spirituality and religiosity. You can do these tasks any time during the week, however, we ask that you complete the full task in one sitting. You will receive daily email reminders for 5 consecutive days or until the task is completed for that week, whichever comes first.
- **1-Month Follow-up:** *Approximately 45 minutes one time.*
 - At one-month following your last weekly task, you will be emailed a link to complete a web-based 30-minute series of self-report questions and complete two short behavioral tasks online.

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What will you do to protect my privacy?

The results of the study may be published or presented, but no information that may identify you will ever be provided or released in publications or presentations. We will take steps to protect your privacy and confidentiality. These steps include not collecting your name. You will be given a unique ID that will help us link your participation each week. A key with participant Unique ID and email address will be kept separately from your questionnaire responses within a password protected file. Despite taking steps to protect your privacy or the confidentiality of your identifiable information we cannot guarantee that your privacy or confidentiality will be protected. For example, if you tell us something that makes us believe that you or others have been or may be physically harmed, we may need to report that information to the appropriate agencies.

Individuals and organizations responsible for conducting or monitoring this research may be permitted access to and inspect the research records. This includes the Florida State University Institutional Review Board (FSU IRB), which reviewed this study, and the Military Suicide Research Consortium who partially funded this study. Electronic questionnaire data will be retained indefinitely on a password-protected computer owned by the Principal Investigator.

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

What are the risks of harms or discomforts associated with this research?

The risks of harms or discomforts associated with the research are minimal.

This study will be asking about sensitive personal topics, including suicide, and some people may experience anxiety or become emotionally upset while completing the questionnaires. If at any time you would like to speak with someone confidentially regarding any distress you might be experiencing, you can call the National Suicide Prevention Lifeline at 1-800-273-TALK, a toll-free 24-hour crisis line. You can also join a confidential live chat at www.suicidepreventionlifeline.org. At the end of each survey, we will provide you with a list of resources to receive help. We will also review responses on questions regarding experiences with suicide and may contact you via email if your responses indicate you are at imminent risk for suicide. Another potential risk is a breach of confidentiality; however, numerous safeguards are in place to protect your privacy. For instance, your name will not be collected, and your provided email address will be stored separately from your responses to questionnaires.

How might I benefit from this research?

There may be no personal benefit from your participation, but the knowledge received may be of value to society. As a result of taking part in this research, we think that you will help researchers learn more about online interventions for suicide-related experiences so that service or treatment can be improved in the future.

What is the compensation for the research?

If you agree to take part in this research study, you will be provided with up to \$40 in compensation for your time and effort. Compensation will be provided via email within 24 hours of the full completion of each study task with the following schedule:

- 1) Baseline questionnaire *45 minutes* - \$10 digital Amazon gift card
- 2) 4 Weekly *15 – 30 minutes* study participation - \$5 digital Amazon gift card

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3) Month Follow-up *45 minutes* - \$10 digital Amazon gift card

The weekly tasks will require less time; therefore, compensation is provided at a prorated amount.

What will happen if I choose not to participate?

It is your choice to participate or not to participate in this research. Participation is voluntary. Alternatives to participation are to not participate.

Is my participation voluntary, and can I withdraw?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time.

If you withdraw from the study, the data collected to the point of withdrawal will be used.

Who do I talk to if I have questions?

If you have questions, concerns, or have experienced a research-related injury, contact the research team at:

Anna Gai
703-244-2764
gai@psy.fsu.edu

Thomas Joiner
850-644-1454
joiner@psy.fsu.edu

The Florida State University Institutional Review Board (“IRB”) is overseeing this research. The FSU IRB is a group of people who perform official independent review of research studies before studies begin to ensure that the rights and welfare of participants are protected. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Florida State University IRB
2010 Levy Drive, Suite 276
Tallahassee, Florida 32306
850-644-7900
humansubjects@fsu.edu

STATEMENT OF CONSENT

I have read and considered the information presented in this form. I confirm that I understand the purpose of the research and the study procedures. I understand that I may ask questions at any time and can withdraw my participation without prejudice. I have read this consent form. My signature below indicates my willingness to participate in this study.

I consent to participate in this study.