Official title: Leveraging Computational Social Sciences and Natural Language Processing to Optimize Engagement and Response to Low-intensity CBT for Depression and Anxiety

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INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH

Guided self-help for common mental disorders.

ABOUT THIS RESEARCH

You are being asked to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.
This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

TAKING PART IN THIS STUDY IS VOLUNTARY

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Indiana University.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to test the acceptability of a guided self-help intervention using a book called "*Doing what matters in times of stress*." The book was originally developed for use in other countries and was recently adapted to the English language. We are interested in seeing how acceptable the book can be to individuals in the United States.
You were selected as a possible participant because you clicked on the link advertised on social media or found out about the study elsewhere.
The study is being conducted by **Dr. Lorenzo Lorenzo-Luaces** in the Department of **Psychological and Brain Sciences** at **Indiana University. It is funded by the National Institutes of Health.**

HOW MANY PEOPLE WILL TAKE PART?

If you agree to participate, you will be one of up to 100 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, you will do the following things:

First you will complete a baseline questionnaire, which will ask about things like your mental health, stress, and your overall well-being. You will also be asked to provide your Twitter handle (e.g., your username), if you use Twitter. The variables we will be collecting include frequency and timing of posts, thinking styles that might be present in the posts, and levels of positive and negative affect. We will be exploring whether we can use social media data to figure out who engages with the book and whether your use of social media changes as you use the book. Sharing your username is voluntary and you can still participate in the study regardless of whether you are a Twitter user and whether or not you share the username with us. The survey should take around 15 minutes. If you are eligible, you will provide your contact information including phone number, email, address, and a list of times you are available. ***Within 1 week a research assistant will contact you and explain the study in further detail.*** This call will last up to 30 minutes. If you still wish to participate, they will introduce you to the *Doing what matters in times of stress* book, and help you come up with a plan for using the book. Then you will schedule weekly meetings with a helper for the following 6 weeks that will occur via Zoom. Prior to the first 5 meetings, you will fill out a short questionnaire assessing your stress and overall well-being. Each of these meetings will last for about 20 minutes and will serve as a "check-in" where you can discuss

the book, any problems you have encountered, or what has helped you use it successfully. The 6th

meeting will occur a week after your last check-in. Before the meeting you will fill out a questionnaire similar to the one you filled out at baseline, which will take around 15 minutes. During this 6th meeting you will be given the opportunity to review the material, as well as answer some questions about the book and the study overall. This meeting will also last around 20 minutes.
Three months after the 6th meeting, you will meet with the helper again, for a 7th meeting. The objective of this follow-up is to check in on your progress as well as to answer questions about the book and study overall. Prior to this meeting you will receive a link to complete a follow up questionnaire. It will have the same measures as the previous surveys and should again take around 15 minutes.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
While participating in the study, the risks, side effects, and/or discomforts include:

- There is a risk that the information you provide becomes compromised and is no longer confidential.
- A risk that while completing the survey questions you may be uncomfortable answering some of the questions.

There is a risk of possible loss of confidentiality. All research interactions will occur on secure platforms, and your data will be kept in a secure location. Information collected from your Twitter account will be assigned an anonymous ID. Nonetheless, we cannot guarantee that your confidentiality is 100% secure, for example, if you take a study call in front of other people. In order to prevent your information from no longer being confidential the research team has made sure that your answers are stored within a protected database. Only the research team will have access to your information during the time of the study. We do not believe that there will be any issues of confidentiality but please be aware that a breach of confidentiality could place you at additional risk. This study will ask questions about your mental health. Any breach of confidentiality could result in damage to your reputation, negative stigma or your ability to be employed.

You could experience some discomfort in answering the survey questions. If at any time you feel uncomfortable with a one of the survey questions or if you feel uncomfortable answering any section of the survey you are allowed to skip that question. You are also allowed to decide if you would like to complete the research study or withdraw. Please contact anyone on the research team at sadcat@indiana.edu, or the PI lolorenz@indiana.edu, or our phone line (812) 855-3456. If you need emotional or psychological support the researcher will provide written information for mental health services/treatment that includes the phone number and location of services provided in the Bloomington, Indiana area. The main researchers for this study are trained in clinical and counseling psychology, and the assistants have been trained to provide you with contact information and locations of services. However, during your participation in the research study we cannot provide direct treatment to you, and so you will be encouraged to contact the services that are provided in the written information.

In the event that your symptoms worsen or you feel the need to seek outside help, participating in this study will not prohibit you from seeking other treatment.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?
We don't expect you to receive any benefit from taking part in this study, but we hope to learn things that will help scientists in the future. The educational skills-based treatment course, may teach you new skills. Additionally, there is a good chance that you may experience a reduction in your anxiety, stress, or depression symptoms.

HOW WILL MY INFORMATION BE PROTECTED?
Efforts will be made to keep your personal information confidential. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law. No information which could identify you will be shared in publications about this study and databases in which results may be stored.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and state or federal agencies who may need to access the research records (as allowed by law).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use any information, documents, or specimens that could identify you in any legal action or lawsuit unless you say it is okay.

However, there are some types of sharing the Certificate does not apply to. The Certificate does not stop reporting required by federal, state, or local laws, such as reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate does not stop a government agency who is funding research from checking records or evaluating programs. The Certificate also does not prevent your information from being used for other research when allowed by federal regulations.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?
Information collected from you for this study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

WILL I BE PAID FOR PARTICIPATION?
You will receive $25 for the baseline assessment, $25 for the session 6 assessment, and $25 for the follow up assessment, totaling $75 if you complete the entire study. Payment will be provided in the form of Amazon gift cards and will be provided directly after completing each respective assessment.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?
For questions about the study, contact the researcher, Lorenzo Lorenzo-Luaces at 812-856-0866.
For questions about your rights as a research participant, to discuss problems, complaints, or concerns about a research study, or to obtain information or to offer input, please contact the IU Human Subjects Office at 800-696-2949 or at irb@iu.edu.

This study is not equipped to provide emergency services. If you feel you are a risk to yourself or others, please contact 911 or get yourself to the nearest emergency room.

CAN I WITHDRAW FROM THE STUDY?
If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, you can inform the helper you are working with or the PI, and we will help you exit the study.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

If this is correct, please type your first and last name in the box. _____

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