



# INDIANA UNIVERSITY

## INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR RESEARCH Combining Guided Self-Help Approaches For Common Mental Disorders

**You are being asked to participate in a research study.** Scientists do research to answer important questions that 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.

**All research is voluntary.** You can choose not to take part in this study. If you decide to participate, you can change your mind later and leave the study at any time. You will not be penalized or lose any benefits if you decide not to participate or choose to leave the study later.

**The purpose of this study** is to test the acceptability of combining two types of interventions: one short online program, and a self-help intervention using a book called *“Doing what matters in times of stress.”* If you participate, you will be randomized, like flipping a coin, to read the self-help intervention on your own time (self-guided) or to read the self-help book and also schedule phone or Zoom calls with a coach (Coach-guided). We are asking you if you want to be in this study 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-Luaces at the Indiana University Department of Psychological and Brain Sciences.

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

First you will complete a questionnaire, which will ask about things like demographic information (e.g., age), mental health, stress, and your overall well-being. You will also be asked to provide your Twitter username (i.e., your Twitter handle), if you use Twitter. The variables we will be collecting from Twitter 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. You will be notified at the end of the survey of your eligibility. If you are eligible, you will provide your contact information including phone number, email, address, and a list of times you are available, and a research assistant will be contacting you within a week or so.

After completing the baseline survey, if you qualify you will be taken directly to an online program. The program will consist of a series of interactive learning modules with educational materials that teach you about health and well-being. The time to complete the program is approximately 45 minutes. You should expect to complete the program in one session. You do not need any special equipment other than a device that can access the internet.

**Depending on which condition you are placed in, you will read the *Doing what matters in times of stress* book either:**

- A) with weekly meetings with a Coach in the study (Coach-guided)**
- B) without guidance from a Coach in the study (Self-guided).**

**A. Coach-guided condition:**

*Within 1 week of completing the program a research assistant will contact you and explain the study in further detail.*

This call will last 20-30 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 3-6 weekly meetings with the Coach for the following 6 weeks that will occur via Zoom or over the phone. 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 10-20 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 6<sup>th</sup> 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 10-15 minutes. During this 6<sup>th</sup> 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 10-20 minutes.

When	What do I have to do?	How much will I be paid?
Today	10-15 minute survey + COMET intervention (30-45 minutes)	\$25
Within the next week	Welcome call (20-30 minutes)	
Weeks 1 - 6	3-6 meetings (10-20 minutes)	
Weeks 1 - 5	5-minute survey assessment each week	
Week 6	10-15 minute survey	\$25
3 months after week 6	10-15 minute survey + meeting (10-20 minutes)	\$25
	Total	\$75

Three months after the 6<sup>th</sup> meeting, you will meet with the Coach again, for a 7<sup>th</sup> meeting (3-month follow-up). 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 10-15 minutes.

#### **B. Self-guided condition:**

*Within 1 week of completing the program a research assistant will send you a copy of the Doing what matters in times of stress book, a planning worksheet, and some instructions for participation.* For 5 weeks, you will be asked to fill out short surveys assessing your stress, overall well-being, and use of the book. We will send out the surveys at a time/date that you say is most convenient to you. During week 6, you will be sent a survey similar to the one you completed at “baseline,” and will be asked to answer a few questions about the book and study overall. It should take 10-15 minutes to complete. Three months after week 6, you will be sent a follow up questionnaire that contains the same survey and questions as week 6 and will take 10-15 minutes to complete.

When	What do I have to do?	How much will I be paid?
Today	10-15 minute survey + COMET intervention (30-45 minutes)	\$25
Weeks 1 - 5	5-minute survey assessment each week	
Week 6	10-15 minute survey	\$25
3 months after week 6	10-15 minute survey	\$25
	Total	\$75

#### **Before agreeing to participate, please consider the risks and potential benefits of taking part in this study.**

There is a risk of possible loss of confidentiality. All research interactions will occur on secure platforms (e.g., Zoom or Skype for business, Qualtrics, REDCap), and your data will be kept in a secure location. Information collected from your Twitter account will be assigned a unique 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 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](mailto:sadcat@indiana.edu), or the PI [lolorenz@indiana.edu](mailto: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.

It's possible you may experience personal benefits from taking part in this study. The educational skills-based treatment courses may teach you new skills. Additionally, there is a good chance that you may experience a reduction in your anxiety, stress, or depression symptoms.

**You will be paid for participating in this study.** You will receive \$25 for the baseline assessment, \$25 for the session 6 assessment, and \$25 for the 7th assessment (3-month follow-up), 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. **There is no cost to participate in the study.**

**We will protect your information** and make every effort to keep your personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study.

Your personal information may be shared outside the research study if required by law. We also may need to share your research records with other groups for quality assurance or data analysis. These groups include 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).

Information collected in this study may be used for other research studies or shared with other researchers for future research. If this happens, information that could identify you, such as your name and other identifiers, will be removed before any information or specimens are shared. Since identifying information will be removed, we will not ask for your additional consent.

**If you have questions about the study or encounter a problem with the research**, 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 Research Protection Program office at 800-696-2949 or at [irb@iu.edu](mailto:irb@iu.edu).

**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.** 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 agree to participate in this research study. I will be given a copy of this informed consent document to keep for my records.

**Participant's Printed Name:** \_\_\_\_\_

**Participant's Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_