

**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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## Describe the purpose of this study in lay terms, including research question(s) and hypothesis.

The purpose of this proposal is to study the feasibility and outcomes of an adapted guided self-help program. The project is entitled, "Guided self-help for common mental disorders." This study will explore the feasibility of implementing an adaptation of the guided self-help program known as *Doing what matters in times of stress*. The targets of this program are stress and symptoms of common stress-based disorders (e.g., anxiety and depression). Stress-based disorders such as anxiety and depression have been associated with poor physical health (Scott et al., 2007), lower adherence to medical treatment (Dimatteo, Lepper, & Croghan, 2000), and unhealthy lifestyle behaviors (Lai et al., 2015). These relationships are particularly prominent in rural areas with low access to treatment providers and effective care. This year Indiana was ranked 45th out of 51 states for having the most unmet mental health treatment needs (Mental Health America, 2020). Due to this shortage many individuals seeking mental health treatment are met with long waiting times and difficulty accessing treatment. One way to address this problem is through self-help interventions, which have a higher reach since they don't require consistent provider access. Guided self-help has proven to be roughly equal in efficacy to face-to-face therapies for stress-based disorders (e.g., anxiety and depression) (Cuijpers et al., 2019). *Doing what matters in times of stress* is a guided self-help program that was developed by the World Health Organization (WHO). The original version consisted of a workbook describing five elements of Acceptance and Commitment Therapy (ACT), as well as psychoeducational guidance in the form of five 2-hour educational groups. However, the group education portion has been criticized for its limited scalability (Hanlon & Jordans, 2020). This study instead will be using phone call coaching support, as this may be less burdensome from an organizational perspective. It would be much easier for individuals who live in rural areas who otherwise would have had to travel long distances, may not wish to gather in groups with others they know, or in a context like observing social distancing. Phone coaching to promote adherence and understanding is the way guided self-help is typically conducted, and prior work supports the equivalence of different forms of guidance in supporting self-help (Cuijpers et al., 2010). *Doing what matters in times of stress* has been studied in low and middle income countries (LMICs) previously, and has been associated with symptom reductions and increases in overall functioning (Tol et al., 2020). Since many LMICs have conditions similar to rural parts of the United States (not enough providers for the amount of individuals seeking help, difficulty accessing treatment), *Doing what matters in times of stress* has the potential to produce similar effects in rural Indiana. The goal of this proposal is to evaluate *Doing what matters in times of stress* in the United States and rural Indiana. We are primarily interested in the feasibility of the program (i.e., how easily we are able to get it to individuals who need it in the community), and how acceptable it is to participants. Secondary outcomes that will be assessed include stress-based disorder symptoms and quality of life, to gain insight into the effectiveness of the program. We also aim to identify potential barriers to recruitment and retention, and assess level of engagement with the guided bibliotherapy. Given that the *Doing what matters in times of stress* book is free, the only cost to the research team is printing the books, which are made freely available to participants, and that all the measures utilized are publicly available, the program is expected to be sustainable.

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## List and describe all research interactions and/or interventions, including the frequency and duration of procedures, and length of participation for individual subjects.

Participants will complete the baseline questionnaire via a REDCap link. The first page participants will see is the informed consent document describing the study, delineating risks/benefits, payment, who to contact with problems, etc. Once participants have read through the informed consent, those who wish to participate will be

taken to the survey battery. The baseline survey battery consists of the Kessler Psychological Distress Scale (K6); PROMIS Emotional Distress, Depression; WHO-5 Well-Being Index (WHO-5); Work and Social Adjustment Scale (WSAS); Proportionality of Stress Reactions; Alcohol Use Disorders Identification Test (AUDIT; only for participants who endorse alcohol use); Adverse Childhood Experiences Scale (ACES); Insomnia Severity Index (ISI); Ten-Item Personality Inventory (TIPI); Emotion Regulation Questionnaire (ERQ), a question to measure satisfaction, and the System Usability Scale (SUS). The 9th item of the Patient Health Questionnaire9 (PHQ-9) will only be asked at baseline and termination. (See Notes and Attachments "Data Collection Procedures" for a schedule of all measures.) The baseline measures will also include demographic information including race, ethnicity, gender, sexual orientation, marital status, extent of religiosity, frequency of attending religious services, spirituality, approximate level of income, highest level of academic achievement, employment status, perceived social support, how often they drink alcohol, previous antidepressant/medication use, current antidepressant/medication use, if they are in some type of therapy, general physical health, and age of onset for problems with anxiety, stress, or depression. Additionally, we will request that participants provide their Twitter handle in order to collect information about their social media timeline. (Participants will not be able to be identified as they will immediately be assigned a unique, anonymous identifier (UUID).) Providing this username is voluntary and participants who either do not use Twitter or choose not to share their username with us will still be allowed to participate in the study. The variables we will be collecting include frequency of posts, timing of posts, a list of cognitive distortions present in the posts, and VADER and ANEW ratings (measure the level of positive-negative affect). We will cease to monitor participants' Twitter accounts after the final follow up call. The baseline survey should take about 15 minutes to complete. Individuals who score at least a 6 on the K6 distress scale are eligible to participate. At the end of the survey participants who qualify will provide their phone number, email, address, whether they would like the book to also be mailed to them, what their preferred method of initial contact is, and a list of timeframes in which they would have the privacy to be contacted by the research team (see Attachments "Eligibility Messages"). Participants who do not qualify will be thanked for their time and receive the link to the book so they can use it on their own time if they wish ("Eligibility Messages"). After they have entered this information they will be emailed a copy of the informed consent, the participation guide (see Attachments "DWM Participation Guide"), and the Doing what matters in times of stress book (see Attachments, "Doing what matters in times of stress."). Within 1 week a member of the research team will either email participants to schedule a time to call, or call eligible participants to confirm their consent, explain the study in more detail, and answer any questions they may have. Each participant will receive a unique Zoom Health link to use for participation. These calls will not be recorded. This initial call will also serve to introduce the participant to the Doing what matters in times of stress book (see "Welcome Call Script"), create a plan for using the book (see "Making a Plan Worksheet"), and schedule the remaining calls. The welcome call should take up to 30 minutes. The next phase of the study involves participants using the Doing what matters in times of stress book with guided interaction over video or phone calls. Each participant will meet weekly with a Research Assistant (RA) who will be trained to the therapeutic material and supportive accountability model (Mohr, 2011). The supportive accountability model frames the relationship in self-help treatments as one in which the helper facilitates the participant's acquisition of skills by being supportive and promoting adherence to the material. This is different than the working alliance in individual therapy in which the patient and therapist work together on a mutually agreed-upon goal in that the relationship in guided self-help puts the emphasis on participants working on their own goals. To be clear, the RA will not be acting as a therapist - their role is only to help participants read through the book. The goal of these weekly guided interactions will be to provide supportive accountability and promote adherence to the intervention (Mohr, 2011). The guided interactions will focus on how the participant interacts with the self-help material (i.e. how the participant feels about the material, goal setting, and performance monitoring) (see "Weekly Meeting Script"). Guidance in the context of self-help has proven to increase treatment adherence compared to unguided self-administered treatment (Titov et al., 2013). This weekly guided self-help will be provided for 6 weeks. During this time the participant and trained RA will meet once a week for 3-6 weeks (depending on what the participant prefers). We will send out a reminder email the day before each meeting. Prior to the start of each of these calls, participants will be

expected to fill out the K6, ERQ, and WHO-5 which track general stress outcomes as well as the psychological flexibility meant to be fostered by the program. This should take around 5 minutes. A link with the survey battery will be sent out 30 minutes prior to each meeting. A week after the 5th meeting, participants will meet with the RA once again to be given a chance to review the material (this meeting is called "Termination" in the Data Collection Procedures). The termination meeting should take around 20 minutes. Prior to the termination meeting they will complete the same survey battery as they did at baseline, which will again take about 15 minutes. During the call they will review their scores, the material, and be asked a series of qualitative questions to assess their perception of the program's feasibility (see "Exit Interview Questions" and "S6 and 3-Month Follow Up Script"). Three months after this 6th session, participants will meet with the RA for one final session. The structure of this session is the exact same as the 6th ("Termination") session. Throughout these interactions we will be tracking information that will inform the feasibility and acceptability of the program. Specifically, we will record the percentage of participants meeting inclusion criteria, percentage of participants who drop out, the percentage who fill out all of the survey measures, and overall recruitment/retention during the program. Below is a complete schedule for participants in the study: Baseline Assessment

Measures/questionnaires: Informed Consent Statement --> Kessler Psychological Distress Scale (K6); PROMIS Emotional Distress, Depression; Adverse Childhood Experiences Scale (ACES); Insomnia Severity Index (ISI); Ten-Item Personality Inventory (TIPI); WHO-5 Well-Being Index (WHO-5); Work and Social Adjustment Scale (WSAS); Proportionality of Stress Reactions; Alcohol Use Disorders Identification Test (AUDIT); Emotion Regulation Questionnaire (ERQ), a question to measure satisfaction, System Usability Scale (SUS), and the 9th item of the PHQ-9. There will also be demographic questions including race, ethnicity, gender, marital status, extent of religiosity, frequency of attending religious services, spirituality, approximate level of income, highest level of academic achievement, employment status, perceived social support, and previous antidepressant/medication use, general physical health, and age of onset for problems with anxiety, stress, or depression. Finally, participants will be asked to provide their Twitter handle. Individuals who qualify (by scoring at least a 6 on the K6) will be asked to provide their phone number, email, address, whether they would like the book to also be mailed to them, their preferred method of contact, and a list of timeframes in which they would have the privacy to be contacted by the research team (see Attachments "Eligibility Messages"). Those who don't qualify will be notified and given a link to the book in case they would like to use it on their own ("Eligibility Messages"). Time to complete: About 15 minutes. Post-Assessment Eligible participants will be emailed a copy of the informed consent, the participation guide (see Attachments, "DWM Participation Guide") and a copy of Doing what matters in times of stress (see Attachments "Doing what matters in times of stress").

Welcome Call During the call: The assigned helper (a member of the research team) will confirm the participant's consent, explain the study in more detail, orient them to the Doing what matters in times of stress book, and answer any questions they may have (see Attachments "Welcome Call Script"). The helper and participant will also collaboratively make a plan for using the guide and schedule the remaining meetings (see Attachments "Making a Plan Worksheet"). Participants will be provided with a Zoom health link for the remaining sessions (if they are meeting via Zoom). These calls will not be recorded. Time to complete: About 5 minutes for the questionnaire, 30 minutes for the Welcome Call. Session 1 (week 1) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the K6, ERQ, and WHO-5. Participants will be shown their scores on these measures. During the call: The helper and participant will discuss their scores on the questionnaire, and check in about the participant's use of the book (see Attachments "Weekly Meeting Script"). Any challenges or successes will be discussed, and the plan to use the book ("Making a Plan Worksheet") will be adjusted if needed. Time to complete: About 5 minutes for the questionnaire, 20 minutes for the session. Session 2 (week 2) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the K6, ERQ, and WHO-5. Participants will be shown their scores on these measures. During the call: The helper and participant will discuss their scores on the questionnaire, and check in about the participant's use of the book (see Attachments "Weekly Meeting Script"). Any challenges or successes will be discussed, and the plan to use the book ("Making a Plan

Worksheet") will be adjusted if needed. Time to complete: About 5 minutes for the questionnaire, 20 minutes for the session. Session 3 (week 3) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the K6, ERQ, and WHO-5. Participants will be shown their scores on these measures. During the call: The helper and participant will discuss their scores on the questionnaire, and check in about the participant's use of the book (see Attachments "Weekly Meeting Script"). Any challenges or successes will be discussed, and the plan to use the book ("Making a Plan Worksheet") will be adjusted if needed. Time to complete: About 5 minutes for the questionnaire, 20 minutes for the session. Session 4 (week 4) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the K6, ERQ, and WHO-5. Participants will be shown their scores on these measures. During the call: The helper and participant will discuss their scores on the questionnaire, and check in about the participant's use of the book (see Attachments "Weekly Meeting Script"). Any challenges or successes will be discussed, and the plan to use the book ("Making a Plan Worksheet") will be adjusted if needed. Time to complete: About 5 minutes for the questionnaire, 20 minutes for the session. Session 5 (week 5) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the K6, ERQ, and WHO-5. Participants will be shown their scores on these measures. During the call: The helper and participant will discuss their scores on the questionnaire, and check in about the participant's use of the book (see Attachments "Weekly Meeting Script"). Any challenges or successes will be discussed, and the plan to use the book ("Making a Plan Worksheet") will be adjusted if needed. Time to complete: About 5 minutes for the questionnaire, 20 minutes for the session. Session 6 (week 6) Prior to the call: Participants will be sent a reminder email the day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the Kessler Psychological Distress Scale (K6); PROMIS Emotional Distress, Depression; Adverse Childhood

Experiences Scale (ACES); Insomnia Severity Index (ISI); Ten-Item Personality Inventory (TIPI); WHO-5 Well-Being Index (WHO-5); Work and Social Adjustment Scale (WSAS); Proportionality of Stress Reactions; Alcohol Use Disorders Identification Test (AUDIT); Emotion Regulation Questionnaire (ERQ), a question to measure satisfaction, System Usability Scale (SUS), and the 9th item of the PHQ-9. During the call: The helper and participant will discuss scores on the K6, ERQ, and WHO-5, and check in about the participant's use of the book (see Attachments "S6 and 3-Month Follow Up Script"). Any challenges or successes will be discussed. Then the participant will be asked a series of qualitative questions about their perception of the book's feasibility (see Attachments "Exit Interview Questions"). Time to complete: About 15 minutes for the questionnaire, 20 minutes for the session. Three Month Follow Up Prior to the call: Participants will be sent reminder emails 1 week and 1 day before the call. 30 minutes before the call, they will be sent a REDCap link to fill out the Kessler Psychological Distress Scale (K6); PROMIS Emotional Distress, Depression; Adverse

Childhood Experiences Scale (ACES); Insomnia Severity Index (ISI); Ten-Item Personality Inventory (TIPI); WHO-5 Well-Being Index (WHO-5); Work and Social Adjustment Scale (WSAS); Alcohol Use Disorders Identification Test (AUDIT); Emotion Regulation Questionnaire (ERQ), a question to measure satisfaction, System Usability Scale (SUS), and the 9th item of the PHQ-9. During the call: The helper and participant will discuss scores on the K6, ERQ, and WHO-5, and check in about the participant's use of the book (see Attachments "S6 and 3-Month Follow Up Script"). Any challenges or successes will be discussed. Then the participant will be asked a series of qualitative questions about their perception of the book's feasibility (see Attachments "Exit Interview Questions"). Time to complete: About 15 minutes for the questionnaire, 20 minutes for the session.