

Healthy Minds Program (HMP) App Dosage Study

Basic Study Information

Simon Goldberg, PhD

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Minimal Risk Research Institutional Review Board

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[compiled from the non-protocol based IRB application]

Healthy Minds Program App Dosage Study

Principal Investigator: Simon Goldberg

Funding: Mindfulness training delivered via mobile health to reduce depression and anxiety

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Overall Purpose

This study will investigate the impact of dosage of meditation practice delivered via a mobile health smartphone application (Healthy Minds Program app) on symptoms of depression and anxiety. We will also investigate the feasibility and acceptability of this program among individuals with elevated symptoms of depression and/or anxiety at baseline.

Study Procedures and Interventions

We anticipate enrolling 110 participants into the study. Recruitment will take place via email, newspaper advertisements, Craigslist, clinics, and flyers. Interested individuals will complete a webscreen to determine eligibility. After passing the webscreen, they will be provided with an overview of the study and will have the option to enroll via an online consent process.

Participants will be asked to complete T1 surveys. After completing T1 surveys, they will be contacted by study staff and assigned to a dosage condition (low dosage = 5 minutes per day, high dosage = 15 minutes per day). Study staff will assist with downloading the mobile app, briefly introducing the participant to the meditation practices, and answering any questions about the practices and/or study. Participants will complete EMA assessments (brief questionnaires delivered as text messages to participants' mobile phones) throughout the duration of the study. Four EMA questionnaires will be delivered per day at random times interspersed between the hours of 9am and 7pm. Participants will complete T2 surveys approximately 4 weeks

after T1. Participants may be invited to an exit interview after completion of the study in order to give feedback on the study.

- Attitudes Towards Psychological Online Interventions (T1, T2)
- AUDIT C (screening only)
- Big Five Inventory, Conscientiousness Items (T1 only)
- Demographics (T1 only)
- Digital Working Alliance Inventory (T2 only)
- EMA items (daily throughout study)
- Experiences Questionnaire decentering subscale (T1, T2)
- Five Facet Mindfulness Questionnaire awareness subscale (T1, T2)
- Healthy Minds Index (T1, T2)
- Marlowe Crowne Social Desirability Scale (T1 only)
- Meaning in Life Questionnaire presence subscale (T1, T2)
- Medication and Therapy Questionnaire (T1, T2)
- Meditation Related Adverse Effects (T2 only)
- Mindfulness Adherence Questionnaire (T2 only)
- NIH Toolbox Loneliness (T1, T2)
- Perseverative Thinking Questionnaire (T1, T2)
- Pre/Post Practice Items (daily throughout study)
- PROMIS Anxiety and Depression Scales (screening, T1, T2)
- PROMIS Sleep Disturbance Scale (T1, T2)
- System Usability Scale (T2 only)
- Well-Being Growth Mindset (T1, T2)
- Qualitative interview questions (T2 only)
- How heard about the study (screening only)

HMP app: After randomization, participants will be asked to spend either 5 minutes or 15 minutes per day practicing meditation with guidance through the HMP smartphone app. The HMP app was developed by Healthy Minds Innovations at the UW Center for Healthy Minds, and is based on the work of Richard Davidson, PhD. It is designed to

promote psychological well-being through well-being skills training. HMP provides content with instruction administered through a curriculum of high-quality guided practices. HMP is based on research on eudaimonic well-being (e.g., environmental mastery, purpose) and brain-based skills that underlie these qualities (e.g., regulation of attention, mental flexibility). Participants will be instructed to use practices from the Awareness module of the HMP app. These attention skills are associated with a number of positive outcomes, including better physical and mental health and increased school and job success. Importantly, evidence increasingly suggests that these attention and awareness skills, specifically, can improve with meditation training. Within the context of the current study, the HMP app is being considered a general wellness device rather than a medical treatment.

Usage data: We will collect information on when and for how long participants listen to recordings, which recordings, and for how long through the application itself. Usage data will be collected through the app itself as well as through EMA questions. Information on their device make, model, and operating system is also collected through the application for quality assurance purposes. All data collected through the application is stored on Amazon Web Services (AWS). All data is encrypted, both at rest (when it is in a database) and in transit (e.g., when it is moving between the application and AWS services). No identifying information, such as IP address, is stored by the application. Data collected through the application will only be identified by study ID numbers.

Potential Benefits to Society

This program offers an innovative public health approach to reducing the burden of depression and anxiety. By investigating the impact of dosage, we will understand the amount of practice that may be necessary to produce clinical benefits.

Inclusion Criteria

1. Elevated symptoms of depression and anxiety.
2. Age 18 or older.
3. Proficient in English.

Exclusion Criteria

1. Non-elevated symptoms of depression and anxiety or having a t-score greater than 70 on the depression scale.
2. Age 17 or younger.
3. Significant meditation experience (as defined below):
 - Meditation retreat experience (meditation retreat or yoga/body practice retreat with significant meditation component).
 - Regular meditation practice weekly for over 1 year OR daily practice within the previous 6 months.
 - Previous practice under the instruction of a meditation teacher, other than in the context of an introductory course.
4. Elevated scores on the Audit-C (greater than or equal to 4 for men and greater than or equal to 3 for women).
5. No access to a smartphone capable of running the HMP app.
6. Self-reported unwillingness to complete EMA surveys 4 times per day during the 4 week study.

Recruitment Plan

These are the primary tools we plan to use for recruitment:

- 1) Flyers: We intend to post in neighborhood settings (e.g., grocery stores, libraries, community centers). We may post at area clinics as well.
- 2) Email: We anticipate using DoIT to email members of the UW-Madison campus community. We may also email UW-Madison community contacts and Madison community contacts directly.
- 3) Newspaper: We anticipate posting advertisements for the study in local newspapers (e.g., The Isthmus).
- 4) Craigslist (under research heading).

Targeted versions of recruitment materials may be used to increase enrollment from underrepresented groups.

Sharing of Data

De-identified data will be made available upon request or shared publicly in an open science format, consistent with NIH data sharing guidelines.

Data that is shared upon request or shared publicly will be completely stripped of HIPAA identifiers including dates.