COVID and the Healthy Minds Program for Educators

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Research Design and Procedures

Overall Purpose

This study will provide and test whether training in well-being practices, using the Healthy Minds Program (HMP) app, is beneficial for employees in the Madison Metropolitan School District (MMSD) as well as other school districts in Wisconsin during the COVID-19 crisis. The HMP app approaches cultivating well-being by training psychological skills with clear mechanistic hypotheses. There is no single definition of well-being, but consensus exists that positive functioning beyond the absence of detrimental mental health symptoms is central. Building on related "eudaimonic" frameworks of psychological flourishing that identify qualities like environmental mastery, positive relations with others, and personal growth, this program targets brain-based skills that underlie the active cultivation of such qualities (e.g., regulating attention, empathic care, mental flexibility), and thus offers straightforward hypotheses about mechanisms of change. The cultivation of such skills aligns with the World Health Organization's definition of mental health, as a state of well-being in which an individual can work productively, cope with the normal stresses of life, contribute to his or her community, and realize his or her own abilities. Viewing well-being as dynamic and skill-based, as opposed to static and set, brings new optimism to cultivating well-being across the lifespan.

The HMP app involves mental exercises that are integrated into daily life, with an approach that parallels the way physical exercise becomes a part of healthy living. A minority of the population is both free of mental illness and high in well-being. This group flourishes mentally and physically (e.g., fewest days of missed work, healthiest psychosocial functioning, lowest risk of cardiovascular disease, lowest health care utilization). Troubling mental health trends in the opposite direction, however, underscore the need for training that bolsters and sustains well-being. National survey data recently revealed that 75% of Americans are significantly impacted by stress (e.g., anxiety, sleeplessness, fatigue), a new high since the survey's inception in 2007. Social divisiveness is an alarming new theme in these reports (59% identified this as a cause of stress), especially given rising trends of social isolation in which people report far fewer trusted confidants (this isolation is even more pronounced now with "safer at home" orders). Whereas mental health interventions have traditionally focused on treating serious mental disorders, this program advocates training and practicing skills even when an individual is relatively healthy. In this framework, exercising these skill sets bolsters well-being and fosters future resilience during inevitable periods of stress and loss. This program offers an innovative public health approach to caring for the mind. By investigating the underlying mechanisms, we will understand whether this potentially transformative approach is viable.

Study Procedures and Interventions

We anticipate recruiting employees from MMSD and other school districts in Wisconsin to participate in this study, so that the final sample of participants who complete the study is 400.

Recruitment will take place via email, center website and social media outlets, social media ads (e.g., Facebook and Instagram ads), flyers and through regular mail (e.g., postcards). We will also work with MMSD to disseminate recruitment materials through their channels (e-newsletters, social media, etc.).

Recruitment materials will provide an overview of the study, including information about the importance of conducting randomized clinical trials. Recruitment materials will also inform potential participants that intervention being studied, the Healthy Minds Program (HMP), is available to the public and if they are not comfortable being randomized to either HMP or a wait-list control they should not participate, but are welcome to use HMP (a link with directions for how to download HMP will be provided). We will also provide a link to the study landing page on the UW ICTR instance of REDCap for those that are interested in participating.

Potential participants will first complete a basic web screen to determine eligibility. Eligible participants will be contacted within 7 days and provided by email with a live study link. The study link will take them to REDCap where they will have the option to enroll via an online consent process. Once consented, participants will move directly to the pre-test survey. Participants will be notified of group assignment after completing the pre-test survey.

Approximately 4-weeks later, participants will complete a similar survey (i.e., post-test). Approximately three months after post-test, participants will complete a final survey (follow-up). We may recontact participants at some point in 2021 to enroll in an optional second follow-up survey. A subset of questionnaires will be administered after weeks 1, 2, and 3.

Study Timeline:

1) Screening

2) Eligible participants consent and complete pre-test

3) Random assignment to intervention or wait-list control

4) Weekly assessment (after weeks 1, 2, and 3)

5) Post-test (after 4-week program)

6) Follow-up (around 3 months after post-test)

Measures - below is a list of measures that may be administered at each time point

Screening Phase:

- PROMIS Depression
- Meditation practice
- HMP use
- MMSD employee, age, and device screening

Pre-test Phase:

- Demographics
- Socially Desirable Response Set Five Item Survey (SDRS-5)
- Treatment Preference

- Predictor of Drop Out
- Credibility Expectancy Motivation Scale

Pre-test, Post-test, Follow-up, Weekly:

- PROMIS Anxiety
- PROMIS Depression
- NIH Toolbox Perceived Stress
- FFMQ awareness subscale
- Drexel Defusion Scale (DDS)
- Meaning in Life Questionnaire
- NIH Toolbox Loneliness

Pre-test, Post-test, Follow-up:

- Conway COVID Questionnaire
- Self-Compassion Scale Short Form
- Attention Check Items
- Perseverative Thought Questionnaire (PTQ)
- WHO-5
- Mindfulness App Usage
- Face rating task

Pre-test and Post-test:

- Growth Mindset Scale for Well-Being

Post-test only:

- Post study program evaluation questions

Weekly Follow-up and Post-test for Treatment Only:

- Digital Working Alliance Inventory

After Week 1 Only For Treatment Only:

- Early Meditation Hindrances Scale

Post-practice For Treatment Only:

- "During the meditation practice, to what extent did you feel each of the following emotions (Happy/Sad/Calm/Nervous)?"
- "How would you rate the overall quality of your meditation practice during this practice? (1 = low, 10 = high)"

Selection of approved measures that may be used:

- Adverse Childhood Experiences Aware; Marlowe Crowne Social Desirability Scale (MCSD); FFMQ non-reactivity subscale; Inclusion of Other in Self; Fear of Missing Out; PTSD Checklist; Psychological Well-Being (PWB); Social Connectedness Scale; Health Anxiety Inventory; Post Traumatic Growth Inventory; PWI; Healthy Minds Index

After randomization, participants in the HMP group will be given instructions on how to download the HMP app, which is publicly available via the app store for iPhones and Google Play for Androids, but requires an activation code. The HMP base program uses about 40MB of memory space, and battery usage is at levels similar to music or podcast programs.

Healthy Minds Program Description:

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. HMP is designed to promote and protect psychological well-being through sustainable skills training. The program is grounded in constituents of psychological well-being identified in empirical literature. HMP provides core 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). HMP has >100 guided audio practices that address 4 constituents of well-being: awareness, connection, insight, and purpose.

Awareness:

The program foundation targets attention and awareness skills that are integral to many conceptions of mindfulness. The importance of executive functions needed to concentrate and pay attention is well established. These attention skills are associated with a number of positive outcomes, including better physical and mental health and increased school and job success. Skillful, goal-directed attention depends heavily on meta-awareness, which involves monitoring experience, often with a focus on the body. Realizing your mind has wandered away from the task at hand, for example, supports voluntarily re-focusing or switching. Investigating failures of meta-awareness has been particularly revealing with regard to well-being. Mind-wandering (which typically occurs without awareness) is associated with less happiness in everyday life and poorer performance on many tasks with important real-world implications (e.g., reading comprehension). Importantly, evidence increasingly suggests that these attention and awareness skills, specifically, can improve with meditation training.

Connection:

The Connection module targets skills underlying social connection, which refers to the sense of having close and positively experienced relationships with others in the social world. Decades of research indicate that social connection is linked to many proximal physical and mental health outcomes and distally to longevity. Neuroscience is increasingly revealing why. Many of the same neural systems

involved in distressing experiences of physical pain are also involved in experiences of social pain resulting from rejection, exclusion, or loss. In contrast to physical pain, though, experiences of social pain are more easily re-experienced and thus appear more likely to stressfully "live on". This and other recent research demonstrating how deeply intertwined we are with others highlights how social connection can prevent and buffer toxic stress. Recent evidence suggests that skillful empathic care, compassion and gratitude, and pro-social behavior foster connection and positive relationships and bolster individual well-being. Building on this basic science, related interventions are revealing initial evidence that these beneficial other-oriented skills can be augmented through training.

Insight:

The Insight module targets skills underlying dynamic self-inquiry and experiential self-knowledge, and is the most novel part of the program. The psychological flexibility that these skills engender is beginning to receive scientific attention as a fundamental aspect of well-being. One set of skills involves developing a new relationship to thoughts about oneself, such that thoughts are experienced as constructed mental events rather than actual depictions of reality. These "decentering" or "dereification" skills foster stepping back from limiting self-schema and thus support viewing oneself as growing and expanding, which is linked to higher well-being in several domains. This flexibility appears to bolster well-being, in part, through navigating life's challenges without surrendering to threat and avoidance. In contrast, rigidity in the form of perseverative thinking is identified as a transdiagnostic dimension of mental health dysfunction. Neuroscience is increasingly shedding light on the underlying neural mechanisms. Self-focused rumination in depressed individuals, for example, appears to emerge through coupling of the default mode network, involved in self-referential processing, and the subgenual prefrontal cortex, involved in affect-laden withdrawal. Many contemplative traditions point to the difficulty of recognizing the dynamic impermanence and subjective reality of our thoughts and emotions without training. One of the primary ways in which this manifests is failing to recognize that a fixed, rigid, and unchanging self-narrative (i.e., reifying the self) translates into self-focused rumination and other forms of suffering. Evidence from meditation intervention studies is converging on the insight realized via decentering/dereification skills as a key mechanism of beneficial change.

Purpose:

The Purpose module targets the deep purpose skills that give us the ability to keep our most deeply held values front and center in our life, relationships, and at work. It helps us to see the bigger picture and focus on the most important things in our lives. There are central life aims that drive us to do the things we do. Inspiring moments from your life can help reveal what's guiding you at the deepest level. Purpose is one of the most important predictors of well-being. It makes us healthier, more resilient, and more engaged. Reflecting on the purpose that inspires the people who you admire can provide a new perspective on your own life. Any single act can be linked with a variety of motivations. Some of these motivations support our well-being, and others undermine it. Pausing to consider your motivations is one of the simplest ways to bring depth and meaning to your life. If you keep asking why, you will quickly find yourself reflecting on your deepest motivations. Remembering the lead up to big moments in our lives reminds us that our actions and decisions matter. When our eyes are on the horizon,

challenges, peaks, and mundane daily experiences can all feel like progress. Clarity of purpose gives us the tools and resources to weather the storms of life, to shift from reactivity to growth. Clarifying your values is only half the battle. You need to apply them in daily life, too. Embodying your values makes them visible to others, and that has a real effect on the world. Guilty pleasures don't seem as attractive when you pay close attention to long-term fulfillment. When we're facing challenges, our values can make a world of difference. If you think of information like food, and you'll see that what you feed your mind has a big impact. Each of us has a role to play in the future of our species. There is no changing the world without changing ourselves. This practice connects you to an emerging movement, a historical tradition, and a global community. When you truly understand that change happens one step at a time, you find meaning in every step.

Inclusion Criteria

- Ages 18 years old and up

- Employees of a K-12 school district in Wisconsin

- Smartphone or device that can download apps from Google Play or the iTunes app store

Exclusion Criteria

- Individuals under 18 years old

- Significant meditation experience:

    - 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; or
    - Previous use of the HMP app

- PROMIS depression score > 70

Analysis Plan

Statistical models

We will use linear mixed effects models with time nested within subject. All randomized participants will be included (i.e., intention-to-treat) and full information maximum likelihood (FIML) estimation will be used for missing data. Treatment effects will be tested by examining the time by group interaction term. We will control for variables that differ between groups at baseline and for social desirable responding, gender, race, and age.

We will follow-up with post-hoc tests to examine Group x time interactions on pre- to post-test, and pre- to follow-up change.

Transformations

Our primary outcome will be z-scored. Covariates will be grand mean centered for interpretation.

Inference criteria

Statistical significance will be set to $p < .05$. All tests are two-tailed. Multiple comparison correction on the analysis of secondary outcomes will be accomplished with False Discovery Rate correction on pre- to post-test and pre- to follow-up change separately.

Data exclusion

Failure of more than 50% of attention checks will result in removal of data. We will conduct model-based examination of outliers. If high leverage points based on model diagnostics exist, we will report results with and without these points.

Missing data

Anticipating differential attrition (e.g., higher attrition in the active condition; Arean et al. 2016), which could indicate violation of missing at random (MAR) assumptions (e.g., treatment group participants who benefited more are more likely to complete post-treatment and follow-up assessments), we will conduct a series of sensitivity analyses to examine not missing at random (NMAR) scenarios. Specifically, we will use Mann Whitney U tests (i.e., non-parametric independent samples test) to compare the treatment and control group residualized change scores. We will report these tests for the completer sample. Then, we will report these tests assuming a worst case scenario (i.e., those with missing data have scores at the maximum / minimum value for the sample). The direction (i.e., maximum versus minimum is based on whether a higher or lower score indicates improvement). We then will examine effects if missing values are assumed to be .25, .50, or .75 standard deviations above or below the sample mean (again, with direction based on the direction of improvement for a given outcome).

Missing data amendment

In place of the sensitivity analysis approach described above, we ultimately used a conceptually similar but more sophisticated pattern-mixture modeling approach (Iddrisu & Gumedze, 2019; Leurent et al., 2018). We selected this approach because it allowed us to examine the robustness of model estimates to different missing not at random (MNAR) assumptions in the same models estimated in primary analyses (i.e., linear mixed effects models). We first used multivariate imputation through chained equations that modeled the nested structure of the data to impute 50 complete datasets under the missing at random (MAR) assumption. After examining imputed datasets for convergence and viability, we scaled imputed values so that they were 10% and separately 20% worse than predicted based on the distribution of observed scores in participants' respective group (HMP/Control). The lower bound scaling factor (i.e., 10%) is based on the minimal symptom change of clinical significance (Dworkin et al., 2008). Finally, we re-estimated linear mixed effects models on each imputed and scaled MNAR dataset separately and pooled the results according to Rubin's rules (Rubin, 2004).

Exploratory analysis

We will conduct exploratory analyses examining potential interactions between baseline characteristics and treatment effects. We will examine three-way interactions (i.e., baseline characteristic X time X group) on the following variables: gender, age, race/ethnicity, job title (i.e., administrator, teacher, other staff), and socioeconomic status.