Psychological Mediators of Reduced Distress: Preregistered Analyses from a Randomized Controlled Trial of a Smartphone-Based Well-Being Training

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Abstract

Understanding why interventions work is essential to optimizing them. Although mechanistic theories of meditation-based interventions (MBIs) exist, empirical evidence is limited. We randomly assigned 662 adults (79.9% reported clinical levels of anxiety or depressive symptoms) to a four-week smartphone-based MBI or wait-list control condition early in the COVID-19 pandemic. Psychological distress and four theory driven preregistered psychological mediators of well-being (mindful action, loneliness, cognitive defusion and purpose) were assessed five times during the intervention period and at three-month follow-up. In preregistered analyses, assignment to the intervention predicted significant gains on all mediators which in turn significantly mediated follow-up distress (21.9%–62.5% of intervention effect on distress). No significant mediation pathway was observed in an exploratory multiple mediator analysis, but reduced loneliness accounted for 61.7% of the combined indirect effect. Multiple psychological pathways may mediate reduced distress in a digital MBI.

Key words: Distress; Meditation; Mobile health; Mechanisms; Mediation

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Meditation-based interventions (MBIs) are more effective at improving stress, anxiety and depressive symptoms than passive control conditions and as effective as other *bona fide* treatments (Goldberg et al., 2018; Hoge et al., 2023). Although many studies have tested the efficacy of various MBIs in different settings and samples, little is known about how these forms of treatment improve mental health (Goldberg, 2022). Understanding not only whether treatments work but how they work is essential to optimizing treatment efficacy and identifying for whom certain treatments may be effective (Kazdin, 2007; van der Velden et al., 2015).

We analyze data from a randomized controlled trial (RCT) of a smartphone-based well-being training with 662 adults, nearly 80% of whom reported clinical levels of anxiety and depressive symptoms, during the early phase (Summer 2020) of the COVID-19 pandemic. We tested preregistered hypotheses about the role of four psychological mediators (mindful action, social connection, cognitive defusion, purpose) in reduced distress that were selected as representative qualities of a recently proposed four pillar framework of well-being (Dahl et al., 2020).

Meditation-Based Interventions

Meditation is an umbrella term for a diverse array of mental training exercises that are intended to strengthen skills, dispositions and behaviors that are thought to promote mental health and well-being. For example, there are meditation practices intended to cultivate focused attention on an object, choiceless awareness of whatever arises in experience, loving-kindness and warmth towards others, and recognition of the suffering of others and a motivation to relieve that suffering (i.e., compassion). We define a MBI as any intervention that includes meditation as

a central component.

MBIs have taken many forms, of which mindfulness-based interventions are the most ubiquitous (American Mindfulness Research Association, 2022). In the scientific literature on MBIs, mindfulness is commonly defined as a skill that consists of paying attention, on purpose, to present moment experience with an attitude of non-judgment (Kabat-Zinn, 2013). Theories of mindfulness-based interventions consistently posit that strengthening attentional capacities is central to positive outcomes (Lindsay & Creswell, 2017; Shapiro et al., 2006; Vago & Silbersweig, 2012). Several theories identify meta-awareness as particularly salient to therapeutic benefits (Dunne et al., 2019; Lindsay & Creswell, 2017; Shapiro et al., 2006; Vago & Silbersweig, 2012). Meta-awareness can be defined as the ability to notice and monitor the on-going contents and processes of experience (i.e., cognitions, sensations, emotions, sensory stimuli; Dahl et al., 2020; Dunne et al., 2019).

Lindsay and Creswell (2017), commenting on how mere attending has the potential to induce greater negative affect (e.g., if what is noticed is distressing and adaptive regulatory skills are insufficient), argued that the attitude one brings to the monitoring of experience is crucial. In their Monitor and Acceptance Theory, the authors suggest that bringing an attitude of acceptance, non-judgment or kindness towards experience is essential to salubrious outcomes (see also Shapiro et al., 2006). Together, attention, meta-awareness and acceptance comprise the major components of mindfulness as defined earlier.

The strengthening of prosocial attitudes, dispositions and behaviors have also been identified as putative mechanisms of improved mental health and well-being in MBIs. In particular, increased awareness of others, empathy and social connection have been posited as mechanisms of benefit (Hölzel et al., 2011; Lindsay & Creswell, 2017; Vago & Silbersweig,

2012). An array of non-mindfulness practice techniques intended to strengthen connection qualities exist (i.e., constructive or connection practices; Dahl et al., 2015; Hirshberg et al., 2018). Consistent with theorizing, research suggests that interventions focusing on connection styles of practices have similar mental health and well-being benefits as mindfulness-based interventions (Galante et al., 2014).

The third commonly proposed category of mechanism is a change in self-perception. Vago and Silbersweig's (2012) framework asserts that fundamental alterations in self-perception, which the authors define as "self-transcendent," modify biases in self-referential processing, enhancing other-oriented, prosocial concern and even softening or eliminating the subject-object perceptual duality between self and other. Others have proposed less transcendent but equally therapeutic modifications of self-processing referred to as cognitive defusion, de-reification or metacognitive insight. These constructs reflect the ability to see that mental events and processes (or more generally all experience) are simply mental events and processes, not the things they seem to represent (Dunne et al., 2019). While closely related to meta-awareness, cognitive defusion, de-reification and metacognitive insight go further by intimating an ontological realization; namely that experience is transient, subjective, and "not-self" (Fresco et al., 2007; Shapiro et al., 2006; Vago & Silbersweig, 2012). The suggested therapeutic potential of this realization is that, by being freed from the (erroneous) notion that thoughts, emotions, and behaviors are the essence of oneself, one limits processes that are antecedent to psychological distress (e.g., perseverative thinking; Ruscio et al., 2011). Just as there are practices to train prosocial qualities, there are numerous practices to enhance cognitive defusion and generate experiential insight (i.e., deconstructive or insight practices; Dahl et al., 2015; 2020).

As this review illustrates, numerous mechanistic theories of MBIs have been put forward

and between them, many different candidate mechanisms have been suggested. Although generative, the number of candidate mechanisms presents methodological challenges for researchers interested in testing proposed pathways of change. In particular, comparatively little theoretical mapping of proposed mechanisms to meditation practices has been undertaken. MBIs can vary significantly in the types of practices employed and without a theoretical mapping of practice type to mechanism, decisions about which mechanisms to test lack theoretical grounding. As a consequence, the limited research on mediators in MBIs has predominately been conducted *post hoc*, weakening the conclusions that can be drawn (Lutz et al., 2015).

Dahl et al. (2015) began to address the mapping problem by categorizing practices into three overarching families: attentional (e.g., mindfulness); constructive (e.g., practices intended to cultivate a positive quality such as compassion); and deconstructive (i.e., practices intended to illicit insight into the nature of self and phenomena). Critically, Dahl et al. included a discussion of practices within each family as well as the sorts of skills and dispositions each family of practice are intended to strengthen. This research as well as other work defining the phenomenology of meditation experience (e.g., Lutz et al., 2015) offer valuable reference points when developing mechanistic hypotheses of MBIs. However, both Dahl et al. (2015) and Lutz et al., (2015) generalized across MBIs and did not provide an exact linking of a theory of change to a specific intervention. Such a linkage is important because MBIs, as already noted, can substantively vary in the practices they employ which in theory would alter expected mechanisms of action.

Dahl et al.'s (2020) awareness, connection, insight and purpose (ACIP) model of well-being proposed that these four domains represent core pillars of well-being. Importantly, their theory rests on evidence of associations between qualities with each pillar and well-being *and*

evidence that these qualities are trainable. The Healthy Minds Program (HMP) is a meditation-based well-being smartphone application training designed around Dahl et al.'s four-pillar model of well-being. Because the HMP structure consists of awareness, connection, insight and purpose modules and each module is intended to strengthen psychological skills and dispositions associated with well-being in that domain, alongside the ACIP model of well-being, the HMP provides the most precise linking of theory to intervention in a MBI, affording specific, testable theories of change.

In the HMP, awareness refers to attention-related skills and dispositions, including the ability to focus attention and to maintain mindfulness (i.e., mindful action) and meta-awareness during day-today activities. The connection pillar comprises skills and dispositions that promote feelings of connection with others and one's environment. Gratitude and compassion are exemplar connection qualities whereas loneliness reflects a lack of connection. Insight refers to an understanding of "the manner in which emotions, thoughts, beliefs, and other factors shape subjective experience, and especially the sense of self" (Dahl et al., 2020, p. 4). Cognitive defusion is an example of an insight quality because it involves meta-awareness as well as the insight that mental events and processes are simply mental events, not the things they seem to represent (Dunne et al., 2019). Although the relationship of purpose to well-being is widely studied in social psychology (Ryff & Keyes, 1995; Seligman, 2018), Dahl et al. are the first to locate purpose as a primary mechanism of change in MBIs. In contrast to traditional operationalizations of purpose as a long-term orientation (e.g., Ryff & Keyes, 1995), they emphasize experiencing purpose on an on-going basis, even during mundane daily activities.

Mediators and Mechanisms of Change

Kazdin (2007) described a mediator as a variable that shows an important statistical

relationship between an intervention and outcome. Statistical mediation, however, does not necessarily explain the process of change (i.e., the mechanism or cause). For instance, statistical mediation can be estimated in cross-sectional data, but these relationships are correlational, not causal. Longitudinal data in which mediator change precedes measurement of the outcome provides temporal precedence but is still insufficient for causal claims. Among applied and clinical researchers it is commonly underappreciated that longitudinal RCTs, which can afford causal claims of intervention impacts on mediator and separately outcome, are alone not sufficient for establishing the causal effect of the mediator on the outcome (MacKinnon & Pirlott, 2015; Nguyen et al., 2020; Rohrer et al., 2022). Inferring causal impacts of the mediator on outcome relies on strong assumptions that may be unreasonable even in longitudinal RCTs (Rohrer et al., 2022), specifically that there are no unmeasured confounder variables and no interaction between treatment and mediator.

Establishing causal mechanistic pathways is an important goal of clinical science. Understanding mechanisms of action is critical to optimizing treatment efficacy and the possibility of personalized intervention. Because of its importance, researchers should appreciate the challenges inherent in making causal claims and the value of rigorously identifying indirect effects (i.e., statistical mediation) in longitudinal designs.

Designs that afford causal mechanism inferences such as randomly assigning participants to different levels of the mediator may be impossible when studying psychological mechanisms that likely covary using interventions that likely affect multiple psychological processes simultaneously (Eronen, 2020). Dismantling trials in which participants are assigned to specific components of an intervention (e.g., meditation practices) may be a feasible way for researchers to establish causal mechanisms of action. However, dismantling trials require that a candidate

mechanism is well identified and there is a precise understanding of the intervention components that change the specified mediator. In MBIs, which are typically comprised of multiple practice techniques, this is akin to understanding that meditation practice *a* promotes psychological mediator *m* (and not other potential mediators), but meditation practice *b* does not. One way to generate this level of understanding is to rigorously test candidate mediators of change. Appropriately powered longitudinal RCTs designed to test theory-specified mediators of change are among the most rigorous approaches for studying mediation. Preregistration of mediation hypotheses adds confidence in the reliability of observed effects.

Although research on meditation has rapidly expanded, research on mediators remains in its infancy. There have been relatively few studies focused on mediators of change and most have been conducted *post hoc* and have been underpowered (Crane et al., 2017; Gu et al., 2015; van der Velden et al., 2015). For example, in reviews of mediators in mindfulness-based cognitive therapy (MBCT) in major recurrent depression (van der Velden et al., 2015) and MBCT and mindfulness-based stress reduction on physical or psychological symptoms (Alsubaie et al., 2017; Gu et al., 2015), the largest individual study samples were n=255 (in a three group RCT), n=219 and n=205, respectively, most studies had sample sizes below 100 (van der Velden et al., 2015; Albusaie et al., 2017; Gu et al., 2015) and none appear to have been preregistered. MBI research is not unique in this respect; mediation research in most other fields of psychology is also commonly underpowered and *post hoc* (Schoemann et al., 2017).

Exploratory analyses can provide important information for future research. However, underpowered and *post hoc* analyses are prone to several biases, including inflated effect size estimates (i.e., promising trial bias) and frequently fail to replicate (Götz et al., 2021; Halsey et al., 2015; Sims et al., 2022). Although some commonly used meta-analytic methods (e.g.,

weighting study-level effect size estimates by the inverse of their variance, using trim-and-fill analyses to estimate the impact of publication bias) can address some of the limitations of small sample studies particularly when sufficient primary studies are included, meta-analytic inferences based on such data are not immune from small sample biases and may therefore lead to erroneous conclusions (Lin, 2018; Simonsohn et al., 2022). While a couple of well-powered studies on mediators in MBIs have been conducted (e.g., Dimidjian et al., 2023), the field of MBI research has produced little strong evidence of statistical mediation and as a consequence, a dearth of knowledge to advance research toward a causal understanding of MBI effects.

The Present Research

We sought to advance MBI research and understanding of the mediating psychological processes involved in MBIs in three ways. First, we analyzed data appropriately powered for mediation analyses (n=662) in a research design (a longitudinal RCT) intended to test processes of change (i.e., weekly assessments during the intervention period, a three-month follow-up). Second, we tested mediation hypotheses based on a well-articulated theory of change (Dahl et al., 2020) in an intervention constructed around that theory of change (the HMP). Third, we preregistered mediation hypotheses we would test.

{FIGURE 1}

Transparency and Openness

The parent trial was registered to ClinicalTrials.gov on June 11, 2020 (NCT04426318) prior to participant recruitment. Study outcomes, hypotheses, and methods were preregistered on June 9, 2020 at the Open Science Foundation (osf.io/7b4wy; parent trial osf.io/eqgt7). We preregistered mediation models using linear mixed effects models but prior to analyses determined latent growth structural equation meditation models were more appropriate to testing our hypotheses.

All data associated with this manuscript as well as Mplus code can be accessed at https://osf.io/t8qxm/. We report how we determined our sample size, all data exclusions, all manipulations, and all measures in the study. All procedures contributing to this work comply with the ethical standards of relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. All participants in all of the studies included in this manuscript provided their written, informed consent before participating. All methods and procedures were reviewed and approved by the University of Wisconsin Madison Institutional Review Board.

Method

Procedure

Recruitment was conducted through web postings and newsletters. Enrollment was open to adults (≥18 years of age) who worked in any capacity in a Wisconsin preK–12 educational system (e.g., public/private/parochial) and possessed a smartphone capable of downloading the HMP. Participants were excluded if they had previously used the HMP, had meditation retreat experience, had a regular meditation practice (i.e., ≥ once per week over the prior year), practiced meditation daily for the prior six months, or at prescreen reported severe depressive symptoms (i.e., ≥2 SDs above population mean).

Eligible participants were sent an email two-days after prescreen with an invitation link to a Research Electronic Data Capture (REDCap) survey. Participants were required to electronically sign the consent document before proceeding to the baseline questionnaire. Enrollment was rolling between June 18 through August 28, 2020. Following baseline survey completion, participants were assigned to condition via an automated simple random assignment procedure coded into REDCap wherein the timestamp of baseline completion determined group

assignment (i.e., completion on an even second resulted in assignment to treatment, odds second assignment to control). Based on enrollment timing, REDCap was programmed to send automated invitations and reminders to subsequent assessments via email. Assessments occurred at baseline (T1), one-week later (T2), two-weeks later (T3), three-weeks later (T4), four-weeks later (T5; post-test) and 16-weeks later (T6; three-month follow-up). Wait-list participants received access to the HMP after T6.

Participants were compensated $150 for completing all measures. All study materials and procedures were approved by the University of Wisconsin-Madison Institutional Review Board (2020-0533) on May 13, 2020. See Supplemental Materials (SM) Figure S2 for CONSORT Diagram.

{FIGURE 2}

Sample Size

Preregistered power analyses were conducted based on the floor for the expected sample size (i.e., n=400). At 80% power, n=400, expecting average attrition in fully remote studies (i.e., 43.4%; Linardon & Fuller-Tyszkiewicz, 2020), at a two-tailed $\alpha = 0.05$, the study was powered to detect between group difference of Cohen's $d \geq 0.38$. Based on the actual analytic sample (n=662) and attrition rate (11.03%), the study was powered to detect between group differences on the primary outcome and candidate mediators of Cohen's $d \geq 0.22$.

Measures

The primary trial outcome was psychological distress, operationalized as the aggregate of the 10-item NIH Perceived Stress Scale (baseline α=.86; Cohen et al., 1983; Cyranowski et al., 2013) and the PROMIS Anxiety and Depression scales (adaptive; Pilkonis et al., 2011). Scale scores were z-scored and aggregated. This approach is consistent with evidence that a single

distress factor may underly all forms of psychopathology; stress, anxiety, and depression all load on a single internalizing factor (Caspi et al., 2014); and, as a rule, anxiety and depressive symptoms are highly comorbid (Kalin, 2020).

The Five Facet Mindfulness Questionnaire Act with Awareness subscale (i.e., mindful action; 8-items, baseline α=.91; Baer et al., 2008), NIH Toolbox Loneliness Questionnaire (5-items, baseline α=.90; Cyranowski et al., 2013), Drexel Defusion Scale (10-items, baseline α=.84) which assesses cognitive defusion, and the Meaning in Life Questionnaire Presence subscale (5-items, baseline α=.91; Steger et al., 2006) were selected as representative qualities of awareness, connection, insight and purpose pillars, respectively.

Statistical Analyses

All analyses were conducted in Mplus version 8.8 (Muthén & Muthén, 2018) using the COMPLEX command, clustering by participant, controlling for baseline distress score, with maximum likelihood estimation which is robust to data missing at random (Graham, 2009) as well as deviations from normality (Muthén & Muthén, 2017). Asymmetric, bias corrected bootstrapped (5000) confidence intervals were used. See SM for Mplus code.

Primary Analyses. We fit a latent growth structural equation mediation model (LGSEM), with three-month follow-up distress as the outcome, for each hypothesized mediator. Mediators, measured five times (baseline, weekly during the intervention period and post-test), were modeled as a latent intercept and latent slope along with the direct effect of assignment to intervention on follow-up distress, and the indirect effect through the mediator of assignment to the intervention on follow-up distress. We controlled for baseline distress in all models. Mediator slopes were all approximately linear and modeled as such (SM Figure S2). Random intercepts and slopes were allowed to correlate. Residual variance of the observed T1 through T5 mediator

measurements were constrained to be time invariant. Betas of group assignment on latent intercept, slope and direct effects on follow-up distress are in *SD* units. Betas of the indirect effect can be interpreted as the effect on follow-up distress (in *SD*) of a one *SD* change in the mediator.

Model fit to the data was assessed using standard relative (e.g., Tucker-Lewis index [TLI]) and absolute fit indices (e.g., root mean squared error of approximation [RMSEA]). Adequate fit was based on standard conventions (Standard Root Mean of the Squared Residual [SRMR]<.08, RMSEA<.05, TLI>.95; Hu & Bentler, 1999; MacCallum et al., 1996). Because the only fit statistic provided when bootstrapping in Mplus is SRMR, we report parameter estimates from bootstrapped models and fit statistics from non-bootstrapped models. Betas were standardized.

LGSEMs that produced convergence warnings were explored by re-estimating the model using the residuals of follow-up distress regressed on baseline distress as the outcome. In all cases, residuals as outcome models converged with fit statistics and estimates equivalent to the planned covariate adjusted, bootstrapped LGSEM, alleviating concerns about the warning.

Exploratory Not Preregistered Analyses. We re-estimated mediator models with the subsample reporting clinical levels of anxiety or depressive symptoms at baseline (T-score>55; 79.9% of sample). In addition, because all preregistered mediators significantly mediated follow-up distress, we fit an exploratory multiple mediator model with all four mediators simultaneously. This model produced convergence warnings and a non-positive latent variable covariance matrix to due to linear dependencies. Re-estimating as a residual as outcome model (as above) resolved these warnings. As a result, we report the residual as outcome for the full sample and clinical subsample multiple mediator models.

Results

Participants

Full participant details are presented in Table 1. Participants were 662 adults working in education systems in Wisconsin. On average, participants reported anxiety levels one *SD* above the population mean and depressive symptoms half a *SD* above the population mean on the Patient-Reported Outcomes Measurement Information System Inventory (PROMIS Anxiety & Depression scales; Pilkonis et al., 2011). Nearly 80% of participants reported clinical levels of anxiety or depressive symptoms (T-score>55).

{TABLE 1}

Study attrition was 11.03%. About 96% of HMP assigned participants downloaded the app (329/344) with 271 (78.78%) using the app on one or more days. On average, HMP group participants used the app on 10.88 days (*SD*=9.08) over the 30-day intervention period, averaging 127.93 minutes of practice (*SD*=130.63; Hirshberg, Frye, et al., 2022). Descriptive statistics by group and timepoint on all variables are presented in SM Table 1.

Primary Analyses

The LGSEMs for each single mediator model had adequate to excellent fit (Table 2).

Mindful action: Assignment to the HMP predicted a 0.21 *SD* pre- to post-test improvement in mindful action ($p<.001$) which significantly mediated 33.3% of the HMP's total effect on follow-up distress ($b=-0.06$, $p=.005$). The direct effect of HMP assignment on follow-up distress was statistically significant in this model ($b=-0.11$, $p=.001$; Table 3).

Loneliness: Assignment to the HMP predicted a 0.31 *SD* pre- to post-test reduction in loneliness ($p<.001$) which significantly mediated 62.5% of the HMP's total effect on follow-up distress ($b=-0.10$, $p<.001$). The direct effect of HMP assignment on follow-up distress was not

significant in the loneliness model (*b*=-0.05, *p*=.148; Table 3).

***Cognitive defusion*:** Assignment to the HMP predicted a 0.33 *SD* pre- to post-test gain in cognitive defusion (*p*<.001) which mediated 44.0% of the HMP's effect on follow-up distress (*b*=-0.07, *p*=.011). The direct effect of HMP assignment on follow-up distress was significant in the cognitive distress model (*b*=-0.09, *p*=.021; Table 3).

Purpose: Assignment to the HMP predicted significant a 0.27 *SD* increase over the intervention period in purpose (*p*<.001) which mediated 21.9% of the HMP's total effect on long-term distress (*b*=-0.04, *p*=.036). The direct effect of HMP assignment on follow-up distress was significant in the purpose model (*b*=-.012, *p*<.001; Table 3).

Exploratory Not Preregistered Analyses

All LGSEMs using the subsample reporting clinical symptoms had adequate to excellent fit (Table 2) and results were consistent with primary analyses (Figure 2). In the multiple mediator model on the full sample (Full results in Table 3), the total indirect effect was statistically significant (*p*=.019, 61.9% of total effect of HMP on distress), but none of the mediators significantly mediated long-term distress controlling for the others. Reduced loneliness explained the largest share of the indirect effect on reduced follow-up distress (61.7%) followed by increased mindful action (39.9%; sum >100% because some mediators predicted increased follow-up distress [Table 3]). The direct effect of the HMP on distress was not significant (*b*=-0.08, *p*=.193). The multiple mediator model restricted to the clinical subsample was consistent with full sample analyses (Table 3; Figure 2).

Discussion

In a longitudinal RCT in which candidate mediators were assessed weekly across the intervention period, we tested a set of preregistered mediation hypotheses based on Dahl et al.'s

(2020) awareness, connection, insight and purpose (ACIP) theory of well-being. As predicted, assignment to the HMP produced significant improvements on each candidate mediator, selected as a representative quality of its respective ACIP pillar. In turn, improvements on each mediator significantly mediated three-month follow-up reductions in psychological distress. These results suggest that strengthening mindful action, reducing loneliness, training cognitive defusion and enhancing a sense of purpose throughout one's daily life are each strong candidate mechanisms of change in the HMP.

Although the sample did not target adults with clinical diagnoses, mean anxiety and depressive symptoms were around one *SD* and one-half *SD* above the population average, respectively. In addition, results from analyses restricted to participants reporting clinically meaningful symptoms were consistent with full sample results. This pattern of findings suggests that improving mindful awareness, loneliness, cognitive defusion and purpose may be pathways to reducing distress across individuals with a range of symptom levels. This conclusion is consistent with existing research. Although much of the prior research on mediators in MBIs is limited due to small sample sizes and *post hoc* analyses, in secondary analyses of a well-powered trial of mindfulness-based cognitive therapy (MBCT) on depressive relapse in patients with residual depressive symptoms, Dimidjian and colleagues (2023) reported that MBCT-associated improvements in mindfulness and decentering, a construct closely related to cognitive defusion, significantly mediated depressive relapse at 15-month follow-up.

In the exploratory multiple mediator model, the four mediators combined explained nearly 62% of the total direct effect of assignment to the HMP on follow-up distress reductions. The majority of this effect was attributable to intervention-related reductions in loneliness (i.e., 61.7% of the indirect effect). Although it is difficult to parse individual mediator effects in

multiple mediator models when the mediators covary (Preacher & Hayes, 2008), and loneliness did not significantly mediate long-term distress in the multiple mediator model, results indicate that reducing perceptions of loneliness may, among the mediators studied, be the most robust pathway through which the HMP was associated with reduced distress. Reinforcing this conclusion, the only single mediator model in the full sample in which the direct effect of the HMP on follow-up distress was no longer statistically significant after accounting for the mediator was loneliness. In the clinical symptoms subsample, the direct effect of the HMP on follow-up distress was no longer significant in both the loneliness and cognitive defusion mediator models.

The possibility that reductions in loneliness are the primary pathway through which the HMP is associated with reduced distress has particular salience when considering that these data were collected during the early phase of the COVID-19 pandemic, before vaccines were available, when many institutions, including schools, continued to mandate remote work, and the follow-up period coincided with the initial surge of Alpha variant-related COVID-19 infections. Given this context, it seems unlikely that participants assigned to the HMP were less lonely because the HMP caused them to be more willing to take health risks by increasing their social interactions. Rather, a more parsimonious explanation may be that the HMP changed how participants perceived their social life. That is, HMP participants *felt* less lonely over the intervention period, even as in-person interactions were similar to control participants.

Loneliness is a growing global public health issue (Cacioppo & Cacioppo, 2018). In contrast to social isolation, loneliness is a subjective experience. One person may feel tremendous loneliness even when regularly in the company of others, whereas another person may feel strong social connection despite regularly spending time alone (Holwerda et al., 2014).

How we perceive and interpret our experience matters. Loneliness is associated with increased risk of all-cause mortality (Rico-Uribe et al., 2018), increased likelihood of dementia (Holwerda et al., 2014) and higher depressive symptoms in both youth (Lee et al., 2020) and adults (Lee et al., 2021). HMP-related reductions in loneliness and the robust mediation effect of these reductions on later distress have potentially significant clinical and public health relevance.

Limitations

There are several important limitations to note. First, the sample was homogenous in terms of gender, race/ethnicity and gender, potentially restricting our ability to make inferences beyond predominately White (89%) females (88%) from the upper Midwest of the United States. Our reliance on self-report indices precludes understanding whether the HMP impacted abilities (e.g., cognitive defusion) or perceptions of ability. Although the sample reported on average high levels of distress and results were consistent when analyzing only the part of the sample with clinically elevated symptoms, it will be important to clinical science to replicate these results in samples comprised only of participants with clinically elevated symptoms. In addition, the present results are based on intervention group effects and do not model the potential significance of intervention adherence and engagement to the observed pathways of change. It is not yet clear how best to operationalize these constructs, particularly in MBIs that suggest that participants should bring formal meditation practice into their lives in an on-going and informal way that is difficult to measure. Nevertheless, examining the relationship between intervention engagement and mediators of change is an important area for future research. Finally, our analyses point toward but do not establish causal mechanisms of change because, for example, it is possible that unmeasured confounder variables including other potential mediators explain the observed effects.

Conclusion

A four-week smartphone-based well-being training resulted in significant post-test improvements on all preregistered measures selected to assess qualities within each pillar of the ACIP theory of well-being (Dahl et al., 2020). In individual mediation models, intervention gains on each of these qualities significantly mediated reductions in psychological distress at three-month follow-up. In a multiple mediator model, reductions in loneliness appeared to be the primary pathway through which the HMP was associated with long-term distress reductions. Improving mindful action, cognitive defusion and purpose, and perhaps particularly reducing perceptions of loneliness, may be pathways to improved mental health.

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Table 1.

Sample Demographics

	HMP Group (n=344)	WLC Group (n=318)
Gender		
Female	302 (86.9%)	281 (88.4%)
Male	42 (12.2%)	37 (11.6%)
Non-binary	1 (0.3%)*	0 (0.0%)
Age (years)		
< 20	0 (0.0%)	1 (0.2%)
20 - 30	55 (16.0%)	46 (14.5%)
30 - 40	105 (30.5%)	90 (28.3%)
40 - 50	103 (29.9%)	93 (29.3%)
50 - 60	61 (17.7%)	79 (24.8%)
> 60	20 (5.8%)	9 (2.8%)
Race / Ethnicity*		
American Indian / Alaskan Native	5 (1.5%)	4 (1.3%)
Asian / Pacific Islander	9 (2.6%)	4 (1.3%)
Black / African American	11 (3.2%)	15 (4.7%)
Hispanic/ Latino	15 (4.4%)	17 (5.3%)
White / Caucasian	315 (91.6%)	287 (90.3%)
Highest Education Level		
< 7 years formal education	1 (0.3%)	2 (0.6%)
Graduated high school	10 (2.9%)	6 (1.9%)
Some college	24 (7.0%)	27 (8.5%)
Graduated college	100 (29.1%)	103 (32.4%)
Advanced degree	208 (60.5%)	178 (56.0%)
NA	1 (0.3%)	2 (0.6%)
Household income (US Dollars)		
<$20,000	8 (2.3%)	9 (2.8%)
$20,000 - $40,000	22 (6.4%)	19 (6.0%)
$40,000 - $70,000	80 (23.3%)	82 (25.8%)
$70,000 - $100,000	87 (25.3%)	74 (23.3%)
$100,000 - $200,000	135 (39.2%)	121 (38.5%)
>$200,000	9 (2.6%)	12 (3.8%)
Employment category		
Classroom teacher	144 (41.9%)	134 (42.1%)
Classroom support	47 (13.7%)	44 (13.8%)
Special Education teacher	29 (8.4%)	31 (9.8%)
School support	38 (11.1%)	35 (11.0%)
School administrator (e.g., Principal)	8 (2.3%)	4 (1.3%)
System staff	20 (5.8%)	27 (8.5%)
Other / Unknown	58 (16.9%)	43 (13.5%)

Note: This table has been reprinted from Hirshberg et al. (2022) with permission. Data are n (%). Gender does not sum to 100% because participants were able to select multiple categories. Race / Ethnicity does not sum to 100% because participants were able to select multiple categories.

Table 2.

Mediation Model Fit Statistics

Model	TLI	RMSEA	SRMR
Mindful Action	0.956	0.083 90% CI[0.07, 0.10]	0.037
Clinical symptoms subsample	0.960	0.080 90% CI[0.06, 0.01]	0.047
Loneliness	0.965	0.075 90% CI[0.01, 0.09]	0.028
Clinical symptoms subsample	0.961	0.079 90% CI[0.06, 0.10]	0.033
Cognitive Defusion	0.963	0.064 90% CI[0.05, 0.08]	0.040
Clinical symptoms subsample	0.965	0.068 90% CI[0.04, 0.08]	0.048
Presence of Meaning	0.995	0.022 90% CI[0.00, 0.04]	0.030
Clinical symptoms subsample	0.981	0.048 90% CI[0.03, 0.07]	0.042
Multiple Mediator	0.963	0.048 90% CI[0.04, 0.05]	0.032
Clinical symptoms subsample	0.961	0.042 90% CI[0.04, 0.05]	0.030

Note. Fit indices are from non-bootstrapped model. TLI = Tucker-Lewis Index. RMSEA = Root mean square error of approximation. SRMR = Standardized root mean square residual.

Table 3

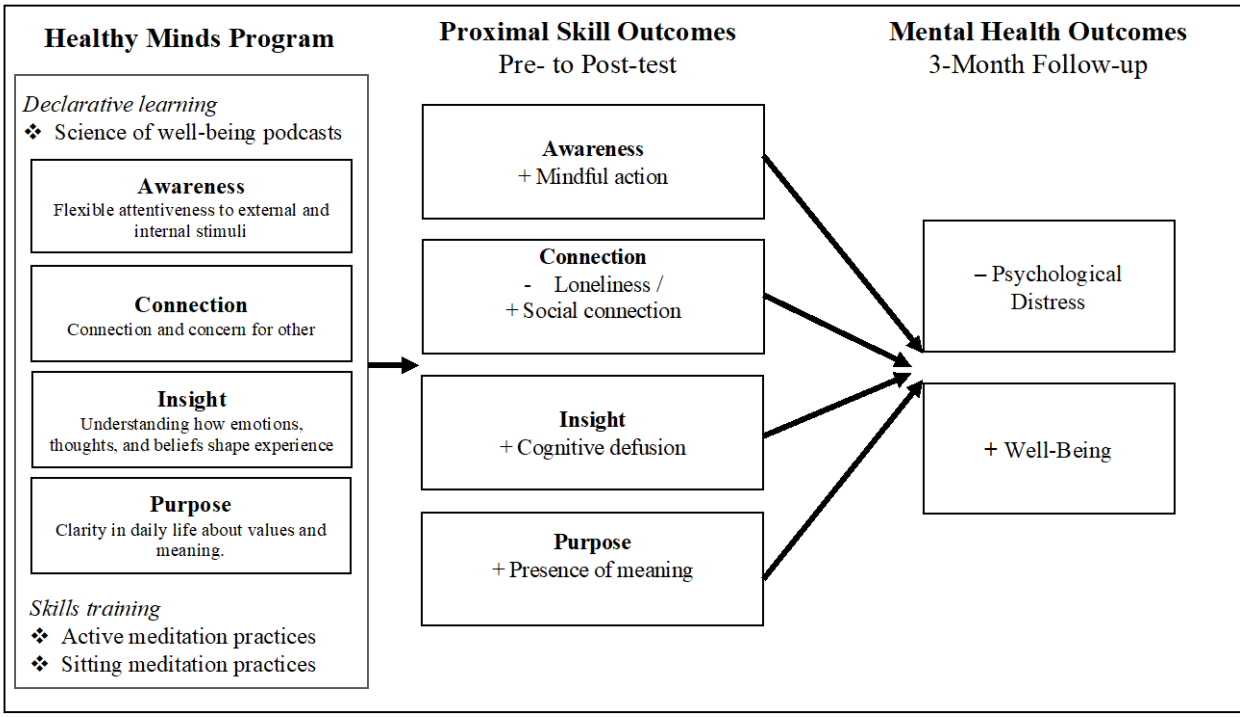
Multiple Mediator Model Results

				95% C.I.		
Type	Effect	Estimate	SE	Lower	Upper	*p*
Indirect	HMP➡ Mindful action intercept➡ Distress	0.01 (0.01)	0.01 (0.01)	-0.00 (-0.00)	0.03 (0.03)	.361 (.376)
	HMP➡ Loneliness intercept ➡ Distress	-0.00 (-0.00)	0.01 (0.00)	-0.02 (-0.01)	0.00 (0.01)	.616 (.936)
	HMP➡ Cognitive defusion intercept➡ Distress	0.00 (0.01)	0.01 (0.01)	-0.01 (-0.00)	0.02 (0.03)	.698 (.522)
	HMP➡ Purpose intercept ➡ Distress	-0.01 (-0.01)	0.01 (0.01)	-0.02 (-0.03)	0.00 (0.01)	.378 (.533)
	HMP➡ Mindful action slope➡ Distress	-0.05 (-0.06)	0.05 (0.06)	-0.16 (-0.20)	0.01 (0.03)	.264 (.342)
	HMP➡ Loneliness slope➡ Distress	-0.08 (-0.08)	0.05 (0.06)	-0.20 (-0.22)	0.00 (0.03)	.129 (.206)
	HMP➡ Cognitive defusion slope➡ Distress	-0.01 (-0.05)	0.04 (0.07)	-0.10 (-0.18)	0.01 (0.04)	.749 (.471)
	HMP➡ Purpose slope ➡Distress	0.02 (0.01)	0.04 (0.05)	-0.04 (-0.06)	0.10 (0.01)	.698 (.882)
Component	HMP➡ Mindful action intercept	-0.10 (-0.11)	0.08 (0.09)	-0.26 (-0.29)	0.06 (0.08)	.248 (.255)
	HMP➡ Loneliness intercept	-0.10 (-0.03)	0.08 (0.10)	-0.27 (-0.21)	0.06 (0.16)	.229 (.730)
	HMP➡ Cognitive defusion intercept	0.04 (0.09)	0.09 (0.10)	-0.13 (-0.11)	0.21 (0.27)	.642 (.380)
	HMP➡ Purpose intercept	0.10 (0.07)	0.08 (0.09)	-0.06 -0.17)	0.26 (0.25)	.215 (.455)
	HMP➡ Mindful action slope	**0.41 (0.57)**	**0.12 (0.12)**	**0.18 (0.33)**	**0.64 (0.82)**	**<.001 (<.001)**
	HMP➡ Loneliness slope	**-0.61 (-0.74)**	**0.11 (0.12)**	**-0.81 (-0.96)**	**-0.39 (-0.49)**	**<.001 (<.001)**
	HMP➡ Cognitive defusion slope	**0.68 (0.75)**	**0.11 (0.12)**	**0.46 (0.51)**	**0.89 (0.97)**	**<.001 (<.001)**
	HMP➡ Purpose slope	**0.55 (0.61)**	**0.12 (0.13)**	**0.32 (0.34)**	**0.78 (0.85)**	**<.001 (<.001)**
Direct	HMP➡ Distress	-0.08 (-0.05)	0.06 (0.07)	-0.20 (-0.18)	0.03 (0.09)	.193 (.529)
Total		**-0.22 (-0.23)**	**0.04 (0.04)**	**-0.29 (-0.31)**	**-0.15 (-0.14)**	**<.001 (<.001)**

Note. HMP = Healthy Minds Program. SE = Standard error. Bold = $p<.05$. C.I. = Confidence interval. Estimates are standardized. Statistics are from the full sample multiple mediator model. Statistics in parentheses are from the clinical symptoms subsample multiple mediator model (n=529).

Figure 1.

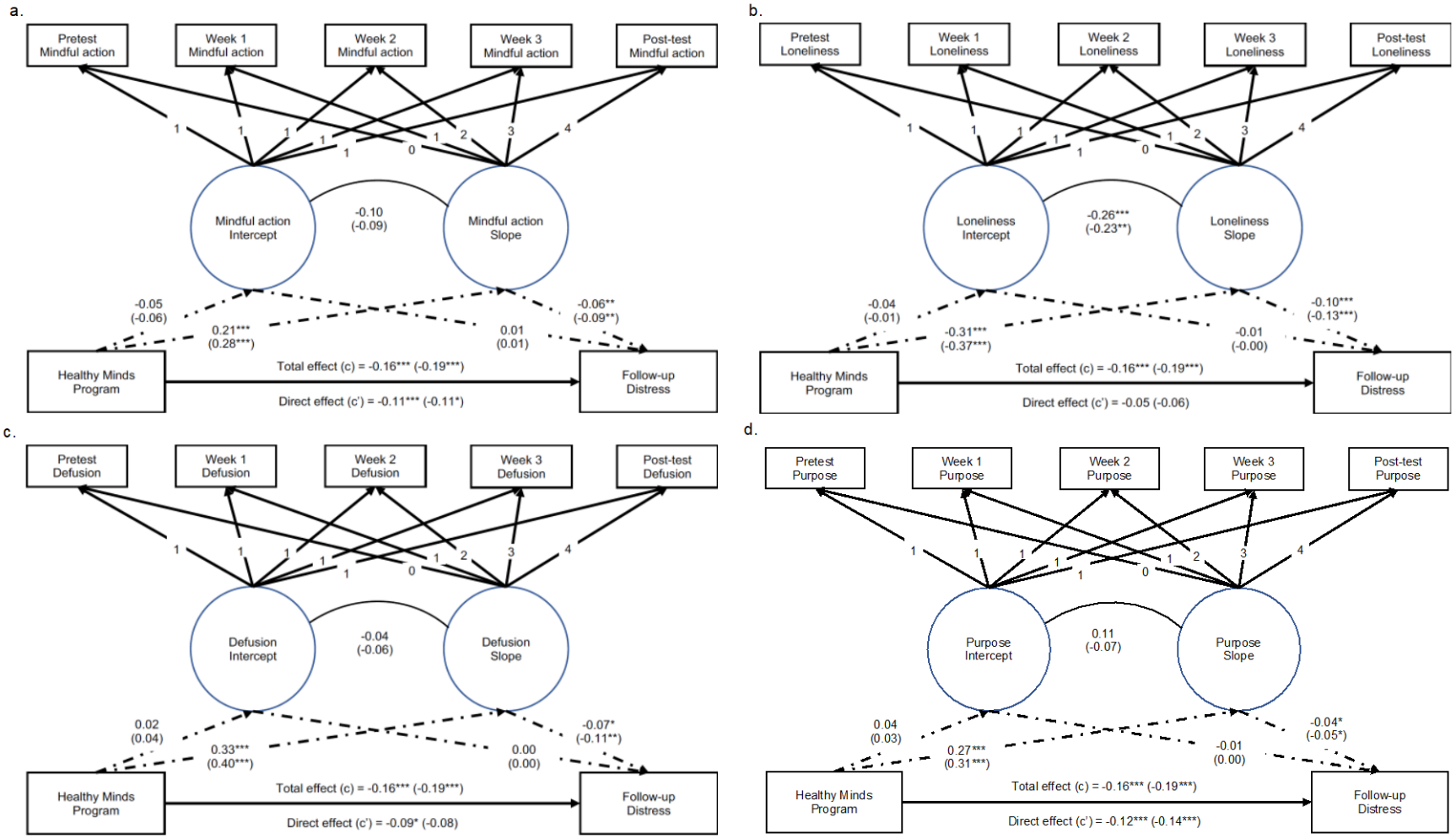
Hypothesized Mechanisms of Change



Note: This figure has been adapted from Hirshberg et al. (2022). Declarative learning is learning about well-being, well-being skills, and the role of training well-being skills in well-being. Skills training is experiential practice of well-being skills through traditional sitting forms of meditation and active practices. Active practices are a unique feature of the Healthy Minds Program in which mundane daily activities are utilized as opportunities to strengthen specific well-being skills. Proximal outcomes are constructs associated with each awareness, connection, insight and purpose domain that were assessed as mediators in this study.

Figure 2.

Results from Awareness, Connection, Insight, and Purpose Latent Growth Mediation Models



Note. All models control for baseline distress with loadings on the latent intercept constrained to 1. Coefficients are from the full

sample. Coefficients in parentheses are from equivalent models restricted to the clinical subsample (n=529) a. Latent intercept and slope of mindful action as mediator. b. Latent intercept and slope of loneliness as mediator. c. Latent intercept and slope of cognitive defusion as mediator. d. Latent intercept and slope of presence of purpose as mediator. ***p<.001, **p<.01, *p<.05

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Conflicts of interest

Richard J. Davidson is the founder, president, and serves on the board of directors for the non-profit organization, Healthy Minds Innovations, Inc. No donors, either anonymous or identified, have participated in the design, conduct, or reporting of research results in this manuscript.

Statement of Ethics

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. *A*ll participants in all of the studies included in

this manuscript provided their written, informed consent before participating. All methods and procedures were reviewed and approved by the University of Wisconsin Madison Institutional Review Board.

Author Contributions

Matthew J. Hirshberg led preregistration, data analysis and manuscript writing. All authors participated in the study design and writing of the manuscript as well as the interpretation of results. All authors have provided final approval of the manuscript for submission.