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Awareness, Connection, and Insight: Testing a Multi-Component, Self-Guided, Smartphone-Based Meditation App in a Three-Armed Randomized Controlled Trial

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**Abstract**

**Background:** A growing number of randomized controlled trials (RCTs) suggest psychological benefits associated with meditation training delivered via mobile health. However, research in this area has primarily focused on mindfulness, only one of many meditative techniques.

**Objective:** This study evaluated the efficacy of two versions of a self-guided, smartphone-based meditation app – the Healthy Minds Program (HMP) – that includes training in mindfulness (Awareness) along with practices designed to cultivate positive relationships (Connection) or insight into the nature of self (Insight). **Methods:** A three-arm, fully remote RCT compared eight weeks of each of two HMP conditions (Awareness + Connection, Awareness + Insight) to a waitlist control. Adults ( $\geq 18$  years) without extensive previous meditation experience were eligible. The primary outcome was psychological distress (depression, anxiety, stress). Secondary outcomes were social connection, empathy, compassion, self-reflection, insight, rumination, defusion, and mindfulness. Measures were completed at pre-test, mid-treatment, and post-test between October 2019 and April 2020. Longitudinal data were analyzed using intention-to-treat principles with maximum likelihood. **Results:** 343 participants were randomized and 186 (54.2%) completed mid-treatment and/or post-test assessments. The majority ( $n=166$ , 72.8%) of those assigned to HMP conditions downloaded the app. The two HMP conditions did not differ from one another in change on any outcomes. Relative to waitlist, the HMP conditions showed larger improvements in distress, social connectedness, mindfulness, and measures theoretically linked to insight training ( $d_s=-0.28$  to  $0.41$ ,  $P_s<.050$ ), despite very modest exposure to connection- and insight-related practice. Results were robust to some assumptions about non-random patterns of missing data. Improvements on distress were

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associated with days of use. Candidate mediators (social connection, insight, rumination, defusion, and mindfulness) and moderators (baseline rumination, defusion, and empathy) of changes in distress were identified. **Conclusions:** This study provides initial evidence of efficacy for the HMP app in reducing distress and improving outcomes related to well-being, including social connectedness. Future studies should make efforts to increase study retention and user engagement.

**Trial Registration:** ClinicalTrials.gov NCT04139005

**Keywords:** meditation; mindfulness; compassion; mobile health; social connection; randomized controlled trial

## Introduction

Mindfulness and meditation have become household words for many in the United States (US) and across the globe in the past 20 years. Derived from Buddhist and Hindu contemplative traditions[1], secularized meditative practices are being taught in schools, recommended by healthcare providers, and employed by businesses[2–4]. Utilization of meditation tripled in the US between 2012 and 2017 (4.1% to 14.2%)[5]. Meta-analyses involving hundreds of randomized controlled trials (RCTs) suggest meditation training can decrease psychological symptoms (e.g., depression, anxiety, stress) and increase aspects of well-being and positive functioning (e.g., meaning in life, compassion, prosocial behavior)[6–15].

To date, the vast majority of research on meditation has focused on interventions delivered in person. Standardized mindfulness-based interventions like mindfulness-based stress reduction (MBSR)[16] and mindfulness-based cognitive therapy (MBCT)[17] were explicitly designed as group-based interventions delivered by trained instructors and these interpersonal elements are viewed as central ingredients (e.g., group format)[18]. Despite the fact that some meditation-based interventions (MBIs) are recommended as first line treatments (e.g., MBCT for depression relapse prevention)[19–21], their availability remains limited[22]. Barriers for dissemination of MBIs are similar to those facing other evidence-based psychotherapies (e.g., lack of available providers, cost, logistical challenges)[23–25].

Delivering interventions through mobile technology has been proposed as one solution for increasing access to psychological interventions, including MBIs[26,27]. Web- and smartphone-based interventions have obvious advantages over traditional in-person delivery in terms of cost and scalability. Further, mobile health (mHealth) interventions can, in theory, do

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things that in-person interventions typically never do, such as provide access 24 hours a day or customize content based on passively-sensed data (e.g., location)[28]. Among mHealth delivery platforms, smartphone-based interventions may be particularly promising, with these devices often kept within arm's reach, charged, turned on, and are owned by the vast majority of the population[29].

There has been a dramatic increase in the past five years in RCTs testing smartphone-based interventions that include training in meditation[30]. These studies have begun examining efficacy in various clinical and non-clinical populations[31–38]. Although preliminary, available evidence suggests smartphone-based interventions that include training in meditation and mindfulness may provide psychological benefits that are similar to in-person MBIs (e.g., decreased psychological symptoms, increased positive functioning), albeit smaller in magnitude[30,39–42].

Like the in-person MBI literature, RCTs testing the mobile delivery of MBIs have focused almost entirely on mindfulness. The term “mindfulness” is derived from the Pali word *sati*, which in Buddhism refers to the cultivation of receptive, present-moment awareness[43]. In the scientific literature, mindfulness can refer to a mental state, trait, or faculty amenable to training[44–47]. Mindfulness-based interventions commonly adopt Kabat Zinn's[48] definition of “paying attention in a particular way: on purpose, in the present moment, and nonjudgmentally.” Meta-analyses suggest that dispositional mindfulness along with both short-term (e.g., mindfulness inductions) and long-term training (e.g., mindfulness-based interventions like MBSR) are associated with decreased psychiatric symptoms, negative affect, substance use, and neuroticism[9,49–53].

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Importantly, mindfulness training represents the implementation of primarily one meditative approach drawn from rich contemplative traditions[54]. Although largely untested, it is possible that a variety of meditative techniques may serve as valuable complements or alternatives to mindfulness. Different meditation practices have shown distinct neural signatures[55,56] and can produce different psychological effects[57]. Dahl, Lutz, and Davidson[54] provide a useful typology for situating mindfulness training within the broader contemplative practice landscape. Using a family resemblance approach, they describe *attentional*, *constructive*, and *deconstructive* families. Mindfulness meditation, as implemented in MBSR, falls primarily within the *attentional family*, with training focused on regulating attention. The *constructive family* includes practices designed to strengthen psychological habits conducive to psychosocial health. This includes connection-based practices which involve cultivating feelings of warmth and friendliness towards oneself and others (e.g., gratitude, loving-kindness, and compassion practices)[58,59]. Experimental evidence suggests connection practices increase well-being and decrease psychological symptoms[8,60]. The *deconstructive family* includes practices designed to modify unhelpful cognitive patterns, particularly in regard to one's view of self and others. Practices in this family involve intentional self-inquiry into the dynamics of conscious experience and the nature of the self with the goal of generating understanding of cognitive patterns (i.e., insight). Deconstructive elements are present in MBCT and cognitive therapy more generally (e.g., seeing thoughts as thoughts)[17,61]. However, research on deconstructive meditative practices specifically has been limited.

Smartphone-based meditation interventions have almost exclusively focused on mindfulness training[30,62], although several studies have investigated Internet-based

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interventions that include connection-related practices, e.g.[63–65]. While some interventions include connection-based practice as one of several guided practices within a general mindfulness framework[32], RCTs primarily examining constructive or deconstructive practices are rare (with some promising exceptions)[66,67].

The current study sought to investigate the effects of a self-guided, smartphone-based meditation intervention that included explicit training in constructive and deconstructive families of practices[54]. In a three-arm RCT, we compared training in mindful awareness, paired with connection or insight practices, to a waitlist control. As both arms included the Awareness module first, we refer to them by their unique module (i.e., Connection or Insight, rather than Awareness + Connection and Awareness + Insight). We included outcome measures designed to detect global effects (psychological distress) and practice-specific effects (e.g., social connection, shift in relationship to one's thoughts). Our primary hypothesis was that participants in both active conditions would show reduced psychological distress relative to the waitlist. In addition, we expected those randomized to connection practices to show larger improvements in connection-related measures and those randomized to insight practice to show larger improvements in insight-related measures. We had several exploratory secondary hypotheses. We hypothesized that app usage would be positively associated with reduced distress. We hypothesized that improvements in connection- and insight-related measures would mediate effects on distress for those in the Connection and Insight arms, respectively. We hypothesized that those lower in mindfulness at baseline would show larger improvements in the active conditions and that those lower in connection- and insight-related measures would show larger

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improvements in the Connection and Insight arms, respectively. These hypotheses were pre-registered at Open Science Framework (OSF)[68]).

### **Methods**

#### **Procedure**

We conducted an eight-week, fully remote RCT comparing two active smartphone-based meditation interventions with a waitlist control. Participants were recruited through emails sent to faculty, staff, and students at the University of Wisconsin-Madison and through a database of individuals who had previously expressed interest in research at the Center for Healthy Minds. All screening procedures and data collection were carried out online using REDCap[69]. Participants completed a screening protocol to determine eligibility and received their group assignment via an automated email following completion of baseline questionnaires. Randomization was achieved by automatically allocating participants to groups based on sequentially assigned participant identification numbers (i.e., 1:1:1 randomization ratio). Participants were contacted by email to complete questionnaires four- and eight-weeks post-baseline.

Progress through the material in the HMP app was self-guided. There was minimal contact with study staff. Participants were provided with a study email address to contact for technical support or study-related questions. All procedures were approved by the Institutional Review Board. The study was registered at ClinicalTrials.gov (NCT04139005).

#### **Participants**

Eligible participants were  $\geq 18$  years old, had access to a smartphone or other device capable of running the intervention app (Android or iOS), and did not have extensive previous

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meditation experience defined as: meditation retreat experience; meditation practice weekly for >1 year or daily practice within the previous 6 months; or previous training under the instruction of a meditation teacher, other than an introductory course. Participants received \$25 for completing assessments.

### **Intervention**

Participants assigned to one of the two active intervention arms were instructed to download the Healthy Minds Program (HMP) app through the Google Play or Apple App Store. The full HMP app includes four modules with practices designed to cultivate categories of mental and emotional skills linked to both hedonic and eudaimonic well-being[70,71]. These include the cultivation of mindful attention (Awareness), positive relationships with self and others (Connection), insight into the nature of self and internal experience (Insight), and purpose, values, and meaning in life (Purpose). In the current study, the two active interventions included four weeks of Awareness training, followed by four weeks of either Connection or Insight training. This design was predicated on the view that training in the stabilization of attention is foundational to skills trained by Connection and Insight[72]. Each module included brief, podcast-style didactic material along with guided meditation practices. Didactic content included discussion of the scientific bases of the practices. Participants were encouraged to follow a pre-specified sequence of material. Participants could select the length of the guided practices (5- to 30-minutes) and a variety of practices were available in each module. For example, the Awareness module included practices focused on awareness of breathing and mindfulness of sound. The Connection module included gratitude and kindness practices. The Insight module included practices involving noticing the changing nature of phenomenon (i.e., impermanence)

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and examining how thoughts and emotions influence perception. Participants in the waitlist condition received access to the full HMP app (i.e., all four modules) at the conclusion of the study.

### **Measures**

A demographic questionnaire was completed at baseline. App usage was measured objectively through the HMP app. Additional information about the psychometric properties and theoretical relevance of the included measures is in Multimedia Appendix 1 Table 1.

**Psychological distress.** A psychological distress composite score was created from measures of depression, anxiety, and stress. We computed a mean across scaled (z-transformed) scores on each measure. The eight-item Patient-Reported Outcome Measures Information System (PROMIS) Depression and Anxiety scales[73] assessed depression and anxiety. Items are rated on a five-point scale (1=never, 5=always), with higher scores indicating greater severity in the past seven days. T-scores $\geq$ 55 suggest mild or greater severity[74,75]. Internal consistency was high ( $\alpha$ =.93 to .94).

The 14-item Perceived Stress Scale (PSS)[76] assessed psychological stress. Items are rated on a five-point scale (0=never, 4=very often), with higher scores indicating greater stress in the past month. Internal consistency was high ( $\alpha$ =.89).

**Measures related to the Connection module.** The 20-item Social Connectedness Scale-Revised (SCS-R)[77] assessed interpersonal connection. Items are rated on a six-point scale (1=strongly disagree, 6=strongly agree), with higher scores indicating higher social connectedness. Internal consistency was high ( $\alpha$ =.95).

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The 28-item Interpersonal Reactivity Index (IRI)[78] assessed empathy. Items are rated based on how well they describe the respondent on a five-point scale (0=not well, 4=very well), with higher scores indicating greater empathy. Internal consistency was high for the total score ( $\alpha=.83$ ).

The 21-item Compassionate Love Scale (CLS)[79] assesses feelings of compassion. Items are rated on a seven-point scale (1=not at all true of me, 7=very true of me). Higher scores indicate greater compassion. Internal consistency was high ( $\alpha=.95$ ).

**Measures related to the Insight module.** The 20-item Self-Reflection and Insight Scale (SRIS)[80] assessed participants' tendency towards self-reflection (e.g., "I frequently examine my feelings") and self-understanding or insight (e.g., "I usually know why I feel the way I do"). Items are rated on a six-point scale (1=strongly disagree, 6=strongly agree) and yield subscales for self-reflection and insight, with higher scores indicating greater self-reflection or insight. Internal consistency was high ( $\alpha$ s=.88 to .92).

The 15-item Perseverative Thinking Questionnaire (PTQ)[81] assessed rumination. For simplicity, we use the term "rumination" to refer to repetitive negative thinking as captured by Perseverative Thinking Questionnaire, although it captures both rumination and worry. Items are rated on a five-point scale (0=never, 4=almost always), with higher scores indicating greater rumination. Internal consistency was high ( $\alpha=.96$ ).

The 10-item Drexel Defusion Scale (DDS)[82] assessed ability to achieve psychological distance from internal experiences (i.e., defusion). Items are rated on a six-point scale (0=not at all, 5=very much), with higher scores indicating greater defusion. Internal consistency was high ( $\alpha=.89$ ).

**Mindfulness.** The 39-item Five Facet Mindfulness Questionnaire (FFMQ)[83] assessed mindfulness. Items are rated on a five-point scale (1=never or very rarely true, 5=very often or always true), with higher scores indicating greater mindfulness. Internal consistency was high for the total score ( $\alpha=.94$ ).

### Data Analysis

Results from all pre-registered primary and secondary measures are reported. For deviations made from the pre-registered data analytic plan, see Multimedia Appendix 1 Table 2.

Data were analyzed using intention-to-treat principles (ITT) (i.e., participants were not excluded based on engagement)[84]. Primary analyses used multilevel models (MLMs)[85] with restricted information maximum likelihood (REML) estimation in the ‘lme4’ package[86] in R[87]. Maximum likelihood is robust to data that are missing at random (MAR)[88]. For each outcome, a MLM was specified in which linear change (coded as 0, 1, 2, for pre-, mid-, and post-test, respectively) in outcome was assumed over time, with participant-level random intercepts; intervention effects were evaluated by the interaction between linear growth and group status, with contrasts comparing the two active conditions (i.e., Connection, Insight), as well as the combined active conditions relative to waitlist (see Multimedia Appendix 1 Table 3 for the model). A subsequent sensitivity analysis restricted the sample to participants above the clinical cut-off for depression and/or anxiety at baseline ( $T \geq 55$ )[75]. Sensitivity analyses were also conducted with outliers (i.e., three *SDs* from the mean) and each participant sequentially removed[89].

Additional analyses assessed the potential impact of attrition, which is common in fully remote RCTs[90]. In this study, it is plausible that missingness was related to the unobserved

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value itself (i.e., missing not at random [MNAR]). For example, individuals who failed to benefit from the HMP app may have been less likely to complete the study and would have shown worse outcomes, had they been observed. Therefore, we relaxed our MAR assumptions to evaluate the degree to which intervention effects would be maintained under MNAR assumptions. We examined intervention effects in the presence of different assumed outcomes for dropout-missing observations, focusing on residualized change scores (from baseline to post-test) to simplify the study of missingness implications. We coded outcomes for dropout missingness at different levels, ranging from no difference in outcomes (relative to those that remained in the study) to all dropout missing values being the worst possible outcome of those in the study. As operationally it becomes easier to study this range of conditions using outcome ranks as opposed to retaining the metrics of the studied measures, we applied a nonparametric Wilcoxon rank sum test to compare the active conditions against the waitlist control under different missingness assumptions.

To test our exploratory mediation hypotheses, we used the ‘mediation’ package in R[91]. In these models, active group status (Connection or Insight) served as the independent variable; pre-post changes in mindfulness or connection- or insight-related measures as the mediators; and post-test distress (controlling for pre-test) as the dependent variable. Pre-post changes were examined as mediators as the unique Connection and Insight content was provided after the mid-treatment assessments. We used MLMs to examine the effect of app usage, testing the time X usage interaction with usage operationalized as the median split of days of use. As noted in Multimedia Appendix Table 2, a median split was used due to deviations from normality in usage metrics. To assess baseline characteristics as moderators of change in distress, we tested three-

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way interactions between time, group, and baseline characteristic within MLMs. False discovery rate (FDR) adjustment[92] was applied to all analyses to control for inflation of Type I error.

### **Sample Size and Power**

We planned on recruiting 300 participants (100/group) which would allow detection of small to moderate differences between any two groups ( $d=0.40$ ) and between the active and waitlist control conditions ( $d=0.34$ ) at 80% power and  $P=.050$ . Power was estimated using the ‘pwr.t.test’ and ‘pwr.t2n.test’ functions in the ‘pwr’ package in R [93].

## **Results**

### **Recruitment and Participant Characteristics**

954 potential participants were assessed for eligibility, of which 343 met inclusion criteria and were randomized to Connection ( $n=121$ ), Insight ( $n=107$ ), or waitlist ( $n=115$ ; Figure 1). Demographics are reported in Table 1. The sample was predominantly White ( $n=280$ , 81.6%), female ( $n=290$ , 84.5%), and with graduate-level education ( $n=190$ , 55.4%). Income was more variable ( $n=89$ , 26.0% earned \$50,000 or less). The mean age was 41.74 years old ( $SD=12.52$ ).

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Table 1. Sample demographics

Variable	Overall ( <i>n</i> =343) % / mean ( <i>SD</i> )	Connection ( <i>n</i> =121) % / mean ( <i>SD</i> )	Insight ( <i>n</i> =107) % / mean ( <i>SD</i> )	Waitlist ( <i>n</i> =115) % / mean ( <i>SD</i> )	<i>P</i>
<b>Race/ethnicity</b>					.911
White	81.63	81.82	80.37	82.61	
Black	1.75	2.48	0.93	1.74	
Latinx	1.17	0.00	3.74	0.00	
Asian	5.25	5.79	5.61	4.35	
Multiracial	9.62	9.92	8.41	10.43	
Not reported	0.58	0.00	0.93	0.87	
<b>Gender</b>					.929
Female	84.46	83.47	84.76	85.22	
Male	14.96	16.53	14.29	13.91	
Nonbinary	0.59	0.00	0.95	0.87	
<b>Income</b>					.176
\$50k or less	26.02	27.27	24.53	26.09	
\$50-100k	35.09	28.93	34.91	41.74	
\$100-150k	22.22	26.45	20.75	19.13	
\$150k+	16.67	17.36	19.81	13.04	
<b>Education</b>					.450
Some HS	0.29	0.00	0.93	0.00	
HS grad	1.75	2.48	0.00	2.61	
Some college	9.33	7.44	10.28	10.43	
College grad	33.24	30.58	33.64	35.65	
Graduate school	55.39	59.50	55.14	51.3	
<b>Age</b>	41.74 (12.52)	42.31 (12.8)	43.21 (12.39)	39.78 (12.2)	.104

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<b>Elevated symptoms</b>	73.47	71.07	75.70	73.91	.728
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Note: *SD*=standard deviation; HS=high school; grad=graduate; Elevated symptoms=PROMIS Depression and/or PROMIS Anxiety in the mild or higher range ( $T \geq 55$ ); *P*=*P*-values based on one-way analysis of variance (ANOVA) with group (Connection, Insight, or Waitlist) predicting demographics (White, female, high income [ $\geq \$100k$ ], graduate school).

### Utilization

Of those randomized to one of the two active conditions, 77.7% ( $n=94$ ) of Connection participants and 67.3% ( $n=72$ ) of Insight participants downloaded and utilized the HMP app at least once. Assigning values of zero to those who did not use the app, average utilization was 10.52 days ( $SD=13.31$ , median=4), 18.09 activities within the app ( $SD=23.30$ , median=7), 9.45 meditation practices ( $SD=13.34$ , median=3), and 102.16 total minutes of meditation practice ( $SD=187.74$ , median=26). All usage metrics were highly zero-inflated (Multimedia Appendix 1 Figure 1). Days of use had the lowest skewness (1.34) and kurtosis (0.91), so a median split of days of use was used in analyses. The median survival time (i.e., time before last use) was 12 days. Group status (Connection vs. Insight) was not associated with usage ( $P>.050$ ) and survival time did not differ between groups (Multimedia Appendix 1 Figure 2,  $P=.242$ ). As Connection or Insight content was provided in the second half of the eight weeks, 32.2% ( $n=39$ ) of Connection and 23.4% ( $n=25$ ) of Insight participants engaged with the unique content. This proportion did not differ between groups ( $OR=0.64$ ,  $P=.138$ ).

### Attrition Analysis

We examined baseline demographic and outcome variables as predictors of attrition from the study. We constructed logistic regression models predicting the presence of any follow-up data (i.e., mid-treatment and/or post-test). Participants were invited to complete post-test measures even if they had not completed mid-treatment measures. Average completion of at least one follow-up assessment (mid- or post-treatment) was 54.2% ( $n=186$ ). Waitlist participants were more likely to complete follow-up assessments (67.0% vs. 47.8%, waitlist  $n=77$ , Connect

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and Insight combined  $n=109$ ,  $OR=2.21$ ,  $P<.001$ ). Completion of follow-up assessments did not differ between Connection and Insight groups ( $OR=0.99$ ,  $P=.967$ ). However, participants who used the app at least once were more likely to complete follow-up assessments ( $OR=3.66$ ,  $P<.001$ ). Completion of follow-up was not associated with demographics (proportion White, female, high income [ $\geq \$100k$ ], graduate education) or outcome measures at baseline ( $P_s>.050$ ), with one exception. Participants with higher empathy scores (IRI) at baseline were more likely to complete follow-up assessments ( $OR=1.02$ ,  $P=.037$ ).

### Primary Analyses

Correlations between outcomes are reported in Multimedia Appendix 1 Table 4. The three groups did not differ on any demographic or outcome measures at baseline ( $P_s>.050$ ; Tables 1 and 2). Within- and between-group effect sizes (Cohen's  $d$ ) and  $P$ -values from MLMs are reported in Table 3. The two active conditions did not differ from one another in change over time for distress or any secondary outcomes (time X group  $P_s>.050$ ). Therefore, all subsequent analyses combined the two active groups. When compared with the waitlist control, the active conditions showed greater decreases in distress ( $d=-0.28$ ) and rumination ( $d=-0.18$ ) and greater increases in social connectedness, self-reflection, insight, defusion, and mindfulness ( $d_s=0.13$  to  $0.41$ ; FDR-adjusted  $P_s<.050$ ; Figure 2). The active conditions did not differ from the waitlist on changes in empathy ( $d=0.02$ ) or compassion ( $d=0.12$ ). Significance tests for time X group interactions did not change when restricting to those with elevated symptoms at baseline (Table 2), when excluding outliers (with the exception of Self-Reflection which became  $P=.051$ , Multimedia Appendix 1 Table 5), nor when each case was excluded sequentially.

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Table 2. Descriptive statistics for repeated measures by group and timepoint

Group	Outcome	Pre-test		Mid-treatment		Post-test		P
		n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	
CO	Psychological Distress	12 1	-0.08 (0.90)	49	-0.74 (0.80)	47	-0.78 (0.78)	.491
CO	Social Connection	12 1	83.41 (21.43)	48	90.62 (17.29)	46	92.32 (18.30)	.732
CO	Empathy	12 1	67.67 (12.33)	48	67.42 (12.55)	47	66.01 (12.90)	.410
CO	Compassion	12 1	99.18 (22.19)	48	102.52 (21.71)	46	101.68 (21.64)	.573
CO	Self-Reflection subscale	12 1	56.31 (11.13)	48	58.45 (10.29)	46	57.49 (11.10)	.965
CO	Insight subscale	12 1	34.12 (7.46)	48	37.06 (6.17)	46	37.54 (6.20)	.459
CO	Rumination	12 1	31.12 (12.65)	46	25.31 (9.63)	46	25.36 (10.71)	.900
CO	Defusion	12 1	22.95 (9.37)	48	28.54 (8.37)	47	30.75 (7.81)	.858
CO	Mindfulness	12 1	122.16 (20.41)	49	136.28 (16.37)	47	139.63 (19.33)	.766
IN	Psychological Distress	10 7	0.04 (0.94)	43	-0.52 (0.88)	44	-0.62 (0.88)	
IN	Social Connection	10 7	83.28 (19.04)	41	87.57 (19.28)	44	90.20 (20.64)	
IN	Empathy	10 7	69.77 (12.45)	41	70.24 (11.76)	44	69.49 (11.05)	
IN	Compassion	10 7	101.57 (21.44)	41	101.07 (24.52)	44	108.88 (23.29)	
IN	Self-Reflection subscale	10 7	55.99 (10.40)	41	55.90 (9.00)	44	57.92 (9.45)	

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IN	Insight subscale	10 7	32.84 (8.42)	41	33.67 (8.28)	44	36.14 (8.44)
IN	Rumination	10 7	30.49 (11.71)	41	27.21 (10.79)	44	23.97 (10.68)
IN	Defusion	10 7	23.62 (10.36)	41	27.36 (10.01)	44	30.49 (10.23)
IN	Mindfulness	10 7	121.55 (24.96)	43	128.56 (22.96)	44	139.11 (19.75)
WL	Psychological Distress	115	0.05 (0.88)	64	-0.23 (1.01)	67	-0.36 (0.91)
WL	Social Connection	115	81.53 (19.68)	60	82.78 (21.10)	63	84.63 (20.24)
WL	Empathy	115	69.31 (12.85)	60	71.09 (13.49)	63	67.96 (13.26)
WL	Compassion	115	98.62 (22.39)	58	99.53 (22.64)	63	100.85 (22.42)
WL	Self-Reflection subscale	115	56.34 (10.78)	57	56.87 (11.14)	63	56.23 (11.26)
WL	Insight subscale	115	33.22 (8.02)	57	35.40 (8.29)	63	35.55 (7.83)
WL	Rumination	115	31.14 (11.56)	56	29.51 (13.04)	62	27.41 (11.92)
WL	Defusion	115	23.49 (9.58)	60	24.88 (9.95)	64	26.71 (9.86)
WL	Mindfulness	115	120.16 (18.93)	62	125.15 (20.21)	65	128.88 (20.23)

Note: *SD*=standard deviation; CO=Awareness + Connection; IN=Awareness + Insight; WL=waitlist; Psychological Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire; *P*=*P*-value from one-way analysis of variance (ANOVA) predicting baseline values for outcome measures by group status.

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Table 3. Results of multilevel models assessing differential change over time

Outcome	CO versus IN				Active versus WL							
	$d_{CO}$	$d_{IN}$	$d_{diff}$	$P$	$P_{FD}$ R	$d_{Activ}$ e	$d_{WL}$	$d_{diff}$	$P$	$P_{FDR}$	Elev $P$	Elev $P_{FDR}$
Psychological Distress	-0.77	-0.70	-0.07	.858	.965	-0.74	-0.46	-0.28	<.001	<.001	<.001	<.001
Social Connection	0.42	0.36	0.06	.540	.822	0.39	0.16	0.23	.003	.007	.012	.018
Empathy	-0.14	-0.02	-0.12	.374	.822	-0.08	-0.10	0.02	.631	.631	.476	.476
Compassion	0.11	0.34	-0.23	.290	.822	0.22	0.10	0.12	.138	.155	.178	.200
Self-Reflection subscale	0.11	0.18	-0.07	.510	.822	0.14	-0.01	0.15	.007	.013	.024	.031
Insight subscale	0.46	0.39	0.07	.984	.984	0.42	0.29	0.13	.015	.019	.001	.002
Rumination	-0.45	-0.56	0.11	.321	.822	-0.52	-0.32	-0.18	.010	.015	.007	.013
Defusion	0.83	0.66	0.17	.780	.965	0.75	0.34	0.41	<.001	<.001	<.001	<.001
Mindfulness	0.86	0.70	0.16	.548	.822	0.77	0.46	0.31	<.001	<.001	<.001	<.001

Note: CO=Awareness + Connection; IN=Awareness + Insight; Active=combined Awareness + Connection and Awareness + Insight; WL=waitlist; Psychological Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire;  $d$ =Cohen's  $d$  calculated as pre-post for within-group effects and the difference between within-group effects (Connection minus Insight, active minus waitlist) for  $d_{diff}$ ; for within-group, subscripted CO (i.e.,  $d_{CO}$ ), IN, Active, and WL refer to subgroups noted;  $P$ = $P$ -value from time X group interaction from multilevel models; FDR=False-Discovery Rate-adjusted  $P$ -values; Elev=active versus waitlist time X group interaction restricted to sample with elevated depression and/or anxiety at baseline ( $T \geq 55$ ).

A larger proportion of participants in the active conditions showed a minimally important decrease in distress ( $d \leq -0.30$ )[94] relative to the waitlist condition (70.3% vs. 49.3%, Connection

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and Insight combined  $n=64$ , waitlist  $n=33$ ,  $OR=2.44$ ,  $P=.008$ ). A smaller proportion in the active conditions showed a minimally important increase in distress (i.e., deterioration,  $d \geq 0.30$ ) relative to the waitlist condition (3.3% vs. 16.4%, Connection and Insight combined  $n=3$ , waitlist  $n=11$ ,  $OR=0.17$ ,  $P=.009$ ).

### **Robustness Check: Sensitivity Analyses**

While maximum likelihood is robust to data missing at random (MAR)[88], subsequent analyses evaluated treatment effects based on varying assumptions under missing not at random (MNAR) conditions. Using the completer sample, a Wilcoxon rank sum test on the residualized gain score mirrored the MLM results, with larger improvements in the active conditions relative to the waitlist on several outcomes (FDR-adjusted  $P_s < .050$ ; Multimedia Appendix 1 Table 6). In the worst-case scenario model in which missing reflects the worst possible outcome across both active and waitlist groups, the groups did not differ although the direction of the mean rank favored the waitlist group for all outcomes. Thus, we examined results in between these extreme conditions to understand where significance goes away and where the direction of intervention effect reverses. When we assumed that missing values are on average 0.25 *SD* above the mean (implying worse than average outcomes for the missing observations), the results continued to favor the active conditions for changes in distress, social connectedness, defusion, and mindfulness (FDR-adjusted  $P_s < .050$ ; Multimedia Appendix 1 Table 7). When we assumed that missing values are on average 0.50 *SD* above the mean, the differences between groups were not statistically significant for any outcome. The difference remained non-significant when we assumed that missing values are on average 0.75 *SD* above the mean. Thus, it appears our results are robust to MNAR up to a point, specifically that missing outcomes are no more than 0.25 *SD*

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above the mean on average, under the assumption that missingness implies comparable outcomes for both the active and waitlist groups.

### **Secondary Analyses**

Results of usage analyses are reported in Table 4. HMP use above the median number of days was associated with larger improvements in distress, insight, defusion, and mindfulness (FDR-adjusted  $P$ s<.050; Figure 3).

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Table 4. Results of multilevel models predicting changes in outcomes from HMP app usage

Outcome	Time X usage <i>B</i>	<i>t</i>	<i>P</i>	<i>P</i> <sub>FDR</sub>
Psychological Distress	-0.17	-2.46	.015	.034
Social Connection	2.42	1.61	.110	.165
Empathy	-0.47	-0.58	.561	.561
Compassion	-1.16	-0.76	.446	.502
Self-Reflection subscale	0.80	0.87	.383	.492
Insight subscale	1.55	2.46	.015	.034
Rumination	-1.85	-2.13	.034	.061
Defusion	2.40	2.64	.009	.034
Mindfulness	5.17	2.93	.004	.034

Note: *B*=multilevel model regression coefficient; *t*=*t*-statistic for time X usage interaction; *P*=*P*-value for time X usage interaction; FDR=False-Discovery Rate-adjusted *P*-values; Psychological Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire. Usage=days of use split into high (median or above) and low (below median) groups. *n*=228.

Results of the mediation analyses are reported in Table 5. Changes in five candidate mechanisms showed a significant average causal mediation effect (FDR-adjusted *P*s<.050) in the expected direction (i.e., improvements in social connection, insight, rumination, defusion, and mindfulness mediated improvements in distress). Changes in mindfulness were associated with the largest proportion mediated (.45).

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Table 5. Results of mediation analyses predicting changes in psychological distress

Outcome	ACME	ADE	Prop Mediated	<i>P</i>	<i>P</i> <sub>FDR</sub>
Social Connection	-0.10	-0.32	0.24	.002	.005
Empathy	0.02	-0.44	-0.03	.402	.471
Compassion	0.01	-0.43	-0.01	.588	.588
Self-Reflection subscale	0.02	-0.44	-0.04	.412	.471
Insight subscale	-0.06	-0.37	0.13	.026	.042
Rumination	-0.10	-0.32	0.23	.018	.036
Defusion	-0.10	-0.32	0.23	.002	.005
Mindfulness	-0.18	-0.22	0.45	<.001	<.001

Note: ACME=average causal mediation effect (i.e., indirect effect); ADE=average direct effect (i.e., from active to post-treatment distress controlling for pre-treatment distress, when active=1 and waitlist=0); Prop Mediated=proportion mediated computed as indirect effect (i.e., ACME) divided by total effect [91]; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire; *P*=*P*-value based on quasi-Bayesian confidence intervals; FDR=False-Discovery Rate-adjusted *P*-values. Models examining pre-post change in constructs related to Awareness, Connection, and Insight modules as mediators of pre-post change in (composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale). Proportion mediated can be negative in instances where direct effect and indirect effect have opposite signs.

Results of baseline moderation analyses are reported in Table 6. Three baseline variables showed significant time X group X baseline interactions after FDR-adjustment. Psychological vulnerability as indicated by two outcomes (higher rumination, lower defusion) at baseline was associated with larger improvements in distress in the HMP conditions relative to the waitlist condition. Baseline empathy showed the opposite pattern, with those higher at baseline showing larger improvements in distress in HMP relative to waitlist (Multimedia Appendix Figure 3).



Table 6. Baseline outcomes as moderators of longitudinal changes in psychological distress

Outcome	Time X group <i>B</i>	Time X group X baseline <i>B</i>	<i>t</i>	<i>P</i>	<i>P</i> <sub>FDR</sub>
Social Connection	-0.64	0.01	2.16	.032	.064
Empathy	0.67	-0.01	-3.23	.001	.008
Compassion	0.07	0.00	-1.20	.231	.290
Self-Reflection subscale	-0.59	0.01	1.55	.121	.194
Insight subscale	-0.44	0.01	1.14	.254	.290
Rumination	0.21	-0.01	-3.15	.002	.008
Defusion	-0.54	0.01	2.86	.004	.011
Mindfulness	-0.44	0.00	0.82	.413	.413

Note: *B*=multilevel model regression coefficient; *t*=*t*-statistic for time X group X baseline (with group coded as active=1, waitlist=0); *P*=*P*-value for time X group X baseline; FDR=False-Discovery Rate-adjusted *P*-values; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire.

## Discussion

The current study sought to expand scientific understanding of the impact of smartphone-delivered meditation training beyond mindfulness. To do so, we evaluated effects of mindfulness training (Awareness) paired with practices designed to cultivate kindness towards oneself and others (Connection) or insight into the nature of self and internal experience (Insight). We assessed effects on psychological distress and constructs theoretically linked to the connection- and insight-based training[54].

Contrary to our expectations, there was no indication that training in connection produced differential effects relative to insight-related practices. There are several potential reasons for

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this. One likely explanation is that the actual content completed by each group was largely overlapping. Both groups began with foundational mindfulness training. Given modest engagement (a perennial concern in mHealth interventions)[95,96], most participants did not engage with the unique Connection or Insight modules. It is also possible that meditation training produces similar effects for novices, regardless of the specific type of training. Novices may spend much of their initial meditation practice simply regathering a wandering attention, no matter the actual practice instructions. Indeed, studies showing distinct neural signatures associated with various forms of meditation practice have primarily been conducted with long-term practitioners with thousands of hours of experience[55]. A third possibility is that various forms of meditation training contain common ingredients (e.g., acceptance, curiosity) that may, especially early in training, be more potent than style-specific ingredients.

Despite the absence of differential effects, results do suggest that meditation delivered via smartphone produced small reductions in psychological distress ( $d=-0.28$ ) and improvements in several candidate mechanisms relative to a waitlist control ( $ds=-0.18$  to  $0.41$ ). These results are generally consistent with meta-analyses of the broader mHealth and mHealth MBI literature which has shown small benefits of self-guided smartphone apps on depression and anxiety symptoms ( $gs=0.21$  to  $0.23$ ) and measures of mindfulness and acceptance ( $g=0.27$ )[30]. These effects are considerably smaller than those produced by in-person MBIs (e.g.,  $d=0.55$  vs. waitlist)[9]. It is likely that mHealth MBIs may be less potent than in-person interventions, indicating trade-offs between scalability, cost, and potency. Based on those completing post-treatment measures, HMP appears safe in that rates of clinically significant increases in distress

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were rare (3.3%) and were less common than rates in the control condition (16.4%). This finding is consistent with a recent large-scale evaluation of deterioration in MBSR [97].

One important caveat for interpreting our findings is high attrition, particularly within the active conditions. Both high attrition and differential attrition are common in mHealth research[90,98]. Our overall attrition rate was almost identical to that typically found in RCTs testing smartphone interventions without telephone or in-person enrollment (45.8% in the current study, 43.4% in meta-analysis)[90]. In addition to employing maximum likelihood estimation in all multilevel models (which is robust to MAR)[88], we conducted a series of sensitivity analyses to assess effects of various MNAR assumptions. Most effects were robust to non-completers having outcomes slightly worse than completers (0.25 *SD*). However, effects did not persist with larger deviations ( $\geq 0.50$  *SD*). It is impossible to directly test which of these scenarios is most likely (as is the case for other MNAR approaches; Enders, 2010). Future studies should include items specifically to predict missingness (e.g., “how likely are you to drop out of this study”)[99]. Responses can then be included as auxiliary variables to improve the performance of MAR methods (effectively converting MNAR to MAR)[99].

In light of the degree of attrition, secondary analyses should be interpreted as exploratory. Still, these models provide tentative possibilities to examine further. We found evidence that higher usage (median or above days of use) was associated with larger improvements in distress and several other outcomes. This mirrors dosage-outcome associations seen in the in-person MBI literature[100]. Mediation analyses suggest candidate mechanisms theoretically linked to each HMP module that may indirectly contribute to decreased distress (i.e., mindfulness, social connectedness, defusion, rumination). This also mirrors reviews of the in-person MBI literature

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that have found changes in mindfulness and rumination mediate effects[101]. The possibility that social connectedness also plays a role should be explored further, particularly as it has been associated with numerous psychological and physical health outcomes[102,103]. Moderation analyses indicated larger improvements among those showing higher rumination or empathy and lower defusion at baseline. These are somewhat conflicting findings, with the rumination and defusion associations suggesting that HMP may be most effective for those with deficits at baseline, while the association with empathy suggesting a higher baseline level may be necessary to benefit most. Given that mHealth interventions could in theory be easily adapted to participant characteristics (e.g., participant routed to receive a particular version based on baseline questionnaires), future experimental work can specifically examine who is likely to benefit from which kind of training (e.g., randomizing to adapted vs. non-adapted versions). The scalability of mHealth RCTs may allow recruitment of the sample sizes necessary for adequately powered tests of moderation[104].

### **Limitations and Future Directions**

As noted, high and differential attrition are limitations in the current study. Although attrition is commonplace in mHealth research[95], future studies should include study design features that decrease attrition (e.g., telephone enrollment)[90]. Relatedly, engagement with the HMP app was relatively modest. Like attrition, low engagement is the rule rather than exception for mHealth[105]. Presumably low engagement diminished any potential effects of the HMP app, making estimates of efficacy more ambiguous. Future studies could evaluate engagement strategies by randomizing participants to receive approaches found to improve adherence to medical regimens (e.g., modifying dosage recommendations, providing reminders)[106]. Micro-

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randomized trials could assess the impact of a variety of small manipulations on short-term engagement outcomes[107].

The lack of a follow-up assessment is another limitation, making it unclear whether any benefits were sustained. Further, the lack of active control condition makes it impossible to rule out effects due to a digital placebo[108]. Likewise, the included self-report measures are vulnerable to social desirability bias, although this may be less of an issue within a fully remote RCT[109]. Sampling procedures and sample demographics raise questions regarding generalizability, especially to racial/ethnic minority populations and to those with lower levels of education. Participants in the Center for Healthy Minds database may have been particularly amenable to the HMP app (although those with prior meditation experience would have been excluded).

An obvious future study would assign participants to receive only Connection or Insight content. This could clarify the unique effects of these types of practices. As we observed effects on distress that persisted when restricted to those with elevated symptoms at baseline, it would be worthwhile replicating the current study within a clinical sample. For this, it could be important or even necessary for safety reasons, to include some amount of professional guidance[41], perhaps telephone or text-based support[110]. Other extensions of the current study could include the use of non-self-report measures, both to rule out social desirability as well as to clarify underlying mechanistic processes. Numerous biological and behavioral mechanisms have been assessed for in-person MBIs (e.g., changes in attention, body awareness, stress physiology)[111–113] and may be operant within mHealth MBIs. A wide variety of extensions could also be made to the HMP app itself. For example, intervention components

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could be provided in response to passively-assessed mood states (e.g., using data streams routinely gathered through phone sensors). This would require not only the validation of passive measures[114,115], but also studies that clarify the optimal pairing of intervention components to mood. Again, micro-randomized trials may be an ideal design for this purpose. The amount of engagement necessary for clinical benefits (i.e., recommended dosage) should be clarified in future studies (e.g., by random assignment to dosage conditions). RCTs using active control conditions can help clarify the role that non-specific factors may play in mHealth MBIs. Based on the robust association between working alliance and outcome within in-person interventions[116], future studies should assess its digital corollary[117]. Finally, a critical future direction is investigating the efficacy of mHealth MBIs specifically among (and ideally tailored for)[118,119] racial/ethnic minorities. Racial/ethnic minority populations are at increased risk for racism-related negative psychological and physical health consequences[120] and have been historically underrepresented in research on mindfulness[121,122].

### **Conclusions**

Research into the mobile delivery of meditation training has expanded rapidly in the past five years. However, the vast majority of this work has focused exclusively on training mindfulness. We found preliminary evidence that two versions of a novel smartphone app that includes training in mindfulness, in addition to skills specifically targeted to improve social connection and intrapersonal insight, is associated with reduced psychological distress, increased social connectedness, and improvements in candidate mechanisms believed to underlie the beneficial effects of MBIs. Future studies, particularly those focused on decreasing study dropout and increasing intervention engagement, are warranted.

**Multimedia Appendix 1: Supplemental Tables and Figures**

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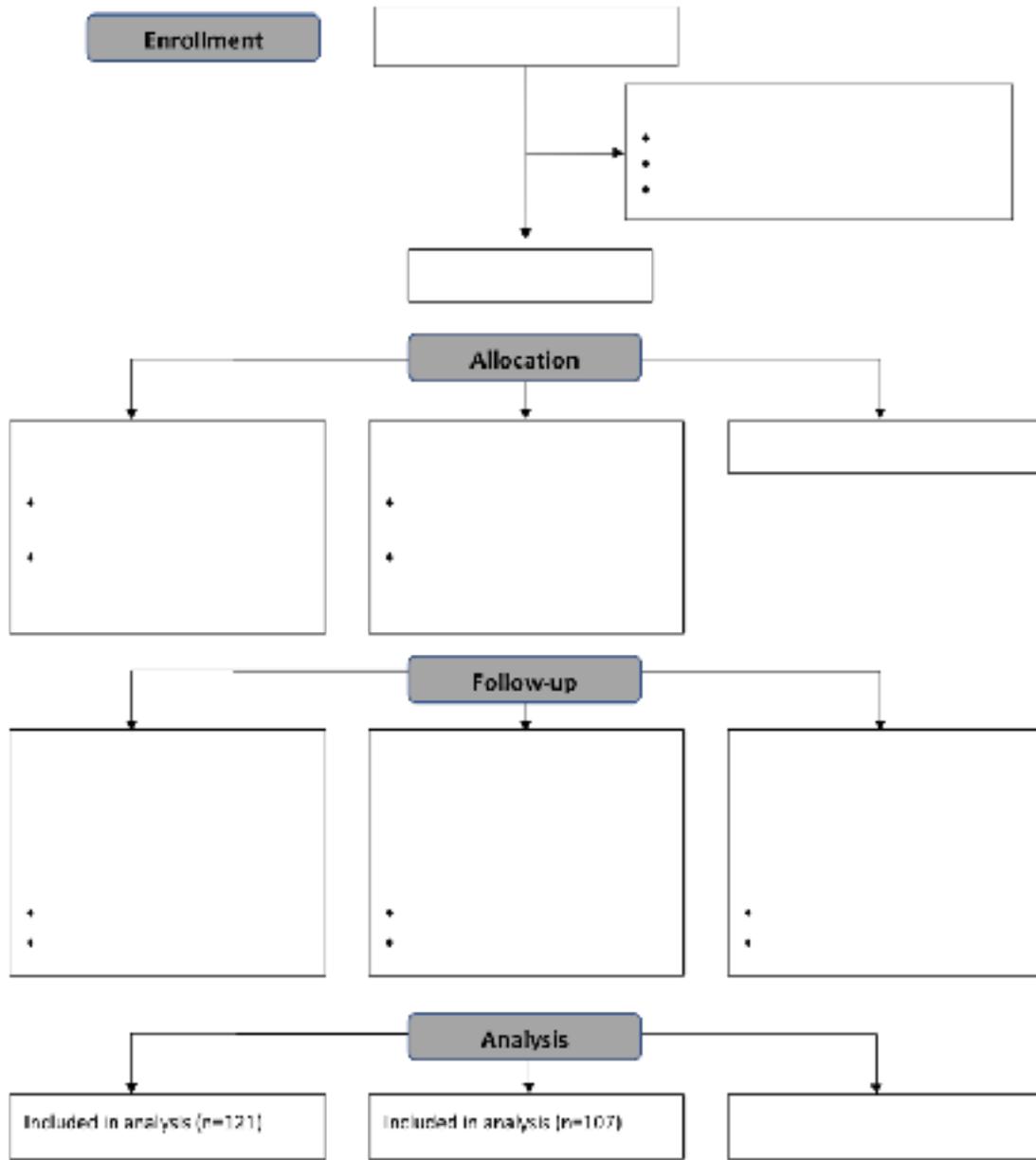


Figure 1. Consort diagram. Mid = week 4 assessment, Post = week 8 assessment.

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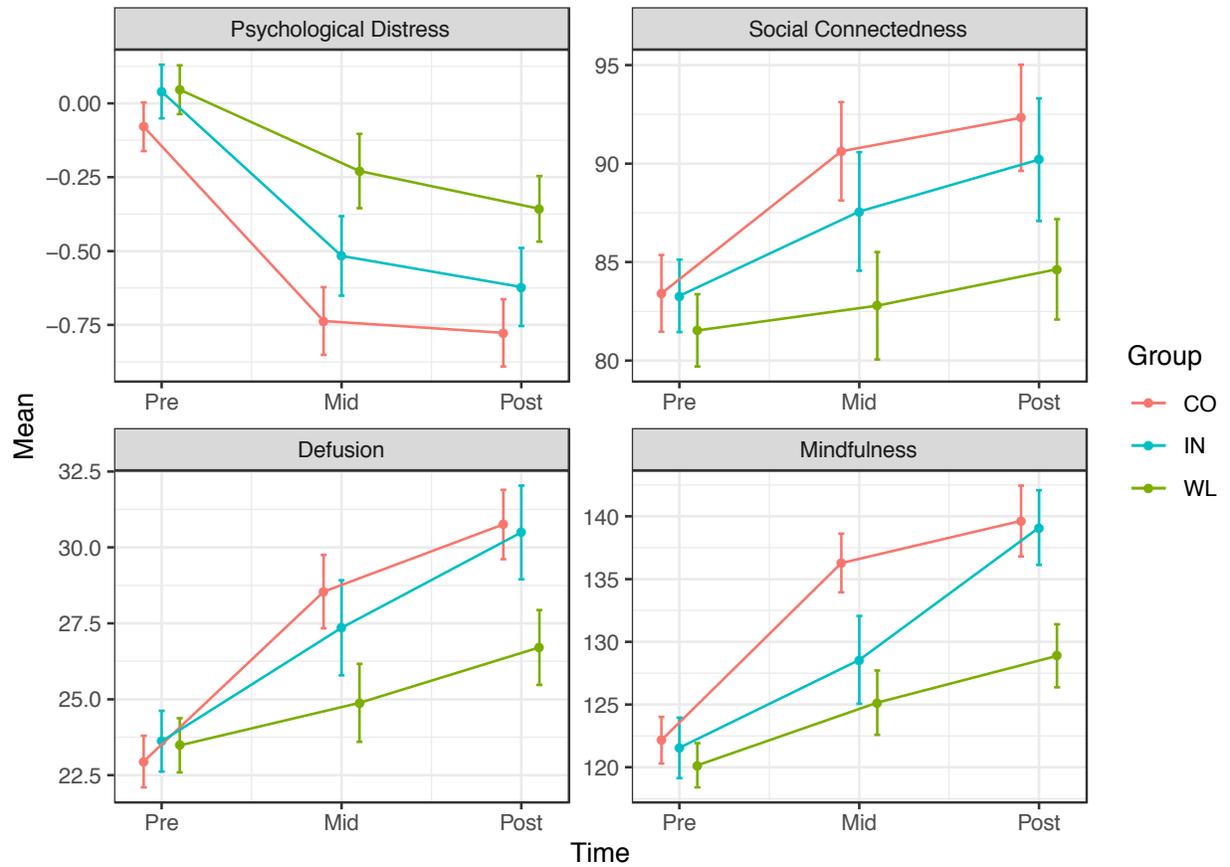


Figure 2. Longitudinal changes in psychological distress, social connectedness, defusion, and mindfulness by group. CO=Awareness + Connection; IN=Awareness + Insight; WL=waitlist. Figure displays observed means and standard errors (error bars=one standard error) based on all available data.  $n=343$ .

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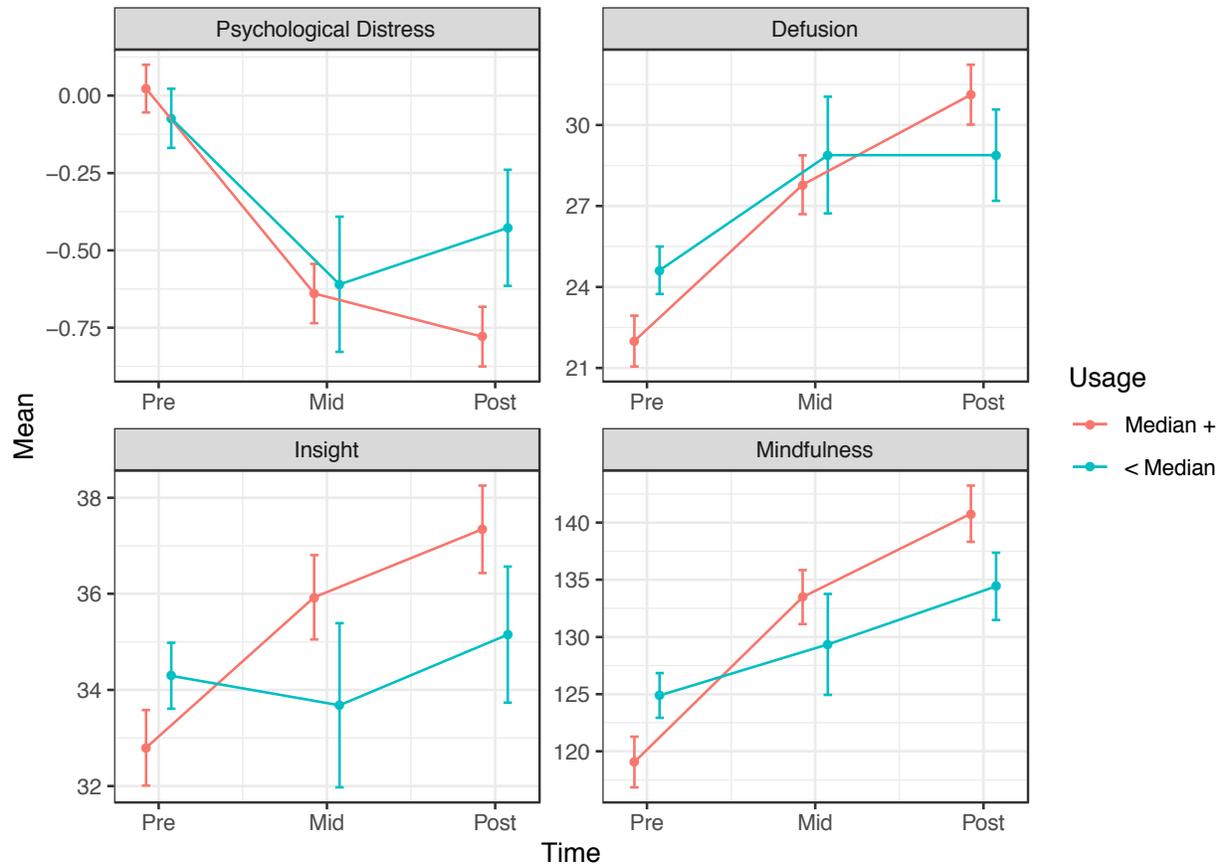


Figure 3. HMP app usage predicting longitudinal changes in psychological distress, defusion, insight, and mindfulness in active conditions ( $P_s < .050$ ). Usage=median split of days of use.  $n=228$ .

### **Multimedia Appendix 1**

Table 1. Additional psychometric information for the included self-report measures

#### **PROMIS Depression and PROMIS Anxiety[1]**

Both measures were developed using item response theory to maximize information provided while minimizing measure length. Sample items include “I felt worthless” (depression) and “I felt fearful” (anxiety). Both measures have shown strong convergent validity with legacy measures[2,3].

#### **Perceived Stress Scale (PSS)[4]**

A sample item is “how often have you been upset because of something that happened unexpectedly?” The measure is widely used and has shown desirable psychometric properties[5].

#### **Social Connectedness Scale-Revised (SCS-R)[6]**

A sample item is “I feel close to people.” The measure has been previously linked to well-being[7]. This measure has shown strong reliability and validity[8] and has previously shown responsiveness to connection-related practices[9].

#### **Interpersonal Reactivity Index (IRI)[10]**

The IRI has four subscales. Sample items from each subscale include “I try to look at everybody’s side of a disagreement before I make a decision” (perspective taking), “I am often quite touched by things I see happen” (empathic concern), “I really get involved with the feelings of characters in a novel” (fantasy), and “I tend to lose control during emergencies” (personal distress). Based on factor analyses suggesting a single overarching factor[11] and consistent with prior studies[12], we calculated a total score from all items.

#### **Compassionate Love Scale (CLS)[13]**

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A sample item is “I spend a lot of time concerned about the well-being of humankind.”

The CLS has shown discriminant validity relative to measures of empathy and predicts prosocial behavior when controlling for empathy[13].

### **Self-Reflection and Insight Scale (SRIS)[14]**

The SRIS has two subscales. Sample items from each subscale include “I frequently examine my feelings” (self-reflection) “I usually know why I feel the way I do” (insight). Scores on the insight subscale have been found to partially mediate cross-sectional associations between mindfulness and well-being[15].

### **Perseverative Thinking Questionnaire (PTQ)[16]**

A sample item is “my thoughts take up all my attention.” The measure has shown high internal consistency and test-retest reliability and is designed to detect transdiagnostic processes associated with clinical diagnoses of anxiety and depression[16]. Assessment of rumination was included as a measure of changes anticipated following Insight training because it includes practices that encourage thoughts, particularly negative thoughts about oneself, to be experienced as constructed mental events rather than actual depictions of reality, which can foster a more flexible and dynamic self-narrative and less rumination.

### **Drexel Defusion Scale (DDS)[17]**

A sample item is “Imagine you bang your knee on a table leg. To what extent would you normally be able to defuse from physical pain?” In order to address concerns that measures of similar constructs are often misunderstood (e.g., mindfulness)[18], the DDS provides an extended definition of the term defusion. The DDS has high convergent validity with measures

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of acceptance and psychological distancing and incremental validity in predicting psychopathology and quality of life.

### **Five Facet Mindfulness Questionnaire (FFMQ)[19]**

The FFMQ has five subscales. Sample items from each subscale include “When I’m walking, I deliberately notice the sensations of my body moving” (observe), “I’m good at finding words to describe my feelings” (describe), “When I do thinking, my mind wanders off and I’m easily distracted” (acting with awareness), “I perceive my feelings and emotions without having to react to them” (non-reactivity), and “I criticize myself for having irrational or inappropriate emotions” (non-judgment). The total score across all item has been frequently used as a global index of dispositional mindfulness[20,21].

Table 2. Deviations from Open Science Framework pre-registration

Some deviations were made from the pre-registered analysis plan in order to streamline analyses, evaluate impact of missingness, account for skewed usage variables, control for multiple comparisons, assess potential adverse effects, and evaluate the impact of influential points on statistical significance. First, due to the amount of missing data, our primary analyses used mixed effects models (MLM)[22] with all three timepoints and maximum likelihood estimation instead of separate analysis of variance (ANOVA) models examining pre-test to mid-treatment and pre-test to post-test. Maximum likelihood can account for data that are missing at random (MAR)[23]. Based on the possibility that missingness was related to the unobserved value itself (i.e., missing not at random [MNAR]), we also conducted sensitivity analyses described below with varying assumptions about the missing data. Second, as our three measures of psychological distress were highly correlated at baseline ( $r_s > .70$ ), we created a composite psychological distress measure in order to simplify our analytic plan. Third, our recruited sample size was slightly larger than our pre-registered sample size of 300. Fourth, our measure of therapeutic alliance was not usable due to an error in its administration. Fifth, due to non-normally distributed usage variables, we operationalized usage as a median split of the least skewed/kurtotic variable (days of use). Sixth, we tested the statistical significance of the indirect effects in our mediation models using quasi-Bayesian confidence intervals which is generally preferred to the Baron and Kenny[24] method we initially proposed[25]. Seventh, we applied a Benjamini-Hochberg[26]  $p$ -value correction to control the false discovery rate (FDR) in each set of analyses. Eighth, we report results for changes in mindfulness. Ninth, we report the proportion of participants showing minimally importance differences in distress (i.e.,  $d=0.30$ )[27] in order to

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characterize potential harm[28]. Tenth, we evaluated influential points specific for MLMs by assessing change in statistical significance with cases sequentially removed[29].

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Table 3. Model formula for primary analyses

$$Y_{ij} = \beta_{00} + \beta_{10}(Time) + \beta_{20}(Group) + \beta_{30}(Time \times Group) + [U_{0j} + e_{ij}]$$

where  $Y_{ij}$  reflects the outcome (e.g., psychological distress) of a given participant ( $i$ ) at a given time ( $j$ ) (i.e., pre-, mid-, or post-test). The fixed intercept ( $\beta_{00}$ ) reflects the grand mean of the outcome at time = 0 (i.e., pre-test). The fixed effect for time ( $\beta_{10}$ ) reflects the overall mean linear change in outcome across all participants. The fixed effect for group ( $\beta_{20}$ ) reflects group differences across all timepoints. Group was coded as either Connection (1) versus Insight (0) or active (1) versus waitlist (0). The fixed effect for time X group ( $\beta_{30}$ ) reflects the degree to which the linear effect for time varies depending on group status (i.e., whether the trajectory of change differs across groups). The parameters inside the brackets were random effects. Participants' variability around the fixed intercept was modeled with a random intercept coefficient ( $U_{0j}$ ) indexing participant  $j$ 's deviation from the overall mean outcome at time = 0 ( $\beta_{00}$ ). The final component,  $e_{ij}$  reflects the error of prediction or residual for participant  $i$  at time  $j$ . Models with random slope coefficients (i.e., allowing trajectories of change to vary not only between groups but between individuals) were not identifiable. This was likely due to the degree of missingness and the limited number of participants with all three observations.

The R syntax for running this model with data in long format (i.e., one row per participant per timepoint per outcome) is:

```
summary(lmer(value ~ time*group + (1|id), data = df.long[df.long$distress==1,]))
```

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Table 4. Baseline correlations between measures

	1	2	3	4	5	6	7	8	9	10	11
1. Depression											
2. Anxiety	.72***										
3. Stress	.74***	.75***									
4. Distress	.90***	.91***	.91***								
5. Social Connect	-.62***	-.46***	-.54***	-.60***							
6. Empathy	.08	.20***	.12*	.15**	.13*						
7. Compassion	-.01	.08	.04	.04	.20***	.58***					
8. Self-Reflection	.00	.12*	.06	.07	.13*	.32***	.38***				
9. Insight	-.47***	-.42***	-.46***	-.50***	.50***	.03	.19***	.27***			
10. Rumination	.61***	.66***	.66***	.71***	-.53***	.19***	.01	.10'	-.51***		
11. Defusion	-.46***	-.47***	-.53***	-.53***	.46***	-.06	.15**	.06	.42***	-.56***	
12. Mindfulness	-.55***	-.55***	-.61***	-.63***	.57***	-.06	.16**	.13*	.68***	-.64***	.63***

Note: Depression=PROMIS Depression; Anxiety=PROMIS Anxiety; Stress=Perceived Stress Scale; Psych Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connect=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire.  $n = 343$ . Values are Pearson's  $r$  correlation coefficient.

\* $P < .050$ ; \*\* $P < .010$ ; \*\*\* $P < .001$

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Table 5. Results of multilevel models assessing differential change over time with outliers removed

Outcome	CO versus IN				Active versus WL							
	<i>d</i> <sub>CO</sub>	<i>d</i> <sub>IN</sub>	<i>d</i> <sub>diff</sub>	<i>P</i>	<i>P</i> <sub>FDR</sub> R	<i>d</i> <sub>activ</sub> e	<i>d</i> <sub>WL</sub>	<i>d</i> <sub>diff</sub>	<i>P</i>	<i>P</i> <sub>FDR</sub>	Elev <i>P</i>	Elev <i>P</i> <sub>FDR</sub>
Psychological Distress	-0.78	-0.70	-0.08	.896	.977	-0.74	-0.46	-0.28	<.001	<.001	.001	.002
Social Connection	0.42	0.36	0.06	.540	.972	0.39	0.16	0.23	.003	.007	.012	.018
Empathy	-0.14	-0.02	-0.12	.374	.972	-0.08	-0.13	0.05	.623	.623	.431	.431
Compassion	0.11	0.34	-0.23	.290	.972	0.22	0.11	0.11	.146	.164	.191	.215
Self-Reflection subscale	0.08	0.18	-0.10	.663	.977	0.13	0.04	0.09	.017	.022	.040	.051
Insight subscale	0.46	0.39	0.07	.977	.977	0.42	0.29	0.13	.014	.021	.001	.002
Rumination	-0.45	-0.56	0.11	.321	.972	-0.52	-0.32	-0.18	.010	.018	.007	.013
Defusion	0.83	0.66	0.17	.780	.977	0.75	0.38	0.37	<.001	<.001	<.001	<.001
Mindfulness	0.93	0.70	0.23	.514	.972	0.80	0.46	0.34	<.001	<.001	<.001	<.001

Note: CO=Awareness + Connection; IN=Awareness + Insight; Active=combined Awareness + Connection and Awareness + Insight; WL=waitlist; Psych Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire; *d*=Cohen’s *d*, calculated as pre-post for within-group effects and the difference between within-group effects (Connection minus Insight, active minus waitlist) for *d*<sub>diff</sub>; for within-group; *p*=*p*-value from time X group interaction from multilevel models; FDR=False-Discovery Rate-adjusted *p*-values; Elev=active versus waitlist time X group interaction restricted to sample with elevated depression and/or anxiety at baseline (*T* ≥ 55). Outlier defined as three standard deviations above or below the mean.



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Table 6. Wilcoxon rank sum test using the completer sample and a worst-case scenario assumption for missingness

Outcome	<u>Completer sample</u>				<u>Worst-case scenario</u>			
	Rank <sub>active</sub>	Rank <sub>WL</sub>	<i>P</i>	<i>P</i> <sub>FDR</sub>	Rank <sub>active</sub>	Rank <sub>WL</sub>	<i>P</i>	<i>P</i> <sub>FDR</sub>
Psychological Distress	69.11	93.61	.001	.003	178.10	159.90	.080	.158
Social Connection	85.65	64.64	.004	.009	166.91	182.08	.142	.168
Empathy	80.36	73.37	.339	.339	164.48	186.91	.030	.158
Compassion	82.33	69.38	.075	.085	165.61	184.68	.065	.158
Self-Reflection subscale	84.09	66.87	.018	.033	165.88	184.13	.077	.158
Insight subscale	83.58	67.60	.028	.042	166.10	183.70	.088	.158
Rumination	70.30	85.50	.037	.047	177.55	160.99	.108	.162
Defusion	88.42	63.19	.001	.003	167.00	181.92	.149	.168
Mindfulness	91.28	60.61	<.001	<.001	167.85	180.23	.233	.233

Note: Rank=mean pre-post residual rank; Active=combined Awareness + Connection and Awareness + Insight; WL=waitlist; Psychological Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire; *P*=*P*-value from two-sample Wilcoxon rank sum test (i.e., Mann-Whitney); FDR=False-Discovery Rate-adjusted *P*-values. Worst-case scenario replaced missing values with the maximum or minimum residual, depending on whether a larger or smaller residual indicates improvement. For outcomes in which lower scores are better (e.g., psychological distress), lower mean rank indicates larger reductions. For outcomes in which higher scores are better (e.g., social connectedness), high mean rank indicates larger increases.

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Table 7. Wilcoxon rank sum test results for three missingness assumptions

Outcome	<u>0.25 SD</u>				<u>0.50 SD</u>				<u>0.75 SD</u>			
	Rank <sub>active</sub>	Rank WL	<i>P</i>	<i>P</i> <sub>FD</sub> R	Rank <sub>active</sub>	Rank WL	<i>P</i>	<i>P</i> <sub>FD</sub> R	Rank <sub>active</sub>	Rank WL	<i>P</i>	<i>P</i> <sub>FD</sub> R
Psychological Distress	163.06	189.73	.010	.031	164.98	185.92	.044	.133	167.32	181.28	.180	.541
Social Connection	180.20	155.74	.018	.040	174.91	166.23	.401	.600	173.71	168.61	.622	.912
Empathy	174.18	167.68	.530	.530	172.11	171.78	.975	.975	171.61	172.77	.912	.912
Compassion	177.83	160.44	.093	.139	171.63	172.74	.915	.975	171.34	173.31	.849	.912
Self-Reflection subscale	176.93	162.22	.155	.179	174.52	167.00	.467	.600	172.64	170.74	.855	.912
Insight subscale	176.88	162.32	.159	.179	175.68	164.78	.288	.600	170.77	174.44	.722	.912
Rumination	165.69	184.50	.068	.123	169.23	177.49	.424	.600	173.19	169.63	.731	.912
Defusion	181.72	152.73	.005	.023	179.75	156.63	.026	.116	176.89	162.31	.160	.541
Mindfulness	185.45	145.34	<.001	.001	181.57	153.02	.006	.054	179.94	156.26	.023	.203

Note: 0.25 SD, 0.50 SD, 0.75 SD=missing values assumed to be 0.25, 0.50, or .075 standard deviation above or below the mean residual, depending on whether larger or smaller residuals indicates improvement; Rank=mean pre-post residual rank; Active=combined Awareness + Connection and Awareness + Insight; WL=waitlist; Psychological Distress=composite of PROMIS Depression, PROMIS Anxiety, and Perceived Stress Scale; Social Connection=Social Connectedness Scale; Empathy=Interpersonal Reactivity Index; Compassion=Compassionate Love Scale; Self-Reflection subscale and Insight subscale=subscales of the Self-Reflection and Insight Scale; Rumination=Perseverative Thinking Questionnaire; Defusion=Drexel Defusion Scale; Mindfulness=total score of Five Facet Mindfulness Questionnaire; *P*=*P*-value from two-sample Wilcoxon rank sum test (i.e., Mann-Whitney); FDR=False-Discovery Rate-adjusted *P*-values. For outcomes in which lower scores are better (e.g., psychological distress), lower mean

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rank indicates larger reductions. For outcomes in which higher scores are better (e.g., social connectedness), high mean rank indicates larger increases.

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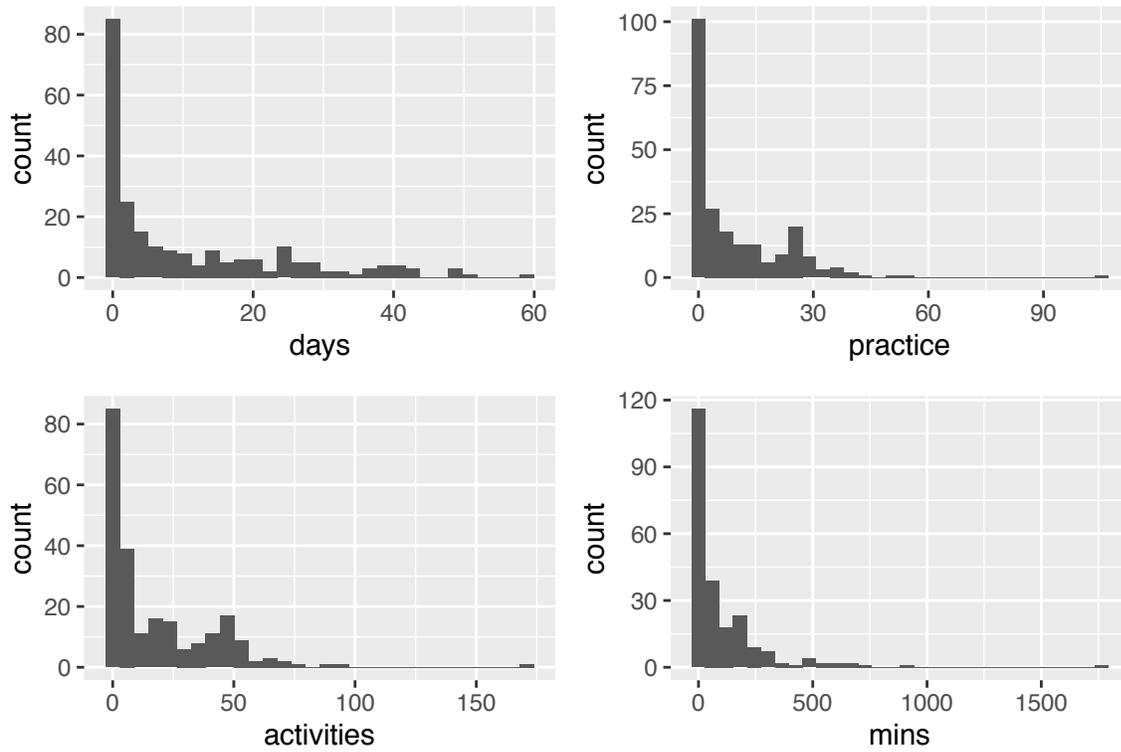


Figure 1. Histograms displaying distribution of usage variables. days=days of use; practice=number of meditation practice sessions completed; activities=number of total activities completed (meditation practices sessions and didactic content); mins=minutes of meditation practice.

# SMARTPHONE-BASED MEDITATION

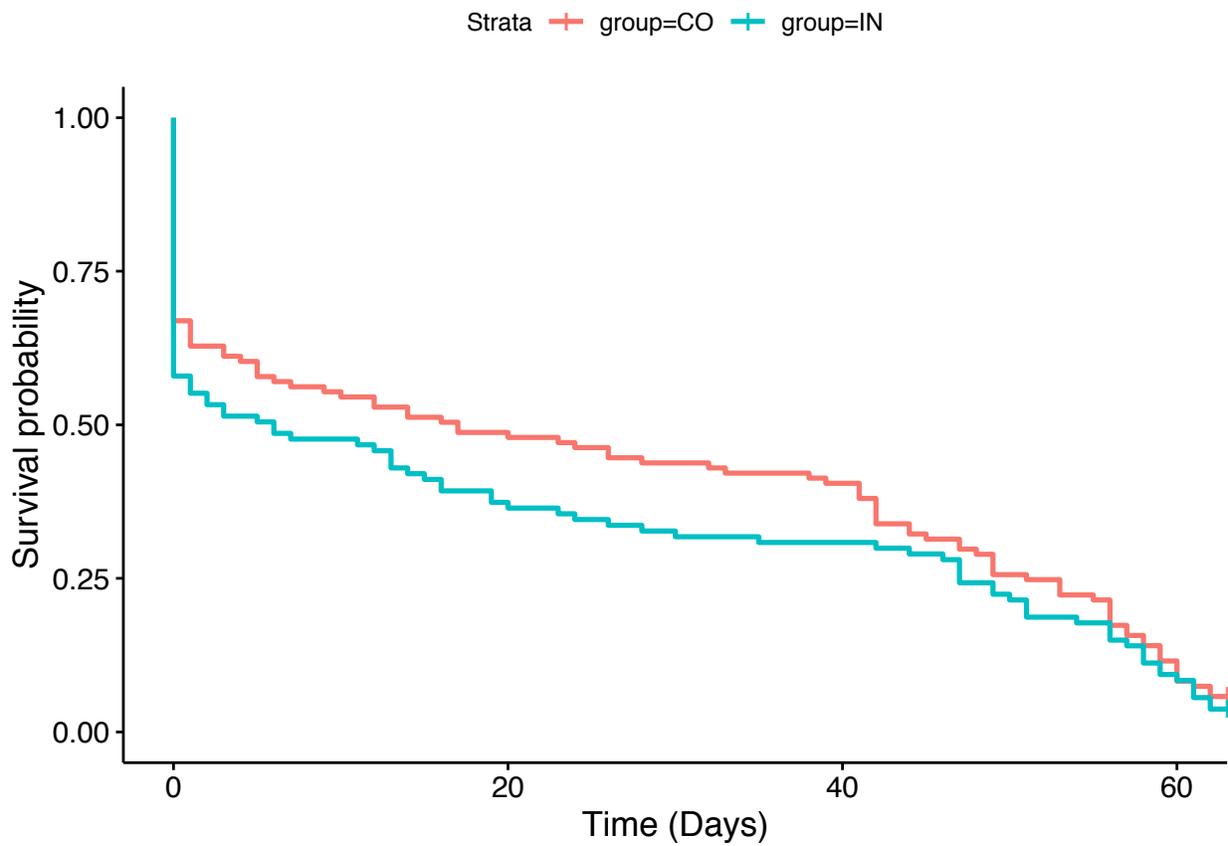


Figure 1. Survival curves for Awareness + Connection (CO) and Awareness + Insight (IN) participants. with 95% confidence intervals. Usage calculated from completion of pre-test survey to 9 weeks (63 days). Groups did not differ in engagement over time (hazard ratio=1.17,  $P=.242$ , with Insight as reference group).

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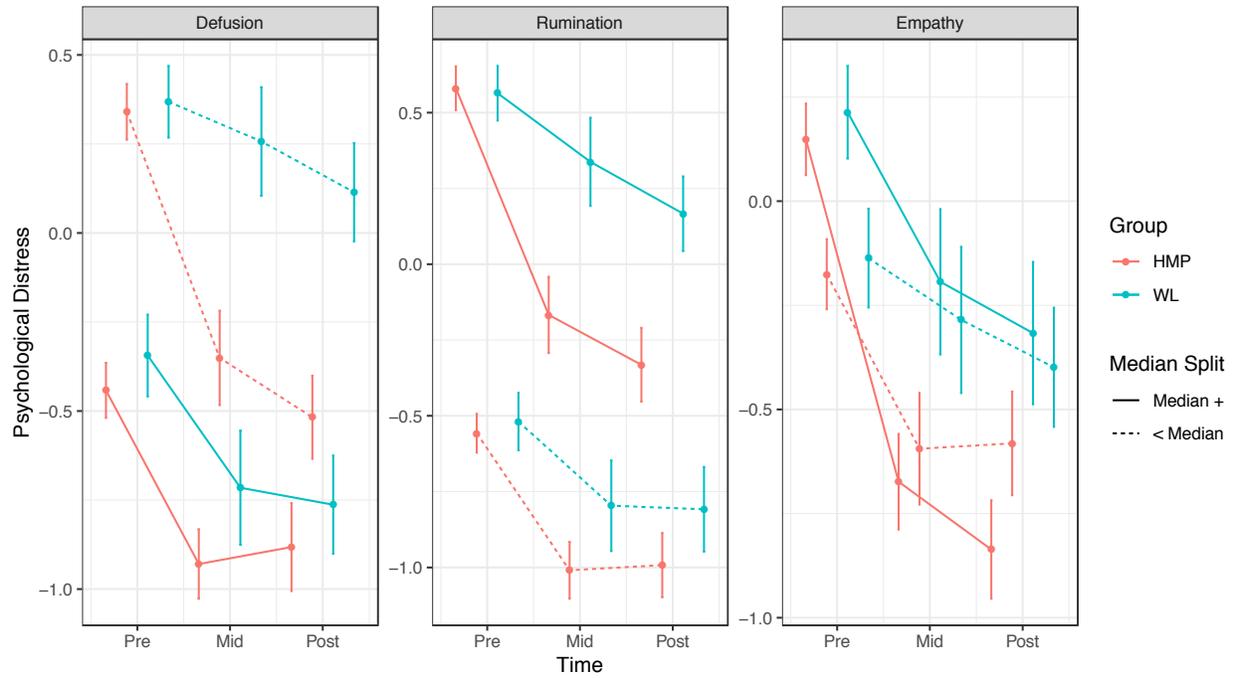


Figure 3. Baseline variables moderate longitudinal changes in psychological distress. Participants higher in baseline rumination and empathy and lower in baseline defusion showed relatively larger reductions in distress.

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