

Boosting the Benefits of Mobile Technology-Delivered Interventions: A Randomized Controlled Trial Examining Human Support to Enhance Engagement, Practice Integration, and Skill Learning in College Students

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Abstract

Background: Mobile technology-delivered interventions (TDIs), or mTDIs, have great promise for maximizing reach, but struggle with low rates of uptake and engagement. Among other evidence-based mTDIs, mindfulness apps such as Headspace have demonstrated numerous benefits for both community and clinical samples. People with depression or other mental health problems can experience many benefits from mTDIs, yet also may face even greater challenges in engaging with app-based interventions. Although users usually value the self-guided nature of mTDIs, they also might benefit from social connection with peers, and instructional guidance from a knowledgeable source, around mTDI use. College students are often studied as mTDI users given their high level of engagement with technology. Students also benefit from ample opportunities for social connection with peers, and instructional settings.

Objective: This randomized controlled trial evaluated the impact of two human support enhancements – a one-time interactive orientation, with or without placement into a peer supportive accountability group – on mTDI engagement, skill integration, and learning among a sample of 123 depressed college students.

Methods: Participants authorized access to their recorded app use data, provided by Headspace. Additionally, at midpoint (1 month), post (2 months) and follow-up (3 months) assessments, participants reported on the extent to which they had been using the intervention's skills outside of the app, how likely they were to continue using the app and related skills in the future, and the extent to which they learned from the intervention.

Results: As compared to those who were simply given access to the app without these enhancements, participants who were randomized to attended orientation, regardless of additional randomization to the peer support group, demonstrated significantly greater mTDI engagement (e.g., more minutes meditated, $F=11.20$, $p<.001$) and rated multiple aspects of skill integration and learning more favorably (e.g., increased awareness of thoughts and feelings, $F=6.05$, $p=.004$), indicating potential implications for amplifying the benefits of mTDIs through increased user engagement.

Conclusions: The results of this study illustrate that an initial face-to-face orientation boosts mTDI engagement, enhances integration of intervention skills in everyday life, and increases learning. Future work is needed to determine the active ingredients of the orientation that might drive increased levels of engagement and the associated positive intervention benefits. Clinical Trial: Open Science Framework (OSF): <https://osf.io/3trzk>

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Original Manuscript

Boosting the Benefits of Mobile Technology-Delivered Interventions: A Randomized Controlled Trial Examining Human Support to Enhance Engagement, Practice Integration, and Skill Learning in College Students

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Abstract

Background: Among evidence-based mobile technology-delivered interventions (mTDIs), mindfulness apps such as Headspace have demonstrated numerous benefits. These benefits are particularly important for college students, who continue to face high rates of depression and psychological distress that are paired with insufficient mental health services to meet these needs. mTDIs offer scalable solutions to ameliorating mental health symptoms and may be able to help address this gap in limited access to mental health services for all populations. While mTDIs have great promise for maximizing reach, their utility can be hamstrung by low rates of user engagement and uptake. Thus, this study implemented 2 human support enhancements designed to boost user engagement within the app, practice integration into daily life (ie, sustainability), and app-related skill learning (ie, perceived benefits), in a sample of depressed college students who were granted full access to an mTDI (Headspace). **Objective:** This randomized controlled trial evaluated the impact of 2 human support enhancements – (1) a one-time interactive orientation, with or without (2) placement into a peer supportive accountability group – on self-reported and objectively captured mTDI engagement, practice integration, and skill learning, among a sample of depressed college students. **Methods:** Participants (N=123) authorized access to their recorded app use data, provided by Headspace. Additionally, at midpoint (1 month), post (2 months) and follow-up (3 months) assessments, participants self-reported on the extent to which they had used the app, how likely they were to continue using the app and related skills in the future, and the extent to which they learned skills and practiced these skills in their daily lives. **Results:** As compared to those who were simply given access to the app (n=37) without these enhancements, participants who attended orientation (n=86), regardless of additional randomization to the peer support group (n=48 of these 86), demonstrated significantly greater mTDI engagement (ie, more minutes meditated, $F=11.20$, $P<.001$, more sessions overall, $F=15.00$, $P<.001$) and rated more favorably multiple aspects of practice integration (ie, more everyday mindfulness practice, $F=6.20$, $P=.003$, greater likelihood of future mindfulness, $F=7.42$, $P<.001$) and skill learning (ie, learning about mindfulness, $F=6.02$, $P=.004$, learning mindfulness skills, $F=11.01$, $P<.001$, increased awareness of thoughts and feelings, $F=6.05$, $P=.004$), indicating potential implications for amplifying the benefits of mTDIs through increased user engagement. **Conclusions:** The results of this study illustrate that an initial face-to-face orientation boosts mTDI engagement, enhances integration of intervention skills in everyday life, and increases learning. Future work is needed to determine the active ingredients of the orientation, as well as to narrow in on the optimal implementation of supportive accountability, that might drive increased levels of engagement and the associated positive intervention benefits.

Trial Registration: Open Science Framework (OSF): <https://osf.io/3trzk>

Keywords: mobile app; digital intervention; human support; engagement; skill integration; skill learning; mindfulness depression

Introduction

Evidence-based technology-delivered interventions (TDIs), including wellness and mental-health promoting *mobile* apps (mTDIs), have demonstrated great promise for improving positive emotional wellbeing and reducing psychological distress across various samples, including college students.[1,2] Mindfulness apps in particular have been effective in reducing depression, anxiety, and stress, and improving psychological wellbeing and life satisfaction.[3] Importantly, mindfulness mTDIs also promote the development of related skills, with participants reporting significant improvements in areas such as awareness, acceptance, nonjudgmental attitude, and focus on the present moment.[4,5] Thus, these tools offer an effective and accessible way to address the large treatment gap that exists between those who need mental health treatment and those who are receiving it, a discrepancy that is particularly large for college students with depression.[6]

Beyond their clinical utility, mTDIs have broad appeal, especially among college students, who appear to prefer the convenience, immediacy, and feelings of confidentiality,[7] paired with the 24-hour access, including availability after in-person clinic hours.[1] Although there are hundreds of mTDIs designed to address mental health problems, and these numbers are growing rapidly, many of these apps are not evidenced-based.[8,9] Further, clinical science grapples with translating the benefits often seen when evaluating mTDIs through *research trials* [10] into best practices for promoting *real-world* applications, often marked by low uptake and engagement.[11] Interventions might work well for a subset of people who engage with them, but not for those who fall short of engagement or adherence standards.[4] Indeed, users cannot benefit from the behavioral changes facilitated by mTDIs if they do not engage with such programs and learn the necessary skills. In order to harness the potential benefits of mTDIs, it is an urgent priority to identify strategies and supports for fostering sustained engagement and integration into daily life so that users can ultimately learn and implement skills for wellbeing.

Although mTDIs are typically designed to be self-guided, they can be integrated with human

support features in order to enhance user engagement and thus benefits. This study is part of a larger randomized controlled trial (RCT) that established the efficacy - specifically psychosocial benefits – of a mindfulness-based mTDI for college students experiencing depressive symptoms.[12] Building on those findings, this study examines whether 2 human support enhancements – a face-to-face orientation and placement into small peer supportive accountability groups – (a) boosted *engagement* with the mindfulness-based mTDI, (b) cultivated increased *practice integration* into daily life, and (c) enhanced users' self-reported *skill learning*.

Engagement with Mobile Interventions: Challenges and Opportunities

Although mTDIs have great potential to deliver effective treatments to a broad population, such programs are marked by low rates of uptake and sustained **user** engagement, particularly for self-guided treatments that involve lower levels of structure and prescriptive guidance.[13,14] Such digital approaches require users to be self-motivated to initiate and sustain their use independently. [15] Further, the mental health symptoms driving users to seek out mTDIs, such as depressive symptoms of reduced interest, energy, and concentration, may themselves interfere with mTDI engagement.[16] Unpacking patterns of **user** engagement s along with **studying** intervention design strategies to boost and maintain engagement **are** critical steps for advancing the efficacy of evidenced-based mTDI interventions.

Engagement has been defined as “a state of energy investment involving physical, affective, and cognitive energies directed toward a focal stimulus or task.”[17,18] For the purpose of **this** study, engagement is measured behaviorally via the number of use minutes and completed sessions recorded by the mTDI software. While there is ongoing debate regarding how to best define and measure engagement [19], tabulating app usage data (including duration and frequency) remains one of the most common methods [20]. User data from mindfulness-based mTDIs generally show engagement rates that start high but gradually reduce over time, with precipitous drops within the first week of uptake.[11] Of concern, engagement is particularly low during self-guided follow-up

study periods.[21,22] For example, Flett and colleagues[4] found that college students used a mindfulness-based mTDI almost daily in the first 10 days of the study, but less than half had *any* use in the subsequent 30 days. This sentiment is reflected in conversations with college student app users as well; despite almost 75 percent reporting some benefit from mTDIs, the same proportion engaged with them weekly or less.[7] Such research highlights the discrepancy between interest in and engagement with mTDIs.

While emerging research in the area of digital mental health frequently recommends the integration of human support to enhance mTDI engagement, there remain many questions related to what type of support is needed. For example, there is great variability in the provider (eg, peers, unlicensed professionals, licensed clinicians), the modality (eg, in-person contact, video visits, phone calls, text-based messaging), and the frequency of support given. Further complicating this issue is that few studies provide a detailed description of the human support that was delivered or examine the role of such support in their study outcomes, making it difficult to draw larger conclusions across studies.[23] This study aims to address this gap by specifically examining the impact of 2 human support features – participation in a pre-intervention orientation session and placement in a peer supportive accountability group – on mTDI engagement, practice integration beyond the app, and skill learning.

Peer Supportive Accountability

Supportive Accountability is a theoretical model that seeks to explain how human support can improve engagement with mTDIs.[15] The model posits that a user is likely to engage more with an mTDI when they are accountable to another person. Accountability includes knowing that actions or inactions with the intervention will be observed and behavioral choices will have to be justified to someone. Ideally, the person a user is being accountable to will be viewed as legitimate and with beneficial knowledge to offer, and therefore the accountability process is viewed as supportive and non-coercive. Though not explicitly testing the supportive accountability model, a systematic review

of 208 studies examining user engagement with mTDIs found that guided or supported interventions had higher engagement than self-guided interventions, and being able to connect with others through the mTDI increased engagement.[16]

The supportive accountability theory has been tested in a number of formats including telephone coaching from clinicians and peers, as well as through digital formats [15,24] Coaching delivered by peers is equally effective at improving engagement as coaching delivered by licensed clinicians.[25] Peer-delivered support typically has been offered through embedded message boards that include components of visible goal setting and completion as well as methods to provide support and communication to increase goal completion (eg, “likes” and comments). Several studies across different populations have demonstrated increased utilization of mTDIs by participants with access to peer support features compared to completely self-guided participants. [26–28] Even in trials with no differences in engagement between groups or no self-guided comparison group, participants tend to rate peer supportive accountability as positive and helpful.[25,29–31] A systematic review of 24 peer-supported digital mental health interventions concluded that utilizing peer support to deliver or supplement mTDIs is feasible, acceptable, and effective at improving engagement and psychological functioning.[32] Ultimately, incorporating supportive accountability features into mTDIs for depression has the potential to improve both engagement and mental health outcomes for a wide array of users.

Pre-Intervention Orientation

Research has less commonly explored the ways in which one-time support interactions, such as an orientation to a TDI, might enhance engagement. Psychotherapy research has explored the benefits of engagement sessions, typically utilizing motivational interviewing (MI) tools, to enhance engagement with traditional mental health services.[33,34] More recently, MI has been incorporated into TDIs as a potential engagement strategy. Such techniques allow for users to interact with programs in a more intentional manner by setting expectations and goals for program use,

encouraging use of problem-solving and other skills, and normalizing challenges.[35] More specifically, using MI to support TDI users as they prepare for, and enact, behavioral changes is particularly encouraged in order to support program engagement.[35] Brief motivational interventions, such as through text messages or phone calls, are viewed positively by TDI users, promote program engagement, and even enhance initial program outcomes.[36–39] Similarly, Linardon and Fuller-Tyszkiewicz[14] found increased engagement for trials that had at least one opportunity for contact with the researchers (either a telephone or in-person interview prior to enrolling) compared to trials where participants could enroll in a study online without contacting a researcher.

Some studies have targeted motivation prior to users engaging with the program, such as through a synchronous (eg, face-to-face; telephone) orientation session with research staff or through a module within the TDI. While some studies appear to incorporate such techniques into their methodological design [30,40] few studies have provided detail about the content of these sessions or explicitly investigated their impact on engagement or other outcomes. Encouragingly, researchers have begun to recognize that such techniques may serve as an active component of treatment that can be investigated in and of itself. For example, Bur and colleagues [41] conducted an RCT of an online self-help program for depression, exploring the effects on user engagement of different types of support, including elements with human contact (personal guidance and a pre-intervention diagnostic interview) and those without human contact (automated reminders and a pre-intervention MI module). At the end of the intervention, participants who received human support in the form of individualized guidance demonstrated both greater reductions in depressive symptoms as well as greater treatment adherence as compared to the other support conditions.[41] Beyond building motivation for engagement, these pre-program touchpoints can help users navigate the technology of a new app as well as the large amounts of content that many TDIs provide, both of which can be overwhelming particularly when users are also contending with mental health challenges such as

depression.[8] Overall, more research is needed to better understand the role that pre-program interventions (eg, introductory, orientation, or engagement sessions) may have and their effects on subsequent program engagement and associated benefits.

Self-Guided Practice for Lasting Benefits

As with skills-based face-to-face treatments, the goal of mTDIs is for users to learn and practice skills so that they become integrated into their daily lives over time. Notably, completion of out-of-session exercises is uniquely linked to symptom improvement and treatment outcome across disorders.[42] In a similar vein, Schlosser and colleagues[43] distinguished between TDI active use (eg, tasks or skill practices completed) and passive use (eg, time on the app that was not spent meaningfully engaging with other users or task completion) and found that only active use was linked to symptom improvement. This signals the critical importance of assessing not only objective engagement counts (eg, TDI use minutes and completed sessions), but also broader elements such as practice integration and skill learning.

Study Aims and Hypotheses

In a sample of college students with elevated depression, we examined the benefits of 2 mTDI enhancements, (1) a face-to-face orientation, with or without (2) placement in a peer supportive accountability group, on 3 sets of outcomes, (1) mTDI engagement, (2) practice integration, and (3) skill learning. For the first outcome, (1) mTDI engagement, we hypothesized that those who were randomized to receive the enhancements would demonstrate greater mTDI engagement (minutes and sessions completed) compared to those who were simply given access to the app without either of these enhancements. We examined whether those in the peer supportive accountability group experienced incremental benefits in engagement, beyond those of the orientation. In an exploratory fashion, we examined whether there were differences among the 3 intervention groups on 2 other sets of self-report outcomes: (2) practice integration, specifically “everyday mindfulness” and likelihood of engaging in future mindfulness practices, whether using

the app, engaging in mindfulness exercises on one's own, or generally being more mindful in daily life, and (3) skill learning, specifically (a) learning about mindfulness as a concept and practice, (b) learning mindfulness skills, and (c) being aware of one's thoughts and feelings.

Methods

Ethical Considerations

This RCT (registered on OSF at <https://osf.io/3trzk> prior to start of analyses) was approved by the Loyola University Chicago's Institutional Review Board (Project 2330), and all participants provided informed consent. Minimal identifying data were collected, and identifiers were removed from the dataset for analysis. Confidential (ie, identifying) data were stored on a university-supported, password-protected network drive and in locked filing cabinets to which only the research team had access. Participants were compensated monetarily (up to \$70) or with participant pool course credits (up to 10) for the completion of study sessions.

Recruitment

Over 8 successive semesters, we recruited undergraduate students from a mid-sized, Midwestern university using a multi-pronged voluntary response sampling strategy, including the psychology participant pool, cross-campus listserv emails, and flyers seeking students who self-identified as "down, sad, or distressed." Recruitment occurred at the beginning of each semester between the years 2017 - 2021. Eligible participants endorsed clinically significant levels of depressive symptoms as indicated by a score of 10 or higher on a brief online screening using the Patient Health Questionnaire (PHQ)-8, which omits the suicidality item.[44,45] Individuals were excluded if they were engaged in psychotherapy at the start of the study, had regular practice of mindfulness or consistent use of the Headspace app within the past 6 months, or reported that they were unwilling to join the peer support group if randomized to that condition. Due to EEG assessments that were part of the broader project, participants were also excluded if they had a history of neurological conditions or head trauma (eg, concussions, seizures). Our sample size (10 to

27 students each semester) was determined by the number of participants who met study criteria each semester, paired with consideration of resource constraints (ie, time, space, funding).[46]

Intervention Groups and Procedures

Participants were randomized into 3 nested groups: App As Usual (APP), App + Orientation (APP+O), and App + Orientation and Peer Support (APP+OPS). Specifically, all participants received the base intervention of access to the app (APP), all APP+O and APP+OPS participants (but not APP participants) attended an orientation, and only the AP+OPS participants were invited to the peer supportive accountability features (as described in the subsequent section).

An unequal allocation procedure was used for randomization to ensure a consistent set of 6 participants was assigned to each peer support group (totaling to 8 groups over 8 semesters). Specifically, we performed a manual blind drawing to randomly allocate 6 participants to each APP+OPS group and to randomly and evenly split the remaining participants among the APP and APP+O groups. As shown in the CONSORT diagram (Figure 1), this yielded a ratio of 1.26:1:00:0.97. Participants completed 4 online self-report surveys providing demographic information at pre-intervention (within 2 weeks before code activation) and assessing their experiences with the intervention at midpoint (1 month after code activation), post-trial (2 months after code activation), and 1-month follow-up (3 months after code activation).

Intervention: Mobile Mindfulness App (Headspace)

Intervention participants received a 3-month code to access all content of Headspace Inc., [47] an online/mobile app that delivers brief, guided mindfulness exercises, as well as some additional wellness-related content (eg, “soundscapes,” “sleepcasts,” “focus music”). The program includes courses that typically include 10 to 30 sessions following a particular theme (eg, Handling Sadness, Managing Anxiety). Headspace also includes single mindfulness meditation sessions, some of which are intended to be used in a specific situation (eg, difficult conversations) or as guided mindful activities (eg, mindful eating, mindful walking). Users can customize the length of most

sessions, ranging from shorter (1-5 minutes) to longer (10-30 minutes) options. Though participants were free to access any of the Headspace content, they were encouraged to engage with mindfulness exercises, particularly the “Basics” courses teaching foundational skills on mindfulness and meditation, and the mental health-related meditations, such as those focused on psychological distress (eg, sadness, stress, anxiety, “SOS” sessions) and positive wellbeing (eg, happiness, self-esteem).

Intervention: Orientation

The APP+O and APP+OPS groups (but not the APP group) attended a 90-minute group orientation session wherein the first 3 authors reviewed study procedures, briefly described the principles and benefits of mindfulness, oriented participants to app features and content, helped participants to activate their accounts with access codes, and provided recommendations for mTDI engagement. Although participants were encouraged to use the app as frequently and consistently as possible (ie, daily) and to use its mental health-focused content, no specific requirements were given and use was ultimately self-guided. As recommended for mTDI engagement,[35] elements of motivational interviewing[48] were interspersed throughout the orientation session. For example, participants were encouraged to identify specific goals for their mTDI engagement and mindfulness practice, to consider their expectations and motivations for engaging in the program, to predict barriers to app use and engage in related problem-solving, and to reflect on approaches that have and have not been successful for them in the past in terms of establishing a new habit. Broader techniques such as eliciting participant thoughts and ideas, providing reflections, and using open-ended questions were incorporated as well. At this point in the orientation, participants in the APP+O group were dismissed, and for the duration of the study did not have additional contact with other study participants or the research staff beyond communication related to research assessments and compensation.

Intervention: Peer Supportive Accountability

Participants randomized to the APP+OPS group attended the group orientation described above, and stayed for an additional 20-30 minutes, reviewing the rationale and procedures for the peer supportive accountability features. Researchers provided an overview of supportive accountability, as well as the benefits of social sharing and of giving and receiving support. In cohorts of 6, APP+OPS participants added each other as Headspace “buddies,” which allowed them to share their progress. As time allowed, participants also set individual and group goals for their mindfulness practice (eg, daily use of the app) and for engagement with the peer support group (eg, weekly posting in the online forum).

Participants in the APP+OPS condition joined a private, closed Facebook group that served as an online forum. Participants were encouraged to post in the forum about their own successes and struggles with mindfulness practice, pose questions to the group, share information, and provide motivation, accountability, and support to other group members. Three to 5 times per week, research staff posted Headspace *Mindful Moments* (eg, “Imagine a world in which we witness thoughts without becoming them and experience feelings without being overwhelmed by them”), along with prompts encouraging participants to share their experiences with mindfulness and the app (eg, “What do you imagine? How would things be different?”). Twice per week, research staff posted user statistics, at the individual and group level (ie, number of sessions and minutes completed, session content, and days of use), along with an email digest that included the same user statistics and quotes from the online forum, examples of research findings demonstrating the benefits of mindfulness, and links to the online group and to Headspace.

In the third semester (and cohort) of the study, a face-to-face component was added to the APP+OPS condition based on participant feedback. Participants met for 3 in-person group sessions approximately every other week (ie, 2, 4, and 6 weeks after the orientation) for 45-60 minutes. Sessions did not include mindfulness exercises, but rather focused on peer supportive accountability, following a general structure wherein research staff gave a brief introduction and reminder of the

purpose of the group sessions, including any goals that were set in the prior session. With minimal direction from research staff, participants openly discussed their experiences with mindfulness (eg, barriers and successes), checked in with one another about progress, and fostered a sense of connectedness. During each meeting, a slide with suggested discussion topics was displayed for the group. At the end, research staff highlighted themes from the discussion and prompted participants to consider setting group and individual goals.

Measures

Social Identities

During the pre-intervention assessment, participants responded to a series of questions about different aspects of social identities, including age, race, gender, and sexual identity.

Engagement With mTDI

With participant consent, Headspace provided user data for each session, including: date, time of day, module (eg, Basics), session number within the module (eg, session 1), and duration in minutes. Researchers calculated each participant's total minutes of mindfulness practice (mindfulness minutes) and total sessions of any type (total sessions). All meditation sessions (the vast majority of content in the app), as well as mindful activities (eg, guided mindful walking) were considered mindfulness practice. Sessions of advice, music ("focus music," "sleep music"), and ambient noise/sounds ("sleepcasts," "soundscapes") were not included in totals of mindfulness minutes; however, they were included in total sessions to capture participants' broader engagement with the app.

Practice Integration: Self-Reported Mindfulness Practices and Likely Future Mindfulness Practice

In order to assess participants' practice integration or use of mindfulness practice outside of the app, at the midpoint, post-trial, and 1-month follow-up assessments, participants were asked about (a) their self-reported frequency of "non-guided, everyday mindfulness" (ie, self-guided

practice) since starting the trial. Participants rated how often they had practiced this on a Likert scale from 1 (“None: Not at all”) to 5 (“A lot: Daily practice”). Participants were also asked how likely they were, *after* the study, to: (b) use Headspace (not considering cost), (c) do mindfulness exercises on their own, and (d) be more mindful in their everyday life. Participants rated each of these items from 1 (“Not likely”) to 5 (“Extremely likely”).

Skill Learning

Finally, at the midpoint, post-trial, and 1-month follow-up assessments, participants were asked about their perceptions of the intervention and its benefits, adapting some items from the Mindfulness Intervention Social Validity Questionnaire.[49] Participants were asked to consider their overall experience with the program and report the extent to which they felt they had, through the program: learned about mindfulness, learned mindfulness skills, and gained awareness of their thoughts and feelings. Participants rated each item from 1 (“Not at all true”) to 5 (“Extremely true”).

Data Analysis Plan

In examining group effects, we used an intent-to-treat strategy, including all participants who were randomized to 1 of the 3 intervention groups and for whom we had relevant data. For example, of the participants with valid engagement data ($n=120$), a small subset ($n=10$; all in the APP group) did not engage with the app. Following an intent-to-treat approach, these participants were included in analyses. Further, all APP+OPS participants with valid data were included in analyses regardless of how much they engaged in the online forum or attended group meetings. All statistical analyses below were conducted using SPSS version 28.0.[50] We report observed effect sizes in the results. Missing data were handled via case-wise deletion for each specific analysis.

To examine overall differences among the 3 groups across 3 timepoints (midpoint, post-trial, 1-month follow-up), we conducted group by time ANOVAs and interpreted the group effects. For outcomes with an overall effect of group (human support condition), we examined pairwise contrasts to identify any differential impact of the orientation alone versus the orientation plus peer supportive

accountability.

Considering the effect of running multiple tests on Type I error, we calculated a Bonferroni correction by dividing .05 by the total number of individual ANOVAs, and we indicate in Table 2 whether each test met the standard significance threshold ($P < .05$) as well as the Bonferroni-adjusted significance threshold ($P < .0055$). We also report effect sizes.[51] Specifically, we examined η^2 values using Cohen's[52] standards for small ($\eta^2 \geq .01$), medium ($\eta^2 \geq .06$), and large ($\eta^2 \geq .14$) effects. We evaluated the distribution (skewness) of outcome variables at each time point, and we also ran Kolmogorov-Smirnov (K-S) tests for each variable.

Results

Participant Characteristics

Participant recruitment yielded 123 undergraduate students (M age 19.1 years, SD 1.5), with an average PHQ-8 screening score of 14.1 (range: 10 to 22), randomized to use the app as following: $n=37$ (30.1%) APP participants, $n=38$ (30.9%) APP+O participants, and $n=48$ (39.0%) APP+OPS participants (see Figure 1 for Consolidated Standards of Reporting Trials [CONSORT] diagram). Of note, the APP group included $n=19$ participants who first completed a waitlist period, and these participants did not differ from the other 18 APP participants who activated their Headspace access code at the same time as the rest of their cohort, or from APP+O or APP+OPS participants, on baseline depression, $F_{3,120}=.30$, $P=.83$. Table 1 presents baseline demographic characteristics for the full sample and for participants randomized to the 3 study groups, reflecting a higher proportion of women attending college and endorsing depression, but demonstrating no baseline group differences (see table note).

A few details in the CONSORT diagram are worth elaborating. Three participants, 1 in the APP group and 2 in the APP+OPS group, did not have valid app-recorded engagement data, due to data recording errors or access code malfunctions, and were therefore excluded from analyses examining objective mTDI engagement. Additionally, there was some missing data from surveys, as

noted in the CONSORT diagram. Notably, participants who completed surveys at all 3 timepoints ($n=82$) did not differ from those who completed surveys at only 1 or 2 timepoints ($n=41$) in gender, $\chi^2_2=.08$, $P=.96$, sexual identity, $\chi^2_4=2.86$, $P=.58$, race, $\chi^2_5=2.92$, $P=.71$, or baseline depression scores, $t_{120}=0.81$, $P=.42$, but were more likely to be younger in age, $t_{121}=2.77$, $P=.006$ and a first-year student $\chi^2_4=10.47$, $P=.03$. Some participants only partially completed surveys (eg, stopped partway through or skipped certain questions) resulting in slightly different sample sizes across outcome measures.

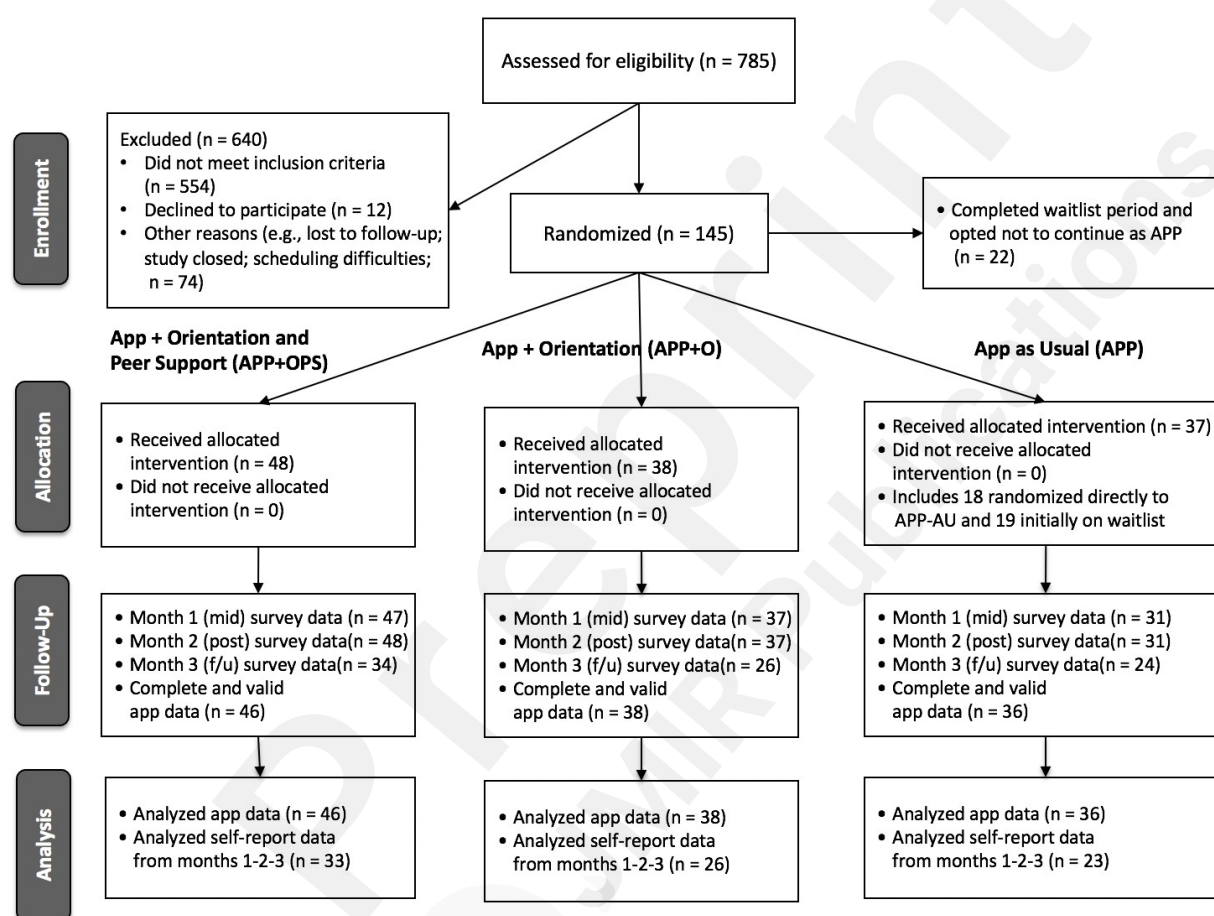


Figure 1. CONSORT Flow Diagram.

Impact of Human Support Enhancements

The following sections present results for the impact of 2 human support enhancements (a face-to-face orientation with or without placement into a peer supportive accountability group) on the 3 categories of outcomes: (a) engagement with the mTDI, (b) practice integration (eg, everyday mindfulness practice beyond the mTDI), and (c) skill learning (eg, self-reported awareness, learning, and skills).

Table 1.

Baseline Demographic Characteristics (Means and Standard Deviations, or Percents) For the Full Sample and for Participants Randomized to the 3 Study Groups.

	Total sample	APP+OPS	APP+O	APP
Age [M (SD)]	19.10 (1.47)	19.17 (1.34)	19.18(1.75)	18.92 (1.12)
Gender				
Female	91.9%	91.7%	89.5%	94.6%
Male	5.7%	8.3%	2.6%	5.4%
Self-identified response (eg, non-binary, transgender)	2.4%	0.0%	7.9%	0.0%
Sexual Identity				
Bisexual	18.7%	10.4%	23.7%	24.3%
Gay	3.3%	6.3%	2.6%	0.0%
Heterosexual	72.4%	77.1%	68.4%	70.3%
Lesbian	0.8%	0.0%	0.0%	2.7%
Self-identified response (eg, asexual, pansexual, queer)	4.9%	6.3%	5.3%	2.7%
Race/Ethnicity				
African American or Black	0.8%	2.1%	0.0%	0.0%
Asian or Asian American	15.4%	10.4%	15.8%	21.6%
Hispanic or Latino	15.4%	10.4%	18.4%	18.9%
Multiracial or Self-Identified (eg, Middle Eastern)	11.4%	18.8%	10.5%	2.7%
Native American or Pacific Islander	0.8%	0.0%	0.0%	2.7%
Non-Hispanic Caucasian/White	56.1%	58.3%	55.3%	54.1%
Year in School				
First-year undergraduate	56.1%	54.2%	52.6%	62.2%
Second-year undergraduate	24.4%	27.1%	31.6%	13.5%
Third-year undergraduate	9.8%	8.3%	5.3%	16.2%
Fourth-year undergraduate	8.1%	6.3%	10.5%	8.1%
Other (eg, accelerated nursing student)	1.6%	4.2%	0.0%	0.0%

Notes. Race/Ethnicity categories were based on NIH reporting guidelines from 2017, which reflected the categories identified by the United States Federal Government Office of Management and Budget's *Standards for the Classification of Federal Data on Race and Ethnicity*. There were no significant differences across groups in age, $F_{2,120}=.42$, $P=.66$, $P=.71$, or other demographic data: gender, $\chi^2(4)=7.98$ $P=.09$, sexual identity, $\chi^2(8)=8.60$, $P=.38$, racial/ethnic identity, $\chi^2(10)=11.72$, $P=.30$, or year in school $\chi^2(8)=9.17$ $P=.33$.

Engagement With mTDI

Table 2 presents group means and standard deviations, and summarizes group effects (F , Partial η^2 , and P) across the trial for each outcome. Additionally, Figure 2 depicts group means over time for each outcome. As shown in Table 2, there was an overall effect of group (human support condition) on cumulative mindfulness minutes. Pairwise comparisons indicate that APP participants had significantly lower mindfulness minutes than APP+O ($P=.005$) and APP+OPS ($P<.001$) participants, but mindfulness minutes did not significantly differ between APP+O and APP+OPS groups ($P=.55$; see Figure 2a).

Similarly, there was an overall effect of group (human support condition) on cumulative total sessions (mindfulness and non-mindfulness). Pairwise comparisons indicate that APP participants completed significantly fewer total sessions than APP+O ($P=.001$) and APP+OPS ($P<.001$) participants, but total sessions did not significantly differ between APP+O and APP+OPS groups ($P=.37$; see Figure 2b).

Table 2

Group Means and Standard Deviations by Timepoint (Mid-, Post-Intervention, and 1-Month Follow-Up), Group Effects Comparing Participants Randomized to Use a Mindfulness App-as-Usual ($n=36$) versus App+Orientation ($n=38$), an App+Orientation+Peer-Supportive-Accountability (PSA) ($n=46$)

Outcome	Group Means (Standard Deviations)			ANOVA Group Effects		
	Mid (1mo)	Post (2mo)	Follow-Up (3mo)	$F(2)$	η^2	P
Engagement with mTDI						
Cumulative Mindfulness Minutes				11.20	.161	<.001*
App as Usual (APP; $n=36$) ^[a]	55.0 (87.2)	85.4 (143.9)	98.6 (162.8)			

Outcome	Group Means (Standard Deviations)			ANOVA Group Effects		
	Mid (1mo)	Post (2mo)	Follow-Up (3mo)	F(2)	η^2	P
+ Orientation (APP+O; n=38) ^[b]	117.4 (97.6)	199.9 (181.0)	223.4 (212.3)	15.00	.204	<.001*
+ Orient+PSA (APP+OPS; n=46) ^[b]	147.8 (80.2)	251.7 (132.6)	260.5 (138.2)			
Cumulative Total Sessions						
App as Usual (APP; n=36) ^[a]	7.22 (9.58)	10.83 (15.35)	12.67 (17.86)	6.20	.147	.003*
+ Orientation (APP+O; n=38) ^[b]	15.76 (10.11)	24.97 (17.31)	27.84 (20.95)			
+ Orient+PSA (APP+OPS; n=46) ^[b]	19.28 (9.48)	31.46 (16.28)	32.91 (17.43)			
Practice Integration [Sustainability]				0.11	.003	.893
Everyday Mindfulness						
App as Usual (APP; n=21) ^[a]	1.48 (1.08)	1.33 (0.73)	1.95 (1.50)			
+ Orientation (APP+O; n=24) ^[b]	2.88 (1.42)	2.42 (1.44)	2.42 (1.59)	3.10	.078	.051
+ Orient+PSA (APP+OPS; n=30) ^[b]	2.33 (1.37)	2.87 (1.59)	2.73 (1.70)			
Future App (Headspace) Use						
App as Usual (APP; n=21)	3.33 (1.24)	3.19 (1.29)	2.67 (1.32)	7.42	.173	.001*
+ Orientation (APP+O; n=23)	3.43 (1.20)	3.00 (1.41)	2.78 (1.38)			
+ Orient+PSA (APP+OPS; n=31)	3.68 (0.98)	3.32 (1.14)	2.55 (1.09)			
Future Mindful Practice on Own				6.02	.142	.004*
App as Usual (APP; n=21) ^[a]	2.81 (1.33)	2.86 (1.35)	3.00 (1.34)			
+ Orientation (APP+O; n=24) ^[b]	3.71 (1.08)	3.75 (1.15)	3.50 (1.29)			
+ Orient+PSA (APP+OPS; n=31) ^[ab]	3.16 (1.16)	3.39 (1.05)	3.32 (1.30)	11.01	.234	<.001*
Future Mindfulness in Life						
App as Usual (APP; n=21) ^[a]	3.10 (1.18)	3.14 (1.35)	2.86 (1.46)			
+ Orientation (APP+O; n=24) ^[b]	4.13 (0.85)	3.96 (1.08)	4.04 (1.23)	6.05	.142	.004*
+ Orient+PSA (APP+OPS; n=29) ^[b]	4.03 (0.82)	4.00 (0.85)	3.66 (1.08)			
Skill Learning [Perceived Benefits]						
Learned About Mindfulness				11.01	.234	<.001*
App as Usual (APP; n=21) ^[a]	3.33 (0.97)	3.57 (1.17)	3.62 (1.02)			
+ Orientation (APP+O; n=24) ^[b]	4.04 (0.75)	4.00 (0.98)	4.29 (0.75)			
+ Orient+PSA (APP+OPS; n=31) ^[b]	4.06 (0.73)	4.19 (0.65)	4.10 (0.70)	6.05	.142	.004*
Learned Mindfulness Skills						
App as Usual (APP; n=21) ^[a]	3.24 (1.09)	3.43 (1.21)	3.67 (0.91)			
+ Orientation (APP+O; n=24) ^[b]	4.17 (0.70)	4.29 (0.75)	4.29 (0.86)	6.05	.142	.004*
+ Orient+PSA (APP+OPS; n=30) ^[b]	4.13 (0.63)	4.33 (0.55)	4.17 (0.70)			
Awareness of Thoughts & Feelings						
App as Usual (APP; n=21) ^[a]	3.10 (1.18)	3.33 (1.24)	3.52 (1.17)	6.05	.142	.004*
+ Orientation (APP+O; n=24) ^[b]	4.04 (0.75)	3.96 (0.81)	4.17 (0.70)			
+ Orient+PSA (APP+OPS; n=31) ^[b]	3.97 (0.84)	4.06 (0.81)	3.84 (0.86)			

Note. Mid = midpoint (1 month after initiating app); Post = post-intervention (2 months after initiating app); Follow-up (3 months after initiating app, and 1 month after post-intervention). We evaluated the skewness of the data for the 9 outcome variables, at each time point (3 time points), across the whole sample (See Multimedia Appendix 1). Only 3 out of the 27 variables exceeded thresholds (-1 to 1) for symmetry of the normal distribution. The skewed distribution for these 3 variables is not anticipated to increase the risk for Type-1 errors [53]. Of note, the distribution of these 3 variables were not skewed at the mid (1 month) time point. Rather, the distribution of these variables became skewed over time. This data pattern indicates a reduction in app use over time, rather than an unexpected pattern of behavior. Kolmogorov-Smirnov tests were significant, indicating that the residuals were not normally distributed. However, the Central Limit Theorem suggests that for larger sample sizes (100 or more), violation of normality does not present a significant concern. Further, the sampling distribution of the observations may be normal, even if the residuals do not precisely follow a normal distribution.

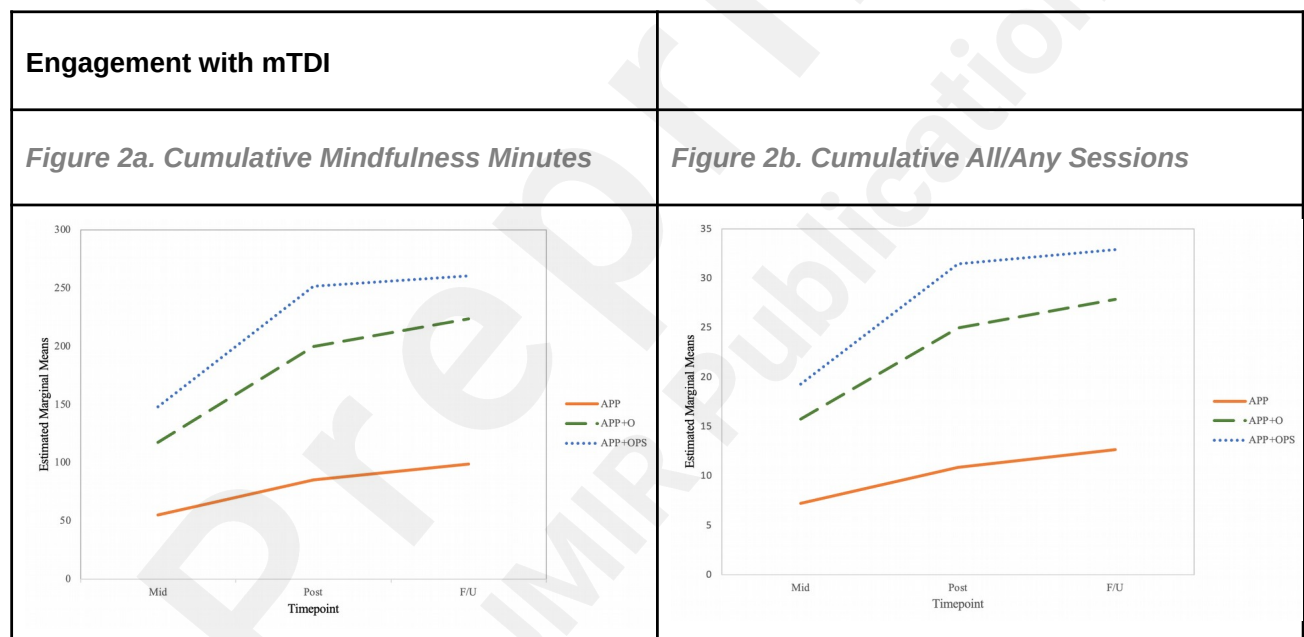
[a, b] Pairwise contrasts with different letters/superscripts are significant, after Bonferroni adjustment for multiple comparisons.

† $\eta^2 \geq 0.01$ (small effect), †† $\eta^2 \geq 0.06$ (medium effect).

* meets criteria for Bonferroni adjustment significance (ie, $P < .0055$).

Figure 2

Group Means by Time (Mid-, Post-Intervention, and 1-Month Follow-Up; F/U), for participants randomized to use the app without human support enhancement (APP, solid orange line), participants randomized to attend a one-time orientation (APP+O, dashed green line), and participants randomized to attend the orientation and be placed in a Peer Supportive Accountability group (APP+OPS, dotted blue line). Y-axes for cumulative mindfulness minutes and cumulative any/all sessions are totals, whereas Y-axes for all other outcomes reflect the scale mean with a range of 1 to 5.



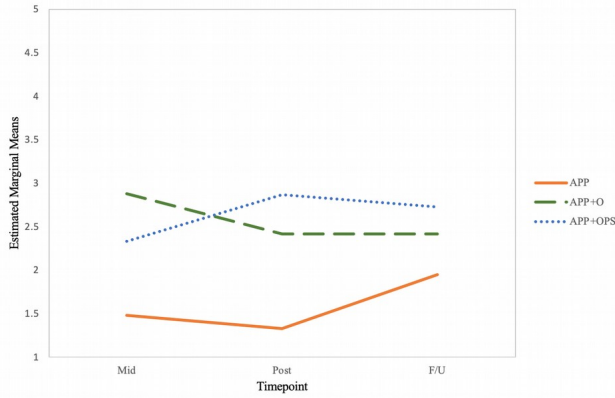
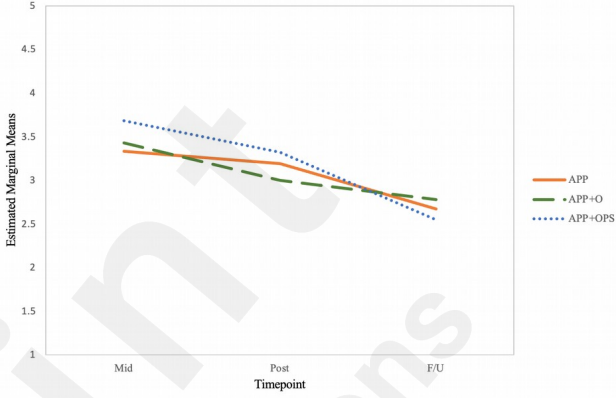
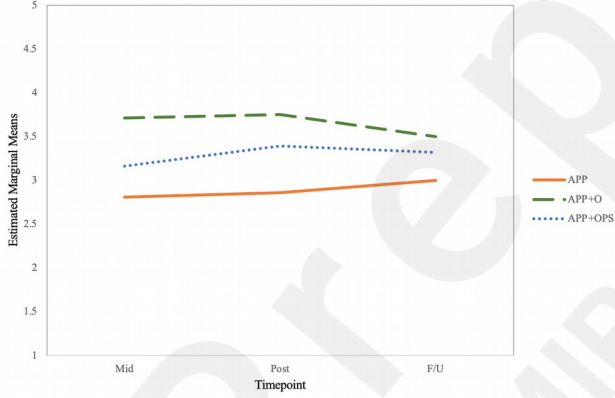
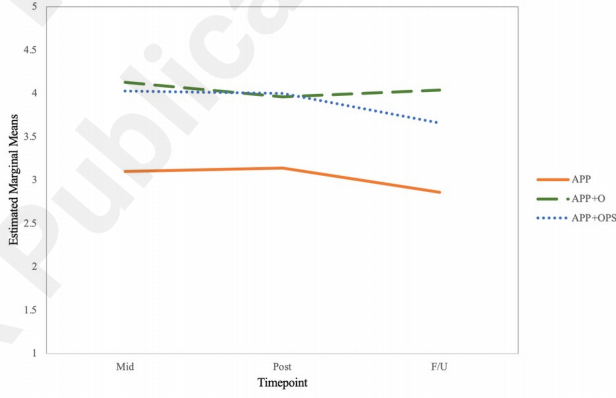
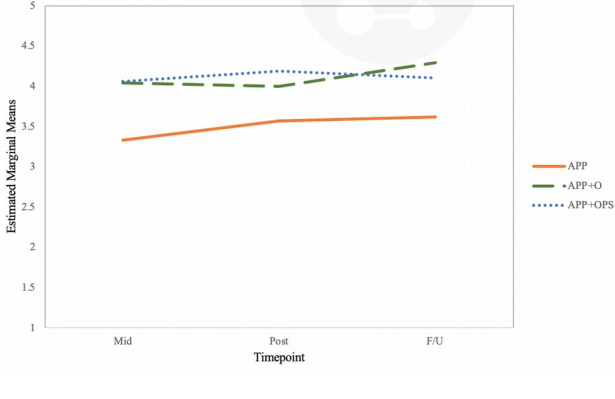
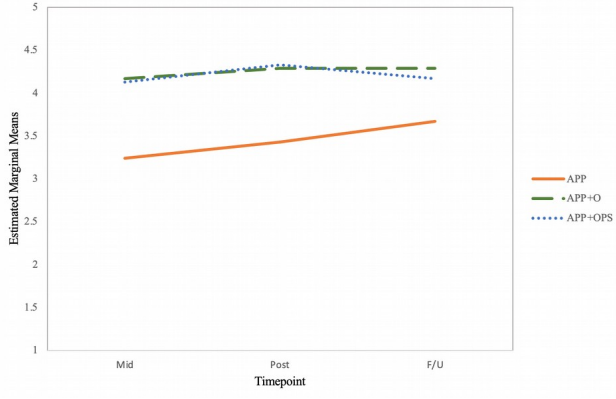
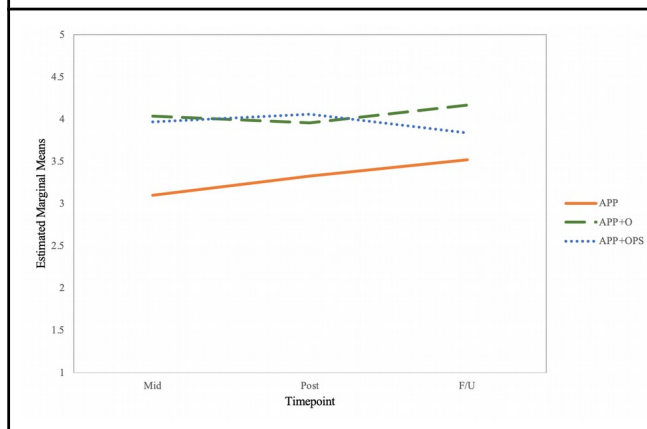
Practice Integration [Sustainability]	
Figure 2c. Self-Reported Everyday Mindfulness	Figure 2d. Future App (Headspace) Use
	
Figure 2e. Future Mindfulness Practice on Own	Figure 2f. Future Mindfulness in Life
	
Skill Learning [Perceived Benefits]	
Figure 2g. Learned About Mindfulness	Figure 2h. Learned Mindfulness Skills
	

Figure 2i. Awareness of Thoughts & Feelings

Practice Integration [Sustainability]

As shown in Table 2, with means and standard deviations, there was an overall effect of group (human support condition) on self-reported everyday non-guided mindfulness practice. Pairwise comparisons, with conservative Bonferroni correction, indicate that APP participants engaged in significantly less non-guided mindfulness practice than APP+O ($P=.02$) and APP+OPS ($P=.005$) participants, but everyday non-guided mindfulness practice did not significantly differ between APP+O and APP+OPS groups ($P=1.00$; see Figure 2c).

There was no effect of group (human support condition) on self-reported likelihood to use the Headspace app in the future, $F_{2,72}=0.11$, $\eta^2 = .003$, $P=.89$ (see Figure 2d). Meanwhile, the effect of group on self-reported likelihood to practice mindfulness exercises on one's own in the future was right at the cutoff of statistical significance, with a medium effect size, $F_{2,73}=3.10$, $\eta^2=.08$, $P=.051$. Pairwise comparisons indicate that APP participants were significantly less likely to believe they would engage in mindfulness exercises on their own in the future, compared to APP+O ($P=.045$) participants. APP+OPS participants did not differ from APP ($P=.51$) or APP+O participants ($P=.60$; see Figure 2e).

There was an overall effect of group (human support condition) on self-reported likelihood of future mindfulness in everyday life, $F_{2,71}=7.42$, $\eta^2=.17$, $P=.001$. Pairwise

comparisons indicate that APP participants were less likely to believe they would engage in everyday mindfulness in the future than APP+O ($P=.002$) and APP+OPS ($P=.006$) participants. APP+O and APP+OPS groups did not differ ($P=1.00$; see Figure 2f).

Skill Learning [Perceived Benefits]

As shown in Table 2, there was an overall effect of group (human support condition) on the extent to which participants reported they had learned about mindfulness through the intervention, $F_{2,73}=6.02$, $\eta^2=.14$, $P=.004$. Pairwise comparisons indicate that APP participants endorsed learning less about mindfulness than did APP+O ($P=.01$) and APP+OPS ($P=.007$) participants, and APP+O and APP+OPS groups did not differ ($P=1.00$; see Figure 2g).

Similarly, there was an overall effect of group (human support condition) on the extent to which participants reported they had gained mindfulness skills through this intervention, $F_{2,72}=11.01$, $\eta^2=.23$, $P<.001$. APP participants endorsed gaining mindfulness skills to a lesser extent than did APP+O ($P<.001$) and APP+OPS ($P<.001$) participants, and APP+O and APP+OPS groups did not differ ($P=1.00$; see Figure 2h).

Finally, there was also an overall effect of group (human support condition) on the extent to which participants reported they had gained awareness of their thoughts and feelings through this intervention, $F_{2,73}=6.05$, $\eta^2=.14$, $P=.004$. APP participants endorsed gaining this awareness to a lesser extent than APP+O ($P=.006$) and APP+OPS ($P=.01$) participants, and APP+O and APP+OPS groups did not differ ($P=1.00$; see Figure 2i).

Discussion

Summary of Findings

This study demonstrated that empirically driven human support enhancements can increase (a) engagement within an mTDI, (b) integration of intervention practice in daily life, and (c) learning, including perceived intervention-based awareness and skills. Specifically, this

study found that users randomized to attend a 90-minute, face-to-face orientation session to the mTDI – whether with or without additional randomization to be in a peer supportive accountability group – demonstrated significantly higher (a) intervention engagement, including total minutes of mindfulness content, and total number of sessions overall, (b) integration of intervention practice into everyday life, both currently and anticipated in the future, and (c) learning about mindfulness and related skills, and awareness of thoughts and feelings. Among participants randomized to attend an orientation, those who were further randomized to peer supportive accountability groups exhibited higher mean scores on app use across the trial assessment points, but this was not a significant difference. Further, participants randomized to either of the human support-enhanced conditions generally demonstrated significant benefits for integration of skills and perceived learning, compared to those randomized to use the app alone, but there were no significant differences between these 2 enhanced groups. These findings highlight the varied benefits of including human support in otherwise self-guided digital mental health interventions, but leave open important questions about the connections among human support, engagement, and broader benefits for daily life integration and learning.

mTDI Engagement, Practice Integration, and Skill Learning: Understanding and Optimizing Connections

This study builds on the extensive evidence base demonstrating *that* mTDIs, and mindfulness-based mTDIs specifically, have numerous benefits[1–3] and contributes to emerging research on *how* best to harness these benefits, both for increased engagement within the mTDI and for extended benefits into daily life. This study demonstrated broad benefits for human support on in-app engagement and real-life learning and applications of the intervention skills. These findings help advance our understanding of mTDI implementation science, yet also point to the need for continued research to better understand - as described in the sections below - (1) the *active ingredients* of human support enhancements, including (2) *supportive accountability*,

and (3) the *optimal dosage* or level of mTDI engagement.

Active Ingredients of Human Support: What Promotes Success?

This study contributes to an emerging field of research attempting to better understand the active ingredients or mechanisms driving the benefits of human support. A recent review highlighted that including human support features that provide guidance (such as this study's orientation session) and foster social connectedness (initiated in this study's orientation session, and deepened by the peer supportive accountability group) facilitate program engagement.[16] It is likely that human support serves, in part, to provide *reminders* for program engagement, which in turn enhance outcomes like engagement, skills learning, and future intended practice.[2] However, it is notable that in this study, participants in the APP+OPS group, who received frequent cues for mTDI engagement via the Facebook group, email digests, and in-person peer meetings, did not exhibit additive benefit beyond the orientation. These findings might indicate that receiving *personal, interactive guidance* at the onset was a critical ingredient for engaging with a new mTDI, similar to other research.[54] Navigating the initial set-up of an mTDI and exploring its content can be overwhelming, especially when lacking guidance and feedback.[55] Similarly, receiving this guidance from research staff early on may have enhanced the *credibility* of the mTDI, which has been linked to greater interest in downloading and using the mTDI[56] as well as continued engagement over time.[57] Having our team of trained interventionists conduct the orientation session may have been particularly impactful on building credibility since the mTDI may have been viewed as having expert endorsement.[56]

In line with prior evidence on the benefits of brief motivational enhancement interventions for mTDI engagement,[36–38] it is also plausible that the *content* of the orientation helped promote participant engagement in the mTDI. Overall, this study adds support for the utility of providing an initial orientation session with participants in order to provide

psychoeducation about the skills incorporated into the mTDI, build familiarity with the mTDI, provide guidance related to engagement, and to foster motivation and connection. This represents an important step in examining and comparing the effects of different components of human support, though future research is needed to isolate the specific active ingredients of the orientation, including credibility, personalized guidance, motivational enhancement, and proactively addressing challenges and barriers. Within the larger field of digital mental health, it is increasingly recognized that human support features vary widely across studies and few adequately describe what exactly these features entailed.[23] As a result, the effects of such enhancements have been mixed, with some studies finding benefits and others not, as reviewed by Bernstein and colleagues.[23] Clarifying the impact of human support and the active ingredients of such support will also inform the answers to questions such as who should provide support (eg, peer, paraprofessional, professional), when it should be provided (eg, once at the beginning or interspersed throughout the intervention), and the content or focus of the support (eg, providing psychoeducation, offering encouragement, evoking motivation, helping with problem-solving). Ultimately, the answers to such questions are likely to be complex and will require future research exploring how individual differences interact with support enhancements.

The Impact of Supportive Accountability on mTDI Engagement

Although participants in the APP+OPS group used the app more than did those in the APP+O group, this was not a significant difference. This finding suggests little additional benefit of the peer supportive accountability group above and beyond the orientation alone. However, there are many considerations when interpreting this finding. First, it is possible that the APP+OPS group may have experienced other, intangible benefits beyond impact on objectively captured mTDI engagement. For example, participants in the APP+OPS group overwhelmingly indicated that they enjoyed connecting with other students over shared experiences and generally

found the group to be helpful and supportive.[58] This corroborates prior findings that peer supportive accountability is typically viewed positively by participants.[25,30,42] Second, the orientation allowed for some interaction with peers, including fellow participants as well as student members of the research team, so APP+O participants may have experienced some degree of peer supportive accountability as well. This study design is not fully sufficient to tease apart the impact of peer supportive accountability alone, and more research is needed on how best to harness its potential benefits.

Third, this study's findings may reflect the utility of integrating supportive accountability from a trained team of clinical *researchers*, without the additional benefit of adding supportive accountability from *peers*. Although all of the intervention groups, including those who used the mTDI without an orientation session (APP), had some degree of researcher contact across the trial (eg, for study consenting and assessment administration), the orientation session may have fostered a greater sense of participant accountability to the clinically trained research team, who facilitated the orientation. This is in line with reviews of mTDIs generally, which find that participants who enroll in mTDIs without any research contact show significantly higher attrition rates over time compared to participants who enroll through contact with research staff.[14] Those users who get started without researcher contact may not fully appreciate the effort and internal motivation that will be required to begin and sustain engagement over time[14], whereas researchers may be able to provide a more realistic picture to participants who do have contact with them. Therefore, it is critical to consider how human support enhancements may be implemented beyond the research context. Engagement with mTDIs is significantly improved by the structure and containment of research trials as compared to engagement with the same programs in the "real world"[11], so finding ways to translate the benefits of an orientation session to the everyday mTDI user will be important.

This study's findings also raise questions about when, as well as how, to integrate human

support. These findings suggest that initial support as users are beginning a new mTDI (eg, an orientation) may be more beneficial for sustained engagement than continued support over time. Further, with high levels of human support throughout the intervention, users could become reliant on external motivation and then decrease or stop engagement when the support is removed. In this study, the APP+OPS group experienced a stark drop in human support, and likely supportive accountability, at the 2-month mark when they stopped meeting and receiving email digests and posts in the online forum. Although app use tapered in all groups during the follow-up period, the decline was visually steepest for the APP+OPS group. Though the pairwise contrasts between APP and APP+O groups were not statistically significant, this pattern is worth investigating in future research. Perhaps there is an optimal level of human support that, when tapered gradually, is conducive to sustaining mTDI engagement longer term.

Optimal Dosage of mTDI Engagement

Although certainly some level of engagement is needed to see benefits, the **optimal dosage** of mTDI use remains an open question. Research has recently begun to move beyond investigating the overall efficacy of mTDIs and toward exploring the dose-response relationship between mTDI engagement and outcomes.[59] Oftentimes, there is an implicit assumption that more is better, but there is little understanding of the dose-response effect between mTDI engagement and outcomes, and therefore the ideal amount of mTDI use.[60,61] More research is needed to better understand the complex relations between usage and treatment response in order to promote optimal engagement and benefits.

There also remain questions about the reasons driving drop-offs in engagement after initial periods of use.[62,63] Declining mTDI use over time may not necessarily be indicative of a user's disinterest in a program, lack of progress, or symptom severity. To the contrary, some users may have internalized the skills learned through the app, or otherwise met their goals (eg,

behavioral change, symptom improvement), such that they no longer need to rely on the mTDI for support. Similar to attending psychotherapy sessions, mTDIs can be viewed as training wheels that provide users with psychoeducation and skills learning and practice. This, in turn, allows users to create personal wellbeing habits beyond the intervention, such as practicing mindfulness or other intervention skills in daily life – outside of an mTDI and beyond trial periods – as evidenced in this study. Thus in some cases, dwindling use of an mTDI after initial engagement might, in fact, be a marker of success. At a minimum, relying only on objectively measured app use through mTDI user data likely does not capture the full scope of individuals' engagement with the intervention content. Similar to this study, others have begun to incorporate additional self-report measures of skills practice outside of mTDIs and find that this is an important element in predicting benefits.[61,64]

Limitations and Future Directions

This study employed a rigorous RCT design with intent-to-treat analyses on multiple indicators of mTDI engagement and benefits, including objectively measured app use and self-reported practice integration and skill learning, into a 1-month follow-up period, yet there are important limitations to address as well. First, although the RCT is considered a gold standard in establishing general intervention effects, other research is important for evaluating diverse intervention benefits (eg, dose-response effects, clinical utility, social validity), as well as revealing processes and mechanisms of change. Future research should continue to explore various designs with a broader array of outcomes, and more diverse samples, in order to improve generalizability. Second, it is important to note that the onset of the COVID-19 pandemic occurred during the sixth semester of data collection, necessitating changes (eg, virtual data collection, orientation, and APP+OPS meetings) impacting cohorts 6-8. Third, although mTDIs provide methodological benefits by tracking engagement and skills practice within the app, data

recording errors can occur. For example, 3 participants were excluded from mTDI engagement analyses due to glitches with their app-recorded usage data. It is possible that other data-tracking errors could have occurred without the researchers' knowledge. Similarly, it is possible that participants could be inattentive, distracted, or asleep during some of the practices recorded by the app. Fourth, although the broad recruitment strategies and voluntary response sampling method has benefits for generalizability, this also yielded a largely female sample (reflecting both a higher percentage of women in college and meeting criteria for depression), which limits generalizability in other ways. Related, not all participants completed the surveys assessing their own reports of practice integration and skill learning, further limiting the generalizability of findings.

Fifth, it is also important to note that the APP condition included participants who activated their Headspace access code at the same time as the rest of the cohort as well as a subset of participants who accessed their code *after* a 3-month waitlist period. Although analyses did not reveal any significant differences in mental health symptoms between APP participants who could access Headspace immediately compared to those who waited 3 months, it is possible that combining these 2 groups may have affected the results of the APP condition, particularly since prior research suggests that intervention engagement can be negatively impacted by time spent waiting for services.[65]

Sixth, and related, the 3 randomized groups were nested, such that participants in all 3 groups received the base intervention (APP), 2 of the nested groups attended an orientation (APP+O, and APP+OPS), and 1 of these nested groups included additional peer supportive accountability features (APP+OPS). Analyses tested for the incremental benefits of the 2 human support enhancements, yet future research might benefit from examining the benefits of an APP+PS condition without an orientation session.

Finally, this study's implementation of peer supportive accountability had some

limitations that may have reduced the potential impact of the group on mTDI engagement and integration of skills. The online forum included a “leaderboard” feature that displayed each member’s use of the app from the current week and the trial period overall. This may have promoted external motivation, which is typically not as effective as intrinsic motivation for sustained engagement.[16] This type of feature also may function differently for those experiencing depression compared to other mental health symptoms. Given that self-criticism and negative self-concept are common for those with depression,[66,67] having progress metrics shared with the larger group may have been perceived as discouraging rather than motivating. Additionally, the use of Facebook for the online forum, which was chosen for this study due to its social connection and privacy features, may have made engagement with the peer group more difficult for these young adult participants, for whom Facebook is becoming increasingly less popular.[68] Future studies should explore alternative platforms for online interaction among participants, ideally integrating all peer support features into the mTDI.

Future research should explore whether the benefits of human support, such as those demonstrated in this study, might also be harnessed with automated support, whether pre-programmed or assisted by interactive artificial intelligence. Beyond the more readily automatized elements such as providing information and reminders, research on the benefits of human support tends to emphasize more complex elements such as personalized prompts, interactive coaching, and professional guidance.[2,23,35,54,55,69] Notably, recent advances in artificial intelligence and machine learning might allow for transfer of some human support elements and benefits to automated programming.[2] Importantly, these developments raise crucial ethical and societal concerns that must be addressed.[70]

Clinical Applications and Research Implications

This study’s findings have important implications that move beyond foundational

research on *whether* to utilize mindfulness-based mobile apps in clinical intervention work, by investigating *how* best to maximize their benefits, such as through brief face-to-face orientations and through small-group peer support networks. These results can be applied more broadly to mTDIs and also are likely to extend to other user populations. For example, the peer supportive accountability model implemented here – with the notable request for more face-to-face contact by the participants themselves – might be similarly relevant for mTDI users who share a common identity or life circumstance, such as high school students, employees, veterans, parents, or medical patients.[26,27,29]

Boosting mTDIs with human support features has numerous applications in various settings and with diverse people who can serve to support engagement and thus enhance benefits. For example, many healthcare systems allow for providers within different departments (eg, behavioral health, primary care, speciality clinics) to refer patients to mTDIs as a means of addressing lower severity symptoms, supplementing pre-existing mental health services, or bridging the patient to other levels of care, such as while they are on a waitlist.[71] Similarly, many employers now offer mental health mTDIs as part of their health insurance package,[72] and there is emerging research on integrating mental health care into routine curricular and extracurricular settings on college campuses.[73–75] While mTDIs are increasingly incorporated into non-traditional settings, the typical approach is simply to provide individuals with access to the mTDI, leaving users to download and engage with the program on their own. Findings from this study suggest that evidence-based mTDIs can be even more effective, and have a more powerful reach and impact, if supplemented with human support. For example, professionals, paraprofessionals (without a mental health degree), or peers can serve as coaches for engaging in evidence-based mTDIs through routine settings such as primary care clinics,[76] workplaces,[54] and college student academic services.[77] This study also suggests that an initial, one-time group introduction to the mTDI conducted by a knowledgeable source can produce a myriad of

benefits, and represents a cost-effective and scalable option for larger institutions. For example, hospitals and clinics, schools and community agencies, and corporate and non-profit organizations can pair their offerings of mTDIs with regularly occurring orientation sessions that assist new users in accessing the program, demonstrate the app and its features, answer questions, and elicit motivation. This would allow for many potential users to join at once, thus improving efficiency, and might also boost social connection and a sense of community – which in turn would promote mTDI use and wellbeing more broadly.

Conclusions

While mTDIs have great promise for increasing access to wellbeing interventions, relatively low rates of user uptake and engagement are current barriers to achieving the potential reach and impact of mTDIs. The results of this study illustrate that human support – particularly an initial face-to-face orientation session that provides psychoeducation, builds familiarity with the mTDI, and promotes motivation and connection – boosts mTDI engagement, enhances integration of intervention practice in everyday life, and increases skill learning. Future work is needed to determine the active ingredients of the orientation (eg, credibility, personalized guidance, motivational enhancement, proactive problem-solving) that might drive increased levels of engagement and the associated positive intervention benefits. Identifying optimal intervention dosage levels for evidenced-based mTDIs also remains critical to fully harness the potential of these interventions and their role in improving societal health and wellbeing.

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Abbreviations

APP: app as usual

APP+O: app + orientation

APP+OPS: app + orientation and peer support

MI: motivational interviewing

mTDI: mobile technology-delivered intervention

PHQ: Patient Health Questionnaire

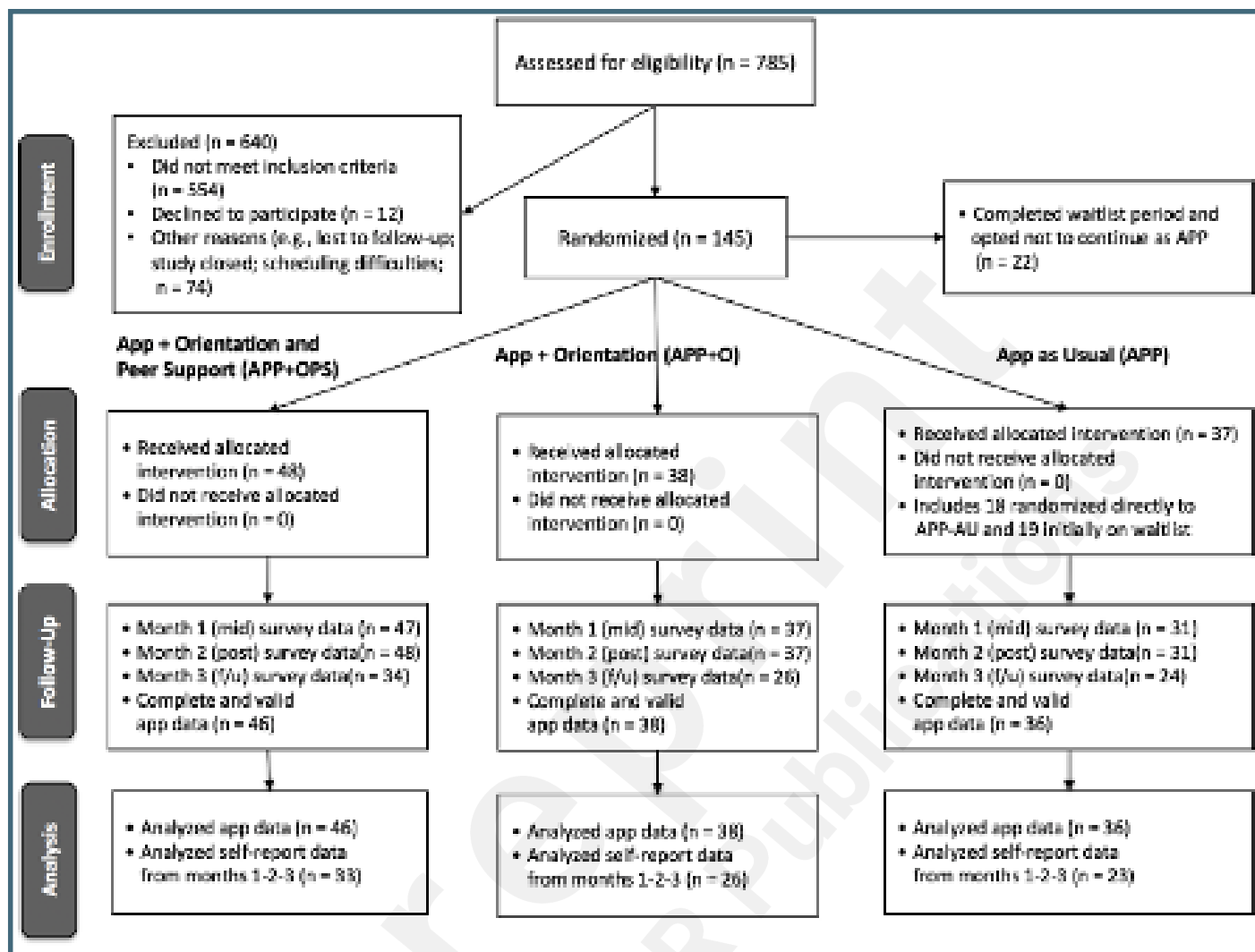
RCT: randomized controlled trial

TDI: technology-delivered intervention

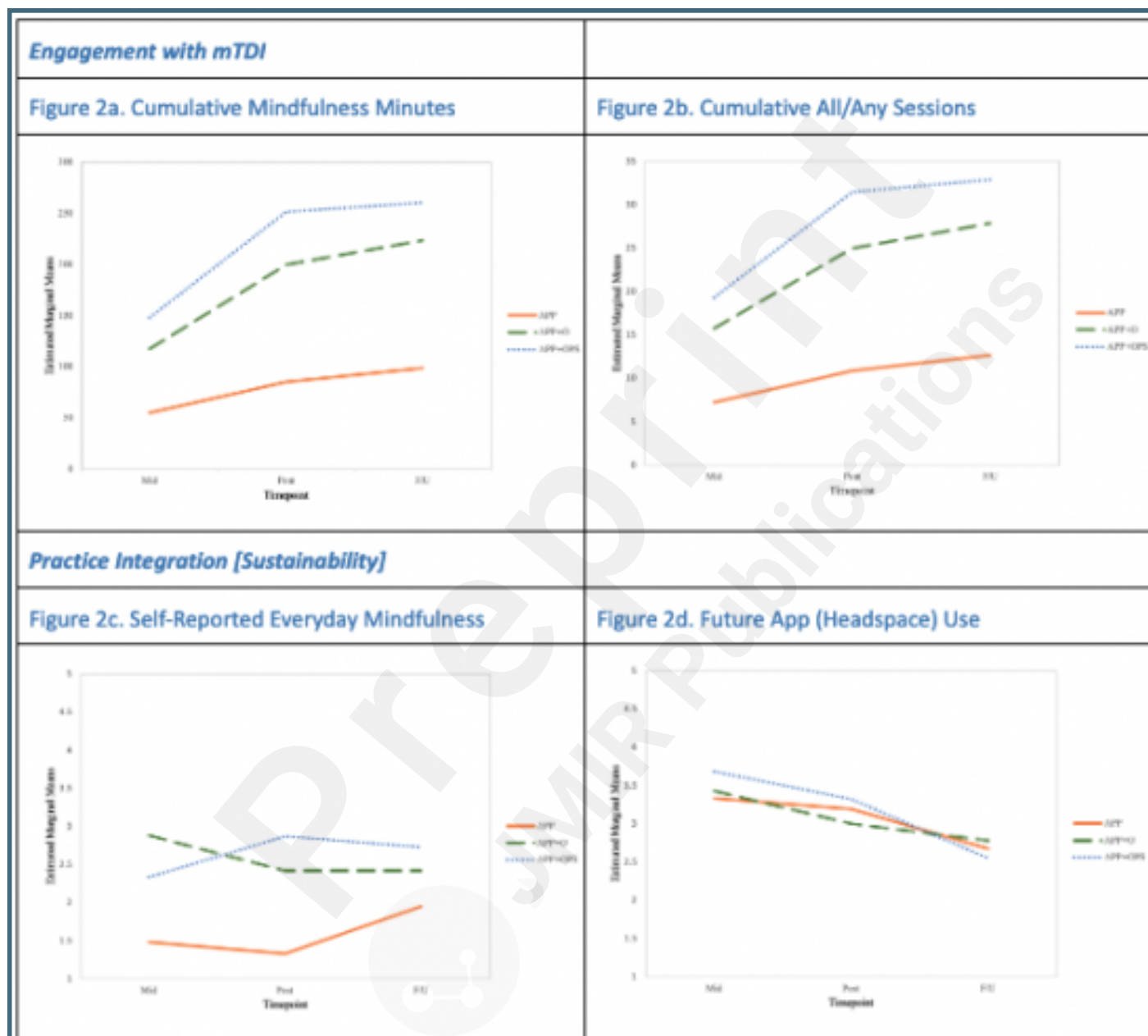
Supplementary Files

Figures

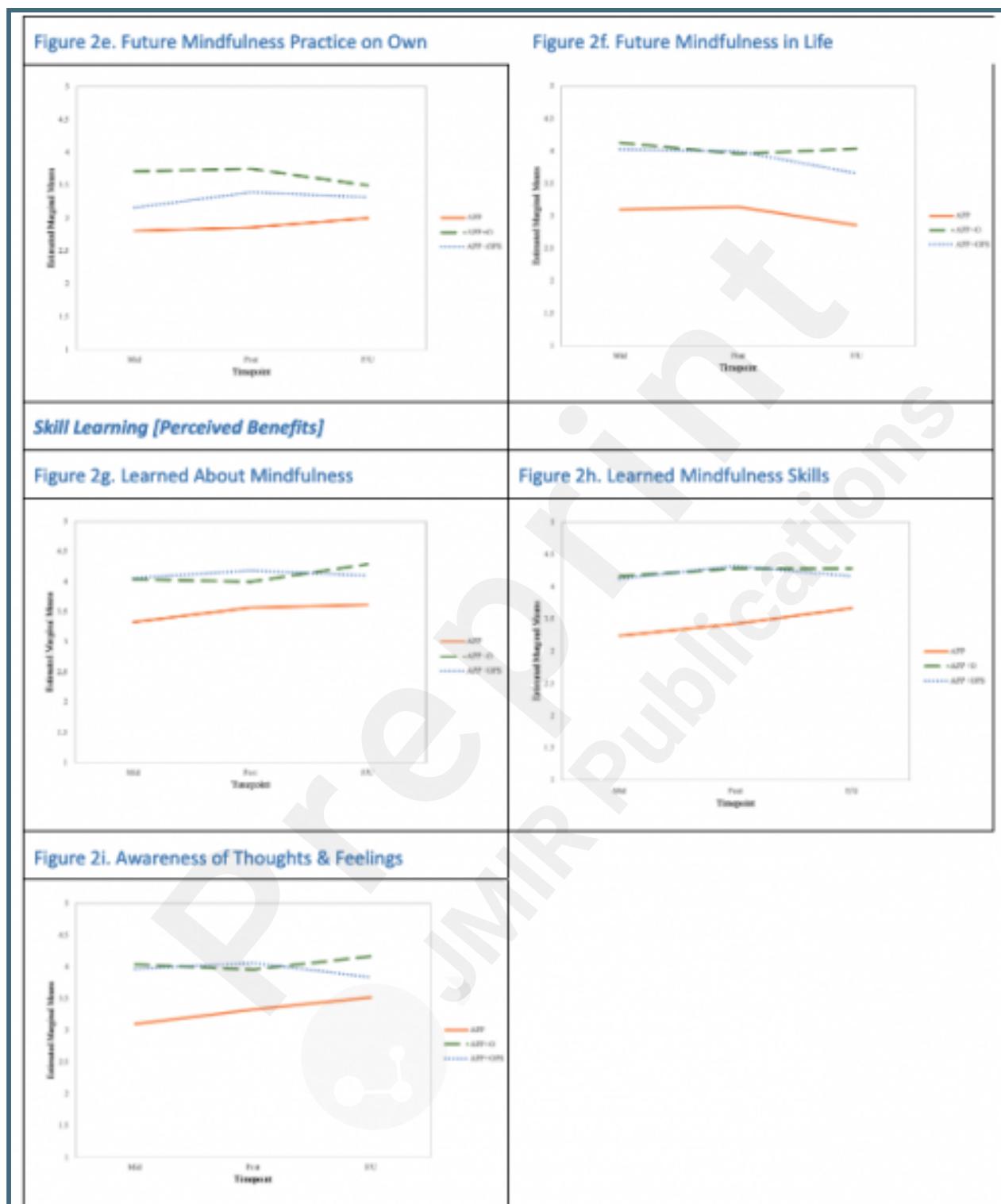
CONSORT Flow Diagram.



Group Means by Time (Mid-, Post-Intervention, and 1-Month Follow-Up), for participants randomized to use the app without human support enhancement (APP, solid orange line), participants randomized to attend a one-time orientation (APP+O, dashed green line), and participants randomized to attend the orientation and be placed in a Peer Supportive Accountability group (APP+OPS, dotted blue line). Y-axes for cumulative mindfulness minutes and cumulative any/all sessions are totals, whereas Y-axes for all other outcomes reflect the scale mean with a range of 1 to 5.



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Multimedia Appendixes

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CONSORT (or other) checklists

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CONSORT checklist updated for November 2024 resubmission.

URL: <http://asset.jmir.pub/assets/ed13906f0f59e9f58dfa11f0d5df6b24.pdf>