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# Evaluating the efficacy of a smartphone mental health app, mindLAMP, in reducing anxiety and depression symptoms

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#### **BOSTON UNIVERSITY**

## ARAM V. CHOBANIAN & EDWARD AVEDISIAN SCHOOL OF MEDICINE

Thesis

# EVALUATING THE EFFICACY OF A SMARTPHONE MENTAL HEALTH APP, MINDLAMP, IN REDUCING ANXIETY AND DEPRESSION SYMPTOMS

by

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B.S., University of California, Davis, 2019

Submitted in partial fulfillment of the

requirements for the degree of

Master of Science

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# DEDICATION

I would like to dedicate this work to my family and friends.

# EVALUATING THE EFFICACY OF A SMARTPHONE MENTAL HEALTH APP, MINDLAMP, IN REDUCING ANXIETY AND DEPRESSION SYMPTOMS SARAH CHANG

#### ABSTRACT

**Background:** Despite the growing popularity and widespread adoption of mobile mental health apps, there is still insufficient high-quality evidence demonstrating their safety and efficacy.

**Aims:** This exploratory analysis investigates the potential effect size of mindLAMP, a smartphone mental health app, on reducing symptoms of depression and anxiety by comparing the results of using mindLAMP in a control implementation and in a intervention implementation.

**Methods:** A total of 238 participants were eligible and finished the study in the control implementation, while 156 participants completed the study in the intervention implementation of the mindLAMP app. All participants (both groups) had access to the same in-app activities, including self-assessments and therapeutic interventions. **Results:** After multiple imputation, analysis revealed significant minor effect sizes of Hedge's g = 0.21 and Hedge's g = 0.34 in the reduction of depression and anxiety symptoms respectively.

**Conclusions:** MindLAMP demonstrates a promising potential in reducing symptoms of depression and anxiety. Additionally, this study underscores the adaptability, reusability, and scalability of smartphone apps, as they can be implemented in diverse settings. These results serve as a basis for further research to examine the effectiveness of not only

mindLAMP but also other mental health apps in addressing symptoms of depression and anxiety.

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#### **INTRODUCTION**

#### **The Prevalence of Mental Illness**

Depression and anxiety are pervasive health conditions that burden individuals and countries across the globe. According to the World Health Organization, depression affected roughly 4.4% of the global population in 2017 while anxiety affected 3.6% (World Health Organization, 2017). Roughly 20% of individuals across the globe met the criteria for mental disorder within a 12-month period, increasing to 30% when considering an individual's lifetime (Steel et al., 2014). Similarly, the National Survey on Drug Use and Health 2021 found that 22.8 percent of surveyed individuals in the United States reported a mental illness in the past year (Substance Abuse and Mental Health Services Administration, 2021). Even before the coronavirus (COVID-19) pandemic began to unfold, the prevalence of mental illness was expanding (Goodwin et al., 2020; Goodwin et al., 2022; Santomauro et al., 2021; Vahratian et al., 2021; Weinberger et al., 2018)

#### **The COVID-19 Pandemic**

Numerous studies have explored the negative impact that the COVID-19 pandemic has had on people's mental health (Santomauro et al., 2021; Vahratian et al., 2021). The onset of the pandemic brought about widespread and significant upheaval in people's daily routines including lockdowns, social distancing, social fragmenting, remote work, and job loss.

A large number of studies have come to the consensus that people's mental health declined over COVID-19. Yet even today, a growing fraction of adults in the United

States have reported experiencing symptoms of anxiety and depression, particularly in young adults (Vahratian et al., 2021). In fact, the incidence of major depressive disorder and anxiety disorders during COVID-19 has increased by 27.5% and 25.6% respectively (Santomauro et al., 2021). A systemic review by Ettman et al. also revealed higher rates of depression during COVID-19 from spring 2020 to spring 2021 in the United States (Ettman et al., 2023). In 2023, the CDC announced that adolescent girls were experiencing the highest ever recorded levels of sadness and suicide risk (CDC, 2023).

The COVID-19 pandemic not only exposed the inadequacies of current mental healthcare systems, but also exacerbated pre-existing issues (Pujolar et al., 2022). The pandemic made it more difficult for individuals to access mental health services due to lockdowns, social distancing, and an overwhelmed healthcare infrastructure (Aragona et al., 2020). Furthermore, the pandemic disproportionately impacted vulnerable populations, including individuals with lower socioeconomic backgrounds, minority groups, and those with pre-existing medical conditions, many of whom already faced barriers in accessing mental healthcare services (Aragona et al., 2020).

#### **The Price of Mental Illness**

On both an individual and societal level, mental illness is associated with significant financial burden. At the personal level, receiving treatment can be costly and as a result, these expenses have been cited as common a barrier to treatment (Coombs et al., 2021; SAMHSA, 2021). However, the personal challenges associated with mental illness extend beyond financial costs. There are also subtle or intangible personal burdens that accompany mental illness. Mental illness has been linked to lower educational

attainment, difficulties in personal relationships, reduced work performance, lower income, and unstable employment (Balkaran et al., 2021; de Oliveira et al., 2022; Mokoena et al., 2019; Seabury et al., 2019). Furthermore, evidence was found for a twoway causal relationship between poverty and mental illness (Ridley et al., 2020), and family members who often provide support may also experience emotional and financial burden as a result of caregiving. (Balkaran et al., 2021). All in all, these challenges create additional stress for individuals already struggling with mental health conditions and often exacerbate financial burdens.

It has also been well established that mental illness affects physical wellness. The current literature suggests that individuals with depression and anxiety have a higher risk for chronic conditions such as hypertension, congestive heart failure, cancer, chronic kidney disease, arthritis, diabetes, and stroke (Bobo et al., 2022). Having a physical illness itself is costly and further compounds any financial issues (Armbrecht et al., 2021). Additionally, mental illness, including depression and anxiety, have been associated with an increased risk of mortality as highlighted in a systemic review by Walker et al. (2015b).

Depression and anxiety not only have significant costs on a personal level, but also impose a substantial burden on society as a whole. Employees struggling with their mental health have both more days out of work and a lower level of productivity even when present at work (de Oliveira et al., 2022). The estimated annual capital loss due to employee absences and lowered productivity associated with depression exceeded 90 billion dollars (Evans-Lacko & Knapp, 2016). It is so costly that in 2013, United States

government spending on mental disorders surpassed that of any other health conditions including cardiovascular disease and cancer (Roehrig, 2016). This massive expense continues to grow; researchers have found that the economic burden of individuals with major depressive disorder increased by almost 40% to 326 billion from 2010 to 2018. The authors further concluded that this may be due to more adults experiencing depression and the fraction of those who remain untreated growing (Greenberg et al., 2021).

Overall, mental illness is a costly and profound issue that adversely affects both individuals and society. Despite the significant impact, not enough is being done to stem this growing problem and mental illness remains a pervasive issue.

#### **Unmet Need and Barriers to Care**

While there has been greater awareness and progress in treatment options, a considerable proportion of individuals with mental illness remains untreated, warranting public concern (Kohn et al., 2018; SAMHSA, 2021; Walker et al., 2015a). Numerous studies have revealed that a significant (estimates of 30 to 60 percent) fraction of individuals suffering from any mental illness reported being unable to access mental health services despite expressing a desire to do so (Kohn et al., 2018; SAMHSA, 2021; Walker et al., 2015a), and this unmet need continues to grow (Goodwin et al., 2022). This has led to a further widening the gap between the need for and the accessibility of mental health care services (Kohn et al., 2018; Goodwin et al., 2022).



**Figure 1. Perceived Unmet Need in Individuals.** From Key substance use and mental health indicators in the United States: Results from the 2020 National Survey on Drug Use and Health by Substance Abuse and Mental Health Services Administration, 2021. (https://www.samhsa.gov/data/). Public Domain.

The underlying reasons for the widening treatment gap are complicated and

multifaceted. Despite this complexity, a number of barriers preventing individuals from

accessing care have been consistently highlighted in the current literature.

The most commonly reported barrier is the lack of treatment affordability

(Coombs et al., 2021; SAMHSA, 2021). These treatment costs can be prohibitively high,

particularly for those without insurance coverage (Walker et al., 2015a). The pandemic

has only continued this trend by causing financial instability, and thus further

exacerbating the pre-existing financial barrier (Lu & Lin, 2021).

The stigma associated with mental illness is another factor preventing individuals from seeking treatment (Crowe et al., 2016). The negative beliefs and attitudes toward mental illness can spawn negative stereotypes and discrimination towards those with mental illness. This may lead to a reluctance to discuss mental health issues and to get treatment, and even if an individual does seek out treatment, they may not be fully engaged due to fear of stigma (Dixon et al., 2016).

In addition to affordability and stigma, the scarcity of mental health professionals is another well-documented barrier to mental healthcare access (Butryn et al., 2017). A 2020 report by SAMSHA noted that the United States would need to train and hire over 4 million individuals into the workforce to be able to provide evidence-based care to all individuals currently suffering from a serious mental illness (SAMHSA, 2020). This workforce shortage is even more of an issue in underserved and rural communities (Moberly et al., 2019). Studies have shown that there are fewer mental health professionals available in rural areas compared to those of urban areas (Andrilla et al., 2018; Moberly et al., 2019). This can lead to longer waitlists and a higher burden on primary care physicians who may not be well equipped with mental health training (Butryn et al., 2017). Additionally, areas with mental health professional shortages experienced higher suicide rates (Ku et al., 2021).

The aforementioned barriers are only a few of the many barriers to care. Often, there are other obstacles to receiving care or a combination of factors that hinder access (SAMHSA, 2021). The sheer number and complexity of these barriers emphasizes that action should be taken.

#### **A Potential Solution: Digital Mental Health Tools**

To overcome a number of the barriers limiting access to mental health care, digital mental health tools have been proposed as an innovative solution. This involves utilizing technology such as smartphones and other wireless devices to assess symptoms, track symptoms longitudinally, and deliver therapeutic interventions (Wies et al., 2021; Bhugra et al., 2017). Digital mental health tools may take the form of wearable technology, smartphone applications, chatbots, text messaging interventions, and computer software. Of these digital mental health tools available, smartphone mental health applications have come to the forefront due to the various advantages they pose (Bughra et al., 2017; Chandrashekar, 2018). For nearly a decade, individuals have expressed an interest in utilizing such mobile apps to help manage their mental health (Torous et al., 2014), and this interest is well reflected in the plethora (over 10,000) of mental health apps currently available in the market (Torous & Roberts, 2017).

Utilizing smartphone applications as a mental health tool has various advantages (Bughra et al., 2017; Chandrashekar, 2018; Koh et al., 2022). Smartphones are ubiquitous, allowing for mental health apps to be easily accessible. The overwhelmingly majority of people have access to a smartphone with roughly 97% of Americans owning a mobile device and 85% owning a smartphone (Pew Research Center, 2021). Rates of smartphone ownership are nearly as high as the general population among those with mental illness (Iliescu et al., 2021). It is clear, then, that these apps represent a scalable means of increasing mental healthcare access.

On top of being easily accessible, smartphones have become an integral part of our daily lives owing to its ability to easily facilitate communication, provide information, and deliver entertainment. A study found that participants spent an average of 2 hours and 39 minutes on their smartphone each day (Deng et al., 2019). Most college students, on the other hand, spent greater than 4 hours on their smartphone each day (Aljomaa et al., 2016). Considering that smartphones are already heavily utilized, apps may allow individuals to incorporate mental healthcare into their daily lives in an unobtrusive and practical manner. Moreover, the portable nature of smartphones means that one could potentially access mental health care services at their convenience and in a discreet manner, regardless of location.

Smartphone mental health apps have also been notable in that they have the potential to overcome barriers that are present in accessing more traditional mental health resources. These apps also have the potential to be a cost-effective alternative to traditional mental health care services. As previously mentioned, one of the most common barriers to getting care is the cost (Coombs et al., 2021, SAMHSA, 2021). Mobile mental health apps are not only convenient to use but are also low cost, with the vast majority of mental health apps being free (Marshall et al., 2019). Apps, therefore, may serve as a convenient and low-cost introduction to mental healthcare.

Mobile mental health apps may also benefit those who may be hesitant to seek out mental health care services due to stigma. Apps may provide a private and discreet way of receiving care in the comfort of one's own home. Overall, the accessibility,

convenience, and low cost of mental health apps make them a promising solution for overcoming many of the traditional barriers to care.

#### **Benefits Beyond Overcoming Barriers:**

Mobile mental health apps have the potential to extend beyond that of overcoming barriers to accessing mental health resources. These apps could decrease the unmet need by benefitting individuals with milder symptoms, freeing up mental health care resources for those experiencing severe symptoms as literature has shown that technology-based treatment is efficacious in managing anxiety and depression (Firth et al., 2017a; Firth et al., 2017b). In particular, young adults, the group that reported the greatest amount of unmet need for mental health care, may benefit greatly from mental health apps (SAMHSA, 2021). Since they are more digitally literate, young adults may find it easy to adopt smartphone apps to manage their mental health as compared to other age groups (McDonough, 2016).

Another benefit of smartphone apps is that they can facilitate ecological momentary assessment (Moore et al., 2016), a research method that involves collecting data about individuals' experiences, behaviors, and environment in real time and in a naturalistic setting (Shiffman et al., 2008). This method has shown to be superior in reliability and validity of data compared to more traditional self-report methods, as it is not limited by recall bias (Shiffman et al., 2008). By leveraging EMA, mobile mental health apps could provide valuable data for both researchers and clinicians in assessing symptoms and treatment effectiveness over time (Moore et al., 2016).

In addition to all the advantages, numerous studies illustrating that smartphone apps may help individuals manage both anxiety and depression have emerged (Firth et al, 2017a; Firth et al., 2017b). Given the possible advantages and the emerging evidence, smartphone mental health apps clearly have the potential to provide substantial benefits to individuals struggling with anxiety and depression (Chandrashekar, 2018; Firth et al., 2017a; Firth et al., 2017b; Wies et al., 2021). Moreover, digital mental health tools could help stem the growing access problem by expanding care to a much wider audience.

#### The Need for More Evidence

The interest and research in digital mental health tools have been steadily increasing. Accordingly, there has been a noticeable increase in the amount of mental health apps available and utilization of mental health apps (Aziz et al., 2022; Sorkin et al., 2021). As a result, it has become even more critical that more research is conducted on the effectiveness and potential drawbacks of these tools.

Despite this, the research and following regulations have yet to catch up (Longyear and Kushlev, 2021). Research has consistently shown that most mental health apps do not have substantial evidence of efficacy (Marshall et al., 2020). The apps that do claim to be effective at diagnosing, managing, or improving mental health often do not have research to substantiate their claims (Larsen et al., 2019). In fact, a systemic review in 2020 found that only 2% of publicly available wellness and stress management apps have peer-reviewed research on efficacy (Lau et al., 2020). Similarly, Marshall and colleagues found that this number was roughly 3 percent (Marshall et al., 2019). Some commercial mental health apps purport the effectiveness of their apps in reducing anxiety

and depression by pointing to their conducted studies. However, this evidence is often questionable as these mental health apps available in the market typically lack high quality evidence (Larsen et al., 2019).

In general, the evidence for app efficacy, although promising, has often been hindered by research design limitations. There is no consensus on the best methods to explore the impact of apps on mental health, highlighting the need for further research in this area (Mohr et al., 2021; Torous et al., 2022). Meta-analyses have found that mental health apps have a small, but statistically significant effect on reducing symptoms of both anxiety(g=0.30-0.33) (Firth et al., 2017b; Linardon et al., 2019) and depression (g=0.27-0.39) (Firth et al., 2017a; Linardon et al., 2019; Six et al., 2021). However, upon closer examination, many of the studies analyzed suffer from a high degree of bias and do not have rigorous control groups (Eisenstadt et al., 2019) or treatment as usual controls (Moore et al., 2015) which are not as rigorous as active control groups.

The digital placebo effect highlights why active control groups are necessary to assess the effect size of mental health apps. The phenomenon refers to the potential for individuals to experience improvements in mental health simply due to the expectation that the digital intervention will be helpful (Torous & Firth, 2016). The digital placebo effect is well documented in a study that showed that a mental health app, PEAR-004 had no statistically significant effect when compared with a digital sham control. This "sham control" app simply displayed a digital clock on the app and did not provide access to any activities or interventions. Even then, upon comparing the intervention group with the sham control, there was no noticeable difference between the two in efficacy (Ghaemi et al., 2022). The digital placebo effect highlights the importance of having appropriate control groups when assessing efficacy.

On top of the need to have more high-quality evidence, there needs to be more regulation on these apps. Insufficient regulation of mental health apps may result in harming users. While the Food and Drug Administration has set some guidelines to regulate digital health tools, there are still gaps in the regulatory framework (Torous et al., 2022).



Figure 2. Frequency of Supporting Statement Categories Corresponding to Each Type of Effectiveness Claim. From "Using science to sell apps: Evaluation of mental

health app store quality claims" by Larsen et al., 2019, *npj Digital Medicine*, 2(1), 18. https://doi.org/10.1038/s41746-019-0093-1. CC BY 4.0.

In summary, there is a clear need to better understand the impact of mental health apps on outcomes, ensure access to evidence-based and safe digital mental health tools, and establish regulations to protect the consumers of these apps. As more research establishes the safety and efficacy, more people may become more willing to utilize mental health apps, allowing even more individuals to benefit from these digital mental health tools.

#### App Engagement

In addition to the lack of regulatory oversight, another significant problem plagues mental health apps; apps often struggle with low engagement. This is especially true in the context of naturalistic usage, which refers to how individuals use the app in their everyday lives (Torous et al., 2020; Nwosu et al., 2022; Aziz et al., 2022; Lattie et al., 2022). In fact, it was found that 95% of users stop using the mental health app after just 10 days (Baumel et al., 2019). Figure 3 depicts the steep decline in app retention just days after downloading an app.



**Figure 3. Mental Health App Retention Rates Over the Number of Days Following Installation.** From "Objective User Engagement With Mental Health Apps: Systemic Search and Panel-Based Usage Analysis" by Baumel et al., 2019, *Journal of Medical Internet Research, Medical Internet Research, 21*(9), e14567. https://doi.org/10.2196/14567. CC BY 4.0.

The potential benefits of mental health apps, such as convenience and

accessibility, can only be realized if users engage with the app (Chandrashekar, 2018;

Lattie et al., 2022). Researchers have recognized this, and as a result, have proposed

strategies to improve app engagement (Lattie et al., 2022; Nwosu et al., 2022). Some of

these strategies include improved user experience (Chandrashekar, 2018; Kaveladze et

al., 2022), providing compensation (Shreekumar and Vautrey, 2022), and enhancing app design (Huberty et al., 2021). Providing human support has also been a commonly proposed and utilized strategy to improve and sustain app engagement (Ben-Zeev et al., 2015; Noel et al., 2019; Wisniewski et al., 2020).

#### **SPECIFIC AIMS**

Mental health apps have received growing interest over the past few years, much of which has been heightened by the COVID-19 pandemic. Their ability to overcome traditional barriers to receiving care and their potential benefits extending beyond this have been recognized. Despite the growing popularity and widespread adoption of these apps, there is still insufficient evidence demonstrating their safety and efficacy. Some developers of smartphone mental health apps claim that their apps can effectively alleviate symptoms of depression and anxiety. However, most of these assertions are not substantiated by high quality research which is often due to the absence of an active control group. This can result in a failure to consider any possible digital placebo effects, leading to inaccurate results.

The aim of this exploratory analysis is to elucidate the potential effect size of mindLAMP, a smartphone mental health app, on reducing symptoms of depression and anxiety. More specifically, the present project examines the utilization of mindLAMP in two distinct settings: an intervention implementation of the app supported by a digital navigator and a self-monitoring implementation with limited human support. The self-monitoring group will function as an active control group, as they had access to the same features in the same app but did not engage with the app. The study will assess the percentage reduction in depression and anxiety symptoms which are quantified by the Patient Health Questionnaire-9 (PHQ-9) (Kroenke et al., 2001) and the General Anxiety Disorder-7 scale (GAD-7) (Spitzer et al., 2011) respectively. By comparing the reduction in symptoms across both groups, this analysis will generate a potential effect size of

mindLAMP on the reduction of depression and anxiety symptoms, and the inclusion of an active control group will lessen any potential digital placebo effects. We hypothesize that mindLAMP will demonstrate a modest effect in reducing symptoms of depression and anxiety, in line with other apps in this space. Given the open-source nature of mindLAMP, these results are impactful as they will support expanding the use of this free and scalable digital health tool.

Due to the limitations of this study, we recognize its preliminary nature. The insights obtained from this analysis will be utilized to guide the development of a future study that will be adequately powered and follow a more rigorous protocol.

#### **METHODS**

#### Recruitment

The protocol for the control implementation has already been published (Melcher et al., 2022). 695 individuals were recruited from November 2020 to May 2021 through online posts. To meet the inclusion criteria, participants were required to possess English fluency, own a mindLAMP compatible Apple or Android smartphone, have an active college email address, and show a student ID card to verify enrollment in college. Furthermore, they had to score a 14 on the Perceived Stress Scale (Cohen et al., 1983) during the screening survey. 83 participants were excluded for never downloading the app. An additional 283 participants were excluded from the analysis for never completing any of the weekly PHQ-9 surveys or GAD-7 surveys.

Recruitment for the six-week interventional study, different than the control condition study discussed above, began in July 2021 and continued through February 2022. Adults with depression or anxiety were recruited through Researchmatch.org, a platform designed to connect researchers and potential study participants. To be eligible, individuals were required to own a mindLAMP compatible smartphone and score at least a 5 on the GAD-7 scale.

#### **Control Protocol**

Participants in the control implementation filled out a screener survey that included demographic questions, the Perceived Stress Scale (PSS) questionnaire, and a question asking if they ever had COVID-19. The survey was completed and stored securely on REDcap, a secure web application for managing e-surveys and databases. Once participants met the inclusion criteria (a score of at least 14 on the PSS), they were directed to an informed consent document on REDcap. After completing the form, participants met with a trained research assistant who introduced mindLAMP and provided the participants with their username and password to the app. The research assistant then answered any questions about the app and the study before concluding the intake session.

Throughout the study, participants were sent daily push notifications via the mindLAMP app prompting them to complete a brief, daily survey. Bi-weekly notifications prompted participants to complete a longer survey on the app. The daily survey was composed of 11 questions drawn from established clinical measures such as the Patient Health Questionnaire-9, the General Anxiety Disorder-7 scale, the Prodromal Questionnaire-16 (Ising et al., 2012), and the PSS. The bi-weekly survey included all of the questions from the aforementioned measures, as well as the UCLA Loneliness scale (Russell et al., 1978), Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989), and the Digital Working Alliance Inventory (D-WAI) (Henson et al., 2019). MindLAMP provided access to the same interventions available in the intervention implementation of the app, such as audio-guided meditations, in the control version as well. These therapeutic interventions were readily accessible by clicking on the 'manage' tab in the app. However, scheduled app notifications were not utilized in the control version.

Upon completion of the study, participants received an email from a research assistant containing an exit survey and instructions to uninstall the app. Compensation was up to \$50 strictly based on completion of the bi-weekly surveys alone.

#### **Intervention Protocol**

After participants met the criteria listed above for the intervention implementation, they had an intake meeting with their digital navigator or coach. This digital navigator is a research assistant who received training to support app use in both care and research settings. This standardized training is published and freely available (Wisniewski et al., 2020). At the intake meeting, the digital navigator introduced mindLAMP to the participants and provided them with their username and password. Following this meeting, digital navigators checked in every other week for a total of two times throughout the six weeks of the intervention protocol. Each of these sessions lasted up to 20 minutes in which the digital navigator provided strictly app-related support and no clinical support. After every meeting with their digital navigator, participants completed a battery of questionnaires, including the PHQ-9, GAD-7, PSQI, PSS, SIAS (Mattick and Clarke, 1998), UCLA Loneliness Scale, Flourishing Scale (Diener et al., 2009), SUS (Brooke, 1995), and the D-WAI, all of which were completed and stored through REDcap. Upon completing the study, participants were compensated with \$75, regardless of their level of app engagement.

#### MindLAMP

MindLAMP is an open-source smartphone application developed by the Division of Digital Psychiatry at Beth Israel Deaconess Medical Center. This smartphone application is a digital phenotyping app that is also capable of delivering customizable interventions to users. Digital phenotyping, defined as the "moment by moment quantification of the human phenotype in situ using data from personal digital devices",

provides a snapshot of a patient's behavioral patterns (Torous et al., 2016). Although the app provides robust digital phenotyping capabilities, we did not analyze any digital phenotyping data in the current analysis as that was not the focus of this work.

MindLAMP consists of five accessible tabs, each with their own core feature: Feed, Learn, Assess, Manage, and Portal. The Feed tab shows the assigned activities for the day while the Learn tab provides psychoeducational tips and resources. The Assess tab includes modules designed to gather data from patient input, such as surveys and cognitive games. The Manage tab contains therapeutic interventions including audioguided meditations and CBT-based activities. The content in each of these tabs is customizable, allowing clinicians and researchers alike to tailor the app to suit their and their patients' needs. This flexibility enables the app to be implemented in various ways as demonstrated by the two different implementations featured in this paper. Furthermore, mindLAMP has already been utilized by researchers and clinicians worldwide in various types of studies (Cohen et al., 2023; Chang et al., 2022).

All participants in both the intervention and control groups had full access to the mindLAMP application. Both studies, including the use of mindLAMP and the associated protocols, were approved by the Institutional Review Board of Beth Israel Deaconess Medical Center.

MindLAMP is currently available for download on both the Apple store and the Google Play Store. A desktop version is available through browsers as well. Further details on the development of mindLAMP can be found in a separate publication (Torous et al., 2019). Screenshots of the app have been included in a figure below.



**Figure 4. MindLAMP Screenshots.** On the far left, the "Feed" page displays the activities assigned for the day. The next screenshot depicts a GAD-7 question in a weekly

survey located in the "Assess" tab. The third screenshot shows the "Manage" tab with the last image being one of the many interventions available on the same tab.

#### **Data Analysis**

The data extracted from mindLAMP was stored in a secure Amazon Web Services Server. It was then pulled through Cortex, an in-house, open-source data analysis pipeline (Division of Digital Psychiatry, 2021). This application programming interface enables users to access and analyze the data collected by mindLAMP with just a few lines of code.

All analysis was done in the Python programming language on a Jupyter Notebook. Any data in which the initial PHQ-9 score and GAD-7 score was lower than 5 was excluded. To check for differences in the demographical characteristics of the two cohorts, the Kruskal-Wallis rank sum test (scipy.stats.kruskal) and the Freeman-Halton test (scipy.stats.fisher\_test) were utilized. The pearsonr function from scipy.stats was applied to note any linear relationship between the demographic characteristics and the PHQ-9 and GAD-7 outcomes.

Outcomes from the intervention implementation were analyzed at both weeks 4 and weeks 6 since this implementation was a 6-week study, while data from the control implementation was only analyzed at week 4 since the control study's duration was 4 weeks. Multiple imputation was used to impute any missing outcomes in the control intervention. The method and reasoning behind choosing multiple imputation is described in a paragraph below. To detect any statistically significant longitudinal change in PHQ-9 or GAD-7 scores for both the control and intervention, we utilized the wilcoxon function (Wilcoxon signed-rank test) from scipy.stats. The Wilcoxon rank-sum test, also known as the Mann-Whitney U test, was used to determine if there was a statistically significant difference in percentage improvement of clinical scores between the two cohorts. Hedges' g was calculated to obtain effect size, and the significance of the effect size was determined using stats.ranksums (Wilcoxon rank-sum test). Hedges' g was selected to quantify effect size because of the nature of this data set with a smaller sample size and unequal variances between the two groups being compared (Cumming, 2013). The Wilcoxon signed-rank test and the Wilcoxon rank-sum test were utilized instead of parametric statistical tests, such as the various ttests, because the initial PHQ-9 and GAD-7 scores of the samples did not follow the same distribution and were not all normally distributed. This was confirmed through the Shapiro-Wilk test and by visually inspecting histograms (figures 6 and 7).

#### **Multiple Imputation**

Missing data is a common issue in clinical research, and there are a number of methods to address it. Imputation is one such method in which you estimate missing values based on the available information. While there are many imputation techniques, multiple imputation is often preferred in the case where there are large amounts of missing data (Donders et al., 2006). This statistical technique involves repeatedly estimating the missing values depending on a number of predictors (features) and then combining the repeated estimates to create an imputed value. Multiple imputation is designed to take uncertainty into account and maintain variability, resulting in less bias, better handling of missing data, and often, more accurate results (Donders et al., 2006; Li





Figure 5. Multiple Imputation for Missing Data. A depiction of the steps taken to complete multiple imputation.

In the control implementation dataset, missing final PHQ-9 or GAD-7 scores were imputed using Scikit-learn's Iterative Imputer. The imputation model used initial score (PHQ-9 or GAD-7 depending on which of the two was being imputed), gender, age, and race and ethnicity as the predictor features. Initial GAD-7 did not serve as a predictor feature for imputing PHQ-9 outcomes, and vice versa, due to collinearity between the two variables. The means of the complete case PHQ-9 and GAD-7 scores and that of just imputed cases was compared using the Wilcoxon rank-sum test (stats.ranksums) to help assess the validity of the imputed outcomes. In addition, complete case analysis was also done to compare the non-imputed outcomes with the imputed results.

#### RESULTS

## **Demographics**

Table 1 presents patient demographic characteristics for participants in the control

implementation and participants in the intervention implementation. There was a

significant difference between the two groups in terms of mean age, gender, and

race/ethnicity.

**Table 1. Demographic Characteristics of Participants.** This includes participants in the control implementation and the participants in the intervention implementation. <sup>1</sup>Kruskal-Wallis rank sum test; <sup>2</sup>Freeman-Halton Test.

Participant	Control	Intervention	p-value
Characteristics			
Age in years, mean (SD)	21.5 (3.9)	35.4 (12.5)	< 0.0011
Gender			$< 0.001^{2}$
Female	211 (64.3%)	120 (76.9%)	
Male	104 (31.7%)	26 (16.7%)	
Non-binary	12 (3.7%)	6 (3.8%)	
Did not disclose	1 (.3%)	4 (2.6%)	
Race and Ethnicity			$< 0.001^{2}$
White	162 (49.4%)	112 (71.8%)	
Black or African American	30 (9.1%)	13 (8.3%)	
Latinx	55 (16.8%)	10 (6.4%)	

Asian	64 (19.5%)	10 (6.4%)
Other	17 (5.2%)	11 (7.1%)
Total	328	156

#### Outcomes

The intervention participants saw a significant reduction in both GAD-7 and PHQ-9 scores at both weeks 4 and weeks 6, with outcomes at week 6 having a greater reduction in score. At week 4, the percentage decrease was -8.14 percent (SD = 31.69) and -7.80 percent (SD = 30.18) for PHQ-9 and GAD-7 respectively. All the reductions were statistically significant at p < 0.01. At week 6, the percentage decrease was -14.19 (SD = 37.85) for PHQ-9 and -13.42 (SD = 41.23) for GAD-7.

The participants of the control implementation had a significant reduction in PHQ-9 scores, but no significant reduction in GAD-7 scores over the four weeks. If the imputed PHQ-9 and GAD-7 values were included, a statistically significant reduction in both PHQ-9 and GAD-7 exists. The mean changes for both complete cases and all the cases including imputed values is described in Table 2. As seen in Table 2, multiple imputation increased the sample size of the control implementation from 44 to 267 (GAD-7) for and 52 to 298 (PHQ-9). The means of the complete case PHQ-9 and GAD-7 changes did not differ between the complete cases and the imputed cases. For the control cohort, there was no difference in the initial symptom severity between participants who completed all four weeks and those that dropped out early.

**Table 2. Mean Percentage Change in GAD-7 and PHQ-9.** \*Indicates the percentage change is statistically significant at p < .05. \*\*Indicates the percentage change is statistically significant at p < .01Modified from "An Exploratory Analysis of the Effect Size of the Mobile Mental Health Application, mindLAMP" by Chang et al., 2023 [Submitted for Publication]).

	Complete Cases Only		Including Imputed Cases	
	n	Mean (SD)	n	Mean (SD)
PHQ-9 % Change	52	-6.02 (51.63)*	298	-1.39 (32.79)**
GAD-7 % Change	44	4.61 (55.99)	267	3.79 (35.52)*

There was no significant correlation observed between the baseline demographic variables and the percentage change in GAD-7 or PHQ-9 scores, in either the intervention or the control group. Although there was no correlation between baseline demographics and outcome measures, both the intervention (-.24 for PHQ and -.22 for GAD) and control participants (-.37 for PHQ and -.35 for GAD) showed a negative correlation between baseline symptom severity and percentage change in scores. Below are sets of histograms that illustrate the distribution of baseline symptom severity and the corresponding change in symptoms for each cohort.



Baseline Symptom Severity vs. Change in PHQ-9

Baseline Symptom Severity vs. Change in GAD-7



**Figure 6: Initial Symptom Severity and Percentage Change in PHQ-9 and GAD-7 for the Active Control Group.** This set of histograms includes imputed values.



Baseline Symptom Severity vs. Change in GAD-7



Figure 7. Initial Symptom Severity and Percentage Change in PHQ-9 and GAD-7 for the Intervention Group.

#### **Effect Size**

Table 3. Hedges' g Values and Corresponding p-values. P-values were obtained using the rank sums test.

	Intervention Week 4 PHQ-9	Intervention Week 6 PHQ-9	Intervention Week 4 GAD- 7	Intervention Week 6 GAD- 7
Control PHQ-9	p = .58 (g=.06)	p = .73 (g=.19)		
Control GAD-7	_	_	p = .12 (g=.33)	p < .05 (g=.39)
With Imputed Control PHQ-9	p = .07 (g=.21)	p < .01 (g=.37)	—	
With Imputed Control GAD-7	_	_	p < .01 (g=.34)	p < .01 (g=.45)

For analysis including the imputed college values, there was a significant difference in percentage improvement between the control group's GAD-7 and the intervention group's GAD-7 at week 4 and at week 6. This was not the case for PHQ-9 as there was no statistically significant difference in the percentage improvement for PHQ-9 at week 4. However, upon comparing the intervention cohort's PHQ-9 improvements at week 6, their percent changes were significantly different than that of the control cohort's PHQ-9.

For complete case analysis, the only significant difference was between the intervention group at week 6 and the control group at week 4 GAD-7. A more detailed

breakdown of the corresponding p-values and Hedges' g values is available above in Table 3.

#### DISCUSSION

The primary objective of this study was to elucidate the effect of mindLAMP, a smartphone mental health app, on reducing depression and anxiety symptoms. This was accomplished by comparing the impact of implementing mindLAMP as an unguided mood monitoring tool (control) to the impact of mindLAMP as a coached intervention on anxiety and depression. The findings suggest that mindLAMP, when implemented as an intervention with coaching, has a small yet significant effect on reducing anxiety and depression symptoms.

Analysis revealed that mindLAMP has an effect size of g=0.34 and g=0.21 for anxiety and depression respectively. Although this is preliminary analysis, it is consistent with previous studies on other mobile mental health apps that reported similar effect sizes on improving depression and anxiety symptoms (Firth et al., 2017a; Firth et al., 2017b).

Unsurprisingly, these effect sizes are lower than that of more traditional forms of interventions such as psychotherapy (Cuijpers et al., 2023), which in some cases have been found to be as effective as medication. (Cuijpers & Gentili, 2017). This does not mean we should discount the potential of apps as despite their lower effectiveness, mental health apps offer exciting possibilities. For one, they could be used in conjunction with traditional therapy (Cuijpers et al., 2016) to enhance outcomes. Furthermore, given the lesser, but evident effectiveness of mental health apps, they may serve as a viable primary treatment option for individuals with clinically mild depression and anxiety. Considering the how easily accessible and scalable apps are, this could increase access for more

people while simultaneously freeing up resources for those who have more severe symptoms and require more effective treatment.

The findings in this paper also indicate that mental health apps, such as mindLAMP, may potentially benefit individuals of different backgrounds. There was a slight negative correlation between initial symptom severity (for both PHQ-9 and GAD-7) and the overall reduction in symptom severity. This suggests that mindLAMP is capable of helping individuals with not only mild symptoms, but also those with more severe symptoms, albeit to a lesser degree than traditional therapy. The analysis also revealed no significant correlation between baseline demographic characteristics and reduction in PHQ-9 or GAD-7, suggesting that mindLAMP can benefit a wide range of patients, as previously demonstrated by a study conducted by our team (Chang et al., 2022). However, it is important to recognize that the intervention cohort was not diverse, consisting of over 70% females and an underrepresented amount of minority participants. As a result, further research is needed to confirm these findings and investigate the effectiveness of mental health apps such as mindLAMP across diverse populations.

Our results were also interesting in that they indicated some differences between GAD-7 and PHQ-9 outcomes. Although the effect size of mindLAMP when comparing the intervention GAD-7 changes at week 4 with the control groups was significant (g=.34), this was not the case for PHQ (g=.21). This result does not necessarily imply that mindLAMP is not effective in improving depression outcomes. Upon comparing the control group's PHQ-9 outcomes to the intervention group's PHQ-9 outcomes at week 6, there was indeed a significant effect size of g = .37. It may, instead, indicate that using

mindLAMP to simply monitor symptoms rather than engage in any interventions may be effective as well. This is corroborated by the fact that participants in the control group had a significant decrease in PHQ-9 scores both when considering only the complete cases and when including the imputed cases as depicted in table 3.

#### Strengths

One of the strengths of this study is the inclusion of an active control group which is uncommon in mental health app efficacy studies (Donker et al., 2019; Moore et al., 2015). The unguided mood monitoring group was able to serve as an active control as they had access to the exact same mental health app with the same functionality and features. However, the active control group did not receive any human support to encourage engagement. This is a plausible explanation for the much lower app engagement in the control group as the current literature suggests that a lack of human support may lead to low engagement with technology based self-monitoring interventions (Borghouts et al., 2021). By utilizing the exact same app both for the intervention and control groups, we were able to control for many confounders relating to the app. This included having access to the same app, the same features, and seeing the same aesthetics. These confounders are often not controlled for in research studies involving mental health apps, and as a result, this study was unique in that it featured a robust, active control group.

Another strength is that mindLAMP is freely and readily available, allowing for researchers to replicate this study in a feasible manner. They may adjust the app to suit their research needs or perhaps build upon this study since the app is flexible and customizable. This could lead to more effective interventions and different implementations of mindLAMP. Similarly, the digital navigator training is also freely available and thus, the role of the digital navigator is easily replicable as well (Wisniewski et al., 2020). This is in contrast to the current norms in this field as many studies that include coaching or some other form of human support are not as transparent about the training or qualifications of the coaches (Bernstein et al., 2022; Meyer et al., 2022). By providing clear information about the training of the digital navigators, we hope that this study will set a positive example for future research.

#### Limitations

There are several limitations that must be considered in the interpretation of the results. First, the preliminary effect size of mindLAMP was calculated by combining two separate studies that had different demographics, as noted in Table 1. It is worth noting, however, that the current literature suggests that app engagement between middle-aged adults and younger adults does not differ significantly (Jacob et al., 2022). The demographics of the intervention group were not only different than that of the control group but also underrepresented males and participants from racial and ethnic minorities. The vast majority of participants were female, and there were few members of minority groups. As a result, the uptake, usage, and efficacy of mental health apps within minority groups is an area that warrants further exploration.

Another notable limitation to consider is that since these studies were conducted separately, the control and intervention implementation had slight variations in their respective protocols; the control implementation spanned 4 weeks, while the intervention

lasted 6 weeks. We believe that this limitation was addressed to some degree by analyzing and reporting the data at both weeks 4 and weeks 6. On a related note, since the control group had no digital navigator support, the impact of the two 20-minute digital navigator meetings was not assessable. However, it was deemed necessary to have these meetings in the intervention study, even if they were just 20 minutes, to increase engagement as human support seems like a promising strategy to do so (Ben-Zeev et al., 2015; Borghouts et al., 2021; Noel et al., 2019; Wisniewski et al., 2020)

Lastly, there was also high missingness of data in the control study. This was a result of many participants not filling out their very last PHQ-9 and GAD-7 surveys in mindLAMP. Missing data is a commonly encountered issue in many digital health research studies, even for those that have received approval from the U.S. Food and Drug Administration (FDA) (Nwosu et al., 2022). We deemed imputation as being necessary for our analysis since the sample size would have been too small to detect smaller effect sizes. As mentioned before, multiple imputation is often better at dealing with large amounts of missing information, so that was the technique chosen in this paper. Complete case analysis was also included for comparison. Lastly, the means of just the complete case values were compared to the means of just the imputed values for both PHQ-9 and GAD-7, and there was no significant difference.

#### **Future Studies**

Given the limitations of this analysis, it can be considered exploratory in nature. To obtain more conclusive results, a study must be conducted in which participant groups have similar demographics and adherence to the same protocol. The findings from this paper will be used inform the design of a randomized controlled trial which will ensure similar participant demographics between groups, adherence to the same protocol, and the use of digital navigators to promote participant engagement.

By addressing this study's limitations, future research can expand upon the existing findings, investigating additional interventions and evaluating their effectiveness across diverse demographic groups. This can provide a more thorough understanding of the potential benefits and limitations of mental health apps in alleviating the symptoms of depression and anxiety.

#### CONCLUSION

This exploratory analysis provides insights into the potential effect size of mindLAMP, a smartphone mental health app, in the reduction of anxiety and depression symptoms. The findings suggest that mindLAMP has a small effect size. Furthermore, this study highlights the scalability, re-usability, flexible nature of smartphone applications allowing for them to be used in various settings. These results provide a foundation for future studies to investigate the efficacy of mindLAMP and other mental health apps in addressing symptoms of anxiety and depression.

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# CURRICULUM VITAE





