The Digital Clinic: Testing the Feasibility of an Innovative Digital Mental Health Care Delivery Model Designed to Increase Access to Care

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Abstract

Background: Mental health concerns have become increasingly prevalent yet care often remains inaccessible to many. While digital mental health interventions offer a promising solution, self-help and even coached apps have not fully addressed these challenges. There is now a growing interest in hybrid care approaches that use apps as tools to augment, rather than to entirely guide, care. The Digital Clinic is one such model, designed to increase access to and the quality of mental health services.

Objective: To assess the feasibility, acceptability, and potential efficacy of the Digital Clinic model, we conducted a non-randomized open trial with participants experiencing depression, anxiety, or both, at various levels of clinical severity.

Methods: Clinicians were trained in conducting brief transdiagnostic evidence-based treatment that is augmented by a mental health app (mindLAMP); digital navigators were trained in supporting participants' app engagement and digital literacy while also sharing app data with both patients and clinicians. Feasibility and acceptability of this 8-week program were assessed against a range of benchmarks. Potential efficacy was assessed by calculating pre-post change in depressive (PHQ-9), anxiety (GAD-7), and co-morbid depressive and anxiety (PHQ-ADS) symptoms, as well as rates of clinically meaningful change and remission. Secondary outcomes included change in functional impairment, self-efficacy in managing emotions, and flourishing.

Results: Participants were 215 individuals, primarily White (70%) cisgender women (63%) with a mean age of 41 (SD = 14). Feasibility and acceptability was good to excellent across a range of domains. The program demonstrated potential efficacy: The average PHQ-9 score decreased from moderate/moderately severe at baseline (M = 13.39, SD = 4.53) to sub-clinical (M = 7.79, SD = 4.61) by the end of the intervention, $t(127) = 12.50$, $p < .001$, $d = 1.11$. Similarly, the average GAD-7 score decreased from moderate at baseline (M = 12.93, SD = 3.67) to sub-clinical (M = 7.35, SD = 4.19) by the end of the intervention, $t(114) = 13$, $p < .001$, $d = 1.22$. Participation in the program was also associated with high rates of clinically significant improvement and remission.

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associated with high rates of clinically significant improvement and remission.

Conclusion: Results suggest that the Digital Clinic model is feasible, acceptable, and potentially efficacious, warranting a future RCT to establish the efficacy of this innovative model of care.

Keywords: digital interventions, transdiagnostic treatment, evidence-based treatment, digital navigator, access to care

Introduction

Common psychiatric disorders, such as depression and anxiety, are prevalent and costly. Recent nationally representative data suggest that approximately one in three US adults – and one in two young adults – struggles with symptoms of anxiety or depression [1]. Although efficacious mental health treatments exist [2], demand for care outpaces its availability, leaving more than half of people with unmet mental health needs unable to access care [1] . Barriers include cost, inadequate insurance coverage, clinician shortage and geographical barriers to clinician access, stigma, and inadequate provider diversity, according to national data [2]. Alongside long-term health care system reforms, there is a need for more immediate, scalable solutions to increase access to care.

Digital mental health interventions (DMHIs), delivered via smartphones or the Internet, offer a promising solution. DMHIs can disseminate evidence-based interventions at scale and low cost, and their inherent privacy can mitigate stigma. Yet existing DMHIs have not yet fully realized their potential.

Problems with Efficacy, Engagement, & Trust

DMHIs range from unguided (i.e., self-help apps, e-learning modules) to guided (those that include varying degrees of human support). Because unguided DMHIs offer greater scalability at lower cost, they have been touted as ideal solutions to access problems. Yet challenges with efficacy, engagement, and trust have undermined their utility in addressing access problems [3,4]. However, guided DMHIs have stronger evidence of efficacy, engagement, and trust.

First, meta-analytic evidence suggests that unguided (versus guided) DMHIs have lower effect sizes and are less effective for those with more severe psychopathology [5,6] . Additionally, when given a choice between using a mental health app as standalone treatment or to augment in-person therapy, people with moderate and severe (versus mild) psychopathology prefer the latter [7]. Even iCBT with minimal human support tends to be less acceptable than individual CBT for people

with higher severity [8]. These findings suggest that the lack of human support lowers perceived quality and acceptability for many, especially those with higher clinical severity.

Second, unguided DMHIs suffer from low real-world engagement. Despite demonstrating efficacy in reducing depression and anxiety in RCTs [9], many standalone mental health apps fail to sustain engagement after just 10 days in real-world settings [10]. Similarly, iCBT's dropout rates are as high as 80%, despite its demonstrated efficacy [11]. A recent systematic review found that DMHI engagement facilitators include greater digital literacy, more structured training in DMHI use, perceived DMHI relevance, and DMHI integration into daily life (12). Perhaps because guided DMHIs can better address such factors, they facilitate engagement [13]. Indeed, studies comparing unguided with guided versions of the same app show the latter has better engagement and outcomes [14,15].

Third, mistrust of data handling hinders DMHI uptake [16]. Most DMHIs operate outside healthcare regulation and lack data use protections and transparency [16]. Examples of problematic data sharing practices and opaque privacy policies abound [17] and have, at times, led to high-profile privacy violations [18]. Such incidents undermine trust [19], contributing to low DMHI engagement [16].

Taken together, these findings suggest that sacrificing human support for scalability can lower quality and acceptability. To reach people with mental health problems ranging in clinical severity, it is key to retain human support, design trustworthy DMHIs, and employ scalable engagement strategies (e.g., support that enhances DMHI use, relevance, and digital literacy). Yet the challenge remains: How can all this be done without sacrificing scalability?

Guided DMHIs: More Viable Solutions?

While guided DMHIs have stronger evidence, they have also been incomplete solutions to access problems. Many simply add digital components to face-to-face care [20–24], which addresses neither cost nor workforce shortage barriers. To address these barriers, other guided DMHIs have

replaced clinicians with less costly supporters (e.g., coaches, non-professionals) [25]. While these guided DMHIs have higher effect sizes than unguided DMHIs [26], it remains unclear when and for whom support is best by a clinician, coach, or non-specialist [27]. Until it is known, retaining a trained clinician in care remains an important ethical consideration in DMHIs.

A Practical Solution: Ensuring Scalability, Quality, Engagement, & Trust

A more comprehensive solution is that of the Digital Clinic, an innovative guided DMHI that offers brief clinician-delivered virtual treatment augmented by an app and a non-specialist supporter called a digital navigator [28,29]. As seen in Figure 1, each of the model's components addresses leading access barriers while supporting effectiveness.

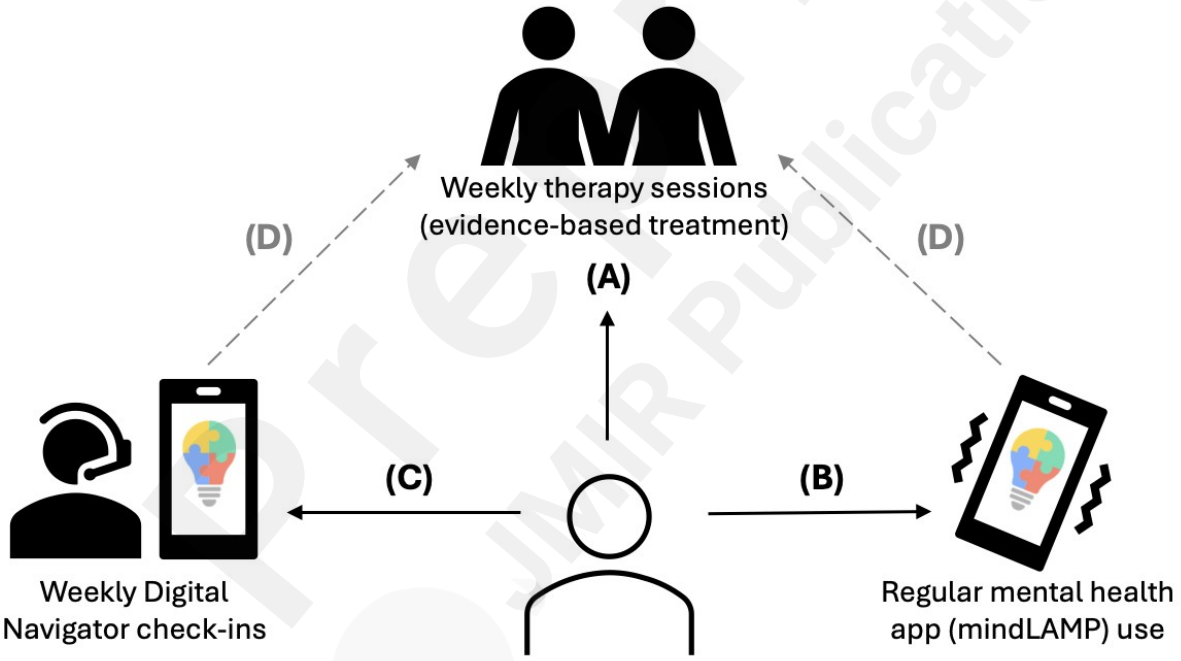

Figure 1. The Digital Clinic | *In the Digital Clinic, (A) the patient receives brief therapy sessions of evidence-based transdiagnostic treatment, provided via telehealth by a trained clinician. (B) The mindLAMP app is integrated into care, enabling real-world skills practice and measurement-based care, including digital phenotyping data collection. (C) Brief weekly check-ins are also held via telehealth with a digital navigator, who provides technology support, shares key data insights, and encourages sustained app engagement.(D) The Digital Navigator also shares data highlights from the app with the clinician, who then uses app data to inform clinical decision-making and enhance patient care in subsequent sessions.*

First, to ensure both scalability and quality, the model offers brief evidence-based

transdiagnostic treatment by a trained clinician (see A in Figure 1). Brief evidence-based interventions are more efficacious than treatment as usual for depression and anxiety [30–32]. Their brevity addresses the workforce shortage by freeing up clinicians faster; retaining the clinician in care increases the likelihood of reaching people with higher-severity problems.

Second, for greater scalability and impact, the mental health app mindLAMP is integrated into care to facilitate real-world skills practice and enable measurement-based care (see B in Figure 1). Recent meta-analytic evidence suggests that supplementing standard interventions with an app has additive effects [5], possibly increasing therapeutic dose without taking up clinical resources [21]. In addition, measurement-based care is a well-established yet underutilized approach to increase care quality [33–35]. To facilitate measurement-based care, mindLAMP streamlines questionnaire administration and data visualization; data is discussed in sessions, informing clinical decision-making. The app's digital phenotyping capacity also enables the collection of behavioral data, offering additional insights for clinical care [29].

Third, to support app engagement, a digital navigator is included in this model of care (see C in Figure 1). The purpose of this role, designed to support innovative technology-enhanced care models, is to make technology usable and useful for patients and clinicians [36–38]. In the Digital Clinic, digital navigators support patients during weekly check-ins in several ways: They explain data use and privacy policies to facilitate trust in mindLAMP, which is designed with the highest privacy and security standards. They provide technical support and app use training, share data highlights, and encourage app use in clinician-recommended ways. The digital navigator also offers clinicians data highlights that can inform patient care so that app data is never burdensome to clinicians [39]. Because the digital navigator does not need clinical expertise, the addition of this role preserves this model's scalability and cost-effectiveness.

Finally, remote delivery methods are prioritized to enhance scalability and mitigate stigma, with therapy sessions and digital navigator check-ins conducted via telehealth. Telehealth is

acceptable to patients [40], and brief evidence-based treatment via telehealth is non-inferior to its in-person equivalent [41]. Additionally, some data suggests that digital approaches can address stigma [42].

Prior research has not focused on or evaluated the feasibility and acceptability of a comprehensive care model incorporating all of these components to address leading access barriers. An earlier report on the development of the Digital Clinic showed that this model is promising [28]. In the present study, we conducted an open trial to evaluate the Digital Clinic model's feasibility, acceptability, and potential efficacy in treating patients with common mental health problems ranging in severity.

Methods

Participants

Participants were 215 adults (63% cisgender women, 34% cisgender men, 1% non-binary), with a mean age of 41 (*SD* = 14). Regarding race/ethnicity, approximately 70% identified as White, 11% Asian, 9% Black or African American, 7% Hispanic or Latinx, 2% Middle Eastern or North African (MENA), 1% biracial, and 1% Native Hawaiian or Pacific Islander.

Ten clinicians were involved in the current study (5 master's and 3 doctoral mental health counseling students, a postdoctoral-level psychologist, and a licensed psychiatrist). Clinicians identified as White (*n* = 6), Asian (*n* = 4), and Black (*n* = 1) and had a background in evidence-based treatment. Additionally, 16 non-clinician volunteers seeking experience in digital interventions were involved as digital navigators in the study [37,39].

Procedures

Recruitment & Enrollment Procedures

Eligible participants a) were at least age 18, b) spoke English, and c) had an Android or Apple phone. Exclusion criteria were a) having cognitive deficits that would interfere with participation in therapy, b) being acutely suicidal and needing a higher level of care, or c) currently being in inpatient

therapy. Participants with subclinical PHQ-9 or GAD-7 scores were not screened out (so as not to deny care to anyone whose distress may not have been detected by these measures) but were later excluded from analyses.

Participants were recruited primarily through referrals from primary care or their healthcare provider. Recruitment began in August 2022. Upon referral receipt, participants were sent an online screening questionnaire via email. Once this form was completed and potential eligibility confirmed, participants were invited to attend a virtual appointment with a trained digital navigator, who would offer details about the intervention and all of its components. If a participant chose to enroll in the clinic during this appointment, the digital navigator scheduled their first therapy appointment and administered a baseline questionnaire. This study was granted a Quality Improvement waiver by the BIDMC IRB.

Intervention Procedures

Enrolled participants were offered 8 weeks of brief app-augmented treatment whose basis was the Unified Protocol (UP) for Transdiagnostic Treatment of Emotional Disorders [43], as further described in the Intervention section below. Treatment was provided free of charge and involved weekly therapy sessions with a trained clinician, weekly check-ins with a digital navigator, and regular use of the mental health app mindLAMP. All sessions and check-ins were conducted via telehealth.

Training & Competency

A brief therapy manual based on the Unified Protocol was created for this study. This manual contained session-by-session guides, including guidance for clinicians to integrate the app and its data into care. Clinicians were first given initial training in evidence-based treatment by a licensed clinical psychologist, who trained clinicians to understand the UP principles and to conduct therapy based on the manual. Once clinicians began seeing participants, their adherence and competency was monitored closely in weekly supervisions. Individual supervisions (with a psychologist or

psychiatrist) focused on conceptualizing patient problems within the UP and conducting treatment in line with evidence-based principles.

Digital navigators were provided a 10-hour training that entails learning how to troubleshoot technical issues and interpreting digital phenotyping data as collected by mindLAMP. They were trained to provide technical support and to support digital literacy by helping patients interpret and understand their data. The training guidelines have been described and are published elsewhere [39].

Intervention Description

The Digital Clinic is a form of blended therapy that offers brief evidence-based treatment augmented by a mobile app [44] (mindLAMP) and a digital navigator, who supports app use. The purpose of integrating mindLAMP into care is twofold: to help patients acquire and generalize new skills and to collect psychosocial insights that inform treatment. The role of the digital navigator is to support the patient in using the app, helping to resolve any difficulties (technological or motivational) that may interfere with the patient's ability to benefit from app use. The digital navigator role has been integrated into this model in light of research showing that app engagement often correlates with clinical improvement yet tends to decline when patients are given a standalone app without support [16]. To avoid overburdening clinicians with app and data tasks on top of therapy tasks, the digital navigator was introduced into the model.

The Digital Clinic intervention has two phases:

Phase I: App Use with Digital Navigator Support. Participants begin the 8-week program with 2 weeks of app use supported by brief, weekly check-ins with a digital navigator. The goal of this period is for participants to start completing daily and weekly self-report measures on the app, and for the app to begin collecting digital phenotyping data. Digital phenotyping data is defined as the "individual-level human phenotype in-situ using data from smartphones and other personal digital devices" [45] and in this study included several behavioral metrics: steps, movement,

screentime, and a sleep estimate. Highlights of this and other data from the app were shared/visualized with participants in the digital navigator check-ins, where digital navigators also offered support to enable continued app use.

Phase II: Therapy Sessions & Continued App Use with Digital Navigator Support. Participants then met weekly for 6 weeks with a clinician, who provided transdiagnostic treatment based on the UP. Sessions lasted between 45 and 50 minutes, with an hourlong intake. In each session, mindLAMP data was reviewed with the participant, and UP skills were discussed and assigned as home practice. Therapists shared their screen at key points in each session to review data together, including week-by-week symptom fluctuation graphs and home practice data from mindLAMP.

The UP was selected as the basis of care in the Digital Clinic because the clinic's primary aim is to increase access to care and a transdiagnostic approach allows for greater scalability, given that it enables training clinicians in a single therapy applicable to a wide range of presentations. The UP is an emotion-focused CBT that targets reactivity and avoidance, two underlying mechanisms that perpetuate distress across various forms of psychopathology. The therapy begins with conceptualization of the patient's problems within the UP framework. The therapist then offers emotion psychoeducation on the adaptive function of emotions and helps the patient learn to self-monitor their mood and identify the three components of emotional experiences (i.e., cognitive, physiological, and behavioral). The goal is to help the patient begin to tolerate and understand, rather than habitually react to, their unpleasant emotions. Core UP interventions include mindfulness, cognitive flexibility, countering avoidance, and exposure (including interoceptive, emotional, and situational). A termination session consolidates learning and assists patients in creating a plan to independently practice skills so as to continue making gains post-termination. The brief treatment manual designed for the Digital Clinic offers guidance on all of these topics, as seen in Table 1.

Table 1

Topics covered in the Digital Clinic manual

Session		Focus	mindLAMP home practice
1	Intake	■Problems, history, goals ■Collaborative UP assessment and case conceptualization ■Psychoeducation on link between the three parts of emotional experience (thoughts, emotions/sensations, behaviors)	Self-monitoring emotional experiences
2	Mindfulness	■Psychoeducation on function of emotions ■Role of aversive reactions in fueling distress ■Mindfulness practice	Mindfulness audio Anchoring in the Present
3	Cognitive Flexibility	■Impact of thoughts on emotions and behavior ■Common thinking traps ■Examining automatic thoughts ■Practice thinking more flexibly	Thinking More Flexibly
4	Countering Avoidance	■Link between emotions and behavior ■Avoidance and emotion-driven behaviors ■Opposite Action practice	Act Opposite
5	Exposure	■Rationale for exposure ■Conduct exposure ■Discussion of exposures as home practice	Exposure
6	Termination	■Progress review ■Plan generation for continued skills practice to maintain gains	n/a

Note. The Digital Clinic manual focuses on emotion-focused CBT-based skill-building interventions that support adaptive coping. The manual is based on the Unified Protocol (UP). Therapists are trained to adhere to its core principles but deliver it flexibly – that is, by slowing down the pace, emphasizing some interventions more than others or adding an adjunctive module to tailor treatment to the client's needs.

Materials

mindLAMP app & dashboard. mindLAMP is an open-source mental health app that is

designed to be easily customizable to meet the needs of different populations and to be integrated into care. mindLAMP comes with an accompanying dashboard that can be accessed on desktop by the patient and clinician. LAMP stands for the app's four prominent navigation tabs: **L**earn (contains psychoeducation modules), **A**ssess (provides self-report measures), **M**anage (facilitates skills practice through interactive therapeutic modules), and **P**ortal (offers visualizations of patient data). mindLAMP also has digital phenotyping capabilities and can automatically collect various types of behavioral data (e.g., steps, screentime) without the patient having to enter it. mindLAMP has a wide variety of sensors available, including access to metrics derived from Apple Sensorkit that the patient can opt in to share data from. The Sensors used in the Digital Clinic are Accelerometer, Ambient Light, Nearby Devices (detected through proximity to Bluetooth), and Screen State. mindLAMP has been described in more detail elsewhere [(28,39)].

Digital Clinic manuals. Clinicians were trained with the Digital Clinic manual for conducting brief, app-augmented UP-based therapy via telehealth. The manual was written by a licensed clinical psychologist and includes guidance for integrating the app and its data into care. Digital navigators were trained with the Digital Navigator manual, which details the protocol for the digital navigator role.

Measures

Feasibility. Feasibility of recruitment was assessed in two ways. First, we calculated the proportion of approached participants who enrolled in the clinic. Approached participants were those we first confirmed to be eligible upon referral and thus invited to an introductory informed consent meeting. Second, we calculated the proportion of participants who agreed to participate after understanding what is involved in the Digital Clinic program during the introductory meeting. For both metrics, a feasibility rate of at least 70% was considered good, with at least 36% considered acceptable for the first metric, given that 36% is the rate of treatment initiation upon receiving a new depressive episode diagnosis in primary care, according to large-scale research [45]. ***Feasibility of***

retention was determined by calculating the proportion of participants who completed the entire 8-week program. A feasibility rate of 70% was considered good, based on large-scale research that found a 30% attrition rate for in-person therapy in high-income countries [46]; a feasibility rate of 76% was considered ideal, based on recent RCT findings showing a 24% attrition rate for blended CBT [47] (i.e., CBT that blended in-person treatment and iCBT components). ***Adherence to mindLAMP home practice*** was determined by the frequency of mindLAMP activities completed in mindLAMP. Adherence was deemed good if at least 70% of participants used the app on at least half the days of their total time in the clinic (i.e., 8 weeks) to complete home practice (i.e., self-monitoring, UP-based skills practice). ***Therapist adherence*** to the manual was closely monitored in ongoing supervision and was deemed good if at least 75% of a random selection of 40% of all clinical notes described session content that was in line with the Digital Clinic therapy manual (i.e., in line with UP core principles and interventions). ***Digital navigator adherence*** to the digital navigator protocol was assessed via checklists that each digital navigator submitted after each weekly digital navigator check-in with a patient. Pre-existing templated checklists for each check-in covered such topics as introducing the clinic structure, setting up and demonstrating the app, reviewing data highlights, and troubleshooting technology issues. Adherence was considered good if at least 75% of a random selection of 10% of all digital navigator meeting checklists completed showed perfect adherence.

Feasibility of quantitative measures was deemed acceptable if 80% completed questionnaires at each timepoint. Finally, ***feasibility of the digital format*** of the program was assessed with one question in the post-intervention questionnaire regarding hurdles to digital access (“What was the biggest hurdle you encountered regarding access to the Digital Clinic?”). Feasibility was deemed good if at least 75% endorsed “No significant hurdles encountered” rather than the other options (i.e., “difficulty getting stable Wi-Fi,” “difficulty finding a quiet place for clinician sessions,” “difficulty using mindLAMP,” or other self-reported hurdles).

Acceptability. Satisfaction with key aspects of the intervention was evaluated using several questions in the post-intervention questionnaire. For ***clinician satisfaction***, participants were asked to rate "How supported did you feel by your clinician?" on a scale of 1 (not supported at all) to 5 (very supported). ***Digital navigator satisfaction*** was assessed with four items ("What was the quality of time you spent with your Digital Navigator?", "What was the quality of information provided by the Digital Navigator?", "The Digital Navigator was willing to understand my questions and concerns, and "The Digital Navigator explained things in a way I understood.") on a scale of 1 to 5, with 1 indicating low satisfaction and 5 high. These four items were averaged to create a composite DN satisfaction score. ***App satisfaction*** was assessed with "How would you rank the mindLAMP user experience?" rated from 1 (very difficult to use) to 5 (very easy to use). Acceptability was deemed good if these components of the Digital Clinic were rated at least a 4, on average.

Two additional indicators of acceptability were assessed: ***therapeutic alliance*** with the clinician (measured via the Working Alliance Inventory-Short Revised; WAI-SR [48]) and ***digital working alliance***, or the perception of the app as a helpful therapeutic tool (measured via the Digital Working Alliance Inventory; DWAI [49]). Both measures were administered weekly via mindLAMP, and the scores closest to the midpoint (i.e., +-10 days) were used in the present study. For the WAI-SR, which has demonstrated good validity and reliability [50, 51] participants rated 12 items (e.g., "What I am doing in therapy gives me a new way to look at my problem") from 1 (seldom) to 5 (always), summed to yield a total score ranging from 12 to 60. For DWAI, which follows the same structure as the WAI and has also shown good reliability and validity [9], participants rated 6 items (e.g., "I believe the app tasks will help me to address my problem") from 1 (strongly disagree) to 7 (strongly agree), yielding a summed total score. Although normative data for determining cutoffs for these scales are not available, it has been suggested that a score of at least a 42 is considered positive/ high on the WAI-SR [52]. Our benchmarks for good acceptability thus became a minimum score of 42 on the WAI-SR and a corresponding minimum score of 30 on the DWAI, on average.

Potential efficacy. Depressive symptom severity and ***anxiety symptom severity*** were assessed with the Patient Health Questionnaire (PHQ-9) [53] and the Generalized Anxiety Disorder 7 Scale; GAD-7) [54], respectively. Participants completed these measures at the pre-post and 3-month follow-up timepoints via an online questionnaire, as well as weekly via mindLAMP during the intervention period. On each measure, participants rated from 0 (not at all) to 3 (nearly every day) how much each symptom bothered them over the past two weeks. Scale items were then summed to yield a total PHQ-9 score (0 to 27) and GAD-7 score (0 to 21). The PHQ-9 has demonstrated excellent internal reliability, construct and criterion validity (α = 0.89) [(53)], as has the GAD-7 (α = .92) [54] . Scores on these two scales were also summed together to derive the Patient Health Questionnaire Anxiety-Depression Scale (PHQ-ADS), a measure of ***co-morbid depressive and anxiety symptom severity*** with high internal consistency reliability and strong convergent and construct validity (α = 0.88) [55]. This measure was included since our treatment is transdiagnostic and targets comorbid disorders.

Secondary clinical outcomes. Emotion regulation self-efficacy, the hypothesized mechanism of treatment, was measured via the PROMIS Item Bank v1.0 - Self-Efficacy for Managing Emotions Short Form 8a [56], which contains 8 items rated from 1 (I am not at all confident) to 5 (I am very confident), summed to yield a total score from 8 to 40; higher scores indicate higher levels of self-efficacy for managing negative emotions. This brief scale has good psychometric properties, with high internal consistency (α = 0.90-0.95) [56]. ***Flourishing***, a measure of psychosocial functioning, was measured with the 8-item Flourishing Scale [57]. Rated from 1 (strongly disagree) to 7 (strongly agree), scale yield a summed total score from 8 to 56, with higher scores representing greater psychological resources [58]. This scale also has good psychometric properties and high internal consistency (α = 0.86). ***Functional impairment*** was measured with the Sheehan Disability Scale (SDS), a 5-item assessment of impairment in 3 domains: work/school, social life, and family life. Three items assessing these three domains are rated from 0 (not at all) to

10 (extremely) and yield a total summed score of 0 (unimpaired) to 30 (highly impaired). The SDS is a psychometrically sound instrument, with good internal consistency (α = 0.83) [59].

Data Analytic Plan

Analyses were conducted in RStudio, version 2022.07.2+579. In line with, and guided by, guidelines for feasibility studies [60], we computed descriptive statistics to assess feasibility and acceptability, and then conducted paired samples *t*-tests (with Cohen's *d* effect sizes) to examine within-group pre-post differences as a marker of potential efficacy. As commonly reported in the therapy outcomes literature, we also computed clinically significant improvement and remission rates to further assess potential efficacy. Clinically significant improvement was determined by the proportion meeting the minimum clinically important difference (MCID) thresholds established in prior empirical research, which is 4 points for the PHQ-9 and GAD-7 [55] and 6 points for the PHQ-ADS [55]. Per published guidelines, remission was defined as <8 on PHQ-9 [61] and <8 on GAD-7 [55,62], corresponding to <16 on the PHQ-ADS. For outcomes analyses, we excluded participants with subclinical (<8) scores on both PHQ-9 and GAD-7.

For participants who missed the post-intervention questionnaire (and thus did not have a PHQ-9 or GAD-7 score), we obtained a score from mindLAMP if they had completed PHQ-9 or GAD-7 in mindLAMP within 10 days of their last therapy session. Seven participants experienced significant life events during the 8-week period, including death of a close loved one (n = 5) and homelessness due to eviction or fire (n = 2). We still offered these individuals care but excluded their data from analysis as these events may have prevented adequate participation in and response from brief treatment at that time. We also excluded data from one individual who was wrongly referred to the clinic for a physical rather than a psychological condition (n = 1).

Results

Feasibility of recruitment. Of the 401 individuals approached after initial eligibility was confirmed, 289 decided to enroll in the clinic – a 72% recruitment rate (good, per the 70%

benchmark). The proportion of participants who agreed to enroll after understanding all the components of the Digital Clinic program during their first introductory meeting was 88% (excellent, per the 70% benchmark). See Figure 2.

Feasibility of retention. Of enrolled participants, 84% completed the 8-week program, an excellent retention rate (given benchmarks of 70%-76%).

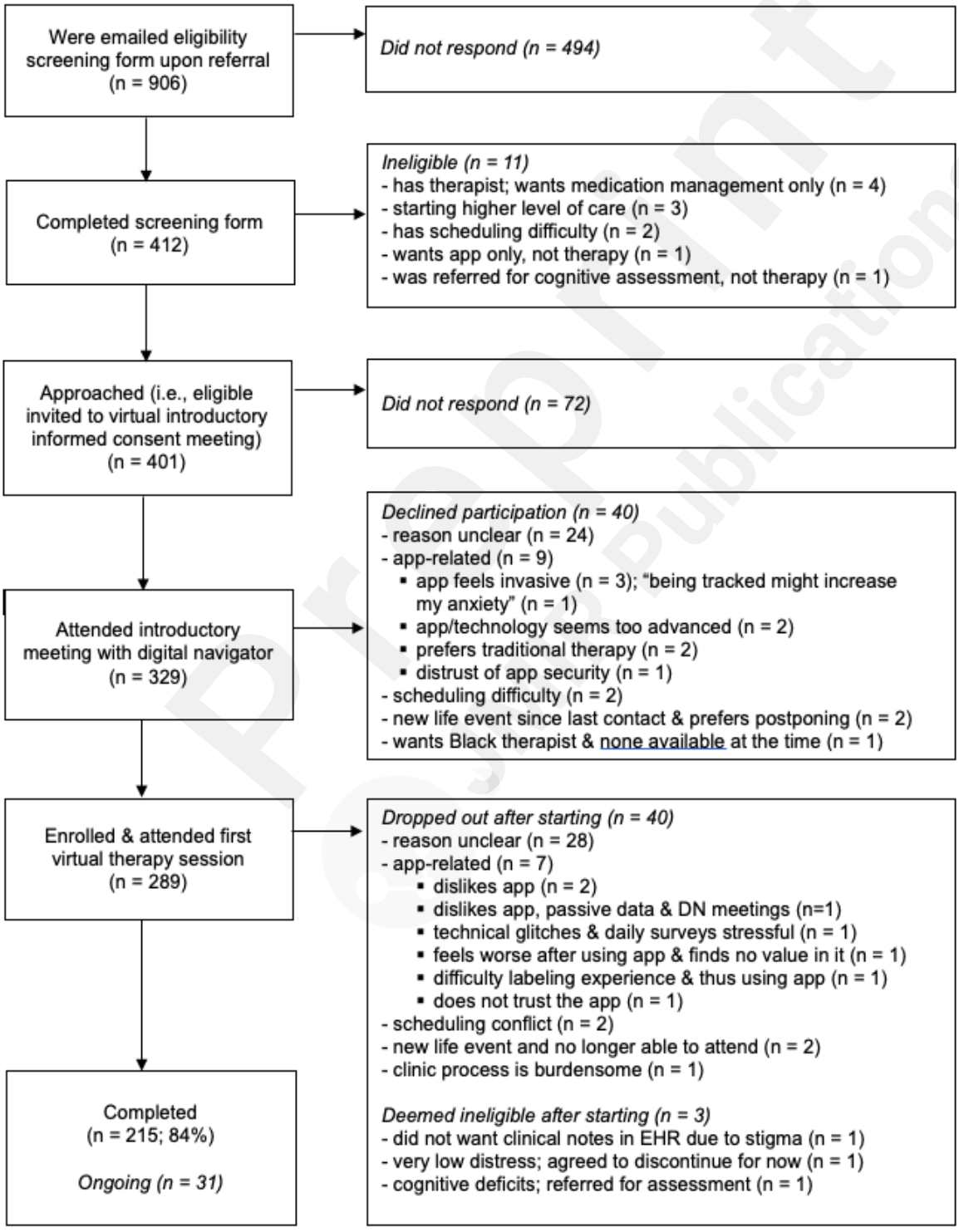

Figure 2. Recruitment & Enrollment Flowchart

Adherence to mindLAMP home practice. Results indicated that 73% of participants used the app on at least half the days of their total time in the clinic (benchmark 70%).

Therapist adherence. A review of a random selection of 51 cases' clinical notes revealed that 87% (n = 265) of all possible session notes closely adhered to UP core principles and interventions described in the Digital Clinic manual. The average adherence rate within each participant's course of care was 87% (*SD* = 17%), indicating that adherence was present in at least 5 of the 6 sessions, on average. Regarding the four core UP interventions, 98% of cases focused on mindfulness practice, 78% on cognitive flexibility, 76% on countering avoidance, and 41% on exposure. The Digital Clinic manual permits the incorporation of additional non-UP adjunctive interventions from other evidence-based treatments, as needed; session notes describing adjunctive interventions most often focused on assertive communication skills (i.e., DEARMAN), additional assessment and problem solving, relaxation (e.g., PMR, deep breathing), gratitude practice, and values clarification.

Digital navigator adherence. A review of a random selection of 22 cases' digital navigator meeting checklists showed that 99% (benchmark: 75%) had perfect adherence (n = 198).

Feasibility of quantitative measures. For the 215 who completed the intervention, there were 0, 28, and 131 missing questionnaires at the baseline, post-intervention, and three-month follow-up timepoints, respectively, corresponding to 100% (baseline), 87% (post-intervention), and 39% (follow-up) feasibility rates. (After excluding those with subclinical scores, the three-month follow-up questionnaire feasibility rate was still low, at 42%.) While the baseline and post-intervention questionnaire feasibility rates met and exceeded our 80% benchmark, the follow-up rate did not.

Feasibility of the digital format. Regarding hurdles to digital access, 72% endorsed no significant hurdles, falling slightly below our benchmark of 75%. Regarding challenges, 11% reported difficulty finding a quiet place for clinician sessions, 11% difficulty using mindLAMP, 3% difficulty getting stable Wi-Fi, 2% challenges remembering to do home practice on the app, and 1%

other self-reported challenges.

Acceptability. The average clinician, digital navigator, and mindLAMP user experience satisfaction rates were 4.81 (*SD* = 0.52), 4.61 (*SD* = 0.62), and 4.18 (*SD* = 0.79), respectively (benchmark: at least a 4). The average midpoint WAI-SR and DWAI scores were 50.15 (*SD* = 7.86) and 32.10 (*SD* = 6.74), respectively, exceeding the benchmarks of 42 (WAI-SR) and 30 (DWAI).

Potential efficacy. The average baseline PHQ-9 score was in the moderate/moderately severe range (*M* = 13.39, *SD* = 4.53) and fell to the sub-clinical range (*M* = 7.79, *SD* = 4.61) by the end of the intervention, a statistically significant mean reduction of 5.61 (95% CI [4.72, 6.49]), $t(127) = 12.50$, $p < .001$, with a large effect size, $d = 1.11$. Gains were maintained at the 3-month follow-up for those who completed the follow-up questionnaire and had a post-intervention PHQ-9 score (*n* = 55, 43%), with scores still in the sub-clinical range (*M* = 7.42, *SD* = 4.60) and not significantly different from post-intervention scores, $t(54) = 1.38$, $p = .17$.

The average baseline GAD-7 score was in the moderate range (*M* = 12.93, *SD* = 3.67) and fell to the sub-clinical range (*M* = 7.35, *SD* = 4.19) by the end of the intervention, a statistically significant mean reduction of 5.58 (95% CI [4.73, 6.43]), $t(114) = 13$, $p <.001$, with a large effect size, $d = 1.22$. Gains were maintained at 3-month follow-up for those who completed the follow-up questionnaire and had a post-intervention GAD-7 score (*n* = 48; 42%), with scores still in the sub-clinical range (*M* = 6.88, *SD* = 4.65) and not significantly different from post-intervention scores, $t(47) = 0.62$, $p = .54$.

The average baseline PHQ-ADS score was in the moderate range (*M* = 25.50, *SD* = 7.05) and fell to the sub-clinical range (*M* = 15.01, *SD* = 8.30) by the end of the intervention, a statistically significant mean reduction of 10.50 (95% CI [8.95, 12]), $t(121) = 13.40$, $p < .001$, with a large effect size, $d = 1.21$. Gains were maintained at 3-month follow-up for those who completed the follow-up questionnaire and had a post-intervention PHQ-ADS score (*n* = 52; 43%), with scores still in the sub-clinical range at three-month follow-up (*M* = 14.56, *SD* = 8.77) and not significantly different from

post-intervention scores, $t(51) = 1.09$, $p = .28$.

From baseline to post-intervention, approximately 69%, 76% and 70% experienced at least a 25% symptom decrease in PHQ-9, GAD-7, and PHQ-ADS, respectively. Over the same time period, approximately 47%, 47%, and 45% experienced at least a 50% symptom decrease in PHQ-9, GAD-7, and PHQ-ADS, respectively. Rates of clinically meaningful change (i.e., a reduction greater than the MCID) were 64%, 67%, and 73% in terms of PHQ-9, GAD-7, and PHQ-ADS, respectively. Remission rates were 53%, 60%, and 56% on the PHQ-9, GAD-7, and PHQ-ADS, respectively. See Table 2 for these rates by baseline severity level.

Secondary clinical outcomes. Emotion regulation self-efficacy significantly increased from baseline ($M = 20.42$, $SD = 4.99$) to post-intervention ($M = 26.97$ $SD = 5.61$), $t(133) = -13.13$, $p < .001$. Flourishing significantly rose from baseline ($M = 39.90$, $SD = 9.06$) to post-intervention ($M = 44.43$, $SD = 8.28$), $t(83) = -6.06$, $p < .001$. Functional impairment significantly decreased from baseline ($M = 18.72$, $SD = 6.41$) to post-intervention ($M = 13.24$ $SD = 8.30$), $t(134) = 8.94$, $p < .001$. Gains were maintained at 3-month follow-up ($M = 9.86$, $SD = 7.68$), with scores significantly lower at the follow-up timepoint, $t(59) = 3.86$, $p < .001$.

Discussion

The present study was an initial evaluation of the Digital Clinic, an innovative model of care designed to mitigate leading access barriers by offering brief, clinician-delivered evidence-based treatment via telehealth that is augmented by an app and a digital navigator [28, 63]. The aim of the present study was to assess the feasibility, acceptability, and potential efficacy of this model by conducting a non-randomized open trial. Results suggest that this model is feasible, acceptable, and has the potential to be an effective solution for increasing access to high-quality, evidence-based mental health intervention.

The open trial showed good to excellent feasibility and acceptability across most metrics. Results indicated that it is feasible to recruit and retain patients. That 88% chose to continue after the

introductory meeting suggests that many patients were not discouraged by the clinic's all-digital format or its various innovative components (i.e., app, digital phenotyping data collection, integration of a digital navigator into care). Moreover, the Digital Clinic's completion rate met and rates seen in other guided DMHIs (e.g., blended CBT [47]) and in-person therapy [64]. It also improved on attrition rates of unguided DMHIs, which reach nearly 50% when accounting for publication bias [34].

Therapist, digital navigator, and mindLAMP adherence were also all high. That therapists were not all highly experienced suggests that the training procedures and clinic manual were able to enable delivery of brief, transdiagnostic, evidence-based treatment by clinicians with a range of experience, supporting the scalability of the model. That digital navigator adherence was also high suggests that checklists helped facilitate smooth check-ins and should be used in future studies. Finally, mindLAMP adherence among patients was high, suggesting that they successfully engaged with the app between sessions, potentially extending the impact of treatment to their own daily lives. These three components of the clinic (app, clinician, digital navigator) appeared to be acceptable to patients, based on high satisfaction ratings with each one.

While the feasibility of quantitative measures was high for baseline and post-intervention timepoints, completion rate of the three-month follow-up measures fell below our benchmark. This suggests room for improvement, with our current method of simple email outreach three months after the intervention being insufficient. Alternative strategies for a future study include offering participants payment or scheduling a study appointment for the 3-month follow-up questionnaire upfront.

Further room for improvement was suggested in terms of feasibility of aspects of the digital format. Overall 72% endorsed that they encountered no significant hurdles, slightly below our 75% benchmark. Most hurdles reported were around finding a quiet place for therapy sessions (11%) and difficulty using mindLAMP (11%). To mitigate the first barriers, in future studies, it will help to

build in protected time at the introductory meeting to discuss and resolve practical barriers with each patient around finding privacy for therapy sessions. Regarding the second hurdle, it is likely that difficulty reported around mindLAMP use was resolved in digital navigator meetings. Nevertheless, a future study analyzing the qualitative feedback obtained in this study will help shed light on this question and inform refinements.

In terms of the potential efficacy of the Digital Clinic, results yielded promising findings. The average depression, anxiety, and co-morbidity scores fell to the sub-clinical range by the end of the intervention, and rates of clinically significant improvement and remission were high. Although this feasibility study was not designed to establish efficacy and thus did not employ a control group, these outcomes meet and exceed outcomes from RCTs of longer-term evidence-based treatments [65,66], warranting a future efficacy RCT.

Strengths & Limitations

Strengths of this study include evaluating a program designed to be a highly scalable yet also effective solution to increase access to care. Several components increase scalability, including brief therapy, the creation of standardized manuals for the clinician and digital navigator roles, and the use of an open-source smartphone app. The focus on disseminating transdiagnostic evidence-based treatment increases the program's reach to people with various clinical presentations. That the program was effective without the need for highly experienced clinicians supports the potential for widespread adoption and implementation of the model in various healthcare settings.

Despite these strengths, several limitations are also worth considering. First, although valid and reliable instruments were used for all outcomes, the PHQ-9 and GAD-7 measures do not adequately capture distress for some clinical presentations (e.g., someone with social anxiety disorder, whose distress is only apparent in specific situations they may generally avoid). Future studies should consider a fuller breadth of outcome measures. Second, because this was a feasibility study [67] designed to primarily examine whether this model is feasible and acceptable to patients

and providers (and secondarily whether it is *potentially* efficacious), no control group was used. The lack of a control group precludes definitive conclusions about clinical improvement resulting from the intervention itself rather than the passage of time or other factors. Third, we did not track treatment fidelity in the traditional manner, relying instead on supervision meetings and the subsequent examination of clinical notes to assess clinician adherence. This method could be strengthened in a future study by using a checklist system as done with digital navigators, or by obtaining session recordings coded for adherence.

Future Directions

Results of the present study suggest that this model of care shows promise as an effective solution for mitigating barriers to quality mental health intervention access. This model was informed by research that shows that digital interventions offered with (versus without) human support are more effective [5], especially for people with higher clinical severity [68]. The inclusion of support in terms of clinicians and digital navigators appears to be effective in increasing access and quality in care for people with various levels of clinical severity. Results suggest that the Digital Clinic warrants a future RCT to establish its efficacy.

Another future direction is to conduct a dismantling study to isolate the additive effects on outcomes of the brief clinician-delivered therapy, the digital navigator, and mindLAMP app integration. Research suggests that the digital components of guided DMHIs may independently contribute to outcomes [69] and that mindLAMP enhanced by a digital navigator alone can have its own beneficial effects [39]. The extent of each component's impact on efficacy can inform future model adaptation and lead to a more cost-effective, stepped-care version of the Digital Clinic, where more clinical resources are offered first to those with higher severity. Recent research supports such models, as they use limited clinical resources in ways that maximize efficacy and are cost-effective [70].

Finally, a still unanswered question in the field is whether gains obtained from participating

in brief, guided DMHIs are sustained in the long term. In this study, clinical improvement was sustained for the 44% of the sample who completed the three-month follow-up questionnaire. This finding once again suggests that this intervention may be potentially efficacious in the short and long term, but it warrants more research to confirm this possibility.

Conclusion

Brief, evidence-based treatment in the Digital Clinic reduces cost and alleviates the provider shortage, while the app increases the impact of brief treatment and enables measurement-based care. The digital navigator supports app engagement and lowers the burden of data and technology use on the clinician. Results from the present study suggest that this model is feasible, accepted, and potentially efficacious, warranting a future RCT.

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