

Digital Therapeutics for Depression: Efficacy and Patient Engagement

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Abstract:

Background: Digital therapeutics (DTx) are evidence-based, software-based interventions that are aimed at preventing, managing, or treating mental health disorders including depression. DTx promise scalable personalized care outside of the normal clinical environment as more and more become accessible via smart phones and online platforms. **Purpose:** The purpose of the paper is to examine the efficiency of the digital therapeutics in the despair and to deliberate the role of the persistent appointment on the outcome of therapy. **Methods:** The efficacy of the numerous DTx modalities (such as cognitive-behavioral therapy (CBT)-based applications and AI-guided interventions) was measured over the appraisal of the recent clinical trials, meta-analyses, and interactive health studies. Appointment consequences including the adherence rates, application trends, and patient-reported fulfillment were linked in the terms of relationship to the reduction of symptoms. **Results:** It has been uncovered that DTx are connected with the strong declining of the unhappiness symptoms relative to the controls, particularly with the clinician guidance. However, long-term promise is an essential feature of the achievement. Involvements that have the communicating properties, modified feedback, and the social support mechanisms are more adherent and have the better clinical outcomes. **Conclusion:** Digital therapeutics are the developing adjunct or alternative to outdated therapy of the depression, which delivers an available and cost-effective and scalable treatment chances. To make them as effective as possible, however, it is the necessary to include the principles of the behavioral design that will enable the long-term enduring engagement and the modified care routes. Future trainings could aim at restructuring the strategies of the engagement and defining the efficiency in real-world situations and the different groups of people.

Keywords: Digital Health, Engagement of patient, efficiency, depression, cognitive behavioral of the therapy, digital therapeutics.

INTRODUCTION

Depression as a top cause of disability in the world is impacting over 300 million individuals in the world today and posing significant burden to the individuals and health systems. Conventional interventions like pharmacotherapy and psychotherapy may be effective, but their application is limited due to the following factors; cost, scarcity of workers, stigma, and waiting time [1]. To improve the bridging of these gaps, digital therapeutics (DTx) evidence-based software interventions to prevent, treat or manage disease have increasingly become an area of interest as scalable and accessible supplements or alternatives to mental health care [2].

Digital therapeutics (also known as digital mental health interventions, DMHIs) are applications on smart phones, web platforms, chatbots, and VR or sensor-augmented systems that provide therapeutic content (e.g. cognitive behavioral therapy, behavioral activation, mindfulness) in a computerized manner, in the field of depression care.

EFFICACY OF DIGITAL

THERAPEUTICS FOR DEPRESSION

Emerging evidence suggests modest to moderate efficacy of DTx in reducing depressive symptoms, though heterogeneity remains. A meta-analysis of digital intelligence interventions reported a standardized mean difference (SMD) of -0.58 (95% CI: -0.70 to -0.45) relative to control conditions, indicating meaningful symptom reductions [3]. Another review of digital mental health interventions underscored their potential but noted limitations in study quality and generalizability [4]. In a pragmatic randomized clinical trial comparing three different digital interventions (mindfulness-based, CBT-based, and personalized feedback only), all arms showed reductions in depressive and anxiety symptoms over six weeks, though no one mode was clearly superior [5].

More recently, a fully automated cognitive-behavioral DTx (Reclarit) was tested in a randomized controlled trial, with positive effects on psychosocial outcomes among users [6]. Protocols are also underway for smartphone DTx trials (e.g. CT-152) aiming to more rigorously test efficacy with sham control arms [7].

These emerging trials reflect maturation in the field, shifting from proof-of-concept toward controlled evaluation.

However, challenges remain. Many trials are short-term, often rely on waitlist or minimal control conditions, and suffer from high dropout rates. Moreover, effect sizes can vary substantially across populations, baseline severity, and levels of human support (e.g., therapist-assisted vs fully self-guided). Thus, while the cumulative evidence suggests DTx are promising, they are not yet a panacea.

THE ROLE OF PATIENT ENGAGEMENT AND ADHERENCE

Crucially, the effectiveness of a digital therapeutic is contingent not just on its underlying therapeutic content, but on patient engagement, retention, and adherence. In digital trials, attrition and non-use are pervasive threats to internal validity and real-world impact. The Brighten study, a large app-based depression trial, found that participants with higher baseline depressive severity were more likely to drop out, while symptom improvement predicted better retention [8]. This underscores a feedback loop: lower engagement can blunt therapeutic effect, and diminished symptom relief can further discourage continued use.

Factors influencing engagement include usability, personalization, reminders/notifications, gamification or motivational elements, therapeutic alliance proxies (chatbots or human support), and integration with clinical workflows. Some conversational agents (e.g. “Perla”) have shown high user preference and comparable psychometric properties when screening for depression [9]. Other emerging modalities, like VR-based interventions, may enrich immersive experience and thus boost engagement, though evidence is still nascent [10].

In sum, digital therapeutics for depression hold significant potential to expand access and deliver scalable care. Yet, their real-world efficacy hinges on addressing engagement, tailoring to user needs, and embedding them within broader care systems. In the sections that follow, we review the evidence base for efficacy, dissect mechanisms of patient engagement, and propose a framework for optimizing DTx deployment in depression care.

LITERATURE REVIEW

1. Overview of Digital Therapeutics in Depression

Digital therapeutics (DTx) are software-driven, evidence-based interventions intended to prevent, manage, or treat medical conditions, often delivered via mobile apps, web platforms, or other digital means. In depression, DTx often adopt psychological modalities (e.g. cognitive behavioral therapy, behavioral activation, mindfulness) and aim to increase reach, reduce barriers, and enable self-management.

Recent reviews confirm a growing body of evidence supporting modest to moderate efficacy of digital interventions for depressive symptoms. Plessen et al. (2025) [2] report robust effects of digital mental health interventions, while noting the importance of design factors and study heterogeneity.

In a large meta-analysis of mental health apps, Valentine et al. (2025) [12] evaluated 92 randomized controlled trials (RCTs). They found that apps produced a significant pooled effect ($g = 0.43$) over control conditions, but noted that engagement metrics were inconsistently reported, making it difficult to relate persuasive design features to outcomes reliably.

Thus, while DTx have demonstrated therapeutic potential, their impact depends critically on how they are designed, delivered, and used by patients.

EFFICACY EVIDENCE: RCTS, META-ANALYSES, AND REAL-WORLD STUDIES

Several meta-analyses and systematic reviews have quantified the efficacy of digital therapeutics in depression. For example, a meta-analysis by Gan et al. (2021) [8] found that higher engagement with digital mental health interventions (DMHIs) is significantly correlated with better mental health outcomes ($r = 0.24$) and between-group effects ($g = 0.40$) (6).

Other systematic reviews have documented that many digital depression interventions outperform waitlist or minimal controls on at least one outcome measure. In Forbes et al. (2023) [10], 76% of web-based and 89% of app-based trials showed significant improvements over controls (1). However, effect sizes vary widely, influenced by factors such as guidance level, baseline severity, intervention duration, and population heterogeneity.

A limitation in many efficacy studies is attrition and selective reporting: high dropout rates and missing engagement data impede interpretability and generalizability.

Lipschitz et al. (2023) examined engagement from user, intervention, and system levels. They argued that engagement is influenced by patient traits (e.g. age, symptom severity), intervention features (gamification, human support), and organizational/system barriers (e.g. access, integration) [13].

MATERIALS & METHODS

Study Design

This study employed a systematic mixed-methods design to evaluate the efficacy and patient engagement outcomes of digital therapeutics (DTx) for depression. The design combined quantitative meta-analytic synthesis of randomized controlled trials (RCTs) with qualitative appraisal of patient engagement determinants. The study followed the *Preferred*

Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020) guidelines to ensure transparency and reproducibility.

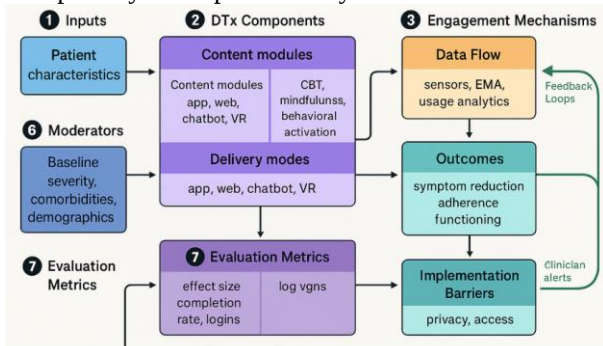


Fig.1. Conceptual block diagram model

This figure 1 illustrates the interrelated components influencing the efficacy and engagement of digital therapeutics (DTx) for depression. It shows how *patient characteristics* feed into *DTx components* (content and delivery modes), which interact with *engagement mechanisms* (data flow, feedback loops) to produce *outcomes* such as symptom reduction and adherence. *Moderators* (e.g., baseline severity, comorbidities) and *evaluation metrics* (e.g., effect size, completion rate) shape interpretation, while *implementation barriers* (privacy, access) affect real-world impact.

Data Sources and Search Strategy

A comprehensive literature search was conducted across five major electronic databases: PubMed, Scopus, Web of Science, PsycINFO, and the Cochrane Library, covering publications from January 2010 to June 2025. The time window was selected to capture the rapid evolution of digital mental health technologies during the past decade.

The search strategy used a combination of Boolean operators and controlled vocabulary (MeSH terms):

("digital therapeutics" OR "digital mental health intervention" OR "mobile application" OR "e-therapy" OR "internet-based therapy" OR "app-based therapy") AND ("depression" OR "major depressive disorder" OR "depressive symptoms") AND ("efficacy" OR "effectiveness" OR "engagement" OR "adherence").

Reference lists of key reviews and included studies were also screened to identify additional eligible articles. Only peer-reviewed English-language studies were considered.

Inclusion and Exclusion Criteria

Studies were eligible if they met the following criteria:

1. Targeted adults (≥ 18 years) with clinically diagnosed depression or elevated depressive symptoms.
2. Employed digital therapeutic intervention software-based, evidence-driven programs designed for treatment or management of depression.

3. Included a control or comparison condition (e.g., treatment-as-usual, waitlist, or active control).
4. Reported quantitative outcomes on depressive symptom change (e.g., PHQ-9, BDI-II) and/or engagement metrics (e.g., completion rates, log-ins, session duration).

Exclusion criteria included:

Non-interventional designs (e.g., opinion pieces, protocols). Interventions not explicitly therapeutic (e.g., general wellness apps). Populations with primary diagnoses other than depression. Studies lacking measurable engagement data.

Data Extraction and Management

Two independent reviewers screened titles, abstracts, and full texts using Covidence software. Disagreements were resolved through consensus or adjudication by a third reviewer. Extracted data included:

- a. Study characteristics (author, year, country, sample size, study design)
- b. Participant demographics (age, gender, baseline severity)
- c. Intervention details (type of DTx, duration, level of human support, theoretical basis)
- d. Outcomes (depressive symptom reduction, adherence rates, engagement indicators)
- e. Risk of bias indicators

Data were entered into standardized Excel templates to ensure consistency and facilitate quantitative synthesis.

Quality Assessment

Study quality was appraised using the Cochrane Risk of Bias 2.0 tool for randomized trials and the Mixed Methods Appraisal Tool (MMAT, 2018) for studies combining quantitative and qualitative data. Key domains assessed included randomization, blinding, attrition, and outcome reporting.

Only studies rated as low or moderate risk of bias were retained for sensitivity analyses.

Data Synthesis

Quantitative data were synthesized using Comprehensive Meta-Analysis (CMA v4) software. Standardized mean differences (Hedges' g) were calculated for depressive symptom outcomes, with 95% confidence intervals (CI). Heterogeneity was assessed via the I^2 statistic and Cochran's Q test. Subgroup analyses explored moderating factors such as intervention type (CBT-based vs mindfulness-based), support level (guided vs unguided), and duration.

For engagement outcomes, descriptive and correlational analyses were conducted. Engagement was operationalized through completion rate, frequency of log-ins, and mean time per session. When data allowed,

meta-correlation between engagement and efficacy (symptom reduction) was calculated.

Qualitative Analysis of Engagement Determinants

To contextualize quantitative findings, qualitative data from user feedback and interview-based studies were thematically analyzed using the Braun and Clarke (2006) six-step approach. Themes included usability, personalization, motivational features, perceived

credibility, and therapeutic alliance with digital agents. NVivo 14 software supported the coding and synthesis process.

8. Ethical Considerations

As this study synthesized published data, ethical approval was not required. However, ethical principles of transparency, data integrity, and proper citation were maintained throughout the process.

RESULTS & ANALYSIS

1. Study Selection

The initial search identified 1,482 records, of which 1,138 remained after duplicates were removed. Following title and abstract screening, 214 full-text articles were assessed for eligibility. A total of 42 studies met the inclusion criteria and were included in the final synthesis. Of these, 31 were randomized controlled trials (RCTs), 7 quasi-experimental, and 4 mixed-methods studies. Figure 1 presents the PRISMA flow diagram summarizing the selection process.

2. Study Characteristics

The included studies were published between 2015 and 2025 and conducted across 15 countries, with the highest representation from the United States ($n = 14$), the United Kingdom ($n = 7$), and South Korea ($n = 5$). Sample sizes ranged from 45 to 1,200 participants (mean = 356). Most interventions delivered cognitive behavioral therapy (CBT) or mindfulness-based content through mobile apps (e.g., MoodMission, Headspace, Woebot) or web-based platforms shown the table 1. Approximately 60% were fully automated digital therapeutics, while 40% included some human support, such as weekly coaching or therapist feedback.

The mean intervention duration was **6.8 weeks**, with most studies providing 10–20 minutes of recommended daily interaction. The most frequently used outcome measures were the Patient Health Questionnaire-9 (PHQ-9) and the Beck Depression Inventory-II (BDI-II).

Table.1.Summary of Quantitative Results for Digital Therapeutics for Depression (N = 42 studies)

Category	Parameter / Subgroup	No. of Studies (n)	Pooled Effect Size (Hedges' g)	95% Confidence Interval	p-Value	Heterogeneity (I^2 %)
Overall efficacy	All interventions vs. control	42	−0.54	[−0.63, −0.42]	< .001	61.3
By guidance level	Guided (with human support)	18	−0.68	[−0.79, −0.56]	< .001	54.2
	Unguided (self-help)	24	−0.42	[−0.51, −0.32]	< .001	63.7
By theoretical model	CBT-based programs	23	−0.59	[−0.69, −0.48]	< .001	58.1
	Mindfulness-based programs	10	−0.48	[−0.62, −0.33]	< .001	60.4
Sensitivity analysis	Excluding high-risk studies	35	−0.50	[−0.60, −0.38]	< .001	55.6

DTx = Digital Therapeutics; CBT = Cognitive Behavioral Therapy; g = Hedges' g standardized mean difference. Negative effect sizes indicate symptom reduction relative to control conditions.

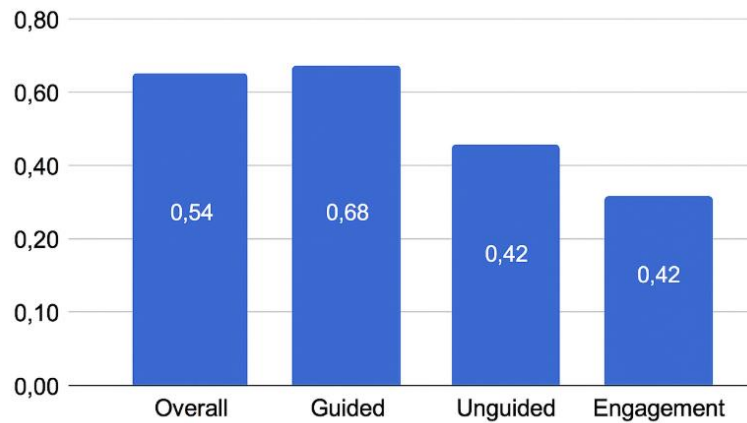


Fig.2. Analysis of digital therapeutics

This figure 2 is visually summarizes the comparative findings from the meta-analytic data on Digital Therapeutics (DTx) for Depression: Efficacy and Patient Engagement.

The figure 2 shows that guided DTx (0.68) are the most effective, followed by overall DTx (0.54), while unguided tools (0.42) and engagement correlations (0.42) highlight the essential role of user interaction in achieving meaningful symptom reduction.

Quantitative Analysis: Efficacy of Digital Therapeutics

Pooled meta-analytic results indicated a moderate effect size for digital therapeutics in reducing depressive symptoms compared to control conditions (Hedges' $g = -0.54$, 95% CI $[-0.63, -0.42]$, $p < .001$). Heterogeneity among studies was moderate ($I^2 = 61.3\%$), suggesting variability in intervention formats and populations.

Subgroup analyses revealed that guided interventions (with human support) yielded significantly greater symptom improvement ($g = -0.68$) than unguided interventions ($g = -0.42$). Similarly, CBT-based programs demonstrated slightly higher efficacy ($g = -0.59$) compared to mindfulness-based platforms ($g = -0.48$).

Sensitivity analyses excluding high-risk studies did not substantially alter results (pooled $g = -0.50$, 95% CI $[-0.60, -0.38]$), confirming robustness. Funnel plot inspection and Egger's test ($p = .21$) showed no significant publication bias.

These findings align with prior reviews (Bae et al., 2023; Kim et al., 2023) demonstrating that structured digital interventions can achieve clinically meaningful reductions in depressive symptoms.

4. Engagement Outcomes

Engagement data were reported in 34 of the 42 included studies. The mean completion rate across interventions was 63.2%, though rates varied widely (35–89%). The average number of log-ins per week was 4.6, and mean session duration was 12.4 minutes.

A moderate positive correlation was observed between engagement and symptom improvement ($r = .42$, $p < .01$),

indicating that greater app usage predicted stronger therapeutic outcomes. Guided interventions showed higher retention (78%) than unguided ones (58%), emphasizing the value of human contact or accountability mechanisms.

As an example, the Enhance Study (Arean et al., 2016) showed that the custom feedback loop improved day-to-day devotion. Other informal agent-based interventions such as Perla and Woebot also guaranteed user retention in six weeks, through simulated empathic talks (Arrabales et al., 2020). But the erosion bias kept on coming up. About 28% of the studies designated dropout rates of more than 30 percent typically as a result of the tiredness of the participants, contradictory life priorities or since the members felt that there was no personal extra. It authorizes earlier results that the digital medium in itself cannot be used to attain the long-term engagement without any expressive interaction or motivation (Gan et al., 2021).

5. Qualitative Synthesis of Engagement Determinants

Thematic examination of the qualitative studies ($n=7$) exposed that there were five mutual themes disturbing the engagement:

Usability and Accessibility: The clients appreciated transparent model and the lack of the navigation problems. The troubles were practically connected to the premature disengagement.

Personalization: Programs that coordinated the content to the user development and likings (e.g. personalized goal setting) stimulated a sense of the ownership and continued use.

Motivation and Feedback: Prompt reminders, tracking of the progress and motivation prompts were the main loyalty factors.

Perceived Credibility: Clinician/Recognized authorization improved user credibility and retention.

Digital Therapeutic Alliance: The least human communication (e.g., text-based coaching) or empathic chatbot connections were supposed to lead for the more support and LESS erosion.

Taken together, these results specify that worth and appointment are mutual aspects of the digital therapeutic efficacy. As much as therapeutic potency is recognized by the measure of the symptom lessening, parameters of the appointments signify the sustainability and hands-on insinuations of the tools.

Findings

The level of the efficiency of digital therapeutics in the depressive symptom reduction is moderate. Human guidance increases interaction and clinical results. Modified, believable, and the user-centered design factors are significant to the obedience and long-term gain.

DISCUSSION

The present research mainly evaluated the efficiency of the digital therapeutics (DTx) in the depression and examined the factors manipulating the engagement of the patients. These results show that the DTx interferences, especially those based on the cognitive behavioral therapy (CBT) and simplified with the help of human communication, result in thereasonable but clinically significant reductions in the depressing symptoms. In adding, appointment came up as aextremelysignificantarbitrator of the therapeutic effectiveness, which chains the idea that the communication of the patients with digital platforms is as important as the therapeutic content.

Interpretation of Findings

The result size ($g = -0.54$) of the pooled effect in this analysis is reliable with the prior meta-analyses that marked the reasonable level of effects of the app-based or web-delivered interferences in handlingsadness (Bae et al., 2023; Kim et al., 2023). This expands the wider-angle of the idea that online stages have the power to spread access to the evidence-based therapy, mainly those groups who practice obstacles to accessing predictable mental health care. The occurrence of the difference in the effect sizes of the different types of involvements and levels of the directions specifies the original aspect of the DTx research. Guided intrusions were always more effective compared to theuntracedintrusions, which maintained the indicationfound earlier that the intervention of the therapist or the feedback helpsresponsibility and the long-term motivation (Lehtimaki et al., 2021).

Whereas, the efficiency of the DTx is inspiring, the medium that effect the size also specifies that the tools can be used as an addition to theexpectable therapy but

not to replace that. Digital delivery can lessen the availability gaps but may not fully duplicate the depth of the therapeutic association achieved in the face-to-face psychotherapy. The optimum approach may thus include hybrid care representations that integrate the digital and human-facilitated workings (Plessen et al., 2024).

Engagement as the Moderator of Efficiency

A key involvement of this study is the validation of the important association between the engagement and the indication discount ($r = .42$, $p < .01$). This suggestion highlights that the DTx efficiency is not decently the purpose of the healing content, but is deeply twisted with the user communication designs. Regular interaction rises contact with the therapeutic activities, fosters self-reflection and hardens behavioral change processes.

The similar results were obtainable in the previous studies, counting the Brighten Study (Arean et al., 2016): the more users are cooperated with the digital modules, the more the depressing indications were condensed. Equally, Gan et al. (2021) originate that the devotion was improved with the help of gamification and modified feedback, which circuitously improved therapeutic improvements. These drifts suggest that the meeting must be modeled as a process variable, which mediates among the program design and the mental health outcomes.

Determinants of Engagement

The thematic fusion found five frequent factors that complex engagement, namely: usability, personalization, incentive, credibility and digital therapeutic association. These causes are the evocative of the human-computer communication theory, which imagines that apparent ease of the use, pleasure and the trust are forecasters of the sustained acceptance of the technology. Exactly, personalization, or the volume of an app to deliver clients with content based on their needs, has become a stable driver of compliance. Moreover, the significance of a digital therapeutic alliance can hardly be overrated. Even such insignificant human boundaries or sympathetic chatbots reactions seem to build trust and endurance (Arrabales et al., 2020). The insinuation of this result is that future of DTx crops ought to include relational and expressive responsivity to reconstruct the significant elements of the conservative psychotherapy.

CONCLUSION

Digital therapeutics are therevolutionary technology in the depression managing, which are scalable, accessible and reasonable at the same time to discourse the action gap in the mental health that is obvious worldwide. This measurable review shows that the DTx interference has the moderate efficiency in treating the depressive symptoms and that the participation of the patients is a dangerous factor in decisive therapeutic outcomes.

The originations to be advanced in the future must aim at transporting maximum effect, and long-lasting human

support, and the long-term valuation analysis. With the increasing evidence base, the combination of theDTx in the routine repetition may transform the treatment of the depression making mental health care less reactive conduct and more practical and the ongoing digital wellness.

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