Evaluation of Digital Mental Health Technologies in the United States: A Systematic Literature Review and Framework Synthesis

Julianna Catania, Steph Beaver, Rakshitha S. Kamath, Emma Worthington, Minyi Lu, Hema Gandhi, Heidi C. Waters, Daniel C. Malone

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Abstract

Background: Digital mental health technologies (DMHT) have the potential to enhance mental healthcare delivery. However, there is little information on how DMHT are evaluated and what factors influence their use.

Objective: A systematic literature review was conducted to understand how DMHT are valued in the United States (US) from user, payer, and employer perspectives.

Methods: Articles published after 2017 were identified from MEDLINE, Embase, PsycInfo, Cochrane Library, the Health Technology Assessment Database, and digital and mental health congresses. Each article was evaluated by two independent reviewers to identify US studies reporting on factors considered in the evaluation of DMHT targeting mental health, Alzheimer's, epilepsy, autism spectrum disorder, or attention deficit hyperactive disorder. Study quality was assessed using the Critical Appraisal Skills Program Qualitative and Cohort Studies checklists. Studies were coded and indexed using the American Psychiatric Association's Mental Health App Evaluation Framework to extract and synthesize relevant information.

Results: Of 4,353 articles screened, data from 26 unique studies from patient, caregiver, and healthcare provider perspectives were included. Engagement style was the most reported theme (n=23 studies), with users valuing DMHT usability, particularly alignment with therapeutic goals through features including anxiety management tools. Key barriers to DMHT use included limited internet access, poor technical literacy, and privacy concerns. Novel findings included discreetness of DMHT to avoid stigma.

Conclusions: Usability, cost, accessibility, technical considerations, and alignment with therapeutic goals are important to users, although DMHT valuation varies across individuals. DMHT apps should be developed and selected with specific user needs in mind.

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RESULTS: Of 4,353 articles screened, data from 26 unique studies from patient, caregiver, and healthcare provider perspectives were included. Engagement style was the most reported theme (n=23 studies), with users valuing DMHT usability, particularly alignment with therapeutic goals through features including anxiety management tools. Key barriers to DMHT use included limited internet access, poor technical literacy, and privacy concerns. Novel findings included discreetness of DMHT to avoid stigma.

CONCLUSIONS: Usability, cost, accessibility, technical considerations, and alignment with therapeutic goals are important to users, although DMHT valuation varies across individuals. DMHT apps should be developed and selected with specific user needs in mind.

Keywords: mental health; mHealth; digital health; digital therapeutics; systematic review; framework synthesis; mixed methods

INTRODUCTION

Background

Digital health is comprised of a broad range of technologies, including mobile health, health information technology, wearable devices, and personalized medicine, which serve as tools to enhance health care delivery. Recently, several digital mental health therapeutics, a category of digital mental health technologies (DMHT), have received United States (US) Food and Drug Administration (FDA) approval to prevent, manage, or treat a medical disorder or disease based on evidence from superiority trials and compliance with technical guidelines [1,2]. However, the majority of DMHT, particularly apps, fall outside FDA jurisdiction because they are not intended to diagnose, treat, or prevent disease, and because they are "low risk" in that they would not cause harm in the event of malfunction [3]. Due to this lack of regulatory framework, few DMHT are supported by published efficacy studies. One study found that only 16% of mental health (MH) apps recommended by college counseling centers were supported by efficacy studies published in peer-reviewed journals [4].

Nonetheless, many healthcare providers (HCPs) use MH apps in clinical practice. Up to 83% of behavioral health providers in a small study covering the greater Boston area reported using apps as part of their clinical care, particularly mindfulness apps for patient anxiety management [5]. As many DMHT are currently widely used in clinical practice without undergoing any formal assessment for quality or relevance, understanding how DMHT should be assessed based on factors impacting their value from the perspective of key stakeholders, such as patients, caregivers, providers, payers, and employers, could improve selection of DMHT for use by patients, thereby increasing care quality and outcomes for those seeking MH support.

Objective

To address identified gaps, a systematic literature review (SLR) was conducted using a published framework to synthesize emerging themes from mixed-methods evidence in order to understand how digital health solutions, encompassing both digital therapeutics and direct-to-consumer digital health technologies, are valued, with a focus on MH disorders, Alzheimer's, epilepsy, autism spectrum disorder (ASD), and attention deficit hyperactive disorder (ADHD) in the US.

METHODS

Overview

The SLR was performed in accordance with a pre-specified protocol and reported in line with the Enhancing Transparency in Reporting the Synthesis of Qualitative Research and Preferred Reporting Items for Systematic Reviews and Meta Analyses guidelines [6,7]. The protocol was not registered.

Search Strategy

Electronic databases, encompassing MEDLINE (including MEDLINE In-Process, MEDLINE Daily and MEDLINE Epub Ahead of Print), Embase, the Cochrane Library (including Cochrane Database of Systematic Reviews and Cochrane Central Register of Controlled Trials), PsycINFO, and the Health Technology Assessment Database, were selected in alignment with this SLR's target indications and were searched on June 17th, 2022. The search terms included combinations of free-text and Medical Subject Heading or Emtree terms related to indications of interest, DMHT, and relevant outcomes or assessment types (e.g., technology assessments, cost) (**Tables S1–S5**). Searches were limited to studies performed in the US and to those published from 2017 onwards.

Manual hand-searches of grey literature, namely, the bibliographies of relevant SLRs identified from the electronic database searches and key conference proceedings (2019–2022), were performed to identify additional studies of relevance (**Table S6**). The FDA website was also searched to identify factors involved in the FDA's appraisal of relevant MH apps, which could supplement the factors identified in this SLR (**Table S7**).

Study Selection

Studies were included in the SLR if they met pre-specified criteria defined using the SPIDER (Sample, Phenomenon of Interest, Design, Evaluation, Research type) framework, which is appropriate for mixed-methods research questions. Eligible studies were published in the English language, set in the US, and reported quantitative or qualitative outcomes relating to factors considered in the evaluation of DMHT. Only studies published in 2017 or later were included because of the rapidly evolving research area. Eligible studies reported on MH, Alzheimer's, epilepsy, ASD, or ADHD from user, payer, or employer perspectives (**Table S8**). While the primary focus of the SLR was MH, neurological conditions

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were also of interest because their pathologies, symptoms, and treatment strategies can overlap with those of mental illnesses. Alzheimer's, epilepsy, ASD, and ADHD were selected because they are highly researched and represent diverse types of neurological conditions.

The titles and abstracts of records were assessed for inclusion against these eligibility criteria by two independent reviewers and discrepancies were resolved by consensus, with arbitration by a third reviewer if necessary. Full texts of potentially relevant articles were acquired and screened using the same methodology.

Study Prioritization

Due to the large volume of evidence identified, further eligibility criteria were applied to prioritize primary research on DMHT valuation factors that were theoretical. In line with the thematic framework synthesis objective, theoretical valuation factors were defined as user or DMHT attributes that impact interaction with or perception of DMHT; therefore, studies only reporting efficacy outcomes, such as mental illness symptom improvement, were deprioritized for full-text review. Secondary research was also deprioritized for full-text review. Studies that reviewed a select app against a framework and studies only reporting outcomes specific to a select app were deprioritized for data extraction. For example, a study reporting the usability of a *specific* app's features would have been deprioritized, while a study reporting what *types* of features increase MH app usability *in general* would not.

Data Extraction

All relevant data were extracted into a pre-specified Microsoft Excel grid and a quality assessment was performed for each study. Studies only reporting qualitative data were assessed with the Critical Appraisal Skills Program (CASP) Qualitative Studies Checklist. Studies only reporting quantitative data were evaluated with the CASP Cohort Study Checklist, and studies reporting both qualitative and quantitative data were evaluated with both checklists [8]. Data extractions and quality assessments were performed by a single individual for each study, with the information verified by a second, independent individual. Discrepancies were resolved by consensus, with arbitration by a third individual if necessary.

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Framework Synthesis

A framework synthesis approach was undertaken to synthesize qualitative and quantitative data identified from the SLR. In line with the "best fit" framework synthesis approach, data were indexed deductively against an existing framework where possible, and novel themes were added inductively as needed [9,10]. The American Psychiatric Association's (APA) Mental Health App Evaluation framework was considered the most appropriate framework to address the research objectives of this SLR because its key valuation themes: were developed using psychiatrist and patient input, are broadly shared by other evaluation frameworks, are widely acknowledged in the literature, and have been described as durable and adaptable [11-13].

The APA model follows a hierarchical and chronological order whereby the evaluator moves through the framework using prompting questions (e.g., "Does the app work offline?"). For this SLR, these questions were either thematically grouped into subthemes or left as prompting questions, as appropriate. The framework was therefore ultimately adapted into three levels: themes, subthemes, and more granular valuation criteria (**Table 1**). It should be emphasized that this SLR did not aim to formally develop an updated framework to be used in practice by HCPs and their patients, but rather was used to form a theoretical basis for understanding DMHT valuation factors, for which novel themes were expected to emerge.

A data-based convergent approach was used to synthesize quantitative and qualitative data [14]. Data were initially indexed deductively against the pre-specified themes within the data collection instrument, then further synthesized within Docear, a mind-map software used to organize and connect data and concepts. Indexing was performed by one reviewer and checked by a second, independent reviewer. New themes and subthemes that emerged from the literature through inductive coding were added *post-hoc* to the thematic framework, with all extracted data then considered against both the pre-specified and novel themes. Evidence identified for each theme was synthesized narratively, taking into consideration the context and design of each study.

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Table 1. Studies reporting on each theme, subtheme, and criterion

Subtheme	Criteria [study reference]
Engagement Style	
Short-term usability	Ease of use [5,15-17]
	Available engagement styles [15,16,18-24]
Long-term usability	Alignment of app with needs and priorities [5,16,18-36]
	Forgot or unmotivated to use [5,15,18,19]
Customizability	No further stratification [16,17,19,20,22,26,28]
Background and Accessibility	
Technical	Offline functionality [15,18,21,32,37,38]
	Compatibility with different operating systems
	Accessibility [5,15,17,26-28,32,35,38]
Business model	Funding sources/conflicts of interest
Costs	Additional/hidden costs [18,33]
	Willingness to pay [15-17,34]
	Insurance restrictions [22]
	Cost saving compared with professional care [27]
	No further stratification [15,16,33,38]
Medical claims	Specific medical claims
	Trustworthiness of source
Stability	Frequency of software updates [17,18]
Privacy and Security	
No specific subtheme[a]	No further stratification [16,18,30]
Data collection and storage	Ability to opt-out of data collection or delete data
	Data storage location
	Security associated with collection, use, and/or transmission of sensitive data (including personal health information) [5,27,28,32,38]
Privacy policy	Transparency and accessibility of privacy policy [16,17,35]
	Declaration of data use and purpose [16]
	Data sharing with third parties [15]
	Systems to respond to potential harms or safety concerns
Personal health information	Description of use of personal health information [16]
	Personal image and stigma [5,15,27,39]
Security measures	Security systems used [17,21,39]
Clinical Foundation	
Impressions of use	Accuracy and relevancy of app content [15,33]
	Alignment in app appearance and its claimed purpose
User feedback	Evidence of specific benefit from user feedback or user research studies [17,38]
	Validation of app usability and feasibility
Clinical validity	Supporting sources or references for use cases of the app [16,17]
	Evidence of specific benefit [16,17,30,38]
	Evidence of effectiveness/efficacy [16,18,28]
	Clarity in functional scope
Therapeutic Goal	
Clinically actionable	Positive change or skill acquisition [5,16,19,21,26,30,31,33,38]
	Ease of sharing and interpretation of data [15,21,33,38]
Therapeutic alliance	Possibility for collaboration with an HCP [5,16,23,24,30,38]

Subtheme	Criteria [study reference]
Data ownership, access, and export	Therapeutic alliance between patient and HCP [5,33]
	User ownership of data
	Opportunity for sharing of data with electronic medical records and other data tools (Apple HealthKit®, Fitbit™)
	Opportunity for use with a provider and ability to export or transfer data

Footnotes: Subthemes and criteria in grey were included in the American Psychiatric Association's framework but were not reported on by studies included in this SLR. Criteria in **bold** were novel findings that emerged from this   SLR.
Abbreviations: HCP, healthcare provider; SLR, systematic literature review.

RESULTS

Included Studies

A total of 4,974 records were retrieved from the electronic databases. Of the 3,374 unique records identified following deduplication across the databases, 2,891 were excluded based on eligibility criteria and an additional 456 were deprioritized because they were not directly related to the topic of interest for this SLR. Excluded and deprioritized full texts are listed in **Table S9** and **Table S10**, respectively. Therefore, 27 articles were included from electronic database searches. Additionally, one article reporting on the same study as an already-included conference abstract was identified during supporting targeted searches and included as a supplementary record, resulting in a total of 28 articles reporting on 26 unique studies (**Figure S1**). No relevant FDA appraisals were identified in the supplementary search.

Of the included studies, eight were quantitative, twelve qualitative, and six used mixed-methods. Five studies assessed prospective cohorts and twenty-two utilized a cross-sectional approach, including one study that contained both a prospective cohort and a cross-sectional cohort (**Table 2**). All studies investigated a user perspective, with none specifically investigating payer or employer perspectives. Only one study, which examined ingestible sensor pills and smart pill dispensers to track adherence, investigated a DMHT that was not an app [34].

Most frequently, studies focused on indications for mood, anxiety, or psychotic disorders (n=15) with other indications of focus including ADHD (n=2), ASD (n=1), and epilepsy (n=1). No relevant studies focused on Alzheimer's were identified.

Eight studies assessed the perspectives toward DMHT of general population participants, who were not necessarily diagnosed with relevant conditions [16-

18,26,27,29,30,32]. Of these populations, several were identified as having an increased risk of MH conditions, such as cancer patients [26], college students [16,27], deaf or hard-of-hearing individuals [32], and people who were unemployed or furloughed during the COVID-19 pandemic [29]. Additionally, one study included a mix of patients who were above and below referral criteria for psychotherapy for depression [18].

Table 2. Summary of included study characteristics and outcomes

Study	Design[a]	Perspective/Population[a]	Objective(s)	Data Collection Method(s)[a]
Afra 2018 [25]	Cross-sectional, quantitative	Patients with epilepsy who were regular smartphone users recruited from the University of Utah Adult Comprehensive Epilepsy Clinic (N=40)	To develop a drug-device combination product using an app in combination with antiseizure medications as an epilepsy treatment	Custom survey
Beard 2019 [31]	Cross-sectional, quantitative	Patients treated at a partial hospitalization program located in a non-profit, insurance-based, psychiatric hospital; diagnoses included MDD, BD, anxiety, OCD, stress-related disorders, and psychotic disorders (N=322)	To characterize general smartphone app and social media usage in an acute transdiagnostic psychiatric sample with high smartphone ownership; characterize current engagement and interest in the use of smartphone apps to support MH; and test demographic and clinical predictors of smartphone use	Custom survey
Borghouts 2022 [32]	Cross-sectional, mixed-methods	General users[b]: members of the Center on Deafness Inland Empire, comprised of people with lived experience as members of the deaf/hard-of-hearing community (N=10)	To investigate the MH needs of the deaf/hard-of-hearing community and how MH apps may be able to support these needs	Custom survey; focus group
Boster 2018 [22]	Cross-sectional, qualitative	Speech language pathologists experienced in augmentative and alternative communication using a device in children with ASD recruited through social media and professional listserves (N=8) Parents (caregivers) of children with ASD recruited through national organizations (N=5)	To gain insight from speech language pathologists and parents of children with ASD regarding appealing features of augmentative and alternative communication apps	Focus groups; poll questions
Buck 2021a [23]	Cross-sectional, quantitative	Caregivers of young adult family members who experienced early psychosis (before age 35) recruited through HCP referrals or ads (N=43)	To assess caregivers' interest in an array of specific potential mHealth functions to guide development of mHealth for caregivers of young adults with early psychosis	Custom survey
Buck 2021b [24]	Cross-sectional, quantitative	Users: young adults (18–30 years) with a diagnosis of a psychotic disorder or self-reported history of psychotic symptoms recruited through HCP referrals or ads (N=77)	To understand the needs, interests, and preferences of young adults with early psychosis regarding mHealth by surveying interest in mHealth features and delivery modalities, and by collecting information about their digital and online behaviors	Custom survey
Carpenter-Song 2018 [37]	Prospective cohort, qualitative	Patients at a community MH center (N=15)	To examine current practices and orientations toward technology among consumers in three mental health settings in the United States	Semi-structured interviews
Casarez	Cross-	Caregivers: spouses or	To explore how the well-being	Focus groups;

Study	Design[a]	Perspective/Population[a]	Objective(s)	Data Collection Method(s)[a]
2019 [20]	sectional, qualitative	partners of patients with BD recruited from a local outpatient psychiatry clinic or psychiatric hospital (N=13)	of spouses or partners of patients with BD can be improved through mHealth technology	minimally structured, open-ended individual interviews
Connolly 2018 [15]	Cross-sectional, qualitative	<u>Patients</u>: US military veterans (18–70 years) who screened positive for PTSD, alcohol use disorder, or MDD during the previous year at nine community-based VA outpatient clinics (N=66)	To examine veterans' attitudes toward smartphone apps and to assess whether openness toward this technology varies by age or rurality	Semi-structured interviews informed by the State of the Art Access Model
Cummings 2019 [33]	Cross-sectional, qualitative	Parents and grandparents with children or grandchildren (<u>caregivers</u>) enrolled in a public health insurance program who received ≥2 months of ADHD treatment at four safety-net clinics (N=37) <u>Administrators</u> at the same clinics (N=41)	To examine stakeholder perspectives regarding whether mHealth tools can improve MH treatment for low-income youth with ADHD in safety net settings; and what functions would improve treatment	Focus groups (caregivers) and interviews (HCPs and staff), both semi-structured and including open-ended questions and targeted probes
Dinkel 2021 [38]	Cross-sectional, qualitative	Adult <u>patients</u> (≥19 years) with a current or prior diagnosis of depression, recruited during medical visits from two integrated primary care clinics (N=17) <u>HCPs</u> and <u>staff</u> at the same clinics (N=15)	To explore patient and clinic-level perceptions of the use of depression self-management apps within an integrated primary care setting	Semi-structured focus groups; semi-structured interviews
Forma 2022 [34]	Cross-sectional, quantitative	<u>Caregivers</u> of patients with BD, MDD, or schizophrenia who believed their patients had adherence issues to second-generation oral atypical antipsychotic medication (N=184)	To assess caregivers' preferences and willingness to pay for digital (ingestible sensor pill, medication containers with electronic monitoring, mobile apps, smart pill dispensers) and non-digital (medication diary, simple pill organizer) tools	Custom discrete choice experiment survey
Hoffman 2019 [5]	Prospective interventional, mixed-methods	<u>HCPs</u> (N=24) in a routine primary care behavioral health setting who reported their own and <u>patients'</u> (N not reported) MH app utilization and feedback; patient conditions included anxiety, stress, depression, and substance use	To test the feasibility of using mHealth apps to augment integrated primary care services; solicit feedback from patients and providers to guide implementation; and develop an MH app toolkit for system-wide dissemination	Custom survey
Huberty 2022 [26]	Cross-sectional (current Calm users) and prospective interventional (nonusers of Calm, HCPs), qualitative	<u>General users</u>[b]: cancer patients/survivors with smartphones, some of whom were current subscribers of Calm, a meditation app (N=17) <u>HCPs</u>, <u>staff</u>, and <u>not-for-profit partners</u> in cancer care with smartphones (N=10)	To develop a mobile meditation app prototype specifically designed for cancer patients/survivors	Custom surveys; focus groups
Kern 2018 [27]	Cross-sectional, quantitative	<u>General users</u>[b]: students from a midwestern university with smartphones (N=721)	To investigate the potential usefulness of MH apps and attitudes toward using them	Custom survey
Knapp 2021 [21]	Prospective cohort, qualitative	<u>Clinical staff members</u> who provide behavioral health care for children and adolescents with conditions including ADHD and depression at a large community service organization in a midwestern	To learn about considerations and perspectives of community behavioral HCPs on incorporating digital tools into their clinical care for children and adolescents	Focus groups

Study	Design[a]	Perspective/Population[a]	Objective(s)	Data Collection Method(s)[a]
		state (N=37)		
Kornfield 2022 [19]	Prospective cohort, qualitative	Users: participants with at least moderate levels of depression or anxiety symptoms on the PHQ-9 or GAD-7 questionnaires, but without serious mental illnesses (e.g., BD, schizophrenia), who were not receiving formal care, recruited upon completing free online MH self-screening surveys hosted by Mental Health America (N=28)	To investigate how digital technologies can engage young adults in self-managing their MH outside the formal care system	Online asynchronous discussion; synchronous online design workshop
Lipschitz 2019 [28]	Cross-sectional, quantitative	Users: veterans enrolled in care at the VA Boston Healthcare System diagnosed with an anxiety disorder (including OCD), unipolar depressive disorder, or PTSD who had at least one encounter in the local primary care clinic (N=149)	To assess patients' interest in mHealth interventions for MH; to identify whether provider endorsement would impact interest; to determine reasons for non-use of mHealth interventions for MH; and to identify what mHealth content or features are of most interest to patients	Custom survey
Mata-Greve 2021 [29]	Cross-sectional, mixed-methods	General users[b]: essential workers during COVID-19 or workers who were unemployed/furloughed due to COVID-19, recruited from an online research platform (N=1,987)	To document psychological stress; to explore DMHT use in response to COVID-19-related stress; to explore the usability and user burden of DMHT; to explore which aspects and features of DMHT were seen as necessary for managing stress during a pandemic by having participants design their own ideal DMHT	Survey combining custom and validated measures (System Usability Scale, Use Burden Scale)
Melcher 2020 [16]	Cross-sectional, mixed-methods	General users[b]: college students aged 18–25 years, recruited through social media and word-of-mouth (N=100)	To examine why college students show poor engagement with MH apps and how apps may be adapted to suit this population	Custom survey; interviews
Schueller 2018 [17]	Cross-sectional, mixed-methods	General users[b]: smartphone owners, recruited from a research registry (N=827)	To understand where users search for MH apps, what aspects of MH apps they find appealing, and what factors influence their decisions to use MH apps	Custom survey; focus group interviews
Schueller 2021 [30]	Cross-sectional, qualitative	General users[b]: participants who had used an app that allowed them to track their mood, feelings, or mental well-being for ≥2 weeks, recruited from a research registry (N=22)	To understand motivations for and experiences in using mood-tracking apps from people who used them in real-world contexts	Semi-structured interviews
Stiles-Shields 2017 [18]	Cross-sectional, qualitative	General users[b]: participants recruited from online postings; approximately equal numbers of participants were above and below the criteria for a referral for psychotherapy for depression (N=20)	To identify barriers to the use of a mobile app to deliver treatment for depression and to provide design implications based on identified barriers	Card sorting task
Storm 2021 [35]	Cross-sectional, qualitative	Patients with diagnoses of schizophrenia, schizoaffective disorder, BD, or persistent MDD in active treatment at a	To identify stakeholders' perspectives on partnering to inform the software development lifecycle of a	Semi-structured interviews

Study	Design[a]	Perspective/Population[a]	Objective(s)	Data Collection Method(s)[a]
		community MH center (N=17) Peer support specialists at the same center (N=15)	smartphone health app intervention for people with serious mental illness	
Torous 2018 [36]	Cross-sectional, quantitative	Outpatients attending psychiatric clinics; one clinic primarily treated mood and anxiety disorders and the other primarily treated psychotic disorders (N=185)	To understand how individuals with mental illness use their mobile phones by exploring their access to mobile phones and their use of MH apps	Custom survey
Zhou 2020 [39]	Cross-sectional, mixed-methods	Users: participants with mild or moderate depression with local privacy concerns when using MH apps, recruited from a research registry (N=40)	To determine user preferences among the several privacy protection methods used in current mHealth apps and the reasons behind those preferences	Custom survey; interview

Footnotes: [a]Only information relevant to this SLR are reported in this table. [b]General users are participants who were not necessarily diagnosed with indications of interest.

Abbreviations: ADHD, attention deficit hyperactivity disorder; ASD, autism spectrum disorder; BD, bipolar disorder; DMHT, digital mental health technologies; GAD, general anxiety disorder; HCP, health care provider; MDD, major depressive disorder; MH, mental health; mHealth, mobile health; OCD, obsessive-compulsive disorder; PHQ, patient health questionnaire; PTSD, post-traumatic stress disorder; US, United States; VA, Veterans Affairs.

Thematic Analysis

Evidence was identified for all five themes included in the APA framework: engagement style (n=23 studies), background and accessibility (n=16), privacy and security (n=13), therapeutic goal (n=12), and clinical foundation (n=8). Five novel criteria were identified and added to the framework *post-hoc*, one each under engagement style (forgetting or feeling unmotivated to use DMHT) and privacy and security (personal image/stigma) and three under background and accessibility (willingness-to-pay, insurance restrictions, and cost saving compared with professional care).

Theme One: Engagement Style

Engagement style was the most reported theme, with evidence identified from 23 studies. Engagement style encompasses how and why users do or do not interact with DMHT. The long-term usability subtheme was reported by 22 studies, short-term usability by 12 studies, and customizability by 7 studies. Findings from short- and long-term usability subthemes were highly interconnected.

Four studies reported that ease of use promoted short-term DMHT engagement. In Schueller *et al*. 2018, 89.6% of a general population of smartphone users reported ease of use for MH apps as "important" or "very important," and users qualitatively reported dislike of "overwhelming," difficult-to-navigate apps [17]. Users also valued apps that were "simplistic" [16], fit into their daily schedules,

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and were available when needed, such as during acute symptom experiences [5,15]. Select supporting qualitative data are presented **Table 3**.

Table 3. Select key quotes identified for SLR findings

Subtheme	Criteria: Findings	Key Quotes
Engagement Style		
Short-term usability	Ease of use	"I like short exercises. I can use them in different places." Patient in routine behavioral health care, Hoffman 2019 [5]
		"Whenever I have one of those outbursts and frustration, I can just open it up, say 'Okay, what's my first step?''" Male veteran, age 26, Connolly 2018 [15]
	Available engagement styles: use of animation and visuals	"They love badges. And decorating their avatars, like getting a new hat...So, they're very motivated to get through their modules when they get to earn something at the end." Pediatric behavioral health clinician, Knapp 2021 [21]
		"It could become visually distracting - children preferring the animation rather than actually creating genuine, communicative messages." Caregiver or speech language pathologist for children with ASD, Boster 2018 [22]
Long-term usability	Alignment of app with needs and priorities: gamification	*"I've seen some kid clients come alive because they're excited because they wanna beat their score. And just helping them like, 'How do you have to communicate? You have to keep talking. You have to keep going.' It's helped with that."* Pediatric behavioral health clinician, Knapp 2021 [21]
	Alignment of app with needs and priorities: anxiety management	*"App features that could help to reduce anxiety, for example, guided meditation, breathing exercises, or positive affirmation [may be] useful."* Community MH center peer support specialist, Storm 2021 [35]
		"Stuff that's purely motivational... can feel alienating if I'm depressed... but focusing on something specific, like doing a breathing exercise... would be cool." Patient with anxiety or depression, Kornfield 2022 [19]
	Alignment of app with needs and priorities: tracking mood, symptoms, or sleep	*"They [the adolescent] can bring it up on their phone...and we look at just is she daily fluctuating? If so, what happened during that day?"* Pediatric behavioral health clinician, Knapp 2021 [21]
		"I don't know... if he's good or he's getting better or worse or anything like that. Just everything being simple in one place, and just hit a couple of buttons and not have to write anything down will be very good." Caregiver of a child with ADHD, Cummings 2019 [33]
	Alignment of app with needs and priorities: social media-like features	*"I like hearing other people's stories and what they did, and it kind of helps me feel a little better. And I kind of like bounce off it and do what they did and try these new things that they're doing."* User with anxiety or depression, Kornfield 2022 [19]
	Alignment of app with needs and priorities: peer support and chat functions	*"Incorporating lived experiences into a [smartphone] app and organize the [intervention] process to address lived experience because that's what it's all about."* Community MH center peer support specialist, Storm 2021 [35]
		"So maybe the bipolar individual also has access to the same app and then so they talk to each other... That way when I get home, I know ahead of time, it was an okay day today... Or if it was not a good day o.k., so I know that I need to come in a little more reserved." Spouse of an individual with BD, Casarez 2019 [20]
	Forgot or unmotivated to use	*"For someone who may be severely depressed, or someone who needs help, [writing messages] is almost like hard to do. Because if they're having a hard time motivating or encouraging themselves, they might not feel like this is something they could do."* User with anxiety or depression, Kornfield 2022 [19]
		"I notice a good number of patients mentions they did not continue using in home. [...] Maybe because this area is still new for patients?"

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Subtheme	Criteria: Findings	Key Quotes
		Routine behavioral health care staff, Hoffman 2019 [5]
		"*[My son] has one of those crazy little phones that you can do everything with. I just don't have an interest.*"
		Female veteran, age 57, Connolly 2018 [15]
Background and Accessibility		
Technical considerations	Accessibility: mobility barriers	"*They can't figure out why my hands shake so bad...so trying to use a smartphone [is frustrating]... I don't have a whole lot of feeling in my hands.*"
		Male veteran, age 40, Connolly 2018 [15]
	Accessibility: technical literacy	"*I haven't gotten acclimated to a smartphone yet...the technology is kind of difficult to navigate.*"
		Male veteran, age 66, Connolly 2018 [15]
	Offline functionality: internet and mobile data access as a barrier to use	"*[A young person's smartphone] is normally one of the first things that get taken away if they do have a bad day. So, this is the thing you can use when you're having a bad day to calm down, but then mom and dad won't let you use it because you had a bad day.*"
		Pediatric behavioral health clinician, Knapp 2021 [21]
		"*There have been times I think people have suggested, 'Check this app out, check that app out,' and for the most part I don't think I have... I do only have so much data.*"
		Patient receiving psychiatric care, Carpenter-Song 2018 [37]
Costs	**Willingness to pay**	"*If they don't have the free trial and they want money, I'm not even gonna look at it. I'm not gonna pay for something before I've gotten the chance to see if it's gonna work for me or not.*"
		General user, smartphone owner, Schueller 2018 [17]
		"*...they gave the option to pay $50.00 a year. And I did that, because I liked the idea of what they were trying to do.*"
		General user, smartphone owner, Schueller 2018 [17]
Privacy and Security		
Data collection and storage	Security associated with collection, use, and/or transmission of sensitive data (including personal health information)	"*I'm worried about my data.*"
		Patient in routine behavioral health care, Hoffman 2019 [5]
		"*Any apps that terms and conditions you're forfeiting your information as soon as you click to that to anything so and I'm not worried about getting identity theft.*"
		Patient with current or prior depression diagnosis, Dinkel 2021 [38]
Privacy policy	Transparency and accessibility of privacy policy	"*To use a smartphone app with a client I would want to make sure it's secure before going any further.*"
		Community MH center peer support specialist, Storm 2021 [35]
Personal health information	**Personal image and stigma**	"*I worry about my virtual image. I'd feel more comfortable using an app from CHA [Cambridge Health Alliance] that is protected in the same way my EMR [electronic medical record] is protected.*"
		Patient in routine behavioral health care, Hoffman 2019 [5]
Security measures	Security systems used	"*The app doesn't read as something like, My Personal Diary...it reads as something that you might just pass by if you don't know what its intention is, which can be good for teenagers who are afraid of people looking into their stuff.*"
		Pediatric behavioral health clinician, Knapp 2021 [21]
Therapeutic Goal		
Clinically actionable	Positive change or skill acquisition: apps that impart skills and encourage positive change, in an easy way	"*Great way to have patients practice exercises between sessions; both provider and patient happy to have concrete tool.*"
		Routine behavioral health care staff, Hoffman 2019 [5]
		"*I almost wonder, like, if you logged in, what would you like to address today, like, symptom management versus stress... You almost need, like, an emergency toolkit and then you almost need, like, your day-to-day stuff.*"
		HCP in cancer care, Huberty 2022 [26]
	Ease of sharing and interpretation of data: increase of engagement and symptom reporting	"*[I] feel like sometimes I'll give parents follow up things to do while I'm not there, and they'll forget about it throughout the week, but because they're on their phone or whatever so much throughout the week, I feel like we could send them reminders or this is what we need to do before the next week. I think that that would encourage them to*

Subtheme	Criteria: Findings	Key Quotes
		be more engaged, at least in the process."
		Pediatric behavioral health clinician, Knapp 2021 [21]
Therapeutic alliance	Therapeutic alliance between patient and HCP	"*Sometimes I think my training in behavioral medicine allows me to create a different tool with the patient that is more specific to them.*"
		Routine behavioral health care staff, Hoffman 2019 [5]
Clinical Foundation		
Clinical validity	Evidence of specific benefit: HCP recommendations	"*My doctor tells me to use an app, I'm probably going to use it.*"
		Patient with current or prior depression diagnosis, Dinkel 2021 [38]
	Evidence of specific benefit: increased usage if supported by research, academic institution, or reputable professional society	"*I would trust an app supported by my university more than a random app I found online.*"
		General user, college student, Melcher 2020 [16]
		"*I think it would be helpful, too, to have like the American Psychiatric Association or something, one of those, the licensure bodies or whatever—if they had official recommendations or backing.*"
		General user, smartphone owner, Schueller 2018 [17]

Footnotes: **Bolded** criteria are novel criteria identified by this SLR.
Abbreviations: ADHD, attention deficit hyperactivity disorder; ASD, autism spectrum disorder; BD, bipolar disorder; HCP, healthcare provider; MH, mental health; SLR, systematic literature review.

The latter finding reflects the long-term usability subtheme, as users valued DMHT features that aligned with their needs and priorities. Across nine studies, quantitative and qualitative findings demonstrated high interest in anxiety management features like relaxation tools, breathing exercises, and mindfulness/ meditation activities, and ten studies identified interest in mood, symptom, or sleep tracking (**Table 3**; **Table 4**). While most studies focused on MH, patients with epilepsy also reported high interest in features to record seizure dates and types [25]. Importantly, users in two studies emphasized the need for developers to tailor DMHT to the needs and priorities of the target population (**Table 3**) [19,26]. Relatedly, mixed attitudes were reported towards positive affirmations and words of encouragement, with many users expressing interest but others emphasizing the value of a human component to DMHT or cautioning against blanket encouragement and automated messages that could feel insincere [15,19,32].

Table 4. Quantitative evidence related to anxiety management and mood, symptom, or sleep tracking features

Study	Perspective	Finding	n	%	Mean (SD) Likert Score
Anxiety management					
Buck 2021b [24]	Young adults with early psychosis	Interest in skill practices for managing stress and improving mood	64	84.2	3.30 (0.98)[a]
		Interest in skill practices for relaxation	57	76.0	3.09 (1.12)[a]
		Interest in information about relaxation exercises	59	77.6	3.00 (1.16)[a]
		Interest in information about healthy sleep practices	56	73.7	2.93 (1.15)[a]
		Interest in mindfulness or meditation practices	44	59.4	2.61 (1.34)[a]

Study	Perspective	Finding	n	%	Mean (SD) Likert Score
Afra 2018 [25]	Patients with epilepsy	Interest in music to help seizure control	-	75	-
		Interest in relaxing music that may help alleviate stress	-	68	-
		Interest in relaxing imagery that may help alleviate stress	-	40	-
		Interest in drawing or writing while listening to music	-	35	-
		Interest in practicing mindfulness	-	63	-
Torous 2018 [36]	Outpatients attending a private psychiatric clinic	Comfort level for mindfulness and therapy	-	-	3.75[b]
	Outpatients attending a state psychiatric clinic		-	-	3.17[b]
Beard 2019 [31]	Patients in a partial hospitalization program in a psychiatric hospital	Current use of an MH app with the primary purpose being mindfulness/meditation	-	71	
Mata-Greve 2021 [29]	Workers furloughed during COVID-19	Most frequently endorsed mindfulness tools as a feature when provided options to build their own app	687	67.8	-
	Essential workers employed during COVID-19		584	60.0	-
	Non-distressed essential workers employed or workers furloughed during COVID-19		305	61.4	-
	Distressed essential workers employed or workers furloughed during COVID-19		966	65.3	-
Hoffman 2019 [5]	Staff in a routine primary care behavioral health setting	Ability to manage mood/anxiety/substance use through use of DMHT was seen as a benefit of incorporating DMHT into clinical care	13	57	-
Symptom, mood, or sleep trackers					
Kern 2018 [27]	General population of college students	Willingness to use an MH app to track mood or anxiety	41	10.3	-
Afra 2018 [25]	Patients with epilepsy	Interest in diary to record date of seizures	-	85	-
		Interest in a digital diary to record type of seizure	-	73	-
		Interest in digital diary to log the missed dosages of their medications	-	78	-
Lipschitz 2019 [28]	Veterans with anxiety/MDD/PTSD	Interested in progress monitoring (track mood/stress/anxiety/PTSD symptoms)	95	63.8	-
	Subgroup of smartphone owners		80	67.2	-
Buck 2021b [24]	Young adults with early psychosis	Interest in a feature to set and track goals	60	78.0	3.10 (1.05)[a]
		Interest in a feature to track symptoms over time	70	90.9	3.44 (0.90)[a]
		Interest in a feature to track changes in progress towards goals	66	86.9	3.37 (0.86)[a]
		Interest in a feature to track wellness behaviors (e.g., steps or activity)	48	64.9	2.86 (1.22)[a]
Beard 2019 [31]	Patients in a partial hospitalization program in a psychiatric hospital	Current use of an MH app with the primary purpose being mood tracking	-	10	-
		Willingness to use an MH app on a daily basis to monitor condition	262	81	-
	Subgroup with higher education	Willingness to use an MH app on a daily basis to monitor condition	-	85	-
	Subgroup with lower education		-	77	-
Mata-Greve 2021 [29]	Workers furloughed during COVID-19	Most frequently endorsed symptom tracking (tracking sleep or mood) as a feature when provided options to build their own app	605	59.7	-
	Essential workers employed during COVID-19		555	57.0	-
	Non-distressed essential workers employed or		270	54.3	-

Study	Perspective	Finding	n	%	Mean (SD) Likert Score
	workers furloughed during COVID-19				
	Distressed essential workers employed or workers furloughed during COVID-19		890	60.2	-
Torous 2018 [36]	Outpatients attending a private psychiatric clinic	Comfort level for in-app symptom surveys	-	-	3.50[b]
	Outpatients attending a state psychiatric clinic		-	-	3.11[b]
	Outpatients attending a private psychiatric clinic	Comfort level for passive call/text monitoring	-	-	2.32[b]
	Outpatients attending a state psychiatric clinic		-	-	2.39[b]
	Outpatients attending a private psychiatric clinic	Comfort level for passive GPS monitoring	-	-	2.31[b]
	Outpatients attending a state psychiatric clinic		-	-	2.78[b]

Footnotes: [a]A five-point (0-4) Likert scale was used. [b]A five-point (1-5) Likert scale was used.
Abbreviations: DMHT, digital mental health technologies; GPS, global positioning system; MDD, major depressive disorder; MH, mental health; n, number of patients; PTSD, post-traumatic stress disorder.

Both patients and caregivers expressed interest in psychoeducational content that aligned with their needs and priorities. When surveyed, more than 60% of veterans with anxiety or major depressive disorder (MDD), patients with epilepsy, young adults with psychosis, and essential and furloughed workers during the COVID-19 pandemic expressed interest in relevant psychoeducational content [24,25,28,29]. In contrast, only 4% of college students in another study reported using an MH app for information about MH, although an MH diagnosis was not required for study participation [27].

Caregivers of young adults with psychosis, caregivers of children with ADHD, and spouses/partners of people with bipolar disorder (BD) were all interested in information related to caring for the individual with the given disorder, such as information on psychological and pharmacological treatments, symptoms and symptom changes, and the MH system [20,23,33]. Comparatively smaller, but still notable, proportions of caregivers of patients with psychosis were interested in caregiver-focused information; for instance, 62% to 69% were interested in relaxation exercises, stress/mood management, and community events for caregivers, while 85% to 90% were interested in the aforementioned patient-focused information [23].

Information delivery style preference was captured under the short-term usability subtheme. Two studies, one in young adults with psychosis and one in their caregivers, revealed that delivering information in a variety of formats was important; when presented with non-mutually exclusive options, >50% of both populations were interested in text content, video content, audio content, and

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discussion boards [23,24].

Social interaction promoted long-term engagement. Qualitatively, three studies found that users valued learning about similar experiences from others via social media-like features, which normalized their experiences and could provide new symptom management strategies (**Table 3**) [19,26,30]. Similarly, 67% of both young adults with psychosis and deaf or hard-of-hearing survey participants (N=9) reported interest in peer support via chat features [24,32]. However, a comparatively smaller proportion of veterans with anxiety or MDD were interested in peer support (48.3% of the full cohort, 51.3% of the smartphone user subgroup) [28].

Users overall endorsed social features to support their MH. In Casarez *et al.* 2019, spouses/partners of people with BD likewise desired features to communicate with other caregivers, and additionally emphasized that DMHT could facilitate conversation and understanding with patients, a sentiment echoed by peer support specialists in Storm *et al.* 2021 (**Table 3**) [20,35]. However, one oncology HCP cautioned that, similar to support groups, "very strict guidelines of what is said" should be implemented to manage potential risks from shared social media-like content, although little additional context was provided [26].

Spouses/partners of people with BD also suggested both in-app information on accessing professional resources and direct counseling for the patient at times where other support might be inaccessible [20]. More than half of all workers, employed or unemployed during the COVID-19 pandemic, likewise endorsed links to resources, counseling, and crisis support as DMHT features and 81.6% of young adults with psychosis endorsed a feature to communicate with professional experts [24,29]. Importantly, patients attending private psychiatric clinics expressed a higher comfort level for in-app communication with HCPs compared with patients attending public clinics, suggesting demographic differences in the valuation of access to professional support through DMHT [36].

Nine studies reported on interest in DMHT reminders and notifications. Across three studies, >70% of patients or caregivers were interested in appointment reminders [23-25]. Additionally, 73% and 68% of patients with epilepsy reported interest in reminders for medication refills and adherence, respectively [25].

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Beyond apps, caregivers of patients with MDD, BD, and schizophrenia preferred an ingestible pill sensor that tracked medication adherence, physical activity, mood, and rest 9.79 (95% confidence interval [CI]: 4.81, 19.9), 7.47 (95% CI: 3.81, 14.65), and 6.71 (95% CI: 3.29, 13.69) times more than a non-digital pill organizer, respectively [34]. Qualitatively, patients and caregivers also appreciated reminders, especially if reasonably timed or delivered via text messages [19,38].

Short-term DMHT engagement was also supported by games and graphics, which could communicate information in an accessible way [20], provide tools for stress management [25,29], and be used therapeutically with children [21,22]. However, some HCPs and caregivers expressed concerns that graphics and games may be distracting for certain children (**Table 3**) [22].

In a novel finding, three studies reported forgetfulness or lack of motivation as influences on DMHT engagement. In some cases, disuse was related to stress, other MH symptoms, or poor technical literacy (**Table 3**) [5,15,19]. In contrast, "forgetting to use" DMHT and "lack of motivation" were perceived as relatively small barriers to use in Stiles-Shield *et al*. 2017 [18].

The third subtheme under engagement style was customizability, which was generally valued by users; 70.9% of a general population of smartphone users noted customization was an important factor [17]. Similarly, 9.4% of all surveyed veterans, and 10.9% of those with smartphones, reported disliking a prior DMHT due to lack of personalization [28]. Users specifically wanted to be able to opt out of irrelevant features, customize audio-visual and design elements, add personal notes to tracked mood data, and provide ongoing feedback to facilitate personalization [16,19,20,22,26].

Theme Two: Background and Accessibility

Sixteen studies reported findings related to DMHT background and accessibility, which considers the developer of the DMHT, as well as functionality and accessibility. Twelve studies reported on the technical considerations subtheme, nine on costs, and two on stability.

Under technical considerations, nine studies assessed diverse accessibility concerns. Broadly, Storm *et al*. 2021 emphasized that DMHT should be

developed in consideration with patients' social, cognitive, and environmental needs to avoid overwhelming users [35]. Specifically, two studies reported language as a barrier. Deaf or hard-of-hearing participants recommended visual content presentation, such as videos and icons, alongside text and American Sign Language translations where possible [32]. Similarly, when discussing English-only apps, one provider stated: "language is a barrier for some [patients]" [5]. Mobility issues related to MH symptoms or other conditions and technical literacy, such as difficulties remembering passwords and navigating smartphones or apps, created accessibility barriers as well (**Table 3**) [5,15,26,38]. Additional concerns included apps that restricted use based on geographic location [32]; user difficulty in how to find relevant, useful apps [28]; and limited mobile device memory for downloading apps [5,32].

Offline functionality, reported by six studies, was also captured under the technical considerations subtheme. A majority (56%, N=9) of participants included in the Borghouts *et al*. 2022 study expressed concern about their mobile data plans when using their devices [32]. Correspondingly, "availability of WiFi" was noted as a top barrier to use for apps for depression by Stiles-Shield *et al*. 2017 and several veterans in another study reported that home Wi-Fi connectivity facilitated app usage by eliminating cellular data fees [15,18]. Quotes from patients and HCPs echoed concern about apps without offline functionality (**Table 3**) [21,37].

Data fees were also captured under the costs subtheme, with hidden or additional costs described as a barrier to app use by two studies [18,33]. Parents of children with ADHD reported that difficulty paying phone bills could result in their phones being shut off, limiting DMHT use; one MH clinic administrator stated: "We often encounter parents' phones being shut off because they haven't paid their bill… If the app were free or low cost, I imagine it could be very helpful" [33]. In addition to hidden costs, this quote identifies up-front app costs as a barrier. Quantitatively, over half of a general population of surveyed college students expressed that cost was a top concern for use of MH apps [16]. Qualitative findings from two additional studies likewise identified cost as a barrier to DMHT use [15,38].

Three novel cost attributes were identified by this SLR: willingness-to-pay, insurance restrictions, and cost saving compared with professional care. Four

studies, three of which focused on apps, explored willingness-to-pay for DMHT from a user perspective. Willingness-to-pay varied based on user preference; some surveyed college students and smartphone users among general populations valued free apps due to financial restrictions or uncertainty around app effectiveness, even though one student commented that the quality of free trials may be inferior [16,17]. Some smartphone users also voiced a limit on how much they would be willing to spend for an app subscription (**Table 3**) [17]. Forma *et al*. 2022 found that caregivers were willing to pay $255.04 (95% CI: $123.21, $386.86) more per month for a pill with an ingestible sensor that tracked medication adherence, physical activity, and rest, and could connect to an app that also collected self-reported mood data. Moreover, the caregivers were willing to pay $124.50 (95% CI: $48.18, $200.81) more per month for an app-connected pill organizer alone compared with a non-digital pill organizer [34]. In contrast, some veterans expressed total disinterest in paid apps, with one user citing poor technical literacy ("don't have the knowledge") in addition to cost as affecting willingness-to-pay [15].

In another novel finding, a speech-language pathologist working with children with ASD preferred a single app including multiple features over separate apps for particular features due to insurance restrictions: "I agree that teaching Apps should be an in-App feature versus their own app because sometimes insurance doesn't allow us to open the iPads purchased through insurance" [22]. Although no further detail was provided for this finding, it suggests that there may be restrictions on the use of other apps on devices purchased under insurance, which may have implications for DMHT use in formal care settings due to the lack of financial support.

In a third novel cost-related finding, a small number of participants from a general population of students (3.6%) in one study preferred using an MH app over seeing an MH professional due to cost savings [27].

Two studies reported on the theme of app stability and technical difficulties, with crashes and poor display quality decreasing DMHT value [17,18]. Participants in Schueller *et al.* 2018 reported technical difficulties often being an issue for apps developed by medical institutions, which may be effective and safe but less usable than apps from other developers [17].

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Theme Three: Privacy and Security

Thirteen studies reported findings related to the privacy and security theme, which covered the use and protection of user data by DMHT. Subthemes were reported relatively equally: data collection and storage (n=5 studies), personal health information (PHI) (n=5), privacy policies (n=4), general privacy (n=3), and security measures (n=3).

Quantitative and qualitative findings from the general privacy (i.e., evidence not categorized under any specific subtheme), data collection and storage, and privacy policies subthemes revealed heterogeneous concern (**Table 3**). A total of 74% of a general population of college students reported privacy as a top concern for MH apps, although further detail on the specific area of concern was unclear [16]. In Stiles-Shields *et al*. 2017, participants were highly concerned with data access, but less so with general privacy [18]. Echoing concern about data collection and storage, 59.1% of veterans with anxiety or MDD in one study were concerned about in-app PHI protection [28]; however, a different, qualitative study in veterans with post-traumatic stress disorder (PTSD), alcohol use disorder, or MDD reported that a relatively small number of participants expressed privacy concerns. In the latter study, reasons for concern included distrust in Veterans Affairs (VA), belief that digital data is inherently not confidential, and fear of phone hacking [15]. From an HCP perspective, 0% of surveyed behavioral health HCPs agreed with the statement "My patients are concerned about data security," despite multiple patients within the same study reporting privacy concerns [5].

Still, privacy policies were important overall, with 70.5% of smartphone MH app users rating having a privacy policy as "very important" or "important" [17]. Melcher *et al*. 2020 found that although users valued data protection, some reported a lack of awareness about data privacy and others concern about obscure privacy policies and PHI use [16]. As noted in the data collection and storage subtheme, veteran concern about government use of PHI was heterogenous [15].

A novel valuation factor not included in the APA framework related to user concern with PHI privacy and security regarding MH diagnoses and MH app use because of a desire to upkeep their personal image or avoid stigma (**Table 3**) [5,15,27,39]. For instance, 21.1% of a general college student population

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preferred MH app use over seeing an MH professional due to anonymity or reduced stigma [27]. One participant in a study of VA health service users described access to professional care via MH apps as convenient because they could avoid disclosing their use of MH services to explain leaving work early for an appointment [15].

In line with overarching concern about PHI privacy and security, users valued app security measures. Schueller *et al*. 2018 reported that 74.2% of users rated data encryption as "important" or "very important" [17]. Users in another study perceived the level of privacy protection as highest for apps utilizing a combination of a generic app name (i.e., not reflecting the indicated MH disorder); easily hidden modules; and secure, user-authenticated Web portals for making module changes [39]. Behavioral health clinic staff echoed the importance of discreet MH app names (**Table 3**) [21].

Theme Four: Therapeutic Goal

Twelve studies reported on factors relating to the integration of DMHT with users' therapeutic goals. The clinical actionability and therapeutic alliance subthemes were reported by ten and seven studies, respectively.

Nine studies reported the value of clinically actionable insights from apps where the users could acquire and practice new skills to make positive changes in their lives (**Table 3**). For instance, patient and caregiver app users reported interest in "daily tips," "new ideas," and "solutions or recommendations" for symptom management [30,33,38]. Furthermore, an app that could serve as a resource for multiple management strategies was preferable [19,26,33]. Quantitatively, 4% of patients receiving acute treatment in a partial hospitalization program for MH conditions, including mood and psychotic disorders, reported that the primary purpose of their DMHT use was therapy skills practice [31]. HCPs likewise appreciated that DMHT could facilitate patients practicing skills outside of formal treatment sessions [5]. In particular, clinicians from a youth behavioral health clinic noted that DMHT may be especially beneficial for young users because they could be conveniently and discreetly incorporated into their daily lives [21].

Users valued easy data-sharing with clinicians, particularly for mood- or symptom-tracking features, which could improve communication and the accuracy of symptom reporting during clinical visits [5,15,16,30,33,38]. For

instance, 53% of a general college student population believed that the potential to share information with their clinician was "one of the top benefits" of using DMHT [16]. Additionally, many HCPs reported active use or interest in use of DMHT in clinical practice to facilitate asynchronous communication and increase patient engagement with treatment outside of formal appointments; however, some preferred traditional care strategies for their personalization and flexibility (**Table 3**) [5,21,33].

Theme Five: Clinical Foundation

Eight studies reported findings related to the clinical foundation of DMHT, meaning their utility and appropriateness for patients. Clinical validity was the most reported subtheme, with evidence identified from six studies. Two studies reported on the user feedback subtheme and two on impressions of use, which captured user perception of app content as accurate and relevant.

Across subthemes, users valued evidence of DMHT benefit or efficacy from various sources. A total of 71.8% of surveyed veterans said they would use a DMHT if they "saw proof that it worked" for their MH conditions [28]. Similarly, among 811 general population participants surveyed, 69.5% ranked direct research evidence as "important" or "very important" for DMHT and 66.8% ranked indirect research evidence the same [17]. Qualitative data identified recommendations from HCPs or academic institutions, as well as evidence of DMHT benefit from publications or research studies, as specific sources for clinically valid evidence of benefit (**Table 3**) [16,17,38].

In addition to academic and professional support, the user feedback subtheme captured user interest in whether DMHT were beneficial for peers or recommended by other trusted individuals. Patients with depression reported that other users' experiences influenced their app usage, with one user wanting to know "…if other people had success using it" [38]. Quantitatively, user ratings and user reviews were ranked as "important" or "very important" factors in DMHT use by 59.4% and 58.7% of general population participants, respectively [17].

Quality Assessment

Risk of bias was overall moderate. Of the 14 studies including quantitative components, only 1 utilized relevant validated outcome measurement

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instruments [29]; all others utilized custom questionnaires. For the 18 studies with qualitative components, 4 were at risk of selection bias due to participants being exclusively recruited using online postings and research registries [16-18,29] and only 1 considered the relationship between researcher and participant when interpreting the results [30]. Full quality assessments for qualitative and quantitative study components can be found in **Table S11** and **Table S12**, respectively.

DISCUSSION

Principal Findings

This SLR aimed to identify and synthesize qualitative and quantitative evidence on how DMHT are valued by users, payers, and employers in the US. Evidence from users with or without diagnosed relevant disorders, caregivers, and HCPs was captured across a wide range of demographics. No study reported evaluated an app from a payer or employer perspective. Further, all but one included study focused on mobile apps.

No relevant appraisals of DMHT were identified from the FDA website searches; however, eight relevant FDA approval labels or notifications for MH apps or guidance documents for industry and FDA staff were identified. Assessment of these materials showed overlap with some valuation factors identified in this SLR, including evidence of clinical efficacy and safety, app maintenance, and privacy and security.

Engagement style, although not covered by the FDA materials, was the most reported theme by studies included in the SLR and was found to overlap heavily with other themes. Engagement may be a key consideration for app developers, as app user retention can be low: one study showed that more than 90% of users abandon free MH apps within 30 days of installation [40]. Engagement is also a key clinical concern in terms of DMHT efficacy; one meta-analysis of 25 studies showed that increased use of DMHT modules was significantly associated with positive outcomes regardless of the target MH condition [41]. The findings of this SLR may therefore be informative to both DMHT designers and HCPs who integrate DMHT into clinical care by providing insight on DMHT valuation, and thus how use and benefit can be improved. For instance, users valued DMHT that were easy to use and aligned with their needs and priorities, particularly through

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features that supported their therapeutic goals. Additionally, content presented through multiple delivery modes, such as both text and visuals, promoted engagement as well as accessibility.

However, engagement and feature preference varied across populations. For instance, DMHT valuation was affected by technical literacy, which may relate to user demographics; in this SLR, veterans repeatedly emphasized technical literacy as a barrier to DMHT use [15]. Similarly, offline functionality may be more important for some users. Despite 85% of the total US population owning smartphones, only 59% of Medicare beneficiaries have access to a smartphone with a wireless plan. Moreover, beneficiaries who are older, less educated, disabled, or Black or Hispanic have even lower digital access [42,43]. These findings emphasize the importance of customizability and suggest that app development and selection in the clinical setting should consider the demographics of the target population, particularly in relation to ease of use and offline functionality.

Background and accessibility findings also identified up-front and hidden costs as barriers to DMHT use, with willingness-to-pay varying among individuals. This has important implications for app development considering that many MH apps currently on the market are direct-to-consumer and require out-of-pocket payment. App developers often take this approach as it does not require the accumulation of formal evidence of clinical benefit for FDA approval [44], but it may present a financial barrier to use for consumers.

Privacy and security, reported by 13 studies, was a prevalent theme, with users primarily concerned with data and PHI security within apps. This finding reflects wider research; a 2019 review of 116 depression-related apps retrieved from iTunes and Google Play stores in 2017 found that only 4% of identified apps had acceptable transparency in privacy and security, with many completely lacking a privacy policy [45]. Similarly, 39% of MH apps recommended by college counseling centers had no privacy policy, and of those with a policy, 88% collected user data and 49% shared that data with third parties [4]. Most evidence identified in this SLR under this theme, as well as findings previously published in the wider literature, focus on these remote privacy risks. However, local privacy concerns are also important to users. In particular, inconspicuous naming and the ability to hide sensitive modules within MH apps were rated as

highly important by both patients and HCPs to maintain user privacy. Users emphasized a desire to avoid stigma associated with mental illness, which was also reflected by findings in the engagement style theme: more young adults with psychosis were more interested in in-app messaging with other patients in psychosis recovery (67.1%) than a provider and family member together (47.3%) or their personal support network (59.8%) [24]. Similarly, youths were interested in apps that could be used discreetly in school or other public settings to avoid potential MH stigma. This is a key, novel finding of this SLR, considering many app or DMHT components on the market are named after their target disorder.

The use of DMHT to achieve therapeutic goals was discussed from patient, caregiver, and HCP perspectives, all of which valued DMHT that had evidence of efficacy, presented clinically actionable information, and facilitated the patient-clinician relationships. Of the five studies that explored how HCPs value DMHT in clinical practice, two were restricted to the oncology or ASD settings and were not readily generalizable to wider MH settings [22,26]. In other studies, providers reported interest in using DMHT to facilitate asynchronous communication with patients and their caregivers, promote patient skill practice, and improve care for children through use of games and visuals [21,33]. However, while HCPs overall believed that DMHT improved care, some believed that their clinical training allowed for care personalization beyond what DMHT could provide. Feature customizability and receipt of input from HCPs and users during app development and testing may be a way to mitigate these concerns, as well as concerns about safety and efficacy, as many available apps do not appropriately address user health concerns [46].

Findings additionally suggested that training and resources on DMHT would be beneficial to ensure that HCPs were equipped to integrate DMHT into their practices [5]. Collaboration between DMHT specialists and HCPs, along with a shift from randomized controlled trials to effectiveness-implementation hybrid trials, may be a way to streamline the integration of DMHT into clinical care and provide more training and resources for HCPs [21,47].

Strengths

This review followed a pre-specified protocol and used systematic methods in line with the York Centre for Reviews and Dissemination guidelines [48] to conduct an exhaustive search of the literature, identifying evidence relevant to

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the review objectives from multiple databases and supplementary sources. The framework synthesis approach allowed for the inclusion and analysis of both qualitative and quantitative data, providing a detailed picture of not only what DMHT features users value, but *why* they value them, especially in areas where valuation varies across patient demographics. Additionally, the APA framework is a robust model created with patient and HCP input that incorporates key valuation themes broadly shared by other frameworks and widely acknowledged in the literature [11-13].

Limitations

Methodological limitations should be considered when interpretating the findings of this SLR. Namely, only publications in English and in US populations were included. As perceptions of value are influenced by factors including cultures, laws, and healthcare settings, the findings of this SLR should not be generalized to other countries. For instance, trust in HCPs and rates of longstanding relationships between patients and primary care providers are lower in the US compared with many European nations [49,50], which could impact the type of support users want from DMHT (i.e., engagement style) or interest in DMHT integration with therapeutic goals.

In addition to the prespecified eligibility criteria, deprioritization strategies were implemented due to the large volume of identified evidence and may have resulted in relevant articles being missed. In particular, deprioritization of secondary research and opinion pieces likely led to the exclusion of relevant discussion around payer perspectives and reimbursement, for which no evidence was included in this SLR. Furthermore, although unlikely, there may have been reporting biases in the included studies due to missing results, which this SLR was not able to assess.

No evidence was identified by this SLR for two subthemes included in the APA framework: business model (background and accessibility), which covers DMHT funding sources and potential sources of conflict; and data ownership, access, and export (therapeutic goal), which includes sharing data with electronic health records or wellness devices (for example, Apple HealthKit®, Fitbit™). The valuation of these subthemes should be evaluated in future research.

Conclusions

In summary, app usability, cost, accessibility and other technical considerations, and alignment with therapeutic goals were the most reported valuation factors identified by this SLR. Many studies also reported user preference for apps that incorporated privacy and security features that provided protection from stigma. However, individual DMHT and their features are valued differently across individuals based on demographics and personal preferences. MH apps should be developed and selected with these specific user needs in mind. Feature customizability and input from users and HCPs during development may improve app usability and clinical benefit.

Acknowledgements

Conflicts of Interest

Abbreviations

ADHD: attention deficit hyperactive disorder

APA: American Psychiatric Association

ASD: autism spectrum disorder

BD: bipolar disorder

CASP: Critical Appraisal Skills Program

DMHT: digital mental health technologies

FDA: Food and Drug Administration

HCP: healthcare provider

MDD: major depressive disorder

MH: mental health

PHI: personal health information

PTSD: post-traumatic stress disorder

SLR: systematic literature review

VA: Veterans Affairs

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MULTIMEDIA APPENDIX

Supplementary Table 1. MEDLINE search terms

Supplementary Table 2. Embase search terms

Supplementary Table 3. PsycINFO search terms

Supplementary Table 4. Cochrane Library search terms

Supplementary Table 5. Health Technology Assessment Database search terms

Supplementary Table 6. Congress website search terms

Supplementary Table 7. FDA website search terms

Supplementary Table 8. Eligibility criteria for the SLR

Supplementary Table 9. Publications excluded at the full text review stage in the SLR

Supplementary Table 10. Publications deprioritized at the full text review stage in the SLR

Supplementary Table 11. Quality assessment of quantitative components of included studies using the CASP cohort study appraisal checklist

Supplementary Table 12. Quality assessment of qualitative components of included studies using the CASP qualitative appraisal checklist

Supplementary Figure 1. PRISMA diagram

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REFERENCES

Supplementary Files

Multimedia Appendixes

Electronic database and supplementary search terms, SLR eligibility criteria, publications excluded or deprioritized at full text review, quality assessments of included studies, and the PRISMA flow diagram of identified publications.
URL: http://asset.jmir.pub/assets/5333c7ff7cdc501ea8574fc549c05637.docx

CONSORT (or other) checklists

PRISMA checklist.
URL: http://asset.jmir.pub/assets/07a9c016746da1ea61368f06a98042b9.pdf