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SPECIAL ARTICLE

The evolving field of digital mental health: current evidence and implementation issues for smartphone apps, generative artificial intelligence, and virtual reality

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The expanding domain of digital mental health is transitioning beyond traditional telehealth to incorporate smartphone apps, virtual reality, and generative artificial intelligence, including large language models. While industry setbacks and methodological critiques have highlighted gaps in evidence and challenges in scaling these technologies, emerging solutions rooted in co-design, rigorous evaluation, and implementation science offer promising pathways forward. This paper underscores the dual necessity of advancing the scientific foundations of digital mental health and increasing its real-world applicability through five themes. First, we discuss recent technological advances in digital phenotyping, virtual reality, and generative artificial intelligence. Progress in this latter area, specifically designed to create new outputs such as conversations and images, holds unique potential for the mental health field. Given the spread of smartphone apps, we then evaluate the evidence supporting their utility across various mental health contexts, including well-being, depression, anxiety, schizophrenia, eating disorders, and substance use disorders. This broad view of the field highlights the need for a new generation of more rigorous, placebo-controlled, and real-world studies. We subsequently explore engagement challenges that hamper all digital mental health tools, and propose solutions, including human support, digital navigators, just-in-time adaptive interventions, and personalized approaches. We then analyze implementation issues, emphasizing clinician engagement, service integration, and scalable delivery models. We finally consider the need to ensure that innovations work for all people and thus can bridge digital health disparities, reviewing the evidence on tailoring digital tools for historically marginalized populations and low- and middle-income countries. Regarding digital mental health innovations as tools to augment and extend care, we conclude that smartphone apps, virtual reality, and large language models can positively impact mental health care if deployed correctly.

Key words: Digital mental health, smartphone apps, virtual reality, generative artificial intelligence, large language models, engagement, implementation science, depression, anxiety, schizophrenia, eating disorders, substance use disorders

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The surge in telehealth related to the COVID-19 pandemic has transformed the behavioral health field[1-3], yet the nature of the emerging domain remains in flux. Synchronous telehealth (video visits) rapidly expanded access to care during the pandemic, and psychiatry recorded the highest use of these visits compared to other medical specialties[3]. However, the reliance of traditional telehealth on clinician availability limited scalability, and growth is already contracting. Recent data indicate that telehealth visits in 2024 were less than 50% of their COVID-19 peak[4]. Few clinics today offer fully virtual practices, with the majority instead providing a blend of online and in-person care options[5,6]. These changes are partly driven by unstable telehealth legislation[7], with many of the regulations that permitted the rapid move to telehealth during the pandemic now expired or in flux. But they also reflect a deeper concern that telehealth alone is insufficient to substantially increase access to care and quality of mental health services.

Asynchronous digital health – such as the use of smartphone apps, virtual reality, and generative artificial intelligence, including large language models (LLMs) – offers unique opportunities to scale care delivery. Unlike traditional telehealth, these tools can function as self-help, coach-guided, or clinician-led interventions, providing flexibility and accessibility outside of immediate clinician interactions[8]. While initial enthusiasm for these technologies remains high, a notable gap in robust, real-world evidence continues to preclude their integration into routine care[9]. Despite significant advancements since our early review published in this journal[1], recent industry failures and research critiques have highlighted the need for more rigorous approaches, including use of digital placebos in controlled trials, generalizable and pre-registered models, and greater transparency in data sharing[10-12]. Much of recent research has focused on how a particular app or artificial intelligence program might work, but has not produced mechanistic and generalizable evidence that the field can utilize to build a strong scientific base. These setbacks, however, lay the groundwork for a new generation of evidence-based digital innovations.

Hybrid models that utilize both traditional telehealth and asynchronous digital health reflect the latest evidence and represent a promising approach to increase access and quality of care. However, blending the use of novel technologies into care requires careful consideration. Emerging usage of digital navigators (technology coaches)[13] to supplement digital mental health interventions and support patients has gained attention with the growing recognition that self-help tools offer limited effectiveness without some degree of human support. The optimal dose and balance of human and digital support, delivered in new hybrid or blended formats, presents a new frontier. It also broadens the concept of digital health

from tools or products to care-delivery platforms. Already successful models have integrated dedicated digital mental health services in Australia[14,15], Denmark[16], Sweden[17], Norway[18], the US[19], and Canada[20], among others. While it is possible that artificial intelligence and LLMs could soon serve some of digital navigator features, the evidence remains scant today, and the importance of the human connection in mental health care should not be underestimated.

To explore the evolution of digital mental health and how this new generation of tools will work with humans to create superior outcomes, this review focuses on five key areas. First, it examines recent advances in smartphones, virtual reality, generative artificial intelligence, and LLMs. Second, it evaluates clinical outcomes for smartphone apps across common mental health conditions. Third, it explores engagement challenges hampering all digital mental health tools, and proposes several solutions. Fourth, it analyzes implementation strategies to support real-world adoption and scalability. Fifth, it addresses how current tools often fail to meet the needs of overlooked populations, including cultural minorities and those living in low-resource settings[21,22], and explores possible ways forward. Common threads across all five themes – around scientific rigor, real-world engagement, community partnerships, and blended-care models – reinforce the transformation of the field from creating tools to improving care.

Looking ahead, innovation in engagement strategies and implementation science will play pivotal roles in advancing the next generation of digital tools. Just-in-time adaptive interventions, digital phenotyping, and personalized approaches are gaining renewed attention for their potential to address long-standing challenges in adherence and effectiveness. This paper offers an optimistic perspective on the field's evolution, and a well-defined roadmap for the years to come.

RECENT TECHNOLOGICAL ADVANCES

Smartphone apps and digital phenotyping

Smartphone apps serving as therapeutics have gained traction, and several of them have been cleared as medical devices by the US Food and Drug Administration (FDA). However, the actual effectiveness of these apps in real-world conditions remains uncertain. To address this complex topic, a subsequent section of this paper will critically review the current evidence available across a range of mental health conditions.

The interest in smartphones extends beyond their potential to deliver apps and interventions. These same devices are also capable of surveying patients in real time, enabling ecological momentary assessment for the vast majority of the population. In addition, data from smartphone sensors can generate behavioral metrics (e.g., sleep patterns, sedentary periods) and information on environmental exposures (e.g., local temperature, light exposure, greenspace) that can provide personalized contexts and temporal trajectories for how individuals experience mental illness. Often referred to as digital phenotyping[23], recent evidence on this approach in youth[24] and adults[25,26] provides promising signals with clinical validity.

A recent review exploring machine learning applied to digital phenotyping noted that mood disorders, anxiety disorders, and schizophrenia spectrum disorders are the three most studied conditions across all health care, even beyond mental health[27]. Relapse detection in schizophrenia and symptom prediction in mood disorders have strong pilot results with replication and external validation[28-30] which provide promising generalizable clinical signals. The vast number of pilot studies suggest that digital phenotyping research should now move towards validation to determine clinical relevance, with larger sample sizes and longer duration studies[31]. Such ongoing efforts include the US National Institutes of Health's Accelerating Medicine Partnership Schizophrenia Study, capturing smartphone digital phenotyping data from over 40 sites around the world in people at clinical high risk for psychosis for up to 12 months[32].

While early evidence suggests that digital phenotyping is feasible and acceptable, key barriers in the field remain a lack of standards for data collection, data processing, and feature creation, with variable data streams derived from different models/brands of smartphones. For example, a recent review of digital phenotyping across mental health found that, even when generating seemingly uncontroversial behavioral features such as sleep duration, each study used a different combination of sensors and processing pipelines, so that comparison of results and generalizability of outcomes were challenging[33]. Efforts to externally validate digital phenotyping work thus remain limited[34].

While research using wearable devices is sometimes labeled as digital phenotyping, this work is best categorized as actigraphy and considered in the framing of that unique field. Core differences include additional needed hardware and results often unique to that hardware and supporting software. While each approach has its merits, digital phenotyping utilizes patients' existing smartphone devices, so it represents a scalable and low-cost method limited primarily by device variance and missing data. Wearable studies offer the benefit of devices with often superior sensors, but are more limited in terms of scalability and longer-term engagement. As smartphone technology and sensors improve, the two fields may continue to blend. Even today, several studies can simultaneously apply both digital phenotyping and wearable devices through Android's Health Connect and Apple HealthKit/SensorKit features.

Given that successful digital phenotyping can support a myriad of other digital health developments, ranging from just-in-time adaptive interventions to precision-guided medication selection, success here will benefit the entire field. A focus on standards around both data collection and data processing in the mental health field, mirroring advances in accelerometry studies generally[35], can generate better science and more synergistic advances. Likewise, standards around protecting privacy and data governance in this sensitive area can engender trust and patient interest in sharing their personal data for research.

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Virtual reality

Virtual reality is emerging as a significant innovation in the field of mental health treatment[36]. In using immersive simulations, it addresses a key limitation of traditional mental health interventions, which are often restricted to clinical settings and rely on patients recalling experiences and subsequently applying therapeutic techniques in their daily lives[37]. A recent review of the field[36] found that a growing body of research supports the efficacy of virtual reality-based interventions across different mental health conditions.

The unique capacity of virtual reality to recreate real-world environments has been particularly effective in augmenting cognitive-behavioral therapy (CBT), otherwise known as VR-CBT[38]. The majority of randomized controlled trials (RCTs) of VR-CBT approaches have been conducted in anxiety disorders, with a recent meta-analysis finding that they were superior to waiting lists or psychoeducation controls[39]. However, significant heterogeneity between effect sizes was evident, and active comparisons yielded non-significant differences. A meta-analysis of VR-CBT for social anxiety disorder also demonstrated that it had superior effects compared to waitlist controls for anxiety symptoms and avoidance behaviors[40]. These findings parallel results from studies in other conditions, such as psychosis, post-traumatic stress disorder (PTSD) and specific phobias, which indicate that VR-CBT is generally as effective as traditional CBT[36,41-43].

Virtual reality treatments have also been developed to support psychosocial and functional recovery, with the majority of evidence in mental disorders where routine functioning is challenging, such as schizophrenia, autism, and attention-deficit/hyperactivity disorder (ADHD)[41,42,44-45]. In these conditions, virtual reality has been found to enhance everyday living skills, including social and vocational tasks, by providing a safe space to learn and practice in relevant scenarios[42,45]. However, results have been mixed: a recent RCT of a virtual reality treatment targeting social cognition in psychosis found no significant difference compared to an active virtual reality relaxation condition[46]. This mirrors the findings of another trial comparing VR-CBT targeting social behaviors with virtual reality relaxation in a psychosis sample, which also found no difference between these conditions[47].

Emerging evidence suggests that virtual reality can be effectively integrated into various therapeutic modalities by leveraging its capacity to represent visual stimuli and influence affective states within virtual environments. A recent systematic review[48] found that virtual reality-based relaxation interventions are equally or more effective than non-virtual reality approaches in reducing short-term stress and anxiety, with the added benefit of being more resource-efficient to deliver. Virtual reality has also shown promise in enhancing "third wave" CBT approaches such as mindfulness, acceptance and commitment therapy, and dialectical behavioral therapy (DBT), which have a focus on separating the self from mental events. Similarly, virtual reality-enhanced DBT has shown the potential to help individuals manage emotional dysregulation more effectively by practicing distress tolerance skills in immersive, controlled environments[49].

Despite extensive research supporting the efficacy of virtual reality treatments for various mental health conditions, there remain few consumer-ready applications available on the market. One of the primary challenges is scaling virtual reality interventions to reach a broader population cost-effectively. Although the technology is becoming more accessible, the expenses associated with high-quality hardware, software development, and clinician training remain significant barriers[50]. Additionally, strategies to make these interventions accessible in under-resourced areas are critical [21,51].

Generative artificial intelligence

Few innovations have garnered so much interest in mental health as generative artificial intelligence. This is a unique subset of artificial intelligence in that it can create novel content, such as conversations or images, based on data and patterns on which it has been trained. The public release of ChatGPT 3.5 unleashed interest in the topic and gave rise to a rush for mental health use.

A new generation of artificial intelligence-driven chatbots is becoming increasingly prevalent in digital mental health, evolving from early rule-based chatbots. However, these latter chatbots are still common, and a 2022 review suggested that, across all of health care, 96% of chatbots were driven by decision-tree-like logic and not actual artificial intelligence[52]. Those earlier systems, which relied on predefined scripts and decision trees, were helpful in controlled environments, but faced limitations in handling complex, real-world interactions. Their inability to process free-text inputs or maintain context in multi-turn conversations raised concerns about their broader applicability[1,52]. Examples include psychotherapy chatbots such as versions of *Wysa* and *Woebot*, which, despite their limitations, offered the advantage of predictability and reduced risk of errors. The importance of such reduced risk was highlighted in 2023, when a generative artificial intelligence code embedded in an eating disorder chatbot led it to make harmful statements to users, prompting its removal within days of its public release[53]. The underlying issues of bias, subtle errors, and more overt errors (often labeled as "hallucinations") must be considered in framing the potential of generative artificial intelligence models and assessing the evolving risks that must be weighed with the expanding benefits.

Recent advancements have shifted toward machine learning-powered models, particularly LLMs. These models, trained on vast datasets from the Internet and other sources, address many of the limitations of rule-based systems. Their ability to generate human-like responses has made them valuable not only as tools but also as virtual companions. Users appreciate their capacity to handle diverse inputs, exhibit personality traits, and respond empathetically, which makes them more effective for personalized mental health support. Research shows that LLMs can demonstrate consistent behavior across the Big Five personality traits[54], and even outperform humans in certain tasks, such as recognizing irony and false beliefs[55]. Furthermore, the multimodal capabilities of modern LLMs enable them to process not just text but also voice and image inputs[56,57], expanding their versatility in digital mental health.

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Preliminary research has demonstrated the potential of LLMs across various stages of mental health care. While much of this work has not been replicated, these pilot studies underscore the broad range of applications. For prevention, LLMs can offer low-risk, personalized psychoeducation, effectively raising mental health awareness by utilizing high-quality resources[58,59]. For relapse or onset detection, LLMs show promise in risk prediction, with studies indicating that models such as GPT-4 can approach clinical accuracy in identifying suicidal ideation and other crisis indicators, though additional safety measures and bias mitigation are necessary[60-62]. In diagnosis, LLMs can facilitate data-driven assessments of mental health conditions, sometimes matching clinicians' ability, for instance in predicting depression scores based on clinical data[63]. For treatment optimization, LLMs can assist in medication selection and therapeutic interventions by leveraging patient-specific data to help clinicians make informed decisions[64,65]. In high-risk situations, such as crisis intervention, LLMs can provide elements of crisis counseling, although this use carries a higher risk of harm[60,66]. Finally, LLMs have been applied to deliver ongoing therapy and counseling, enhancing access to routine mental health services by analyzing past therapy outcomes to improve care[67,68].

Despite the growing popularity of LLM-powered chatbots for mental health support, this field remains underexplored at its current stage, particularly related to the lack of transparency in training data, explainability of models, and standardized evaluation methods[69]. All base models for LLMs have been trained, at least partially, on social media data. This is understandable given that the newest models need billions, and likely trillions, of parameters (data points) to learn from. But, in learning about mental health mainly from social media, these models have also learned about stigma and bias. This point was well illustrated in a 2022 paper showing a range of stigmatizing images generated in response to prompts around schizophrenia[70].

Studies have also pointed out that, while these models can perform some theory-of-mind tasks, they still struggle with more complex social reasoning, highlighting the gap between artificial intelligence-driven reasoning and human cognition[71]. Finally, while many models have been proposed to evaluate LLM chatbots on criteria ranging from ethics to efficiency, none are well utilized today, and no standard has emerged[72]. Thus, comparison between chatbots, let alone evaluation of evolving chatbots, remains a challenge.

While LLMs have shown promise in providing human-like companionship, their unpredictability remains a major challenge. LLMs highlight the therapeutic potential of conversation and the rule-based nature of human language, meaning that they can produce convincing conversations. However, psychiatry is less rule-based, with debates about nosology and etiology ongoing today. Thus, LLMs will continue to face challenges as they confront a relative dearth of high-quality training data. In the meantime, debates on the delineation between conversation vs. therapy and companionship vs. care will continue to shift. Anyway, regardless of where the line is drawn, it is clear that some people are already finding benefits in talking with LLMs.

The current uncertainty around the patient-facing use of LLMs contrasts with their rapidly evolving use around clinical documentation. While the subject of less media attention and research, the transformative potential of clinician-facing artificial intelligence tools should not be underestimated. There is already enthusiasm for nascent efforts to utilize LLMs to document clinical encounters [73,74], likely saving clinicians' hours per day of note-writing. Other efforts to use artificial intelligence in upskilling of non-clinicians, in training of clinicians, and in offering clinical decision support are also evolving[75-77], and could represent a paradigm shift in workforce and training while facilitating evidence- and measurement-based care.

With so many use cases and such rapid progress, LLMs have the potential to drive research and care trends in mental health, if the field can unify such work under clear standards and safety procedures. We have already seen the emergence of ethical issues calling international attention in relation to LLMs, including the eating disorder chatbot case[53] and a case with help-seeking people explicitly told that they were interacting with a human while it was actually a LLM[78]. Without such standards and safety considerations, impressive technical achievements by LLMs may find a limited role in clinical care beyond documentation.

SMARTPHONE APP INTERVENTIONS

Access to the Internet is now more common via smartphones than computers[79]. The number of smartphone mental health apps has been estimated at 10,000[80] and remains a dynamic landscape, with new apps frequently introduced and others disappearing from the marketplace[81]. Some apps, such as *PTSD Coach*[82], are still functional after several years, but most are far less stable. Since most research in the digital mental health field focuses on smartphone apps, we cover this issue in detail in this section.

While the clinical outcomes of studies are important to consider, any benefits, including those discussed below, must be considered along with risks. Adverse events are often not well reported in digital health studies, despite calls to change this[83-87]. In some cases, assumed adverse events – such as technology making people with schizophrenia paranoid or delusional – have been disproven through specific studies[85]. Of course, negative effects are not unique to apps, but have also been reported for Internet interventions[88], face-to-face psychotherapies[89], and virtual reality treatments[90].

Negative effects from apps can range from mild (e.g., frustration with glitches, boredom) to severe (e.g., symptom deterioration, onset of new symptoms, suicidal ideation). Concerns have been raised that current marketplace offerings have the potential to induce negative effects because many publicly available apps provide content that is either inaccurate or not grounded in evidence-based treatments[91]. It is difficult to quantify the extent of negative effects, given heterogeneous study designs, sample characteristics, and types of apps delivered. Yet, recent clinical trials in people with a severe mental illness have reported rates of negative effects to be as high as 20%[92-95].

This state of research on adverse events makes it difficult to in-

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tegrate apps into clinical practice safely[83,96]. In particular, the degree to which adverse events, such as deterioration, are caused by the use of the smartphone device itself or other external factors may be difficult to understand[87,97]. Researchers involved in future clinical trials of apps should plan from the outset to build data-driven risk prediction models, because this would help ensure that relevant data are collected, enabling better opportunities to match patients to appropriate treatments safely.

Well-being enhancement apps

A significant proportion of people who download a mental health app report doing so to acquire adaptive psychological skills useful to improve their overall well-being[98]. Many well-being apps include meditation, especially mindfulness, practices as a prominent element. For example, during the COVID-19 pandemic, one app curation service reported that searches for mindfulness apps rose by nearly 2,500% compared to the 156% increase observed for depression-specific apps[99]. Investment in this space has flourished, with well over 99% of publicly available mental health-related apps marketing themselves as well-being and not health devices[100].

Several RCTs have reported positive effects of self-guided well-being apps on various adaptive psychological attributes, including emotion regulation[101], mindful awareness[102], psychological flexibility[103], subjective well-being[104], social functioning[105], and self-esteem[106]. However, recent meta-analyses have found that these apps produce modest improvements relative to control conditions on subjective quality of life, positive affect, general well-being, mindful awareness, psychological flexibility, and self-compassion[107-109]. Additional high-quality RCTs are needed to confirm the utility of well-being apps, as concerns about the quality of existing research have been raised around small sample sizes, inadequate control groups, high risk of bias, high attrition, and low adherence, which likely explain the different published findings[107,109].

Given that as few as 2% of publicly available well-being apps have scientific evidence supporting their feasibility and efficacy[110], research partnerships could quickly transform this crowded space. Research focusing on mechanisms of action could also be useful. There is evidence that some well-being apps may exert their effects through enhanced mindful awareness[102]. However, a similar degree of evidence has been reported for other possible mediators (e.g., purpose in life, cognitive defusion) of effects on psychological distress[111]. Since multiple mechanisms are likely to be at work, tailoring choice to individual users based on such potential mechanisms may usher in a new era of more rational use of these apps.

Depression and anxiety self-management

Depression and anxiety, at both diagnostic and sub-threshold levels, are the most prevalent mental health conditions, and are linked with significant impairments in psychological, social and occupational functioning[112]. Since few people with depression or anxiety have access to specialized psychological treatments[113], apps that are grounded in an evidence-based framework and offer credible skills, resources or tips have the potential to represent an accessible, cost-effective and viable option for users to manage their symptoms.

Alongside the proliferation of commercially available depression and anxiety apps[114,115], the number of RCTs evaluating these apps has grown exponentially in recent years. The largest and most recent available meta-analysis[114] identified 176 RCTs of standalone mental health apps for depressive or anxiety symptoms, 67% of which have been published since 2020. This meta-analysis found significant although small effects for mental health apps over control conditions in reducing depressive and generalized anxiety symptoms, which corroborates the findings of recent but more narrow meta-analyses on the effects of apps on these symptoms in specific contexts (e.g., mindfulness meditation apps only[116], clinically diagnosed depressed patients[117], the perinatal period[118]). The large meta-analysis[114] also found evidence from a smaller number of trials that apps may be beneficial for reducing social anxiety, obsessive-compulsive, post-traumatic stress, and acrophobia symptoms, although the findings were considered preliminary due to the small sample sizes and high risk of bias.

Research has recently sought to understand the characteristics of apps that make them more or less effective for depression and anxiety. Knowledge of the mechanisms involved and of "active ingredients" is critical for producing more efficient apps. Such mechanisms and components can be prioritized, added or refined, while the ineffective or redundant components can be discarded[119]. The above-mentioned recent meta-analysis[114] showed that effects were larger in trials that delivered apps based on CBT principles (compared to mindfulness or cognitive training) or containing chatbot technology or mood monitoring features. These components could offer greater personalization or foster emotional self-awareness, resulting in more significant clinical benefit.

One methodological design that can help identify effective components of an app is the factorial trial, in which participants are randomly assigned to the presence or absence of a particular treatment component. A factorial trial was recently conducted[120] to test the efficacy of five CBT skills (self-monitoring, cognitive restructuring, assertiveness training, behavioral activation, and problem-solving) delivered through the *Resilience Training* app in 1,093 university students with sub-threshold depression. The authors could not identify whether one CBT skill was more effective than another, as reductions in depressive symptoms were observed for all participants, regardless of the presence or absence of the five CBT skills. However, this trial is noteworthy, and it is encouraging to see further factorial trials on depression apps underway[121]. These trials will ideally shed light on active ingredients, generate hypotheses for future research, and inform the development of more effective self-management apps.

A consistent trend observed in recent research is that the provision of human guidance augments the effect sizes found for depression and anxiety apps[122]. This finding may be due to human support increasing app engagement, offering additional therapy, or mediating/moderating outcomes through the benefits of thera-

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peutic alliance. The involvement of digital navigators may be useful in this respect. Moreover, the next generation of chatbots that can better personalize recommendations and simulate emotional and empathic responses may offer a novel and complementary approach to increase the efficacy of digital health tools[123].

Overall, the effects of depression and anxiety self-management apps are now established on the basis of nearly 200 trials, underscoring the need to use ongoing research opportunities for further advancements. Carefully designed studies focusing on mechanisms of change, the impact of engagement on clinical outcomes, the use of automated support systems, and integration into real-world settings will likely prove more valuable than additional trials confirming already available results.

Clinical management of mood disorders

Existing research has mostly focused on the effects of apps as a standalone, low-intensity intervention option among community or student samples screened for mild-to-moderate symptoms of depression. Less is known about the utility of apps in severe mood disorders.

New meta-analytic evidence suggests that apps may enhance the efficacy of conventional treatments for major depressive disorder. A systematic review[124] recently located five RCTs that assessed the added value of integrating apps into standard treatment for this disorder. From seven comparisons, a small but significant effect was found in favor of app-augmented treatment arms, which was robust after removing trials with high risk of bias. Although preliminary, these findings are promising and suggest that apps may offer an incremental benefit to standard care for major depression. Additional research is needed to identify the optimal timing, dosage and content to combine these interventions effectively with established approaches for maximum benefit.

The fluctuations in mood, cognition and behavior that characterize bipolar disorder support the use of data continuously collected through real-time approaches such as digital phenotyping, and indicate a possible value of apps to provide tailored treatment strategies. However, the clinical benefit of apps in the management of this disorder is currently unclear. A recent meta-analysis[125] identified seven RCTs that integrated monitoring apps in the treatment of bipolar disorder, concluding that there was no evidence that they assist in reducing the severity of depressive and manic symptoms. In fact, individual trials have found that, in some cases, monitoring apps may even increase the risk of depressive episodes[126] or be associated with an escalation in manic symptoms[127].

These findings led to recommendations from the International Society for Bipolar Disorders Big Data Task Force that future trials of monitoring apps should consider using more sensitive outcomes, such as mood instability, in addition to relapses and psychiatric hospitalizations[125]. Indeed, a more recent trial evaluating the *LiveWell* self-management app in 205 patients with bipolar disorder[128] found no difference in reduction of relapse risk for those assigned to the app relative to treatment as usual, but did detect positive effects on depressive symptoms and relational quality of life. Overall, while there are some promising trends in the use of monitoring apps for the clinical management of bipolar disorder [129], there is a clear need for further research aiming to better understand how, for whom, and under what set of circumstances these apps can be safely integrated into the clinical management of the disorder.

While the clinical focus of apps for management of mood disorders requires their integration into ordinary care, a core issue today is clinicians' hesitancy and limited awareness. For example, survey research[130] shows that two-thirds of health care providers have little to no knowledge about apps available for bipolar disorder, and only 10% of clinicians surveyed in another study perceived apps to be helpful for patients with severe depression[131], despite the abovementioned empirical evidence. Investment in workshops and educational videos that provide trustworthy, up-to-date information about apps could increase provider confidence[132-134].

Schizophrenia/psychosis

Smartphone technology represents a potential tool to increase access to care of people with schizophrenia, and has been studied as such for over a decade[135]. Concerns that app-assisted monitoring tools and interventions could increase paranoia and delusions are refuted by clear data suggesting that people with schizophrenia are receptive and eager to use smartphone technology as part of their treatment plan[85]. As a consequence, research on apps for early diagnosis, real-time monitoring, psychoeducation, lifestyle, relapse prevention, and intervention among people with schizophrenia has rapidly expanded in the last ten years[136].

Several RCTs of app-supported interventions in individuals with schizophrenia have found positive effects on important clinical outcomes, including reduced fear of relapse[137], and improvement of psychotic symptoms[138], cognitive functioning[139,140], depressive symptoms[141], and medication adherence[139]. However, not all trials have reported favorable results. For instance, incorporating an app that offered a toolbox of behavioral and cognitive skills (*PEAR-004*) conferred no added clinical benefit on symptom scores relative to a non-specific digital sham control among 112 patients with schizophrenia receiving antipsychotic medication[142]. Similarly, the delivery of the self-guided *Temstem* app, designed to provide coping skills to deal with voice hearing, was not superior to a placebo monitoring app in reducing voice hearing distress, and in increasing social functioning and control over voices, among 89 patients with severe mental illness[143]. Likewise, the CBT-informed *Actissist* app study reported no difference in outcomes for people with schizophrenia when compared to a mood-tracking app[144]. The *SlowMo*[145] and *Horyzons*[146] blended interventions also reported null primary results, but some effects on secondary outcomes were promising, underscoring both the potential of blended approaches and the need for more rigorous research.

A recent systematic review and meta-analysis of 26 RCTs considering smartphones and other digital technologies in people with

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schizophrenia reported minimal effects, but found that these may increase when the technology is paired with human support[147]. The critical role of human support was highlighted in another recent review paper[148].

The potential for smartphone apps to address the significant physical health inequalities among people with schizophrenia is emerging as a new direction. While digital innovations for physical health have hitherto been neglected in this population, there are signs of renewed interest[149]. Encouragingly, findings of a recent review indicated that digital health behavior change interventions, including apps, were broadly feasible and acceptable to people with severe mental illness[150].

Even if apps are to be integrated into clinical care for schizophrenia spectrum disorders, concerns with their current accessibility and availability have been highlighted. A review of the marketplace[151] identified 25 apps aimed to support people with psychosis. Crucially, 19 of these apps were either non-functional, inaccessible without an access code, or contained outdated, stigmatizing or harmful information. Of the six easily accessible, appropriate and psychosis-specific marketplace apps, five exclusively provided psychoeducation content, while only one offered therapeutic and monitoring features. These findings suggest an urgent need for better translation of apps from research to the marketplace.

Eating disorders

As less than one-quarter of people with eating disorders have access to specialized treatment[152], our early review on digital mental health in this journal[1] highlighted the potential clinical value of apps for these conditions, as evidenced by a handful of RCTs finding CBT apps to be efficacious as either a standalone intervention or as an adjunct to traditional treatment services. Since then, research on apps for eating disorders has been relatively limited, which is surprising, given that these apps are in high demand and are met with great enthusiasm among this clinical population[153,154].

The need for more rigorous research on eating disorder apps has been highlighted recently[154]. A review of the marketplace identified 65 apps aimed to support the treatment of these disorders[154], whose quality was suboptimal, with 92% omitting key in-app features, and only 7% having any research support. Several RCTs evaluating eating disorder apps have emerged since that review. One trial delivered a blended CBT digital intervention for binge-eating disorder, comprised of a web program supported by a mobile app that enabled users to practice homework skills in daily life. The intervention group reported greater reductions in eating disorder symptoms and psychological distress than the control group[155]. Another trial[156] investigated whether a monitoring app enhanced the efficacy of a CBT web program in a symptomatic sample of 293 participants. While no between-group differences emerged on key symptoms, those allocated to the app-augmented intervention were less likely to drop out, suggesting that monitoring apps could help retain users for longer periods in this context.

Recent efforts have explored whether app-enabled micro-intervention prompts in high-risk settings could have therapeutic value in eating disorders. Juarascio et al[157] developed a just-in-time adaptive intervention that provided personalized skill recommendations in real time based on data recorded through digital monitoring mechanisms. In a small pilot trial[158], they compared the presence versus absence of the intervention among 56 patients with bulimia nervosa who were receiving standard CBT. The intervention demonstrated feasibility and acceptability, but did not produce a greater rate of symptom change, possibly because the study was underpowered. It is encouraging to see larger trials of just-in-time adaptive interventions for eating disorders in progress[159], which will ideally shed more light on whether these interventions offer clinical benefit to a population who find it difficult to forecast warning signs of symptom escalation and relapse.

Substance use disorders

People with a substance use disorder are typically reluctant to seek professional help, are prone to relapse, and find it difficult to anticipate those events that trigger cravings[160,161]. This, coupled with the fact that smartphone ownership is as high as 92% among people with these disorders[162], indicates the potential for apps to enhance treatment seeking, mental health literacy, and therapeutic outcomes in this clinical population.

While some of the earliest FDA clearances for apps were around substance use disorders, a 2020 report from the Institute for Clinical and Economic Review suggested that the underlying evidence for these early apps was poor[163]. However, since then, the empirical research exploring the role of apps for these disorders has been continually evolving. In the context of smoking, a recent meta-analysis[124] identified ten RCTs which tested whether apps can increase the efficacy of conventional treatment, and reported a significant moderate effect in favor of augmented treatment conditions. Another recent meta-analysis[164] examined the efficacy of apps as either a standalone or adjunctive intervention on smoking abstinence rates, finding no significant between-group difference from nine RCTs. However, follow-up analysis showed that apps produced higher rates of smoking cessation than control conditions when paired with pharmacotherapy, further demonstrating the potential for apps to augment conventional treatment approaches.

Comparatively, less research has been conducted on apps for other substance use disorders. A systematic review[165] of mobile interventions identified three pilot studies that focused on cannabis use, which all reported positive treatment effects. In contrast, some systematic reviews have synthesized evidence for smartphone interventions targeting risky alcohol use across distinct population groups, concluding that the evidence for their effectiveness is uncertain[166]. The clinical benefit of app-based just-in-time adaptive interventions specifically designed to target illicit substance use was recently summarized in a systematic review[167], which concluded that the evidence for their therapeutic value is mixed and that adequately powered efficacy trials are lacking.

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Summary for apps across all conditions

From the rapidly evolving evidence base available, it emerges that app-based interventions have an established efficacy in the self-management of depression and anxiety, while the evidence is mixed concerning their role in well-being enhancement, clinical management of mood disorders, schizophrenia/psychosis, eating disorders, and substance use disorders.

Further research is obviously needed in order to study these interventions with more rigorous methods, such as digital placebos and factorial trial designs; to investigate the working mechanisms of these devices; to explore innovative ways to embed these technologies into practice to ensure that they meet their potential as scalable tools; and to build clinical prediction models helping to select the best available treatment approach for each patient given his/her profile and ongoing progress.

CHALLENGES IN ENGAGEMENT

One of the most widely cited challenges to the utilization of mental health digital tools is low engagement, which refers to a lack of uptake and/or poor adherence to interventions in service users[168,169]. Even among individuals who consent to participate in a study on a mental health app, as many as 50% never download the app[170]. Furthermore, those who download the app are unlikely to use it for more than a few days, and even fewer complete the entire treatment program. For example, one study found that nearly half of the participants allocated to the popular *Headspace* and *Smiling Mind* apps reported never using the app again after ten days[171]. Another study on *Headspace* found that only 2% of stressed employees completed all of the prescribed meditation sessions[172]. Engagement issues in mental health app trials appear to be a problem not localized to specific settings, populations or clinical groups[173].

Poor engagement is an even greater problem in real-world settings. Investigation of real-world objective data on user engagement with 93 popular mental health apps showed a median daily open rate of 4%, with around a 3% retention rate over a 30-day period[174]. A recent naturalistic evaluation[175] of the *HeadGear* depression app showed that, while there were over 26,000 new downloads over the study period, there were only 90 average active daily users, and less than 6% of those who commenced the 30-day challenge component of the app completed it in its entirety. Another recent study[176] examined objective engagement data from 158,930 individuals who downloaded the publicly available *MoodTools* app. Analyses showed that nearly 50% never logged into the app a second time, one-third of active sessions lasted between 0 and 10 seconds, and less than 1% of sessions occurred following a 3-month to 1-year period of inactivity.

Knowing the causes of low engagement is necessary for developing solutions. Factors likely contributing to low engagement include poor usability, lack of user-centric design, concerns about privacy, skepticism about benefits/usefulness, limited digital literacy skills, and lack of personalization features[169,177,178].

Addressing engagement through personalized fit and integration into daily life

Systematic reviews report that customizable, personalized content which aligns with users' values and culture supports better engagement[177,179], while one-size-fits-all approaches are less engaging[179,180]. Digital mental health interventions need to better align with users' needs and expectations[168,180], and be tailored to be inclusive for minority groups[181,182] and by age[183]. Customizable reminders and assessments are reported as beneficial to enhancing engagement[184,185]. It has been suggested[186] that personalized coaching could enable digital mental health interventions to better align with end users' needs.

Time constraints are often mentioned as considerable barriers to engagement with digital mental health interventions[179,180]. For example, a study[187] provided the following end-user perspective: "*I assume a lot of people who are in my situation are in a crazy schedule… and not always have appointments booked for you is good*". People often report forgetting about the digital intervention or struggling to engage with it, particularly during periods of stress, indicating some challenges in integrating these tools into daily life[185,188]. End-users are more likely to engage with digital mental health interventions when these are flexible and can be integrated into their daily routines[177,179-181,184,189].

Addressing engagement through inclusion and trust

Issues about safety continue to be raised as critical factors influencing end-user engagement with digital mental health interventions. Barriers include concerns over privacy[181,185], unauthorized access[181,183], data security and protection[181,183], and lack of confidentiality[179,181-184]. For example, an older person reported[190]: "*Websites being hacked, people's personal details being hacked, y'know it's nothing, nothing is safe. Nothing is secure – and I know that nothing on the web is 100% safe, it can't be*". Greater trust in digital tools can be fostered by providing secure ways to record information[181], and assuring strong data protection measures[183] and clear communication of privacy settings[181,184].

Recent efforts to address these engagement barriers have shown encouraging results. Using co-design principles by gathering the target population's needs, preferences and feedback has generated mental health apps with higher ratings of usability, satisfaction and adherence[177,179,188]. Delivery of acceptance-facilitating interventions – such as training or brief educational videos that provide trustworthy information about the role of digital interventions and address common concerns and misconceptions – has been shown to enhance motivation, positive attitudes and self-efficacy, and reduce digital anxiety, security concerns, and skepticism[133,191,192], which appears to translate into greater uptake and adherence[193].

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Addressing engagement through human support: from technical support to coaching

Technical issues – including bugs, usability and accessibility challenges – are major barriers hindering engagement[177,180,182,189]. One young person highlighted[194]: "*So yeah, because I'm not a technical person at all… that's the only downside of it, if it doesn't work okay, then it has quite an impact*". Barriers to engagement include problems with Internet connection ("*Because if Internet connection is not great and you click next then it takes a while for the next page to come up and you know it gets frustrating*"[176]) and digital mental health interventions not being accessible on a smartphone ("*The pages weren't phone friendly – lots of scrolling left to right*"[195]). Rural participants face unique barriers in terms of limited Internet access and poor connectivity[177,184].

Multiple reviews report that professional guidance – whether from therapists, coaches, counselors, or other health professionals – is crucial for user engagement and adherence[177,179,182,183,186,188]. End-users consistently prefer digital mental health interventions that include professional support, finding these more engaging and safer than unguided or self-guided interventions, which could be viewed as impersonal or distressing[177,183-185,189,196]. Some reviews report that end-users prefer a digital mental health intervention as a complement to existing, in-person therapy rather than a replacement[177,185]. For instance, a qualitative study with veterans highlighted that most participants who had used a digital intervention (*PTSD Coach Australia*) had done so as an adjunct to therapy, as it was "*more helpful if you are seeing a psychologist or psychiatrist*"[197]. Importantly, however, negative attitudes from health care providers could diminish end-user engagement[181].

Including human support in digital mental health interventions may be flexible. For example, therapists could be directly involved in facilitating interventions or providing reminders[177]. Some end-users report satisfaction with instantaneous support through digital channels such as chat or email[179], while others emphasize the value of structured interactions with coaches[186]. Infrequent or delayed responses from professionals are reported barriers to engagement[179]. Regular interactions and personalization of feedback from professionals during delivery of digital mental health interventions are found by end-users to be essential for maintaining engagement and feeling supported[179,180,183,186,188]. This reinforces the potential of roles such as that of digital navigators[11,13] in improving engagement rates and therapeutic outcomes[198].

Addressing engagement through just-in-time adaptive interventions

Just-in-time adaptive interventions are an innovative approach that leverages mobile devices to collect real-time data from sensors or user input, allowing them to deliver brief, tailored "micro-interventions" at precise moments when individuals are most in need or receptive to support[199]. For example, an intervention of this kind was designed to support smoking cessation by delivering brief mindfulness exercises when individuals reported increased negative affect or smoking behaviors[200]. By aligning support with the user's immediate needs, just-in-time adaptive interventions may enhance the effectiveness and engagement of treatment through increased personalization.

Although numerous trials have been conducted of just-in-time adaptive interventions for health conditions[201], a significant research gap exists in the development and testing of these interventions for mental health problems. There has been some progress in mental health conditions where behavioral patterns are more discrete and measurable, such as eating disorders[202], suicide prevention[203], and addictive behaviors[204]. For example, a just-in-time adaptive intervention targeting opioid addiction in chronic pain prompted mindfulness exercises when stress was detected via a smartwatch[205]. A just-in-time adaptive intervention for youth depression and anxiety (*Mello*[206]), targeting repetitive negative thinking (rumination and worry), showed moderate to large effects over six weeks in a pilot RCT. Another pilot RCT of a just-in-time adaptive intervention for depressive rumination in adults found that the intervention showed greater improvement in rumination relative to a control condition[207]. Finally, a pilot trial of a just-in-time adaptive intervention targeting sleep in veterans found that using the app in conjunction with clinical support improved sleep outcomes[208].

While early results are promising, more development is needed alongside RCTs to thoroughly assess the efficacy of just-in-time adaptive interventions across a range of mental health conditions, and empirically determine whether they can increase engagement.

Addressing engagement through digital literacy

The effectiveness of digital mental health interventions has been closely tied to factors such as digital literacy, familiarity with technology, and availability of training[177]. Limited technological skills and low digital literacy among users are substantial barriers to effective usage of digital interventions[177,181,183-185,188], and these issues are compounded when end-users are confronted with technological barriers. Programs designed to teach digital literacy to people with serious mental illness have shown promising pilot results [209,210] and offer a tangible solution that should be expanded.

Positive beliefs about technology[177,188] and understanding its benefits[177] increase engagement, while low self-efficacy concerning using technology poses a challenge[183]. Increased exposure to technology improved the comfort of young First Nations people and their families over time with using digital mental health interventions[182]. Training and support are essential in improving digital skills, confidence and overall engagement with digital interventions, particularly for users initially struggling with technology[181,184].

Addressing engagement through social influence

Social influence is reported to play a critical role in end-user engagement with digital mental health interventions. Positive influ-

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ence from peers and family consistently emerges as a factor encouraging initial adoption and sustained engagement[177,185,188]. Family involvement increases over time with repeated use of technology [182], and sharing tasks with family or friends supports end-users' regular practice[180]. However, the presence of family or caregivers may inhibit open discussion in older adults[183] and in community forums[179].

Social connectedness-related features in digital mental health interventions – such as peer support, community forums, and family involvement – are valued across studies and found to contribute to user retention[177,181,186]. However, these features might instead give rise to feelings of isolation and disengagement[179]. For example, one young person in a qualitative study commented[212]: "*I felt even if I had something to say, I didn't feel comfortable saying it. I wasn't sure if I wrote something it'd make it worse, or I'm not sure how to feel about giving other people advice*".

CHALLENGES IN IMPLEMENTATION

Translating evidence-based practices into real-world use is an increasingly recognized challenge in mental health research[213]. Notoriously, fewer than 50% of clinical innovations are adopted in practice, and those that are adopted often take up to 17-20 years to do so[214]. This challenge is particularly critical in digital mental health, where the perceived benefits of accessibility, reach and scalability are key drivers of interest, funding and innovation, but few examples of implementation success exist[215,216]. This underscores the need for systematic approaches to bridge the knowledge-practice gap in digital mental health. Implementation science provides these approaches, employing a variety of key theories, models and frameworks[217].

Barriers and facilitators in digital tool implementation

A growing body of research has identified barriers and facilitators at multiple levels in implementation of digital mental health interventions, aligning with the domains outlined in key frameworks such as the Consolidated Framework for Implementation Research[218].

Practitioner level

Clinical staff of mental health services can play a critical role in translating digital mental health interventions into routine care. Factors influencing clinicians' motivation, capability and opportunity are key to successful implementation[219-221].

Despite high interest in digital support generated by the COVID-19 pandemic[1,220], negative perceptions – such as concerns about the quality of digital interventions compared to face-to-face care, and privacy issues – remain significant barriers[181]. Moreover, poor digital literacy and lack of confidence in using digital tools[221,222] can impede clinician adoption, which is compounded by concerns about safety and risk management in digital spaces[223,224]. Further, concerns about the potential impact on the therapeutic relationship, with digital interventions often perceived as impersonal or "cold", also act as barriers[223-226].

Like many professionals with established competencies, clinicians can resist changes to practice, creating an additional obstacle[20,224,227]. This highlights the importance of training in the digital space, which has not kept pace with the rapid development of digital tools and their growing evidence base, especially around generative artificial intelligence and LLMs[228]. While training is among the most cited facilitators for digital implementation at the clinician level[181], recent research reveals a lack of content concerning digital mental health interventions within clinical training programs[229]. Moreover, the high-stress, high-demand nature of many mental health services, and the high burden placed on clinicians, must be acknowledged, which may limit opportunities to learn, understand and integrate digital interventions[20,223,224], further emphasizing the need for digital competency training to occur before clinicians are recruited in mental health services. The above factors also affect motivation, capability and opportunity at the leadership level, where a lack of active support or resources for digital implementation can create significant barriers within services[222,224,230].

Practitioner-level facilitators include training, co-design and co-production with clinicians[226], and a belief in a digital future for mental health care[181]. Involving clinicians in the design process increases their buy-in and ensures that digital tools enhance their work meaningfully. Motivated, innovation-minded leaders who demonstrate, model and are accountable are also critical to driving implementation[20]. In addition, integrating digital mental health into curricula for trainee clinicians would build digital competencies earlier and help shift expectations around future clinical roles, addressing some of the barriers to digital adoption. Together, these strategies can address individual-level barriers and create a workforce better equipped to embrace digital transformation in mental health care.

Service level

Several service level determinants relate to both the characteristics of the setting and the factors involved in implementation delivery. Significant barriers are the lack of alignment between digital mental health interventions and existing workflows, the compatibility between digital and face-to-face care[181], and the perceived priority of digital interventions compared to critical clinical tasks, such as responding to emergencies[20,222,224]. Although interoperability and integration with existing technology systems are proposed as solutions, real-world examples remain scarce, due to the high complexity and variability of technological systems used in care settings.

The value of co-designing digital tools with service stakeholders is clear. In the same way that the field now recognizes the impor-

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tance of user-centered design and participatory research in the development and evaluation of digital mental health interventions, an early understanding of contextual factors is key to scalability models that include integration and implementation. The involvement of service stakeholders can better support a fit between technology and practice, and ensure that digital tools enhance and complement, rather than compete with, clinical tasks.

The availability and reliability of technology in mental health services – especially in remote or low-resource areas – is a further barrier[222]. Moreover, staff shortage and personnel turnover also hinder implementation and sustainability, as those who have developed expertise and confidence in digital mental health interventions may be replaced by less experienced professionals[20,224], underscoring the key role of training programs conducted before clinicians are recruited in services[229].

Service setting implementation facilitators include adequate resourcing, infrastructure and staffing[181], as well as collaboration and communication between team members or service staff[221,225]. New roles such as that of digital navigators, discussed above, may also help alleviate the staffing issues when clinicians need support to utilize digital mental health technologies in care optimally.

System level

System level barriers include policy, regulatory and financial issues. Regulatory and reimbursement frameworks remain an ongoing challenge. Unclear, restrictive and not fit-for-purpose regulations pose barriers to digital mental health implementation[223,226]. Conversely, regulations that mandate privacy and data protection can shape the digital health ecosystem, influencing confidence in digital mental health interventions among both clinicians and users.

The certification or endorsement of specific interventions can facilitate their implementation, alongside their integration in clinical guidelines[226]. In many Western countries, such as the US and Australia, regulatory agencies do not actively enforce regulatory or certification requirements for digital interventions that fall under the wellness or low-risk sphere. However, the regulatory landscape is evolving rapidly. For example, the UK National Health Service and the Australian government have introduced frameworks such as the Digital Technology Assessment Criteria[230] and the National Safety and Quality Digital Mental Health Standards[231], respectively, with significant implications for future government funding.

In Germany, the Digital Health Application (DiGA) system has linked regulatory approval with reimbursement[232]. The US FDA has recently issued several new guidances[233,234] for digital health technologies that are likely to preview future regulation and enforcement. Decisions are being made regarding whether the recently announced US Medicare billing codes to reimburse digital mental health interventions will stipulate that these interventions must be FDA-cleared to qualify for reimbursement[235]. Thus, the regulatory and reimbursement space is dynamic, with frequent consultation and revision, indicating that, while progress is being made, keeping abreast of developments requires close monitoring of relevant policies and processes.

New developments

The above-mentioned barriers and facilitators have focused on the implementation of digital mental health interventions into mental health care settings, reflecting the predominant focus of current research and scoping efforts. However, a nascent literature also exists exploring the integration of these interventions across schools and educational environments, workplaces, and community services[236]. Given the flexibility and adaptability of digital interventions to "meet people where they are", it is crucial for implementation research to extend beyond traditional care settings.

Further, most progress in digital mental health implementation research has been in identifying and understanding barriers and facilitators. Less is known about which implementation strategies may facilitate real-world use, and under what conditions[215,237]. A recent notable exception is the *ImpleMentAll* trial, which tested a tailored implementation toolkit for Internet-based CBT (iCBT) against "implementation as usual" across Europe and Australia[216]. Results indicated that the toolkit had a small but statistically significant effect on the degree to which iCBT is considered a normal part of work within the context. While this study provides valuable evidence and resources for tailored implementation, detailed insights into how the tailored strategy differed from "implementation as usual" has yet to be published.

To support research on implementation strategies and outcomes in the digital space, methods of the traditional research pipeline should be replaced by methods that develop and test digital mental health interventions within the real-world contexts in which they will be implemented or scaled[213]. One such design is the hybrid implementation-effectiveness trial, which evaluates both effectiveness and implementation to varying degrees[238]. By adopting these and other novel methodologies and involving multidisciplinary teams – including key stakeholders and implementation scientists – the next generation of digital mental health interventions, particularly in expanding areas such as artificial intelligence and virtual reality, can have a more solid foundation for implementation and impact at scale.

DIGITAL MENTAL HEALTH FOR MINORITIES AND LOW-RESOURCE CONTEXTS

The potential of digital mental health to increase access to care is often discussed around serving the unmet needs for care in historically marginalized communities, cultural minorities, and low-resource settings. However, digital approaches could have unintended effects of exclusion without a concomitant focus on digital access and literacy. This section reviews how digital mental health is evolving to meet these important needs and ensure that no patients are left behind.

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Historically marginalized communities and cultural minorities

Communities historically affected by discrimination, marginalization and stigma – e.g., racial and ethnic minorities; lesbian, gay, bisexual, transgender, queer/questioning (LGBTQ+) populations; and low-income communities – experience disparities in mental health access and treatment. For instance, although these minorities tend to have a higher prevalence of common mental health problems, they are less likely to seek professional mental health treatment and more likely to prematurely drop out when they are in care, as well as to experience persistent symptoms[239-242]. Blacks, Asians and Hispanics/Latinos are also more likely to receive a diagnosis of severe mental disorder when they seek mental health services[242]. If implemented skillfully, the rise of digital mental health may help reduce such disparities by increasing access to care, reducing cost, removing the stigma associated with seeking mental health care in in-person settings, and engaging underserved communities[243,244].

Research on mental health apps not customized for these populations suggests that they have not fulfilled the promise of broadening access and utilization. A recent study on a freely available meditation app found that African Americans were much less likely to access and utilize the app[245]. As evidence from psychotherapy research consistently shows, culturally tailored interventions are more efficacious than non-tailored ones[246]. Effectively tailored efforts that appeal to and engage people from underserved communities will be critical in digital mental health as well. A recent systematic review and meta-analysis[247] found that culturally adapted digital mental health interventions for racial and ethnic minorities produced a large and significant effect across outcomes (g=0.90) compared to waitlist and treatment-as-usual conditions, although the average attrition was somewhat high (42%). A lack of research with Black and Indigenous populations was highlighted. Tailored digital mental health programs have also been piloted in sexual and gender minorities, a population heavily affected by discrimination, stigma, early life adversity, and more prevalent mental health concerns compared to their heterosexual counterparts[248-250].

Improving access and engagement is one of the most important challenges for digital mental health program designers when tailoring such efforts to underserved communities. To this end, employing participatory designs, such as the community-based participatory research method, may be fruitful in developing community-specific, culturally relevant content and improving delivery design (e.g., frequency, dosage) and engagement strategies (e.g., reminders, peer interventions, personalized messages)[251]. This may be particularly pertinent to historically marginalized communities to overcome potential barriers such as mistrust of traditional health care systems and medical research, stigma in seeking and receiving mental health services, and literacy and language-related issues.

The development and evaluation of digital mental health interventions for historically marginalized populations are still in their infancy, and much work is needed to understand the best approaches to digital mental health for subgroups of minority populations and outcomes. With the advancement and growth of technology, using artificial intelligence and machine learning in digital mental health with marginalized individuals and groups has been an area of both promise and caution, and requires deeper and purposeful research. For instance, a recent study evaluated a personalized artificial intelligence-facilitated self-referral chatbot in the UK, and found that increases in referrals were particularly pronounced among gender non-binary and ethnic minority individuals, with the participants' need for treatment as well as the chatbot's human-free nature (thus reducing the likelihood of stigmatizing interactions with a provider) being potential contributors[252].

Despite the promise of artificial intelligence and machine learning for personalized interventions, they could exacerbate health disparities by displaying biases against marginalized and underserved groups due to algorithms and predictions built on data that reflect social biases[253]. For example, diagnostic algorithms built on historical data might be more likely to suggest diagnoses of severe mental disorders for Black/African Americans despite displaying similar symptoms to their non-Hispanic White peers. Validating computational models with minority populations, training artificial intelligence to overcome social biases, and exploring how artificial intelligence and machine learning may facilitate or hinder addressing factors that lead to mental health disparities, including structural inequalities, are important issues for this area in the future.

Low- and middle-income countries and low-resource settings

Globally, there are significant disparities in access to mental health care, and the World Health Organization (WHO) has called for action to address this inequality as a major global health challenge[254]. It is estimated that 76-85% of severe mental health cases in low- and middle-income countries (LMICs) do not receive treatment due to the scarcity of resources and trained professionals[255]. Today, people in LMICs increasingly own smartphones and want to use them towards health[256]. However, research in digital mental health remains relatively scarce. A systematic review conducted in 2020 found 22 controlled studies that employed mobile/Internet-based psychological interventions in LMIC settings, with the majority conducted in Asia (59%) and focusing on adults with elevated depression, anxiety, PTSD or substance use symptoms[257].

Another systematic review[258] uncovered 55 studies (including those with only qualitative reports) that conducted cultural adaptation of Internet- and mobile-based mental health interventions in LMIC settings, or with migrants and Indigenous people in high-income countries. The study provided a taxonomy of 17 components of cultural adaptation that range from content to methodological (e.g., functions, aesthetics) and procedural (e.g., who is involved, how information is gathered) aspects, and highlighted the complexity in situating and tailoring digital interventions in new cultural contexts. Further evidence from more diverse regions and populations is needed.

In addition to digital mental health tools in direct clinical roles,

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there is also great potential for digital interventions to address training needs, reduce the burden of care for providers and mental health care systems, and build local capacity in low-resource LMIC settings. This may include engaging lay providers (i.e., digital navigators) as part of the prevention-to-treatment spectrum of care[259]. For example, to address the surge of suicide among adolescents in China[260] and the lack of resources in rural school systems in that country, a localized gatekeeper for teachers program was developed and delivered via digital training[261]. In India, the EMPOWER study[262] uses digital tools for training and supervising non-specialist providers. A 2024 review of digital psychiatry in LMIC countries offers further examples[256].

Another relevant area for digital mental health globally is its application for people and communities affected by the growing number of wars and conflicts[263]. To this end, digital mental health may offer scalable solutions to address accessibility issues and provide needed real-time support. Examples of this work include a recent RCT of a WHO-guided digital health intervention for depression (*Step by Step*) for Syrian refugees in Lebanon[264], and an RCT with refugees in Germany[265] which found that a hybrid approach (combining digital treatment with in-person intervention based on symptom severity) was sustainable and cost-effective for depression. A recent review of digital mental health interventions for children and adolescents affected by war found that most interventions suffered from gaps, including that most programs were not culturally or linguistically adapted to their contexts[266]. Appropriate contextual tailoring often takes time and resources, and how to best adapt an evidence-based digital health intervention for conflict-affected communities in times of need remains a challenge. Evaluating and ensuring that such interventions are not only efficacious but also scalable is critical, given the large refugee and migrant populations in need of care.

Given the significant need for addressing mental health needs in LMIC settings and the limited resources, digital mental health efforts in these contexts should adopt a population health approach and expand beyond an individual patient focus. This may involve public education to raise awareness of mental health and reduce stigma, as well as engaging key people in communities, schools, and family and work settings[267]. Employing implementation science perspectives and engaging with policy makers early in the research process could also be beneficial to scaling up effective programs, increasing impact, and fostering translation from empirical evidence to practice[268,269].

CONCLUSIONS

The digital mental health space is rapidly growing far beyond traditional telehealth visits. New tools such as LLMs have rapidly emerged, while relatively older ones such as smartphone apps and virtual reality have quickly expanded. While each tool has offered evidence of clinical impact, broad real-world impact remains aloof for all. This paper has highlighted many of the factors involved and proposed actionable solutions. While it is impossible to summarize such a vast and evolving space neatly, two key points around the scientific nature of digital health research and real-world engagement must be highlighted.

First, the vast majority of research reviewed in this paper focused on individual products, particular apps, unique virtual reality programs, and specific LLM models. This focus on digital health as a tool instead of the generalizable principles behind the tools has hindered scientific progress. Clinical research requires synergies, which remain limited in the digital mental health field because of a lack of common metrics and, in part, a lack of shared tools/softwares.

Second, results of our review underscore that the human connection supporting any of these technologies is critical for real-world impact outside of research studies. The next generation of digital tools must be better co-designed, personalized, and responsive to patient needs. These tools must also be studied, beyond efficacy trials, through methods prioritizing external validity and generalizability, such as hybrid research designs guided by implementation science frameworks. With this approach, new tools may better engage clinicians and achieve integration into complex clinical systems.

There are many pathways to improved clinical research and real-world use of digital mental health tools. The extent to which future digital mental health interventions will be genuinely beneficial for people with mental health conditions will directly reflect the intersection of progress across those two domains.

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