





# Moving Evidence-Based Mental Health Interventions into Practice: Implementation of Digital Mental Health Interventions

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## Opinion statement

Digital mental health interventions (DMHIs) offer a modern solution to increase access to mental health services, by supporting existing services or providing new services to those who are not as accessible to traditional mental healthcare. DMHIs, however, often face challenges transitioning from research to practice. Implementation science aims to enhance and establish frameworks to help identify barriers and facilitators towards implementing DMHIs in different communities. We analyze the barriers and facilitators towards successful implementation using the Consolidated Framework for Implementation Research (CFIR) domains and summarize the implementation strategies used to enhance the adoption, implementation, and sustainment of DMHIs. Finally, we address the ethical and safety principles that should be followed to protect the consumers/patients. With the growing amount of evidence supporting the effectiveness of DMHIs, this paper provides an overview of implementation considerations for DMHIs and its role in improving mental healthcare delivery. However, the role of DMHIs and their implementation need to be better defined in various settings. Implementation science and its frameworks can offer us a better understanding of determinants to better identify, create, and evaluate implementation strategies.

## Introduction

The past decades have seen increasing interest in digital mental health interventions (DMHIs) in research and practice. In the USA, this interest has been driven by multiple factors including achieving the triple aim of healthcare: personalized care, with greater population impact, at lower costs. DMHIs have been demonstrated to be effective for various concerns including depression [1], anxiety [2], and stress [3]. Emerging evidence has also demonstrated the potential of DMHIs in specific populations such as youth and adolescents [4], university students [5], and even youth experiencing homelessness [6]. Private funding in the mental health space has increased dramatically over the past decade with \$637 million invested in 2019 alone [7], although perhaps cooling a bit recently. This combination of scientific support and development has led to an opportune moment for DMHIs to help expand access to high-quality care for those in need. And yet, the digital mental health revolution has not been realized. Recent calls have suggested that DMHIs should be frontline treatments [8•] while noting that the important question is not if, but which DMHIs should be provided [9]. In short, we need to get effective, safe, and scalable DMHIs into the hands of those who need them.

The scientific study of moving evidence-based innovations into routine care settings is referred to as implementation science [10]. Implementation science is a burgeoning field whose importance has been demonstrated recently with the recognition that most

scientific discoveries take too long to impact practice or fail to transverse the research-to-practice chasm altogether [11, 12]. Early thinking about DMHIs tended to suggest that because they were low cost and highly scalable, implementation would be an emergent property of translating evidence-based psychosocial interventions into digital products. Although the app stores provide a potentially easy access point to direct-to-consumer dissemination, research has demonstrated that few DMHIs available on these stores are downloaded or used, with two products (Headspace and Calm) accounting for about 90% of all regular users [13]. To impact mental healthcare, DMHIs also need to be integrated into practice workflows, which require active efforts. In implementation science, these active efforts are referred to as implementation strategies and the evaluation of their effectiveness on implementation outcomes is the primary focus of implementation research.

This paper provides an overview of implementation considerations for DMHIs. We start with an introduction to the Consolidated Framework for Implementation Research (CFIR) [14••], a determinant framework of implementation that identifies characteristics that contribute to implementation success. We then discuss various determinants that have been identified for DMHIs organized by the CFIR domains. We next present different implementation strategies that might support DMHI implementation. We conclude with ethical considerations as to the use of DMHIs.

## An implementation science lens to moving DMHIs into practice

Implementation science focuses on the study of the factors and processes that support moving evidence-based innovations into practice. An expert group conferred at the Banbury Forum concluded that sufficient evidence exists to support that guided DMHIs should be provided as frontline treatments for depression, anxiety, and posttraumatic stress disorder [8•]. In the USA, however, no standard exists to determine whether a given DMHI meets sufficient evidence thresholds to be ready for implementation and this consideration is often made on a case-by-case basis for each setting.

Once a given DMHI is selected to be implemented, however, it will likely face many challenges to successful implementation. Many attempts to implement DMHIs in real-world settings have been unsuccessful. Consumers may fail to engage with DMHIs (e.g., [15]), few providers may refer to them (e.g., [16]), and the costs associated with them may not be commensurate with their impact (e.g., [17]). Several conceptual frameworks in implementation science exist, including determinant frameworks that describe factors that serve as barriers and facilitators to influence implementation outcomes. One influential determinant framework is the Consolidated Framework for Implementation Research. The CFIR is a comprehensive implementation science framework that was developed by reviewing published theories and identifying common domains that occurred across these theories [18]. The CFIR has been used in a multitude of studies to identify potential determinants of implementation (see [19]).

CFIR constructs are sorted into five domains: the innovation/intervention, the individuals involved, the inner setting, the outer setting, and the implementation processes. The “innovation/intervention” domain includes aspects related to the innovation or intervention which is being implemented, in this case, the DMHI itself. The “individuals involved” domain includes aspects related to the primary, secondary, or tertiary users of the DMHI such as consumers, providers, and other people within the implementation setting. The “inner setting” domain refers to the setting in which the DMHI is being implemented such as a care clinic, a city, or a school. The “outer setting” domain includes the settings in which the inner setting exists such as the healthcare system, county or state, or school district. The “implementation process” domain includes the implementation activities and how they are planned and executed.

CFIR is useful because it can organize factors related to implementation success and help identify potential solutions to address barriers or opportunities to take advantage of facilitators. Its application can help identify common barriers and facilitators that have occurred in DMHI implementations to anticipate potential aspects that might occur in other implementations. The CFIR can also guide contextual assessments for a given setting before implementation to consider aspects that should be addressed or considered. In the next sections we review some barriers and facilitators identified in prior studies of DMHIs to provide some synthesis of what is currently known in this area.

## Barriers to successful implementation of DMHIs

Despite the potential impact of DMHIs, their implementation can be unsuccessful due to barriers that occur at multiple levels. We organize identified barriers according to the CFIR domains below. Understanding barriers may be helpful to create implementation strategies responsive to these barriers but might also speak to the types of DMHIs that might be best implemented or the types of settings more appropriate to use DMHIs to meet their needs.

### Innovation/intervention domain

Aspects of a given DMHI itself might impact its ability or desirability to be implemented. This includes both characteristics of the DMHI, such as its content and user interface, as well as its function such as how it integrates into workflow patterns. Many DMHIs may be overly complicated. This often results from attempts to translate complex, multi-component behavioral therapies into digital content that is hard for consumers to understand [20]. Others may have poor user experience [21•]. These challenges lead consumers to drop out or discontinue the program. Some of these challenges may be mitigated by support people, either provided by the DMHI platform or the implementing context. However, software updates to the DMHI might make it hard for supporters to keep up with the evolving DMHI or confuse consumers who need to regularly update and learn a new version. Even DMHIs that function well for most people may not work well for everyone, especially for subpopulations such as racial and ethnic, or gender minorities [22] or individuals with various accessibility concerns [23]. In some instances, the consistency of the presentation of a DMHI might be a strength that allows the delivery of evidence-based interventions with fidelity. However, in other instances, this fidelity might result in a lack of adaptability, and in the case of cultural and language limitations, this might impact the success of the DMHI for different groups [24].

### Individuals involved domain

DMHIs may be consumer-facing and/or provider-facing, and factors related to both the consumers and providers may pose significant challenges to adoption and use. For both consumers and providers, negative perceptions may impact their willingness to use DMHIs. Negative perceptions might result from concerns such as credibility and security [20], and these concerns might be exacerbated by negative press received from digital mental health companies due to their practices. Negative perceptions can also result from experiences, such as poor user experience, which can lead to discontinuation of any DMHI and hesitancy to use subsequent DMHIs [25]. Consumers may not have the resources or knowledge to use DMHIs. Limited access to digital devices or limited digital health literacy skills can impact the use of DMHIs [20]. Device access and digital health literacy may intersect with racial and ethnic groups or socio-economic status which can impact implementation in different population pockets [8•]. While all people—consumers and providers—might interact with DMHIs differently, understanding their desire and ability can help identify barriers.

### Inner setting domain

Characteristics of the settings where the DMHI is being implemented might present barriers. Sometimes, this comes from mission misalignment as DMHIs may be selected to provide mental health resources where no others exist such as in schools or workplaces, but these settings may not be equipped

to do so. Some community and mental health centers lack specialized staff to help deliver the intervention or the existing staff lack the necessary time or knowledge. Although DMHIs are often cheap to use, implementing them and setting users up can be costly [26]. Lower-income or rural communities might have even more difficulties implementing DMHIs due to the lack of resources, such as the necessary technologies [27]. Widespread adoption of DMHIs, especially in settings with limited resources for health, will require demonstrating their cost-effectiveness and effectiveness data resulting from target subpopulations to justify their value [4].

### Outer setting domain

The outer settings refers to the setting (or settings) in which the setting where a DMHI is being implemented exists. As such, the outer setting can capture multi-levels of contextual ecologies. For example, a given healthcare clinic might exist within a healthcare system that operates within a specific state. System-level, state, and federal factors might all pose barriers to successful DMHI implementation. Some pervasive and wide-reaching outer setting factors in the USA result from resources, policies, and legislation. Within the USA, high-speed broadband internet is not widely available. Because many DMHIs rely on connectivity, individuals who live in areas of poorer connectivity may be disadvantaged to use DMHIs in the moments when needed most [27]. Financial resources and payment mechanisms are not optimized for DMHIs. Different insurance companies set different policies and guidelines for their patients in accessing mental healthcare. Variables exist across insurance plans in the payment methods and reimbursements for different DMHIs [8•]. The Current Procedural Terminology (CPT) codes or the Healthcare Common Procedure Coding System gives insurance companies different standards of how patients or users can pay for their intervention. Some insurance plans provide a “fee-for-service” model, while some do not. Federal funding for mental health services, such as block grants, does not specifically consider DMHIs, which limits their use in various settings. Limited financial resources, lack of reimbursement mechanisms, or inadequate funding models can create barriers to scaling and maintaining these interventions. Insufficient financial support may result in limited resources for research, development, implementation, and ongoing support for digital interventions.

### Implementation process domain

The process of implementing DMHIs may also present barriers to successfully doing so. One challenge arises from the fact that DMHIs include both technological and mental health service components [28], which each have different implementation considerations. In many settings, the individuals responsible for implementing technologies are different from those responsible for implementing services. As such, DMHIs might require coordination from individuals

not used to working together, and approvals, contracts, or workflow considerations that cross-technology and service teams. Implementing DMHIs requires providing adequate user support and integrating the app into existing clinical workflows or treatment plans [29]. Sufficient individuals to do so might not exist, and even if they do, it might require redefining job roles or activities. In one implementation study, providers noted that they were uncomfortable implementing DMHIs due to their lack of training and education to better understand their new clinical workflows that introduced DMHIs into patient care [30••].

## Facilitators of successful implementation of DMHIs

Successful implementation of DMHIs results from the interplay of factors across multiple levels. This includes ensuring that effective and usable DMHIs get introduced to accepting and supporting environments [31], which are shaped by client and community factors, delivery capability, resources, and acceptance. Having community leaders and healthcare professionals foster acceptance of different DMHIs can lead to effective health education and continuous use of interventions [32]. Considering the patient and user preferences for the use of digital devices and modes of technology to connect with and use DMHIs is necessary [33]. Population empowerment of their lived experience with different mental health conditions can promote successful recruitment and implementation [26]. By leveraging these facilitators, organizations can promote the successful implementation of DMHIs, improve access to quality mental healthcare, and reduce the burden of mental illness on individuals and society.

### Innovation/intervention domain

Whereas evaluation of the innovations themselves has been understudied in implementation science generally [31], DMHI development and research have a long history of evaluating the intervention through human-centered design, usability testing, and feasibility trials. DMHIs that are simple, intuitive, and engaging are likely to be more acceptable to both consumers and providers. Compatibility and adaptability can also foster successful implementation. DMHIs that align with existing workflows, values, and incentives within the implementing setting support adoption and integration [30••]. If a given DMHI does not start tailored for a specific context, customizing it to fit the specific needs and wants of consumers and providers within that setting can enhance the intervention's perceived usefulness and acceptability [26].

### Individuals involved domain

Individuals are more likely to adopt and sustain DMHIs if they perceive them to be advantageous compared to other options. A positive user experience can

enhance the acceptability and adherence to a DMHI [26]. When individuals enjoy the features of the DMHI, like the content, appreciate the user interface, and find it easy to use and learn, they are motivated to try and continue with a DMHI [34]. Factors such as the perceived need for intervention, self-efficacy, personal relevance, and willingness to use technology can facilitate adoption and sustained engagement. Knowledge and proficiency in using digital devices, software, apps, and online platforms support both consumer and provider adoption [35]. Providers also need to be knowledgeable about the specific DMHI(s) being implemented. In Kaiser Permanente, one aspect of their DMHI eco-system was educating providers [29]. Similarly, a training program in the best practices for using mobile health in clinical care provided by the Department of Defense and Department of Veterans Administration resulted in providers being more knowledgeable about digital health interventions and more likely to use them in their practice [36].

### Inner setting domain

When it comes to implementing DMHIs, several facilitators within the inner setting domain can contribute to successful implementation. Organizational preparation and motivation to embrace change can support implementation. Factors such as a positive attitude towards innovation, openness to new approaches, and a willingness to adapt existing processes to accommodate DMHIs can enhance implementation success [37]. Effective collaboration and communication among different stakeholders within the organization also can foster implementation success. When clinical teams, departments, and individuals work together, share knowledge, exchange feedback, and engage in ongoing communication, it can enhance the integration of DMHIs into existing practices. DMHIs that align with existing workflows, clinical guidelines, and routines within a setting are more likely to be successfully implemented with community members. When interventions fit seamlessly into existing processes, they are easier to adopt, integrate, and sustain within the inner setting [26].

### Outer setting domain

Facilitators within the outer setting domain refer to factors outside of the implementing organization or setting but in settings to which that organization or set belongs. Partnerships that have a strong respect for the cultural considerations within a community can provide additional expertise and resources to facilitate the successful implementation of DMHIs [38]. Creating partnerships with healthcare settings can be beneficial because they are tasked with alleviating the burden of mental health among their patients. Community healthcare settings have the knowledge and standards to improve the possibilities of tailoring the implementation of the DMHI to create a sustainable health plan for their patients [15]. Having external pressure to



drive an increased delivery of DMHIs within a community can also facilitate the success of implementation. Feedback from patients and clinicians on the apps they have used can inform health systems on what they should explore further [27].

## Implementation process domain

Clearly defining goals and objectives, developing an implementation plan, establishing timelines and milestones, identifying necessary resources, and assigning responsibilities to individuals or teams involved are all steps in the implementation process [39]. We discuss more about implementation strategies and their application to DMHIs in the next section. Some processes that have seemed to be important within DMHI implementation include training of both the consumers, such as digital health literacy training [40], and the providers to support competencies in using mobile health [36]. Given the complex interplay between technological, human services, and implementation aspects, several arguments have been made to conduct early development and testing within the contexts in which DMHIs will ultimately be deployed [28] and to consider the simultaneous development of DMHIs and implementation strategies and blueprints [41]. This demonstrates how implementation processes intersect with aspects of the innovation, individuals involved, and the inner setting.

## Implementation strategies

Addressing barriers and leveraging facilitators require coordination of the needs and interests of the various actors involved in DMHI implementation. Understanding the roles that all these actors play in implementation can help identify specific activities they can take to support implementation success. Implementation strategies are the methods or techniques used to enhance the adoption, implementation, sustainment, and scale-up or scale-out of an innovation. Evaluating implementation strategies' effectiveness is the primary focus of implementation research. Implementation strategies vary in their scope ranging from a discrete strategy to multi-faced and packaged strategy bundles, to protocolized programs consisting of multiple implementation strategies. Efforts have been made to identify common implementation strategies such as the Expert Recommendations for Implementing Change (ERIC; [39]). The properties of DMHIs might require unique considerations, such as their evidence-based properties, stakeholders such as industry partners, and the value proposition of digital options. Selected implementation strategies from the ERIC have been identified specifically for DMHIs [30••].

One consideration that can be useful in identifying and selecting appropriate implementation strategies is to consider the phase of implementation processes. The Exploration, Preparation, Implementation, and Sustainment (EPIS)



framework proposes four well-defined phases that occur during this process [42]. In the exploration phase, strategies should focus on understanding the characteristics of the DMHI(s), the individuals involved, and the setting. For example, selecting a DMHI or DMHIs by using standardized evaluation criteria (e.g., [29]; [43]). During this exploration phase, needs assessments can determine provider- or setting-level factors that should be addressed. During the preparation phase, strategies need to address identified deficits, such as providing training to providers to address knowledge deficits, acquiring devices for consumer or clinic use to address technology access deficits, or providing digital health literacy training to address consumer knowledge deficits. Additional programming might be necessary during this phase such as adapting DMHIs to fit the implementation setting or integrating DMHIs into EHRs for referral or data monitoring. The implementation phase requires not just activities to deploy DMHIs, such as internal or external facilitation or technical assistance, but activities that monitor the success of DMHI deployments such as fidelity monitoring, resource tracking, and learning collaboratives. Lastly, during the sustainment phase, it is important to appreciate that the same strategies that lead to implementation success may not necessarily support ongoing sustainment. Implementation plans and strategies need to be optimized over time. The changing needs and preferences of consumers and providers need to be considered alongside updates and iterations to the DMHIs and technology trends more broadly. For example, a successfully deployed iOS app might become less impactful if the consumer population in a setting shifts from predominantly iPhone users to predominantly Android users.

## Discussion

DMHIs have the potential to revolutionize mental healthcare by providing innovative, accessible, and cost-effective solutions. However, their ultimate impact will depend on whether they get used. Use is unlikely to be driven entirely by direct-to-consumer approaches but will instead require integration into traditional mental healthcare delivery pathways. However, it is worth noting that DMHIs are not a panacea. Merely making them available to consumers and providers will not ensure that they are adopted, used, or sustained. As such, successful implementation of DMHIs requires addressing several barriers as well as leveraging facilitators. Current implementation efforts in the USA have been fragmented due to a lack of clear ethical guidelines, evidence standards, and reimbursement mechanisms. These issues lie in the outer setting of the CFIR which is less frequently explored in implementation research that preferences inner setting aspects.

### Considerations of ethics and standards

The use of DMHIs at this point seems inevitable. Considerable implementation momentum exists. A sufficient mental health workforce does not exist

to meet the need for mental health services for all Americans suffering from mental health challenges. Considerable investment has been made in DMHIs. Despite this momentum, it is worth asking whether we should be implementing DMHIs currently. Clear ethical and regulatory guidelines for the use of DMHIs in the USA do not exist. The United States Food and Drug Administration has regulated some DMHIs under their regulatory authority over software as a medical device but has suggested that a new regulatory paradigm would be useful, which would require legislative change [44]. Serious privacy and security concerns have been raised about some DMHIs [45] and research has demonstrated other safety concerns as well [46]. Implementation science traditionally has focused on implementing evidence-based interventions and innovations, but in the case of DMHIs, an open question is what counts as evidence-based. For example, strong evidence supports the effectiveness of digital cognitive-behavioral therapy for depression [8•], but even an analysis of digital cognitive-behavioral therapy apps shows their fidelity to cognitive-behavioral therapy principles is inconsistent [47]. Standards need to consider not only the bar for implementing a DMHI but also the requirements that DMHI must meet to be sustained. Such principles align with how digital health interventions are used in other countries such as the *Digitale Gesundheitsanwendungen (DiGA)* in Germany and other suggestions to conduct ongoing monitoring of DMHIs once deployed [48]. Developing similar principles in the USA of learning health systems and post-marketing surveillance could support consumer protection and confidence.

## Conclusion

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The growing body of evidence supporting the effectiveness of DMHIs suggests they have a role to play in improving mental healthcare delivery. However, that role is still being defined by efforts to better understand these innovations and their implementation in various settings. Implementation science offers several frameworks to better understand and characterize implementation determinants as well as models and methods to better identify, create, and evaluate implementation strategies. The next phase of work needs to move beyond determining whether DMHIs are good seeds to identifying and creating hospitable soil for them to grow.

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## Declarations

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Human and Animal Rights and Informed Consent.

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