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Scaling Evidence-Based Treatments through Digital Mental Health

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Abstract

A large number of Internet websites, mobile apps, wearable devices, and video games that are hoped to improve behavioral, cognitive, and affective targets associated with mental health have been developed. Although technology provides the promising potential to help spread evidence-based mental health treatments, that potential is still largely unrealized. The vast majority of technology-based mental health products, deemed digital mental health interventions (DHMIs), have not been tested and show little fidelity to evidence-based treatments. Furthermore, best practices around the use of technologies in clinical services are underdeveloped and few clinicians have been trained to integrate these tools in their practice. We present an overview of DHMIs and discuss key aspects related to their implementation. We organize these aspects according to the Consolidating Framework for Implementation Research, a framework that identifies constructs related to effective implementation. These constructs are categorized into five domains including characteristics of DMHIs, the individuals involved, associated processes, the inner setting, and the outer setting. Our goal is to highlight key areas of consideration for leveraging technology to support the implementation of evidence-based treatments and to emphasize challenges and opportunities that come from using technology to scale evidence-based mental health treatments.

Keywords

implementation science; technology; mental health services; mobile health

One goal of implementation science is to spread effective practices as far as possible. This means spreading practices into new settings and contexts, as well as new mediums. One medium that has enjoyed considerable enthusiasm recently is technology, including Internet websites, mobile apps, wearables devices, and video games. These technologies, deemed digital mental health interventions (DMHIs), offer the promise of cost-effective and widely

accessible mental health services that could leverage the pervasiveness of technologies, like smartphones, to literally put "therapists in your pockets" (Anthes, 2016). DMHIs are digital translations of psychosocial interventions that may be provided as standalone interventions, i.e., those people could use on their own, without the need for a specialty mental health provider, such as self-guided Internet-based cognitive-behavioral therapy programs like Beating the Blues (Proudfoot et al., 2004) or MoodGYM (Christensen, Griffiths, Groves, & Korten, 2006), or guided versions that include some form of human supporter to increase engagement and/or outcomes like Joyable (Dryman, McTeague, Olino, & Heimberg, 2017) or IntelliCare (Mohr et al., 2019). Guided DMHIs also include tools deployed as adjuncts to traditional treatments in order to increase their impact and efficiency (Wright et al., 2005) such as the suite of tools developed by the Department of Defense and Veterans Administration to support evidence-based treatments (EBTs) including ACT Coach, CBTi-Coach, CPT Coach, PE Coach, and STAIR Coach. The efficacy of DMHIs has been shown for a multitude of mental health conditions (Andersson, 2018), spanning common mental health issues such as depression and anxiety (Karyotaki et al., 2018; Sucala et al., 2017) and serious mental health conditions such as bipolar disorder and schizophrenia (Nicholas, Larsen, Proudfoot, & Christensen, 2015; Firth & Torous, 2015).

DMHIs can serve several roles in the delivery of mental health services. They have been used as frontline treatments in traditional settings (i.e., Gilbody et al., 2015), as direct-to-consumer tools including over 10,000 available mobile mental health apps (Torous & Roberts, 2017), and in combination with traditional services in what is referred to as "blended care" (Kenter et al., 2015). However, despite the proliferation of research on and the number of DMHIs, such tools have yet to have a significant impact on clinical practice or the burden of mental health disorders. Current practices of development and evaluation have resulted in DMHIs that might be efficacious, yet hard to deploy (Mohr, Weingardt, Reddy, & Schueller, 2017). Few providers use DMHIs in their practices (Schueller, Washburn, & Price, 2016) with major barriers including lack of provider knowledge about DMHIs, as well as the necessary training to integrate them into their work (Berry, Bucci, & Lobban, 2017). Advancing effective implementation of DMHIs requires understanding the roles that these technologies could play within mental health service delivery, and the barriers and facilitators to do so. This could be aided by integration of theories, frameworks, and methodologies from dissemination and implementation science to support translation from EBTs into technology-enabled evidence-based services.

In this paper we highlight key challenges and opportunities for the use of technology to scale EBTs. We organize these aspects according to the Consolidated Framework for Implementation Research (CFIR; Damschroder et al., 2009). The CFIR was developed to compile various constructs identified with successful implementation into a single organizing framework. Such constructs are sorted into five domains that are key to implementation: the intervention characteristics, the characteristics of individuals involved, implementation processes, and the inner and outer settings. The CFIR is a determinant framework, which means that its goal is to help understand and organize the factors that contribute to implementation outcomes and ultimately successful implementation. Within each domain associated constructs are used to identify barriers and facilitators to successful implementation. We use this framework to identify aspects related to implementation of

EBTs using technology in Figure 1 as a guide for issues related to the implementation of DMHIs.

Intervention Characteristics

Mental health interventions tend to be complex, multi-faceted, and have many components involved in their delivery. DMHIs are no exceptions. In fact, in practice they may have increased complexity due to the need to consider technical features such as the digital tools and interface elements, and human components which might be structured by technological affordances or protocols. With respect to the human components DMHIs can be divided into two overarching categories – (1) self-guided DMHIs and (2) guided or supported DMHIs – that broadly capture a continuum of interaction between technological and human elements (see Hermes et al., 2019). Self-guided DMHIs are those that consumers can use entirely on their own with no involvement from a trained supporter. Guided or supported DMHIs have a trained supporter, who may or may not be a specialty mental health provider. This supporter provides interactions via messaging, phone calls, or face-to-face visits, in order to promote usage or increase impact.

Self-Guided

The vast majority of DMHIs available to consumers are "self-guided" in that they include no human support and are intended mostly for self-help purposes (van Ameringen et al., 2017). Self-guided DMHIs are entirely technological in their delivery. Their features typically involve digital versions of strategies in traditional treatments including assessments, didactics or education, and interactive tools. In self-guided DMHIs they attempt to teach the skills of EBTs through the use of these various technological features. Early self-guided DMHIs attempted to investigate whether EBTs could be translated into digital forms while maintaining efficacy (e.g., Proudfoot et al., 2004; Christensen et al., 2005); these interventions often mirrored self-help books but updated with the latest technologies. Newer self-guided DMHIs have leveraged more advanced technologies, for example creating chatbots that mirror therapeutic interactions (Fitzpatrick, Darcy, & Vierhile, 2017).

Guided or Supported DMHIs

Some DMHIs maintain a human in the loop, either in efforts to increase engagement to and effectiveness of the digital treatment, or to use digital components to supplement traditional care. The inclusion of human support is based on clinical and pragmatic considerations. For example, research broadly supports that DMHIs provided with human support are effective with large and robust rates of treatment response and remission (Karyotaki et al., 2018). Not only does human inclusion tend to increase benefits, but it is often required for other purposes. Payment models and billing codes, for example, are typically tied to the amount of time in which services involving human contact time are provided (Powell, Bowman, & Harbin, 2019). Thus, in current payment models, DMHIs may require human involvement to be reimbursed.

Guided or supported DMHIs differ from self-guided DMHIs in various ways. First, they include digital features for both the consumer and the supporter. Second, they may include

synchronous and/or asynchronous communication features, increasing people's ability to access mental health services at times and places of need and convenience. However, they also introduce new concerns related to data security and user safety as outlined later in this paper. This includes addressing acute needs, such as suicidality, that might be revealed through these platforms or defining the necessary training for an individual to provide support.

Relative Advantages

DMHIs might offer several benefits over traditional EBTs. Self-guided DMHIs have the potential to be delivered at scale, with marginally increasing costs for each additional individual who accesses and benefits from such an intervention (Muñoz, 2010). Cost-effectiveness is a commonly touted benefit of DMHIs (Olff, 2015), however some work suggests that this advantage may not be realized when introduced into traditional care delivery pathways, as some tools might lead to increased communication and visits with a provider (Kenter et al., 2015). As such, the cost advantage of DMHIs requires further exploration of when these benefits occur. Another advantage of DMHIs is the potential to deliver interventions with perfect fidelity or promote fidelity to an EBT when a DMHI is used as an adjunct to traditional care. DMHIs can produce digital traces that can be used to determine what elements a person receives and when.

Relative Disadvantages

DMHIs, however, might have disadvantages when compared to traditional care. Although more people might initiate treatment using a DMHI, few people actually complete the treatment (Christensen et al., 2005; Baumel, Edan, & Kane, 2019), and thus, few people might receive a therapeutic dose. DMHIs might be ill-equipped to deal with consumers with various levels of motivation; and technologies might not have the capacity to engage people in referrals to appropriate follow-ups when initial treatments fail. DMHIs might introduce new privacy and security concerns, which will be discussed later, that do not exist in traditional care delivery. Furthermore, many DMHIs, may not be designed in ways that are easily accessible, especially for populations with mental health issues. For example, a usability evaluation of apps for depression found considerable usability issues among service users (Sarkar et al., 2016). Thus, DMHIs are not a panacea and they will not solve all of our problems in service delivery. For DMHIs as a whole, and for any specific DMHI, the relative advantages and disadvantages need to be weighed against each other to result in thoughtful decision-making regarding its introduction as a potential clinical resource (Torous, Luo, & Chan, 2018).

Evidence Strength and Quality

The ability for DMHIs to address the evidence-to-practice gap rests on the degree to which these products are actually evidence-based. Several efficacy trials have demonstrated that DMHIs are effective, with meta-analyses supporting reliable, yet small, benefits for self-guided versions and larger effect sizes for guided or support (Linardon et al., 2019). However, most of the products that have been evaluated in efficacy trials are not publicly available, and the majority of the publicly available products have not been directly evaluated in research studies (Larsen, Nicholas, & Christensen, 2016; Sucala et al., 2017).

Even when products found efficacious are made publicly available, the public versions may lack certain aspects that were present in the efficacy trials including human support (e.g., IntelliCare, Mohr et al., 2019), regular assessments (e.g., Schlosser et al., 2016), or monetary incentives (Arean et al., 2016). Given the lack of direct evidence, most available "evidence-based" apps, therefore make evidentiary claims based on indirect evidence. That means that although they have not been evaluated themselves, they purport to be digital versions of traditional treatments. This transitive property does not hold well in the digital health, especially in DMHIs where the mode of delivery is often part of the treatment frame and therapeutic benefit. Instead, evidentiary support depends on whether they actually translate EBTs with fidelity.

A review of over 100 apps proposing to offer cognitive-behavioral therapy (CBT) or behavioral activation (BA) found that only 10% contained features consistent with CBT and BA (Huguet et al., 2016). Even the apps with features consistent with CBT or BA had low average levels of fidelity with core principles, with only 2 apps having above 50% of the qualifying criteria. Fidelity, therefore, is a key concept when considering the evidence strength and quality of DMHIs. Fidelity to evidence-based principles in features and the use of those features might be a better lens to understand what constitutes an effective dose rather than app use.

The strength of evidence base for a DMHI is the combination of three sources: (1) direct research evidence, i.e., studies demonstrating its effectiveness, (2) indirect research evidence from fidelity to EBTs, (3) indirect research evidence from indication that DMHIs have that type are effective for the proposed form of service delivery.

Trialability

Trialability refers to the ability to test and preview a potential intervention to inform decisions around adoption. DMHIs provide good opportunities to preview the tool. Often a quick examination of an app can offer important information about its quality and clinical potential. Many apps lack a privacy policy (O'Loughlin et al., 2018); this simple proxy for safety offers a quick way to screen out dangerous apps. Examining the content to ensure that, for example, proposed CBT skills are actually delivered, provides a simple means to understand what an app offers and whether it conforms with the desired intervention targets. Many DMHI may seem simple to trial and implement, but if it lacks fidelity to the EBT then its use might not produce the desired outcomes and be potentially dangerous. Furthermore, using an app for even a few minutes or a single session can provide useful information regarding how engaging and sustainable long-term use may be. As many people abandon apps after less than one session (Baumel et al., 2019), an initial review often provides enough information to understand the features that might promote sustained use. Such a quick overview of an app does not guarantee it will be safe or useful, but given the low quality of most apps on the marketplace today, it will likely offer productive information in deciding whether to use the app or not.

Design Quality and Packaging

The ability for DMHIs to address the treatment gap is related to how people adopt these tools. Many factors may drive the adoption of DMHIs; identified contributing factors include rankings and ratings from commercial app marketplaces (Huang & Bashir, 2017). Some work suggests that products with titles that use less clinical language are more likely to be adopted (Huang & Bashir, 2017), but it is unclear why. It could be possible that people realize that formal mental health supports are inappropriate in a self-help context and are therefore looking for more informal interventions focused on non-clinical issues, that people seeking DMHIs in app marketplaces are not thinking of the issues they deal with as formal mental health issues, or that mental health stigma reduces the likelihood someone will adopt an app with clinical language. Understanding appropriateness, however, also requires better understanding from researchers and clinicians as to what EBTs might be most effective in self-help settings and how to reduce potential negative effects such as over-diagnosis, delayed treatment, or the lost opportunity to do some other form of self-guided treatment that is effective.

Characteristics of Individuals Involved

Characteristics of the individuals involved in the CFIR typically refers to individuals involved with the intervention and/or the implementation process. We highlight important characteristics of clinicians associated with such DMHIs, as well as the consumers who use them which might impact successful implementation. As DMHIs may contribute to disruptions (both positive and negative) in traditional relationships between consumers and care by enabling more frequent, timely, and responsive interactions, characteristics of both groups is critical to understand implementation.

Clinicians

While DMHIs are often easy to access – downloading and installing on one's smartphone or using on a desktop, using them in clinical care requires further consideration. Several characteristics of clinicians relate to successful implementation. This section will offer an overview of such characters including issues of beliefs, knowledge, and self-efficacy.

In general, studies have shown that many clinicians hold favorable views of DMHIs (Schueller et al., 2016; Miller, Kuhn, Yu, et al., 2019; Lattie et al., 2020). They believe that such tools might make treatment more accessible and available to those in need, allowing 24/7 support without the need to contact a clinician. Clinicians, however, do report some concerns of such resources, especially whether they properly handle issues of data security and clinical safety (Bucci et al., 2019). Importantly, clinicians believe that DMHIs should enhance, but not replace, traditional care, as doing so may have implications on the therapeutic relationship or consumers' ability to receive personalized care (Berry, Bucci, & Loban, 2017).

Despite the notion that such tools need to be integrated into care, many clinicians report concerns and barriers to doing so. These concerns include a lack of knowledge of how to find and evaluate DMHIs, and how to use a DMHI within one's practice (Cliffe, Croker,

Denne, & Stallard, 2019; Miller, Kuhn, Yu, et al., 2019). Across two studies looking at clinician's long-term use of DMHIs in their practice, it was found that about 50% were using such tools, despite 93–98% of clinicians intending to use the tools (Miller, Kuhn, Owen, et al., 2019; Kuhn et al., 2015). Clinicians were more likely to use such tools if they had their own experiences, either with health apps generally, or the specific DMHI itself. Although the earlier study found that clinician age related to such perceptions (Kuhn et al., 2015), this was not found in the more recent study (Miller, Kuhn, Owen, et al., 2019), which might reflect changing trends in smartphone ownership and comfort.

As such, the enthusiasm of clinicians is balanced by realistic concerns regarding such products, in addition to the lack of knowledge and self-efficacy regarding the use of DMHIs in their practice. Clinicians play an important role as gatekeepers to clients' use of digital tools and people report that clinicians' recommendations play a major role in their decision to adopt DMHIs (Schueller et al., 2018). Thus, increasing the use of DMHIs to scale EBT requires finding practical ways to support clinicians' adoption and perceptions of DMHIs, like training, incentives, or additional personnel.

Consumers

Although many people might be eager to use DMHIs, others may not possess the same enthusiasm or the requisite level of technology literacy or competencies. Smartphone ownership in the United States is at 81% (Pew, 2019), with many studies of mental health consumers demonstrating similar rates (Lipschitz et al., 2019; Torous, Friedman, & Keshavan, 2014). The majority of consumers who own a smartphone may not actually download or use health app (Torous et al, 2018). While reasons will vary across people, they appear to be similar reasons to those noted by clinicians: concerns over the efficacy, security, and usability of the DMHIs (Lipschitz et al., 2019). Importantly, one consistent predictor of adoption is the recommendation by a clinician (Schueller et al., 2018; Lipschitz et al., 2019), which suggests the need to target both clinicians and consumers. It is clear that there are some who want to use apps but do not possess the technology literacy required to utilize health apps in a meaningful way.

Consumers knowledge, beliefs, or self-efficacy related to technologies generally and DMHI specifically might also serve as important barriers or facilitators to implementation. Indeed, some consumers are very comfortable with using technology generally and DMHIs specifically to support their mental health (Eschler, Burgess, Mohr, & Reddy, 2020). Other consumers are not aware that technologies could help their mental health or that DMHIs exist. Frameworks may be useful in assisting consumers to make structured decisions related to DMHI adoption such as the American Psychiatric Association's App Evaluation Framework (Torous et al., 2018). This framework aims to boost consumers knowledge and in turn self-efficacy by providing structured questions they can ask to consider adoption of a product.

Implementation Process

The implementation process refers to the active efforts undertaken to integrate a DMHI into a setting. Processes might relate to aspects of preparedness or changes that occur to facilitate

successful implementation. Similar to findings regarding the sustainment of other mental health services, implementation is an active process. As such, DMHI are not products that can be purchased, deployed, and succeed on their own. Active processes considered here are training and integration. Such processes support considerations of adoption, adaptation, and sustainment.

Training

Today standardized training for competencies for technology and app use do not exist, although such have been proposed (Torous, Chan, et al., 2018, Hilty et al., 2019). The Department of Defense's mobile health practice guide is an important starting point (Armstrong et al., 2019). This guide outlines five core competencies for the use of mobile health in clinical care including (1) evidence base, (2) clinical integration, (3) security and privacy, (4) ethical issues, and (5) cultural considerations. As such, clinicians need to be able to evaluate, deploy, and troubleshoot the technologies (Armstrong et al., 2019; Hilty et al., 2019). When delivered, training appears to support adoption and sustainment of DMHIs in clinical settings (Armstrong et al., 2018). Another important part of training is giving clinicians the necessary support to troubleshoot issues that may be beyond their control, like device ownership and WiFi (Armstrong et al., 2018). Given the developing nature of such training programs, precedents for supervision will need to emerge as well. Nevertheless, DMHIs may offer exciting potentials for supporting supervision when data from such tools can be used to facilitate concrete conversations in supervisory settings.

Training programs for consumers are nascent as well. One example is the Digital Opportunities in Recovery Services (DOORS) program (Hoffman et al., 2019). The DOORS program is a series of pragmatic and interactive group lessons designed to develop new functional skills for accessing and utilizing the promise of digital health, which focus on digital competencies, autonomy, and relatedness. Lessons, offered over six-week one-hour sessions, educate and empower patients to make informed decisions around smartphone use and digital tools that can contribute to their personal wellness and recovery.

Integration

Integration of DMHIs into service settings requires consideration of both the clinical and technological integration of such tools. Clinical integration refers to how such tools fit into clinical workflow practices and make use of current staffing to support delivery of technology-enabled care. Technical integration refers to the ability to provide the tools given the hardware and software constraints including issues of interoperability and communication with electronic medical records (EMRs). Barriers to successful clinical integration often result from systems and organizations thinking of DMHIs as products, rather than services (Mohr et al., 2017), and as previously discussed, lack of knowledge about how to use these tools in one's practices. Barriers to successful technical integration comes from lack of appropriate devices either owned by consumers or by clinics, or by infrastructure constraints such as unreliable WiFi or EMRs.

Clinical integration includes a consideration of the current working practices and resources of the clinic in which a DMHI will be deployed. Using DMHIs in clinical practice might

require sufficient time, training, and incentives promote a successful implementation. The incentives, however, may not always match with the full use of DMHI features. For example, an evaluation of implementation of PE Coach found that many providers used the app solely for its recording feature, as that feature helped overcome other regulatory hurdles to audio-recording sessions within the VA (Reger et al., 2017). More careful evaluation of clinical workflows in the development and evaluation of DMHIs might uncover potentials for technology to simplify clinicians' practices and meet the real needs of practicing clinicians.

Technical integration includes a consideration of the technology resources and capabilities of consumers and service settings. Although it is often proposed that internet access and smartphone ownership is nearly ubiquitous, what this looks like in clinical settings often varies. Consumers may have access to a smartphone, but devices may be between family members, or memory storage or data plan issues might impact one's willingness and ability to use their smartphones for the purposes of mental health treatment (Lattie et al., 2020). It is also often overlooked that many DMHIs are still only available on either the Apple iOS or Android platform, and that consumers are unlikely to change their device to accommodate this limitation. Clinical settings may not be set-up to facilitate the use of digital tools in treatment sessions, which might include ways to display clinician portals on screens that are visible to both consumers and clinician, or set ups to facilitate mutual review of devices. Very few DMHIs contain features that facilitate secure communication with a clinician or can transmit data to an EMR. Such issues should drive pre-implementation assessments focused on appropriateness, fit, or feasibility.

Inner Setting

The inner setting in the CFIR refers to the specific organization or setting in which a DMHI will be deployed. Although the differentiation between the inner and outer setting will based on the specific implementation (e.g., an specific clinic implementing DMHIs may function as the inner setting within the broader organization that clinic is involved in representing the outer setting. Likewise, an organization may function as the inner setting with a State or country serving as the outer setting), and factors in each of these settings are critical for successful implementation. DMHIs are unique among other interventions in that they require both technological and human readiness for their implementation and we note aspects related to each of these including implementation climate, infrastructure, and champions.

Implementation Climate

Little information is known about the implementation climate that facilitates successful DMHI adoption and sustainment, mainly because such few instances of successful DMHI implementation exist. Health settings can be extremely resistant to change, especially when changes are required at multiple levels, as is often true with DMHIs (Titov et al., 2019). Given the inherent complex nature of DMHIs, their implementation in a system often requires cross-disciplinary collaboration between groups that might not be used to collaborating, such as clinicians and IT staff (Dugstad, Eide, Nilsen, & Eide, 2019). Previous digital transformations such as the adoption of EHRs highlight the substantial challenges (Takian, Sheikh, & Barber, 2012), and encourage resistantace to future efforts to introduce

technologies into their workflow that might be required of DMHI. Suffice it to say, despite the novelty of DMHIs themselves, they carry a significant legacy and implications that must be locally understood to facilitate their success.

Infrastructure

Multiple infrastructure issues relate to the success of DMHI implementation. Infrastructure issues, like numerous other considerations raised in this paper, must be considered in light of both technological infrastructure requirements and the human service infrastructure requirements. Reliable access to technologies has been found to be a specific determinant of implementation of DMHIs (Vis et al., 2018). Similarly, trained staff actually able to provide and support DMHIs is equally critical. In some cases, this staff might be frontline clinicians, especially when DMHIs are intended to augment traditional care such as "blended care" models. In other instances, however, this may be Peers (Fortuna et al., 2019), nurses, or novel roles still being defined (i.e., Wisniewski & Torous, 2020). A thorough evaluation of infrastructure issues that serve to advance or slow DMHI implementation needs to address each factor.

Champions

A common finding across implementation of EBTs is that champions help support sustainment. Champions in DMHI might refer to both, individuals in the inner setting who assist with issues related to training and integration, as well as individuals in the outer setting who are pushing forward knowledge and practices around DMHI. Pioneering work in DMHI has been conducted by the Department of Defense (DoD) and Veteran Administration (VA); not only has the DoD and VA developed several such apps for EBTs, including those for CBT for Insomnia (CBT-i Coach), Cognitive Processing Therapy (CPT Coach), Prolonged Exposure (PE Coach 2), Skills Training in Affective & Interpersonal Regulation (STAIR Coach), but they have also developed a mobile health practice guide to help train providers in their use (Armstrong et al., 2017). They have also created communities of practice through the development of online groups, webinars, and other training opportunities. The American Psychiatric Association has also demonstrated leadership in contributing not only a framework for evaluating DMHIs (Torous et al., 2018), but also materials to assist with clinicians' decisions to adopt such tools.

Internal champions need to have the proper training, resources, and institutional support to support use of DMHIs in systems. Indeed, strong leadership support and clinical champions who are able to integrate discussions of the technology into regular meetings, have been demonstrated to be important facilitators of sustained use of DMHIs in clinical settings (Ford II et al., 2015). Competencies of such champions align with what those noted in terms of clinician predictors of adoption, including knowledge of technology generally and DMHI specifically, confidence in using those tools in their settings, and ability to address logistical concerns necessary for use.

Outer Setting

The outer setting in the CFIR includes the broader context in which organizations or settings that might implement DMHIs reside. This includes economic, political, or social contexts. In DMHI we identify 3 contextual factors that related to the outer setting that relate to their implementation including payment and funding, privacy and ethics, and regulation. Although these factors are not unique to DMHI, technologies introduce new challenges to consider with regards to each factor as they challenge traditional models of who is delivering care and who is responsible for ensuring and monitoring the quality of that care.

Payment and Funding

A major issue facing the implementation of DMHIs is determining who will pay for such products and how. Many products adopt a direct-to-consumer payment model, asking individuals to pay for these products out of pocket, despite surveys demonstrating that consumers see paid DMHIs as significantly less desirable than free products (Schueller et al., 2018). The most common way of passing costs to consumers is through subscription models rather than one time download charges (Powell et al. 2019). Other business models for DMHIs draw from various areas, including advertising and digital platforms, and include models of generating revenue through advertising, monetizing data obtained from the consumers, and paying for the service provided through the technology. Although it is unclear how many DMH interventions are monetizing data coming from these products, a recent analysis of depression and smoking cessation apps found that 92% were transmitting data to thirty-parties, and some did not contain privacy policies to disclose this information (Huckvale, Torous, & Larsen, 2019). Such practices might reduce the cost that is pushed to the consumer directly, but opens up critical issues regarding the ethics around data ownership and data privacy.

Other models have treated DMHIs more similar to traditional healthcare interventions. These models often reimburse products based on clinician time on DMHI platforms. Reimbursement practices based on contact time disadvantages DMHIs whose goal is to increase clinical efficiency by reducing human provision of services. DMHIs, therefore, might need new models of payment that are tied to principles of care unique to digital platforms rather than adaptations from face-to-face delivery. One model of payment is pay-for-engagement, pay-for-outcomes, in which payments are provided to app developers when an app is used (engagement) or when a consumer benefits from it (outcomes). However, such models require tracking engagement and outcomes, hopefully in accords with standardized metrics, and the return of this information to purchasers in order to justify payment. Quantifying what an effective "dose" of a DMHI is, presents its own challenges, and will likely require an understanding of the concept of fidelity of effective EBT delivery elements within a DMHI. It is still yet to be determined who will end up paying for such resources when integrated into practice, but understanding payment models will be an important piece of DMHI implementation.

Privacy and Ethics

While DMHIs, their use, and their evidence is still evolving, traditional ethical principles offer a robust and important lens to approach the field. These traditional ethical principles, such as those established by the Belmont Report, can help ensure that DMHIs do no harm, protect and promote the safety and security, and ultimately, benefit users. The three core principles of the Belmont Report are autonomy, beneficence, and justice.

Autonomy refers to the right of individuals to make their own choice once provided with information in a setting conducive to decision making. Today, many apps can threaten autonomy as they do not provide the information or setting appropriate for informed decision making. Many apps do not outline the risks, especially around privacy (Torous et al., 2019), often overestimate the benefits (Larsen at al., 2019), may provide privacy policies/information at a reading level far beyond that of patients seeking help (Powell et al., 2019), or may provide information only after they have already collected data (O'Loughlin et al., 2019). In some cases, such as Facebook's ongoing efforts around screening for risk of suicide, there is no clear effort made at consent, opting in/or out, or accessible information on how the program even works (Barnett & Torous, 2019). Autonomy cannot be ignored, as user control over their data and transparency over what a product contains is paramount.

Beneficence refers to ensuring the benefits outweigh the risks; those who use a DMHI can potentially benefit from it. As with any new field, it is not always possible to have clear evidence of benefit for different groups. Still it is possible to share what information exists in a transparent manner and to support autonomy as outlined above. More concerning are efforts to market DMHIs in a deceptive manner that clearly violate the principles of beneficence. For example, in Fall 2018 the startup BASIS (now defunct) marketed to consumers its platform to support therapy with unlicensed therapists. The company's webpage and marketing underplayed that its "therapists" were not actually licensed therapists, a clear example of misuse of this term, and moreover, had no evidence to support their interventions, a clear example of consumer deception. DMHIs could consistently share updated information about benefits users received, and such transparency could offer a potential solution to promoting the standardization of beneficence principles in DMHI adaptation.

Justice refers to the fairness and equality among individuals and access to those who may benefit from it. In the case of DMHIs, the potential to reach those who are underserved and have difficulty accessing health resources, is one of the driving forces of the entire field. Although DMHIs have the potential to increase access, developing for underserved and marginalized populations is often an afterthought (Schueller, Hunter, Figueroa, & Aguilera, 2019). As such, evidence suggests that many apps are actually not usable for actual patients and that they may struggle meaningfully engage and use even popular apps (Sarkar et al., 2016). Furthermore, few DMHIs are available in languages other than English or are able to run on older smartphones that do not have the graphics, memory, and processing powers of newer and more expensive devices. Deploying digital health solutions without considerations for the principle of justice will likely only further worsen health inequality and will not help deliver care to those who need it the most.

Regulation

Many apps today may appear as health tools, which creates the assumption that they must offer privacy protections for user's data. In reality, many apps and wearable sensors designate themselves as wellness devices, exempting them from medical regulation and the need to comply with standard medical privacy regulations and federal mandates, like HIPAA. Thus, when using apps, clinicians should review whether the app actually offers protections for data, otherwise the client should be made aware that use may result in some loss of privacy. Often evaluating an app's privacy policy offers clues to the actual nature of this risk. The United States' (US) Office of National Coordinator for Health Information Technology, Department of Health and Human Services, PsyberGuide, and the American Psychiatry Association's app evaluation framework, all offer resources to educate about privacy risks and how to interpret privacy policies. One study applied a heuristic evaluation to depression apps and found that few even had a privacy policy, and many of those that did were deemed unacceptable (O'Loughlin, Neary, Adkins, & Schueller, 2019). Research suggests most clinicians and consumers are unaware of these privacy risks (O'Loughlin et al., 2019; Powell, Singh, & Torous, 2019).

Future Directions and Considerations

We are past a tipping point in that it is no longer a question of if technology will be used in mental health services, but rather a question of how. Thus, we need to consider the role of clinical practitioners and researchers vis-à-vis these technologies and industries. Otherwise, we risk these tools and practices being built and deployed without our input. As the current evidence demonstrates that the most effective tools are those that integrate with human services, it is worth emphasizing that this is not an issue of technology replacing clinicians, but rather how clinicians might best team with technologies to provide more effective and efficient care.

Understanding the role DMHIs will play in mental health service delivery needs to include multiple facets related to their implementation and sustainability. The CFIR provides a useful model to consider these facets including aspects related to the intervention, the individuals involved, the inner setting, the outer setting, and the implementation processes. In terms of insights the CFIR can offer for future work in DMHIs we consider select points within each domain. With regards to aspects of the intervention characteristics, such as acceptability, appropriateness, and feasibility, should be considered early in the process. For the individuals involved we need to develop competencies such that people can use these tools effectively. For clinicians, clinical training programs could begin training clinicians in aspects related to DMHIs. This could include classes that cover topics such as reviewing and selecting DMHIs and clinical practicum that build skills in delivering treatment through DMHI platforms (Gratzer & Goldbloom, 2020). For consumers, a key part of advancing best practices related to DMHIs is assessing and appreciating differences across diverse groups such as how people use technologies and/or the appropriateness of DMHIs for such groups. Consideration in the inner setting will ensure appropriate technological infrastructure and a positive climate for implementation for DMHI is ready. Whether DMHIs are ready for prime time must be consider, least we introduce tools that will negatively impact care today and a

willingness to adopt them tomorrow. For the outer setting DMHIs pathways need to be create not only to provide DMHIs but also to reimburse and regulate such tools. For the processes we need DMHIs that can simplify clinicians' workflow while extending and improving the impact of the care they provide. Value propositions need to ensure benefit to both consumers and clinicians.

Finally, although we have identified various aspects related to the implementation of DMHIs, we have not exhaustively covered implementation strategies that would support their implementation. Elsewhere it has been noted that DMHIs can be considered interventions themselves rather than implementation strategies (Hermes et al., 2019) and thus would require intervention strategies themselves to support successful implementation. Although broad classifications of implementation strategies have been suggested (Powell et al., 2015), some efforts have focused on understanding needs for contextualized compilations such as for school settings (Cook et al., 2019). Understanding implementation strategies most appropriate for DMHIs is an important avenue to pursue to further improve their reach and impact.
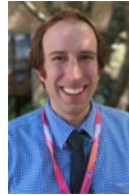
Conclusions

Technology has been used to scale EBTs in various ways, and has produced a new pathway to go direct-to-consumers with a plethora of new tools to introduce and monitor EBT delivery to supporters with various levels of training and experience. At the same time, the combination of technology with EBTs has presented several challenges; although the marriage of technology and EBTs holds considerable potential, today that potential is under realized. Continuous growth of knowledge around DMHIs can help provide an evidence-base to translate and scale EBTs through technology and can help find ways to effectively and sustainably integrate these tools into various avenues of mental health service delivery. Combining knowledge in DMHIs with implementation science is a promising venue to unlock the potential of these tools to improve mental health service delivery. The CFIR model offers one lens to understand this synthesis and as such the CFIR domains, as presented here, identify key barriers and facilitators to address for successful implementation.

Acknowledgments

Biography

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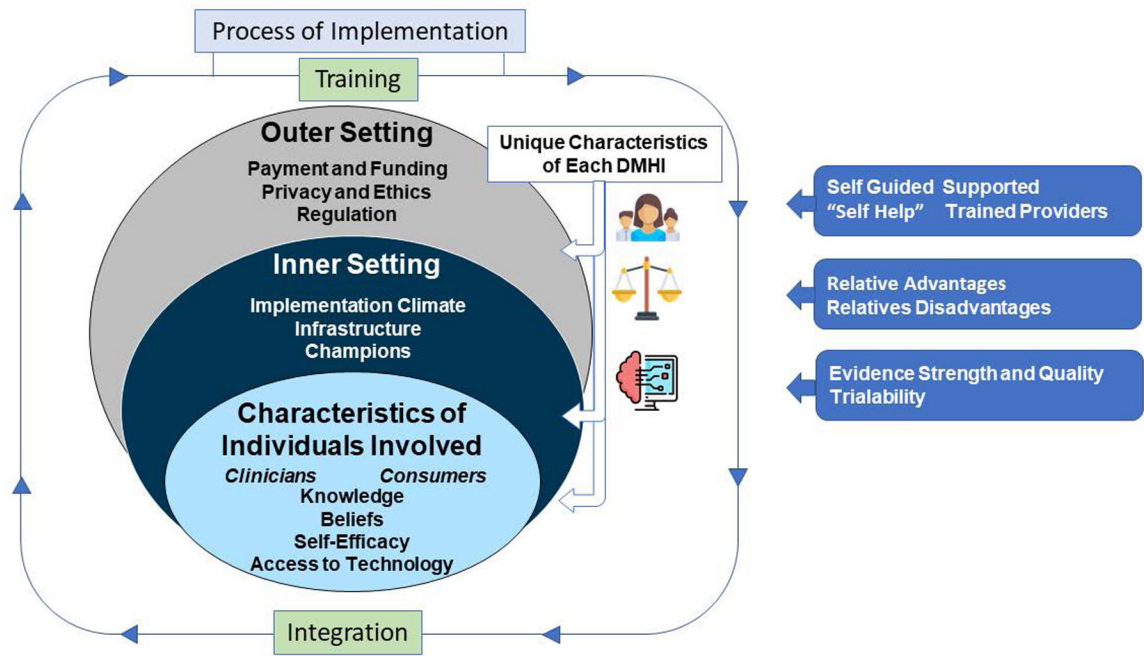
Figure 1.
Key Aspects of Digital Mental Health Implementation Organized by the Consolidated
Framework of Implementation Research.