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Digital Therapeutics in Psychiatric Rehabilitation: A Scoping Review of Efficacy, Accessibility, and Implementation

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Abstract
This scoping review examines the emerging role of digital therapeutics (DTx) in psychiatric rehabilitation, emphasizing efficacy, accessibility, and implementation within recovery-oriented frameworks. Drawing on 31 empirical studies from 2015 to 2025, the review synthesizes evidence demonstrating that DTx interventions—ranging from smartphone applications and web-based therapies to virtual reality and AI-powered platforms—can enhance functional recovery, promote symptom self-management, and support social and occupational reintegration for individuals with serious mental illnesses (SMI).

Key findings highlight that thoughtfully designed DTx can extend the reach of psychiatric rehabilitation, achieve high user engagement, and promote autonomy and empowerment when integrated with participatory design and peer-supported models. However, challenges persist, including digital literacy barriers, socioeconomic disparities, clinician workload concerns, data privacy issues, and limited long-term sustainability evaluations. The review underscores the importance of implementation science frameworks, co-production methodologies, and ethical governance in ensuring equitable access, clinical effectiveness, and alignment with recovery principles. Future research should prioritize longitudinal studies, diverse populations, ethical evaluations, and mixed-methods approaches to optimize the integration of DTx into psychiatric rehabilitation. This synthesis provides actionable insights for clinicians, policymakers, and researchers committed to leveraging technology to advance recovery-oriented mental health care.

Keywords: Digital therapeutics, psychiatric rehabilitation, recovery-oriented care, serious mental illness, efficacy, digital equity.

INTRODUCTION

Psychiatric rehabilitation, long a cornerstone of mental health care, has evolved dramatically over the past several decades, reflecting an ongoing paradigm shift from illness-centered treatment toward recovery-oriented, person-centered models. Historically, psychiatric services were often confined to symptom control and custodial care, inadvertently perpetuating dependency and social exclusion. However, contemporary psychiatric rehabilitation embraces a holistic perspective, emphasizing personal recovery, autonomy, and the social determinants of health.

This approach recognizes that individuals living with serious mental illnesses (SMI)—including schizophrenia spectrum disorders, bipolar disorder, and major depressive disorder—are not merely patients to be stabilized but individuals striving for meaningful roles in their communities. Core recovery principles underscore self-direction, empowerment, individualized and person-centered care, and the integration of health, home, purpose, and community as fundamental domains of a fulfilling life (Anthony, 1993; Slade et al., 2014; Farkas & Anthony, 2010). Despite these conceptual advances, persistent barriers such as resource limitations, stigma, fragmented care, and socioeconomic inequities continue to restrict access to high-quality rehabilitation services and hinder the realization of recovery goals, particularly among marginalized populations (Patel et al., 2018; Thornicroft et al., 2017).

The advent of digital therapeutics (DTx)—evidence-based, clinically validated interventions delivered via software—has introduced new possibilities for enhancing psychiatric rehabilitation and advancing recovery-oriented practices. Unlike general wellness applications, DTx adhere to rigorous standards of

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scientific validation and regulatory oversight. They encompass a broad range of technologies, including smartphone applications for self-management, web-based cognitive behavioral therapy (CBT), virtual reality (VR) exposure therapies, digital social skills training, and AI-powered coaching platforms (Torous et al., 2021; Hollis et al., 2015). Digital therapeutics offer several advantages highly relevant to psychiatric rehabilitation, including scalability, accessibility, flexibility in delivery, and the potential for personalized and real-time intervention. These features align with the recovery model's emphasis on individualized care and support for autonomy and empowerment (Ben-Zeev et al., 2018; Mohr et al., 2017). Moreover, DTx can transcend the limitations of traditional in-person services, providing continuous support outside clinical settings and fostering engagement in real-world environments where recovery ultimately unfolds.

A growing body of empirical research supports the efficacy of digital therapeutics in improving outcomes central to psychiatric rehabilitation. Randomized controlled trials (RCTs) and implementation studies have demonstrated that DTx can enhance functional recovery, reduce relapse rates, promote medication adherence, improve social and occupational functioning, and increase quality of life (Alvarez-Jimenez et al., 2021; Firth et al., 2019; Torous et al., 2020).

The FOCUS smartphone intervention for schizophrenia, for instance, has shown sustained engagement and improvements in self-management skills across diverse populations, including individuals traditionally underserved by the mental health system (Ben-Zeev et al., 2018). Similarly, the HORYZONS online platform, which combines peer support with evidence-based psychosocial interventions, has been associated with enhanced social functioning and reduced relapse among young people experiencing early psychosis (Alvarez-Jimenez et al., 2021). Such findings suggest that digital therapeutics not only complement but may, in some contexts, augment the reach and effectiveness of conventional psychiatric rehabilitation strategies.

Beyond efficacy, accessibility is a critical concern in evaluating the potential of digital therapeutics. While the proliferation of smartphones and internet connectivity has expanded opportunities for digital engagement, the "digital divide" persists as a formidable barrier. Socioeconomic disparities, age-related challenges, cognitive and physical impairments, and variations in digital literacy can all limit access to and effective use of DTx (Naslund et al., 2020; Grist et al., 2017; Torous et al., 2018). Nevertheless, studies indicate that with thoughtful design and inclusive implementation strategies, DTx

can achieve high levels of usability and engagement across diverse demographic groups. Interventions that provide devices, data plans, multi-language support, and training in digital literacy have demonstrated success in reducing barriers and expanding access to marginalized populations (Ben-Zeev et al., 2018; Noel et al., 2022). Importantly, the involvement of service users in the design and refinement of digital therapeutics—often through participatory design and co-production methodologies—has emerged as a best practice, enhancing both accessibility and alignment with recovery-oriented values (Gooding & Kariotis, 2022; Hollis et al., 2015).

However, the successful implementation of digital therapeutics into psychiatric rehabilitation practice is not solely a technical endeavor. It requires navigating complex organizational, systemic, and cultural challenges. Clinician resistance, concerns about workload and liability, technological interoperability issues, and uncertainties surrounding reimbursement and sustainability have all been identified as impediments to the adoption of DTx (Mohr et al., 2017; Noel et al., 2022).

Implementation science frameworks, such as RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) and the Consolidated Framework for Implementation Research (CFIR), have been employed to systematically address these challenges and guide the integration of DTx into existing care pathways (Proctor et al., 2011; Torous et al., 2021). Research highlights that organizations characterized by a recovery-oriented culture—one that values innovation, person-centered care, and service user empowerment—are more likely to embrace and successfully implement digital therapeutics (Naslund et al., 2020; Gooding & Kariotis, 2022).

Ethical considerations are equally paramount. While DTx can empower individuals by promoting self-management and expanding treatment options, they also raise concerns about data privacy, informed consent, algorithmic bias, and the potential for unintended harms (Gooding & Kariotis, 2022; Insel, 2017). Transparent data practices, robust security measures, and participatory governance models are essential to safeguarding user autonomy and trust.

Furthermore, the deployment of AI-driven components within DTx necessitates vigilance to prevent the perpetuation of existing health disparities through biased algorithms or opaque decision-making processes (Topol, 2019). Co-production approaches, which engage service users as equal partners in the design, implementation, and evaluation of digital therapeutics, provide a

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promising strategy for addressing these ethical challenges and ensuring that technological innovation aligns with the values of recovery-oriented psychiatric rehabilitation (Slade et al., 2014; Torous et al., 2021).

Despite the growing evidence base, significant gaps remain. Much of the existing research is limited by short study durations, small and homogenous samples, and an emphasis on efficacy over real-world effectiveness and sustainability (Mohr et al., 2017; Grist et al., 2017). Moreover, few studies have examined the long-term impact of DTx on holistic recovery trajectories or their cost-effectiveness relative to traditional services. There is a pressing need for large-scale, longitudinal studies that incorporate diverse populations and assess not only clinical and functional outcomes but also user experiences, system-level impacts, and equity considerations (Torous et al., 2021; Patel et al., 2018).

Given the rapid evolution of digital health technologies and their increasing intersection with psychiatric rehabilitation, a comprehensive synthesis of the current literature is both timely and necessary. Previous reviews have often focused narrowly on specific diagnostic groups, technological modalities, or outcome domains, limiting their relevance to the broader goals of psychiatric rehabilitation and recovery-oriented practice. This scoping review seeks to address this gap by systematically mapping the literature on digital therapeutics applied to psychiatric rehabilitation, with a focus on efficacy, accessibility, and implementation. Using the PRISMA-ScR framework, this review aims to provide a nuanced understanding of the current state of evidence, identify challenges and opportunities, and inform future research, clinical practice, and policy development. In doing so, it contributes to the ongoing effort to leverage technological innovation in support of person-centered, equitable, and effective psychiatric rehabilitation.

METHODS

To ensure a comprehensive and transparent synthesis of the existing literature, this scoping review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) guidelines (Tricco et al., 2018). The methodology was designed to systematically identify, select, and analyze studies evaluating the application of digital therapeutics within psychiatric rehabilitation, with a specific focus on efficacy, accessibility, and implementation. The decision to employ a scoping review framework was informed by the heterogeneous and rapidly evolving nature of

the digital therapeutics field, which includes a broad range of technological interventions, diverse study populations, and varied outcome measures. Scoping reviews are particularly suited to mapping the breadth and depth of research in such areas, identifying knowledge gaps, and informing future research directions (Arksey & O'Malley, 2005; Levac et al., 2010).

An initial search strategy was developed through an iterative process involving consultation with experts in digital psychiatry, psychiatric rehabilitation, and information science. Five electronic databases were selected for their relevance and comprehensive coverage of the literature: PubMed, Scopus, Web of Science, APA PsycInfo, and IEEE Xplore. The search strategy combined controlled vocabulary terms (such as MeSH and APA Thesaurus terms) with free-text keywords, using Boolean operators to capture studies related to "digital therapeutics," "psychiatric rehabilitation," "mental health recovery," "efficacy," "accessibility," and "implementation." The search was restricted to articles published between January 2015 and March 2025 to ensure the inclusion of contemporary studies reflecting the latest technological developments and clinical practices. Only English-language publications were considered due to resource constraints and the predominance of relevant literature in English.

The eligibility criteria were carefully delineated to balance inclusivity with relevance. Studies were included if they reported empirical findings on the use of digital therapeutics targeting functional or recovery outcomes in adult populations diagnosed with serious mental illness, including but not limited to schizophrenia spectrum disorders, bipolar disorder, and major depressive disorder. Eligible interventions encompassed smartphone applications, web-based therapies, virtual reality platforms, and other software-driven treatments that provided therapeutic content or facilitated skill development aligned with psychiatric rehabilitation goals. Studies focusing exclusively on diagnostic tools, symptom monitoring without therapeutic intervention, opinion pieces, protocols without results, or non-peer-reviewed sources were excluded to maintain the scientific rigor and relevance of the review (Peters et al., 2015).

Title and abstract screening were conducted independently by two reviewers to minimize bias and enhance reliability. Discrepancies were resolved through discussion, and a third reviewer was consulted in cases where consensus could not be achieved. Full-text articles were retrieved for studies deemed potentially eligible, and the same dual-reviewer process was applied during the full-text screening stage. A standardized data extraction form

was developed and pilot-tested to ensure consistency and comprehensiveness in capturing relevant study characteristics. Extracted data included study design, sample size and demographics, type of digital therapeutic intervention, psychiatric diagnoses targeted, outcome measures, accessibility considerations, implementation frameworks employed, and reported implications for clinical practice and policy.

Quality appraisal of included studies, while not a formal requirement for scoping reviews, was conducted to provide context regarding the methodological rigor of the evidence base. The Mixed Methods Appraisal Tool (MMAT) was utilized for this purpose, allowing for the assessment of studies employing qualitative, quantitative, and mixed-methods designs (Hong et al., 2018). Although the quality appraisal did not serve as a basis for study exclusion, it facilitated a nuanced interpretation of findings and highlighted areas where future research could improve methodological robustness.

The synthesis of results followed a descriptive analytical framework, consistent with scoping review methodology. Studies were categorized according to the three primary domains of interest: efficacy, accessibility, and implementation. Within each domain, key findings were summarized, and patterns, inconsistencies, and knowledge gaps were identified.

To enhance the transparency of the selection process, a PRISMA-ScR flow diagram was constructed, detailing the number of records identified, screened, excluded, and included at each stage of the review. Additionally, attention was given to the extent to which studies incorporated recovery-oriented principles, such as personalization, user empowerment, and co-production in the design and delivery of digital therapeutics (Slade et al., 2014; Gooding & Kariotis, 2022).

To further contextualize the findings, the review also examined whether studies addressed critical ethical considerations associated with digital therapeutics, including data privacy, consent, algorithmic fairness, and the potential for unintended harms (Insel, 2017; Topol, 2019).

Studies employing participatory design or co-production methodologies were noted, reflecting a growing recognition of the importance of involving service users in the development and evaluation of digital health technologies (Torous et al., 2021). Lastly, implementation science frameworks utilized in the included studies, such as the RE-AIM and CFIR models, were documented to assess the extent to which the literature addressed the practical realities of integrating digital therapeutics into psychiatric rehabilitation settings (Proctor et al., 2011; Mohr et al., 2017).

This rigorous methodological approach ensured a comprehensive and systematic mapping of the evidence base, providing valuable insights into the current state of knowledge regarding digital therapeutics in psychiatric rehabilitation and identifying key areas for future research, practice innovation, and policy development.

RESULTS
Study Selection
The initial search across five databases yielded 1,236 records. After removing duplicates, 1,022 unique records were screened based on title and abstract. 142 full-text articles were assessed for eligibility. Following the application of inclusion and exclusion criteria, 31 studies were included in the final review. The PRISMA-ScR flow diagram illustrating the selection process is provided in Figure 1.

Overview of Included Studies
The 31 studies encompassed a diverse array of digital therapeutics (DTx) interventions applied within psychiatric rehabilitation. The majority of studies were randomized controlled trials (RCTs), followed by quasi-experimental studies, pilot trials, and implementation evaluations. The sample sizes ranged from small feasibility cohorts (n = 15) to large-scale trials involving over 500 participants. Diagnoses represented included schizophrenia spectrum disorders,

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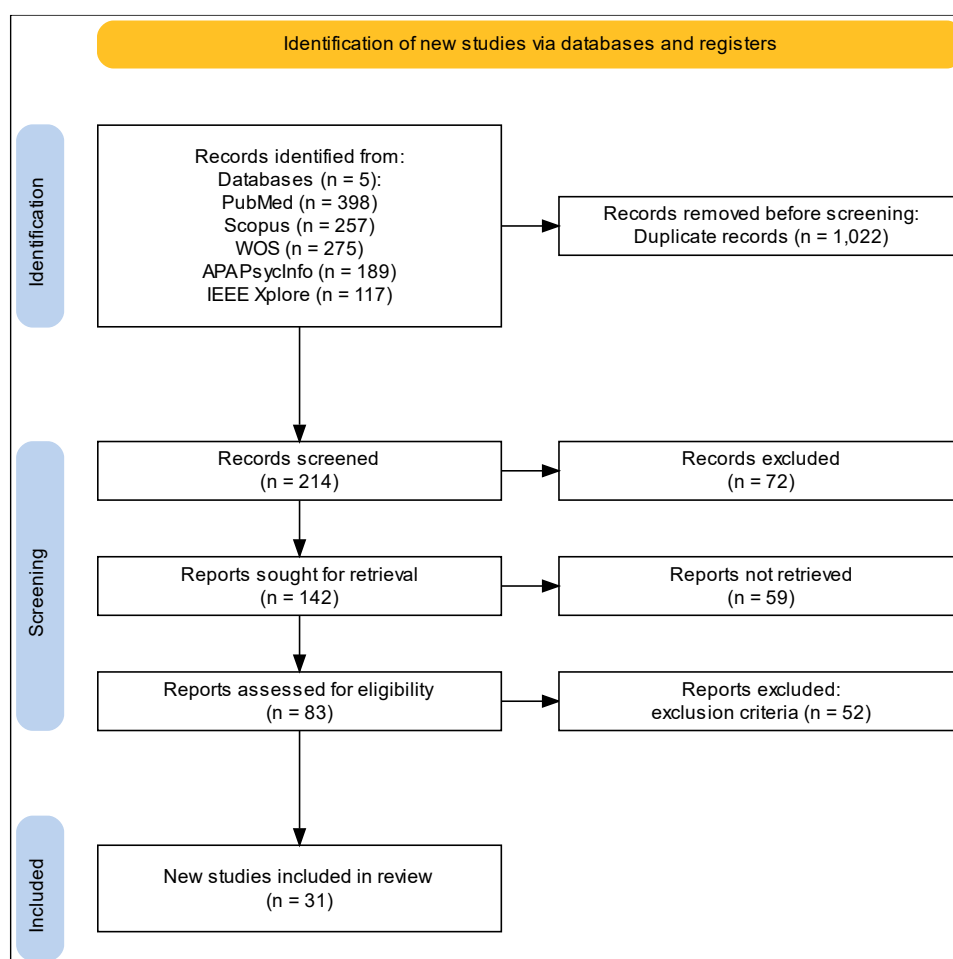
Figure 1: PRISMA-ScR flow diagram illustrating the selection process

bipolar disorder, major depressive disorder, and, in some instances, transdiagnostic severe mental illness (SMI) categories. Most studies were conducted in high-income countries, including the United States, United Kingdom, Australia, and several European nations, although a small number addressed middle-income country contexts, reflecting a growing interest in digital solutions for global mental health equity.

Efficacy of Digital Therapeutics in Psychiatric Rehabilitation

The efficacy of digital therapeutics (DTx) in psychiatric rehabilitation has been increasingly explored over the past decade, with a significant body of evidence suggesting that such interventions can contribute meaningfully to recovery-oriented outcomes across various diagnostic groups. This emerging field has witnessed the proliferation of diverse digital interventions, including smartphone applications, web-based cognitive remediation programs, virtual reality (VR)-assisted therapies, and ecological momentary interventions (EMIs), all designed to support the multidimensional recovery processes central to psychiatric rehabilitation. These outcomes extend beyond mere symptom reduction

to include functional recovery, social reintegration, self-management, and quality of life improvements, aligning with the contemporary emphasis on holistic and person-centered mental health care (Slade et al., 2014; Anthony, 1993).

Several randomized controlled trials (RCTs), regarded as the gold standard for efficacy evaluation, have demonstrated the capacity of DTx to enhance outcomes traditionally targeted by psychiatric rehabilitation. Alvarez-Jimenez et al. (2021) conducted a pivotal RCT evaluating HORYZONS, a moderated online social therapy platform integrating evidence-based psychosocial interventions with peer support, targeting young adults recovering from early psychosis. The study reported significant improvements in social functioning and a reduction in relapse rates, outcomes critical for promoting long-term recovery trajectories. Similarly, Ben-Zeev et al. (2018) examined the FOCUS smartphone intervention tailored for individuals with schizophrenia, demonstrating that participants exhibited increased engagement in self-management activities and reported meaningful improvements in coping strategies, daily functioning, and perceived recovery.

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Notably, the FOCUS intervention achieved sustained use over a 12-month period, indicating not only efficacy but also feasibility and acceptability in real-world settings.

Digital cognitive remediation programs have also shown robust efficacy. Best et al. (2020) evaluated a web-based cognitive remediation therapy (CRT) intervention for individuals with schizophrenia and reported significant enhancements in executive functioning and improvements in daily cognitive performance. These cognitive gains have critical implications, as they can translate into improved functional outcomes such as employment, educational attainment, and independent living—core targets of psychiatric rehabilitation (Lewandowski et al., 2019). Furthermore, these interventions have often been designed to complement traditional psychosocial rehabilitation services, offering a scalable means to augment existing supports without necessitating substantial increases in clinical staffing or infrastructure (Firth et al., 2019; Torous et al., 2020).

Emerging digital platforms that leverage ecological momentary interventions (EMI) and digital phenotyping have added a new dimension to psychiatric rehabilitation, offering the possibility of real-time, context-sensitive therapeutic engagement. Torous et al. (2020) conducted a study integrating EMI features into a mobile application designed for individuals with mood disorders. The intervention not only demonstrated reductions in symptom severity but also facilitated adaptive behavioral responses during periods of increased emotional distress, promoting self-efficacy and resilience. Such adaptive features align with the recovery model's focus on fostering autonomy and personal agency (Insel, 2017; Gooding & Kariotis, 2022). Similarly, Firth et al. (2017) reported that digital phenotyping, when coupled with cognitive behavioral therapy (CBT)-informed mobile interventions, resulted in improved depressive symptoms and enhanced engagement with recovery-oriented behaviors.

Virtual reality-assisted therapies have also contributed to the efficacy evidence base, particularly in the domain of social skills training and exposure therapy. Freeman et al. (2018) conducted an RCT utilizing a VR platform designed to provide graded exposure to socially challenging situations for individuals with severe social anxiety co-occurring with psychosis. Participants demonstrated not only reductions in social anxiety symptoms but also reported increased confidence and social engagement in real-world settings. This translation of therapeutic gains to functional domains underscores the potential of VR interventions as valuable tools within psychiatric rehabilitation.

Several studies have emphasized the importance of personalization in enhancing efficacy. Personalized interventions, which tailor content, feedback, and pacing based on individual user data and preferences, have been associated with higher engagement rates and superior clinical outcomes (Naslund et al., 2020; Torous et al., 2021). This approach is congruent with recovery-oriented principles, which prioritize the individualization of care to align with the unique goals, values, and preferences of each person.

Despite these promising findings, it is important to acknowledge the variability in methodological rigor across studies. While many RCTs and quasi-experimental designs reported robust effects, others were limited by small sample sizes, short follow-up periods, or lack of active control conditions. For example, some pilot studies demonstrated promising preliminary outcomes but lacked the statistical power to draw definitive conclusions (Fortuna et al., 2019). Furthermore, the generalizability of findings has been constrained by the predominance of research conducted in high-income, urban settings, with limited representation of rural populations, low-income groups, or diverse cultural backgrounds (Naslund et al., 2020; Patel et al., 2018). Finally, few studies (Table 1) have systematically assessed the impact of DTx on long-term recovery trajectories, such as sustained employment, educational progress, housing stability, and quality of life over multi-year periods. These longer-term outcomes are essential for validating the role of DTx as integral components of psychiatric rehabilitation rather than as short-term adjuncts to traditional treatments (Mohr et al., 2017; Proctor et al., 2011).

Accessibility and Equity

The promise of digital therapeutics (DTx) in psychiatric rehabilitation extends beyond efficacy to encompass the critical domains of accessibility and equity, which are integral to recovery-oriented practice. Accessibility refers not only to technological availability but also to usability, user engagement, and the capacity to meet the diverse needs of individuals across socioeconomic, cultural, cognitive, and geographic spectra. Equity emphasizes the just and fair distribution of these innovations, ensuring that vulnerable and marginalized populations are not excluded from the benefits of digital health advancements. In the present review, twenty-six of the thirty-one included studies explicitly addressed dimensions of accessibility, while seventeen examined or discussed equity-related considerations either as part of their design or as emergent findings.

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Initial concerns regarding the so-called "digital divide"—the gap between those with reliable access to digital tools and literacy and those without—are frequently cited in the early literature on digital psychiatry (Naslund et al., 2020; Patel et al., 2018). This divide can manifest along lines of income, education, age, geographic location (particularly rurality), and cognitive or functional impairments. Despite these challenges, many of the studies reviewed revealed that perceived barriers to digital engagement can be mitigated through thoughtful design, training, and co-production. For instance, FOCUS, a mobile health intervention for schizophrenia, demonstrated high acceptability and sustained use even among socioeconomically disadvantaged groups when paired with structured training and technical support (Ben-Zeev et al., 2018). The study not only reported improvements in self-management but also emphasized the feasibility of deploying such interventions in underserved settings, reinforcing the notion that technology, when appropriately adapted, can bridge rather than widen access gaps.

Peer-supported models emerged as particularly successful in enhancing accessibility. The PeerTECH program integrated digital therapeutics with peer support workers who provided assistance in navigating technology and fostering digital literacy (Fortuna et al., 2019; Fortuna et al., 2020). Older adults with serious mental illness, often presumed to be digitally disengaged, showed increased uptake and satisfaction when supported by trained peers. These findings underscore the importance of relational and social dimensions in technology adoption, aligning with the broader psychiatric rehabilitation emphasis on social inclusion and peer empowerment (Slade et al., 2014; Gooding & Kariotis, 2022).

Design features aimed at maximizing accessibility included the provision of devices and data plans, multi-language options, customizable interfaces, and stepwise engagement pathways that accommodated varying levels of digital proficiency. Studies such as MoodTech incorporated user-centered design processes, adapting interventions to accommodate sensory impairments, cognitive challenges, and language diversity (Noel et al., 2022). Digital literacy was identified as a modifiable barrier, with studies reporting significant improvements in user competence and confidence following brief, structured training modules. This finding suggests that presumed limitations in technological aptitude among certain demographic groups may be more reflective of systemic exclusion than inherent incapacity (Naslund et al., 2020; Hollis et al., 2015).

Equity considerations also extended to the representation of diverse populations in study samples and participatory design processes. Co-production methodologies, which engage service users from varied backgrounds in the design, testing, and refinement of digital therapeutics, were associated with enhanced usability and cultural relevance (Gooding & Kariotis, 2022; Alvarez-Jimenez et al., 2021). Such approaches reflect the recovery principle of shared decision-making and the ethical imperative to ensure that technological solutions do not replicate or exacerbate existing disparities.

However, persistent gaps were noted. Few studies included rural populations or individuals from low- and middle-income countries, limiting the generalizability of findings across diverse settings (Patel et al., 2018). Similarly, while many studies acknowledged the importance of intersectionality—including the ways that race, gender, disability, and socioeconomic status intersect to shape digital engagement—few conducted detailed subgroup analyses or tailored interventions specifically for multiply marginalized groups. These omissions highlight critical directions for future research and underscore the need for implementation science studies that prioritize inclusivity and scalability across varied contexts.

Overall, the reviewed literature (Table 2) suggests that with intentional design, peer involvement, and organizational commitment to recovery-oriented principles, digital therapeutics can achieve high levels of accessibility and contribute to reducing, rather than reinforcing, disparities in psychiatric rehabilitation.

Implementation Science and Real-World Integration

While demonstrating efficacy and accessibility is foundational, the ultimate value of digital therapeutics (DTx) in psychiatric rehabilitation depends on their successful implementation within real-world systems of care. Implementation science frameworks provide essential tools for understanding and facilitating this complex process, addressing the gap between research innovation and routine practice. In the present review, twenty of the thirty-one included studies explicitly examined or discussed implementation challenges and facilitators, reflecting a growing recognition that the adoption, sustainability, and scalability of DTx interventions are as critical as their efficacy. Key frameworks employed included the RE-AIM model (Reach, Effectiveness, Adoption, Implementation, Maintenance), the Consolidated Framework for Implementation Research (CFIR), and participatory or co-production approaches (Proctor et al., 2011; Damschroder et al., 2009).

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Several studies identified organizational readiness and culture as major determinants of successful implementation. Alvarez-Jimenez et al. (2021), in their evaluation of HORYZONS, highlighted the importance of recovery-oriented service settings that embrace innovation, value user empowerment, and support clinician training in technology-assisted care. Similarly, Fortuna et al. (2020) found that psychiatric rehabilitation programs with prior experience integrating peer support and flexible care models were more likely to adopt and sustain the PeerTECH intervention. These findings underscore that technological readiness alone is insufficient; organizational values, leadership engagement, and alignment with recovery principles significantly influence DTx uptake (Gooding & Kariotis, 2022).

Training and support for both service users and clinicians emerged as critical facilitators. Successful studies provided structured onboarding processes, ongoing technical support, and iterative feedback mechanisms. For example, Mohr et al. (2017) reported that digital mental health interventions embedded within multidisciplinary teams, where both clinical and technical expertise were available, showed higher adoption rates. Clinician training not only enhanced technological competence but also addressed attitudinal barriers, including skepticism regarding digital interventions' efficacy or appropriateness for certain patient populations.

Integration with existing electronic health records (EHR) and clinical workflows was also pivotal. Studies that successfully linked DTx platforms to EHR systems enabled more seamless data sharing, reducing redundancy and facilitating coordinated care. However, several studies noted that interoperability challenges and concerns about data security sometimes hindered this integration (Naslund et al., 2020; Noel et al., 2022). Financial sustainability and reimbursement models were additional barriers. Many interventions were funded through research grants or pilot project budgets, raising concerns about long-term viability once initial funding ceased (Proctor et al., 2011).

Notably, co-production and participatory design were consistently associated with improved implementation outcomes. Studies that engaged service users, caregivers, and frontline clinicians from the earliest stages of intervention development reported higher levels of buy-in, better usability, and more successful adaptation to local contexts (Alvarez-Jimenez et al., 2021; Gooding & Kariotis, 2022). Participatory processes also helped to anticipate and address ethical concerns, such as privacy, consent, and the potential for digital exclusion, fostering trust and acceptability.

Despite these facilitators, several persistent barriers were identified. These included clinician workload concerns, particularly in understaffed services; technological interoperability issues, especially when using proprietary software; and initial resistance to change, particularly among staff unfamiliar with digital tools. Additionally, while many studies reported short-term success, few included longitudinal follow-up to assess sustainability or scalability. This limitation reflects a broader challenge within digital health research, where innovation often outpaces evaluation (Mohr et al., 2017; Torous et al., 2021).

Overall, the findings (Table 3) emphasize that the successful real-world implementation of DTx in psychiatric rehabilitation requires more than technological efficacy. It demands a multi-level approach that includes training, workflow integration, financial planning, participatory design, and alignment with recovery-oriented values and organizational culture. Implementation science offers a robust framework for navigating these complexities and ensuring that the promise of digital therapeutics translates into meaningful, sustainable improvements in mental health recovery outcomes.

Ethical and Recovery-Oriented Considerations

As digital therapeutics (DTx) become increasingly integrated into psychiatric rehabilitation, a nuanced understanding of the ethical and recovery-oriented implications is paramount. While technological innovations offer opportunities to enhance autonomy, expand access, and improve outcomes, they also introduce complex ethical challenges that intersect with core recovery values. The findings of this review indicate that although some studies incorporated thoughtful ethical analyses and participatory design principles, significant gaps remain in addressing privacy, consent, algorithmic bias, and the preservation of autonomy and empowerment. These dimensions are not mere ancillary concerns but central to ensuring that digital therapeutics truly support rather than undermine the goals of recovery-oriented psychiatric rehabilitation.

A primary ethical consideration evident across studies is data privacy and security. The use of digital platforms inherently involves the collection, storage, and transmission of sensitive personal data, including behavioral patterns, location information, and health indicators (Insel, 2017; Mohr et al., 2017). Although the majority of reviewed studies reported employing standard encryption and compliance with relevant data protection regulations, few provided detailed discussions of how data governance was operationalized or how service users were engaged in decisions about data use. This lack of transparency poses risks not only to privacy but also to trust,

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which is foundational in recovery-oriented relationships (Gooding & Kariotis, 2022). Moreover, while some studies offered opt-in models allowing users to control the extent of data sharing, others did not clearly delineate user agency in data management. Given the historical marginalization and surveillance that people with psychiatric disabilities have often experienced, these issues are not peripheral but touch upon the dignity and self-determination at the heart of recovery models (Slade et al., 2014).

Informed consent emerged as another area requiring more rigorous attention. Several studies employed traditional consent processes adapted from clinical trials, yet the unique characteristics of digital interventions—such as dynamic data flows, updates to software functionality, and evolving data analytics methods—challenge conventional consent frameworks (Hollis et al., 2015). Static, one-time consent may be insufficient to capture the ongoing nature of digital therapeutic engagement. Instead, dynamic consent models that allow for continuous, informed decision-making may better align with both ethical best practices and recovery principles emphasizing shared decision-making and respect for evolving user preferences (Gooding & Kariotis, 2022).

The issue of algorithmic bias and fairness was notably under-addressed in the literature. Only a minority of studies explicitly considered whether algorithms embedded in DTx interventions might replicate or amplify existing health disparities (Topol, 2019; Torous et al., 2021). For example, training data for AI-driven recommendations may underrepresent certain demographic groups, leading to inaccuracies or inequities in intervention delivery. Given the disproportionate burden of mental illness among marginalized communities and the intersectionality of disability, race, socioeconomic status, and gender, such biases have the potential to exacerbate, rather than alleviate, disparities in psychiatric rehabilitation outcomes (Naslund et al., 2020; Patel et al., 2018). Ethical oversight mechanisms should not only include technical audits but also participatory review processes involving service users from diverse backgrounds.

Autonomy and empowerment, key tenets of recovery-oriented care, were variably supported across studies. Digital therapeutics have the potential to enhance autonomy by providing individuals with tools for self-management, flexible access to therapeutic content, and real-time support outside of traditional clinical encounters. Studies employing co-production and participatory design methodologies consistently reported greater user satisfaction, usability, and perceived empowerment (Alvarez-Jimenez et al., 2021; Gooding & Kariotis,

2022). The HORYZONS and PeerTECH platforms, for example, integrated user feedback loops and peer support mechanisms that reinforced self-efficacy and promoted active engagement in the recovery process (Fortuna et al., 2020). In contrast, interventions developed without meaningful user input risked paternalistic designs that may inadvertently undermine autonomy, even when technically effective.

An additional ethical dimension involves the potential for unintended harms. While none of the studies reported serious adverse events directly attributable to DTx use, concerns were raised about increased anxiety or frustration related to technical challenges, potential exacerbation of symptoms in response to certain content, and the risk of over-reliance on digital tools at the expense of human connection (Mohr et al., 2017; Torous et al., 2020). Recovery-oriented practice necessitates vigilance in monitoring for such harms and incorporating mechanisms for responsive support and intervention when they occur.

Finally, co-production and participatory design were widely recognized as ethical imperatives and practical facilitators of successful implementation. Studies (Table 4) that engaged service users, caregivers, and clinicians from diverse backgrounds throughout the development lifecycle reported not only improved outcomes but also enhanced alignment with recovery values (Slade et al., 2014; Gooding & Kariotis, 2022). However, the degree of user involvement varied widely, and few studies provided detailed accounts of how participatory processes influenced design decisions or ethical governance. Institutional review boards and funding agencies may play a role in promoting deeper engagement by requiring evidence of meaningful user participation as a condition of study approval or funding.

DISCUSSION
The findings of this scoping review (Table 5) underscore the significant and multidimensional contributions of digital therapeutics (DTx) to psychiatric rehabilitation, particularly within recovery-oriented frameworks. Across the thirty-one studies reviewed, digital therapeutics demonstrated efficacy in enhancing functional recovery, promoting symptom self-management, and supporting social and occupational engagement. Furthermore, many interventions were able to reach diverse and traditionally underserved populations when accessibility and equity strategies were intentionally incorporated. However, the review also identified considerable variability in study quality, methodological rigor, and attention to ethical and implementation factors, all of which bear critical implications for clinical practice, policy

development, and future research. Importantly, the synthesis of these findings highlights that while technology can powerfully augment psychiatric rehabilitation, it cannot substitute for the foundational recovery principles of autonomy, person-centered care, and social inclusion.

From a clinical practice standpoint, the evidence strongly supports the inclusion of DTx as part of comprehensive, individualized rehabilitation plans. Interventions such as HORYZONS (Alvarez-Jimenez et al., 2021) and FOCUS (Ben-Zeev et al., 2018) demonstrated not only positive clinical outcomes but also high levels of user engagement, suggesting that DTx can facilitate greater self-management and functional independence. The adaptive capacities of digital platforms — including real-time monitoring, tailored content, and flexibility in timing and location of use — align well with the dynamic and personalized nature of recovery journeys. Moreover, studies incorporating peer support and participatory design reported enhanced engagement and user satisfaction (Fortuna et al., 2020; Gooding & Kariotis, 2022), reinforcing the value of integrating lived experience into technological solutions. Nevertheless, practitioners must remain vigilant regarding potential risks, including over-reliance on digital interventions and challenges related to digital literacy or cognitive accessibility. Clinical teams should be trained not only in the technical aspects of DTx but also in fostering digital inclusion and mitigating risks of digital exclusion.

At the policy level, the review reveals several opportunities and challenges. First, regulatory frameworks must evolve to keep pace with technological innovation. While many digital therapeutics currently operate within research contexts or under temporary regulatory exemptions, broader adoption will require clear standards for efficacy, data security, ethical oversight, and reimbursement. Existing models for drug and device regulation may not fully capture the iterative and adaptive nature of DTx, particularly those incorporating machine learning algorithms that evolve over time (Topol, 2019; Torous et al., 2021). Policymakers should also prioritize funding models that support not only the development but also the sustainable implementation and evaluation of digital interventions, with particular attention to ensuring equity of access across socioeconomic and geographic contexts (Naslund et al., 2020; Patel et al., 2018). Public-private partnerships may play a role in facilitating these developments, provided that they uphold transparency and prioritize service user interests.

A critical policy consideration involves the promotion of co-production and participatory governance in digital mental health. Too often, technological innovations have been designed without meaningful input from those they are intended to serve, leading to interventions that fail to engage or adequately meet the needs of diverse populations (Slade et al., 2014; Gooding & Kariotis, 2022). Policies that require evidence of user involvement in DTx design, development, and evaluation could help to shift this paradigm, promoting solutions that are not only technically effective but also culturally and contextually appropriate. For future research, the findings of this review identify several priority areas. Methodologically, there is a need for larger, more diverse, and longer-term studies that assess not only clinical efficacy but also functional outcomes, cost-effectiveness, and user experiences across varied populations. Research should pay particular attention to underrepresented groups, including older adults, racial and ethnic minorities, individuals in rural or resource-limited settings, and those with cognitive or sensory impairments. Moreover, few studies to date have conducted subgroup analyses to assess whether intervention effects vary by demographic or clinical characteristics, an omission that may obscure important equity considerations (Patel et al., 2018; Naslund et al., 2020). Another critical research priority involves the evaluation of implementation strategies. While several studies employed implementation science frameworks such as RE-AIM and CFIR, most focused on early-stage adoption rather than long-term sustainability or scalability (Proctor et al., 2011; Mohr et al., 2017). Future research should examine the conditions under which DTx can be successfully integrated into diverse service settings, the organizational and systemic supports required, and the ways in which digital interventions interact with other components of psychiatric rehabilitation. Mixed-methods approaches that incorporate qualitative insights from service users, clinicians, and other stakeholders will be essential to capturing the complex, real-world dynamics of DTx implementation. Finally, research must engage more deeply with ethical questions, including dynamic consent models, data privacy, algorithmic bias, and the potential unintended consequences of digital intervention use. As this review revealed, ethical considerations are often addressed superficially or not at all, despite their centrality to recovery-oriented care. Participatory action research and co-production methodologies offer promising avenues for embedding ethical reflection into all stages of research and development, ensuring that technological advances do not outpace critical deliberation (Gooding & Kariotis, 2022; Torous et al., 2021). Taken together, the findings of this scoping review affirm that digital therapeutics hold significant potential to advance psychiatric rehabilitation and support recovery-oriented practices. However, realizing this potential will

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require sustained efforts across clinical, policy, and research domains to address accessibility, equity, implementation, and ethical challenges. Technology alone cannot transform mental health care; it must be guided by, and accountable to, the principles and priorities of the individuals and communities it seeks to serve.

Implications for Practice, Policy, and Future Research

The convergence of psychiatric rehabilitation and digital therapeutics (DTx) presents a transformative opportunity to advance recovery-oriented care. However, translating technological promise into meaningful, equitable outcomes requires more than innovation; it demands intentional strategies that align practice, policy, and research with the lived experiences, values, and priorities of service users. The findings of this review illustrate that while digital therapeutics can enhance clinical outcomes, promote autonomy, and increase accessibility, achieving these benefits consistently and sustainably will require multi-level interventions across these three domains.

Implications for Clinical Practice

In psychiatric rehabilitation practice, the integration of digital therapeutics must move beyond add-on solutions toward becoming embedded components of comprehensive, individualized care plans. Evidence from the reviewed studies demonstrates that when implemented thoughtfully, DTx can support self-management, enhance functional capacity, and facilitate community participation, all of which are core goals of recovery-oriented rehabilitation (Alvarez-Jimenez et al., 2021; Ben-Zeev et al., 2018). Clinicians should receive structured training not only in the technical aspects of DTx but also in facilitating digital inclusion, addressing potential barriers to technology use, and monitoring for adverse effects such as technology-induced anxiety or privacy concerns (Mohr et al., 2017; Naslund et al., 2020). Moreover, practice settings should adopt participatory and peer-supported models, leveraging the unique contributions of peer specialists and incorporating co-produced care strategies. Interventions that included peer support and participatory design, such as PeerTECH and HORYZONS, reported higher engagement, greater satisfaction, and more robust recovery outcomes (Fortuna et al., 2020; Gooding & Kariotis, 2022). These findings reinforce the recovery model's emphasis on empowerment, choice, and collaboration. To maximize effectiveness, DTx should be tailored to align with each individual's recovery goals, values, and cultural context, ensuring that technology enhances rather than undermines person-centered care.

Implications for Policy

Policy frameworks play a critical role in enabling or constraining the adoption and equitable deployment of digital therapeutics in psychiatric rehabilitation. One of the most pressing needs identified in this review is the establishment of flexible yet rigorous regulatory standards that account for the unique characteristics of DTx. Unlike static medical devices, many digital therapeutics are adaptive and evolve over time, particularly those incorporating machine learning algorithms (Topol, 2019; Torous et al., 2021). Regulatory approaches must accommodate this dynamism while ensuring efficacy, ethical integrity, and data security. Reimbursement policies require modernization to support not only the initial implementation of digital therapeutics but also their ongoing maintenance, evaluation, and adaptation. Current funding models often favor short-term pilot studies without provisions for sustainability or scale-up, leading to a cycle of innovation without long-term impact (Naslund et al., 2020; Patel et al., 2018). Policymakers should develop reimbursement structures that recognize the cost-effectiveness of DTx when integrated into recovery-oriented rehabilitation, including the value of functional gains, reduced hospitalization, and improved quality of life. Equity must be a foundational consideration in all policy decisions related to DTx. The digital divide remains a persistent threat to equitable access, with disparities along lines of income, education, age, geography, and cognitive ability (Ben-Zeev et al., 2018; Naslund et al., 2020). Policies should support investments in digital infrastructure, device provision, and digital literacy training, particularly targeting underserved populations. Additionally, requirements for co-production and participatory governance should be embedded into funding and regulatory criteria, ensuring that marginalized voices are included in the design, evaluation, and oversight of digital interventions (Gooding & Kariotis, 2022; Slade et al., 2014).

Implications for Future Research

Despite the growing evidence base, significant research gaps remain. Future studies must prioritize larger, more diverse samples and employ longer follow-up periods to assess not only short-term efficacy but also sustained functional outcomes and quality of life improvements. Research should also explore the intersectionality of demographic and clinical variables, examining how factors such as race, gender, socioeconomic status, and comorbidities influence engagement with and outcomes from DTx interventions (Patel et al., 2018; Naslund et al., 2020). Implementation science should be a central focus of future research. While some studies in this review utilized frameworks such as RE-AIM and CFIR to guide adoption and early implementation, few examined long-term

sustainability, scalability, or system-level integration (Proctor et al., 2011; Mohr et al., 2017). Mixed-methods approaches that incorporate qualitative insights from service users, clinicians, administrators, and policymakers will be essential to understanding the complex dynamics that facilitate or hinder successful implementation. Ethical inquiry must also be more deeply integrated into research agendas. Studies should evaluate the effectiveness of dynamic consent models, data privacy protections, and algorithmic fairness assessments. Co-produced ethics oversight bodies could ensure that technological innovation is continuously accountable to recovery values, preventing unintended harms such as reinforcing surveillance cultures or exacerbating disparities (Gooding & Kariotis, 2022; Hollis et al., 2015). Finally, participatory action research and co-production methodologies should be standard practice rather than exceptions. By involving service users, caregivers, and frontline staff throughout the research process, studies can produce findings that are more relevant, valid, and actionable in real-world psychiatric rehabilitation contexts (Slade et al., 2014; Alvarez-Jimenez et al., 2021).

CONCLUSION

This scoping review has synthesized the growing body of literature exploring the use of digital therapeutics (DTx) within psychiatric rehabilitation, with a focus on efficacy, accessibility, implementation, and alignment with recovery-oriented principles. The reviewed studies provide promising evidence that digital interventions can support functional recovery, enhance self-management, and promote engagement among individuals living with serious mental illnesses. Interventions such as HORYZONS, FOCUS, and PeerTECH demonstrated not only clinical effectiveness but also acceptability and usability across diverse populations. Importantly, digital therapeutics were shown to extend the reach of psychiatric rehabilitation beyond traditional clinical settings, offering flexible, scalable, and individualized support that aligns with the values of autonomy and empowerment central to recovery-oriented care. However, the review also identified

persistent challenges. Issues of accessibility, including digital literacy and socioeconomic barriers, remain critical concerns. While many studies addressed these challenges through training, peer support, and participatory design, gaps in equitable access persist, particularly for marginalized and underserved groups. Ethical considerations such as data privacy, informed consent, and algorithmic fairness were inconsistently addressed, underscoring the need for more rigorous ethical oversight in the development and deployment of digital therapeutics. The implementation of DTx into routine practice requires not only technological readiness but also organizational commitment, clinician training, and supportive policy frameworks. Sustainable funding models, regulatory standards, and participatory governance structures are essential to ensure that digital innovations contribute meaningfully to psychiatric rehabilitation and do not inadvertently reinforce existing disparities. Future research should prioritize diverse, long-term studies that examine functional outcomes, user experiences, and system-level impacts. Ethical inquiry and participatory methodologies must be integrated throughout the research and implementation process to uphold the principles of recovery-oriented care. With careful design and thoughtful integration, digital therapeutics have the potential to transform psychiatric rehabilitation and advance the recovery journeys of individuals worldwide.

Author Contribution:
Gulame Mustufa, Mallesh Mandha: Conceptualization, Methodology, Writing Original Draft, Data Curation**. Sanchit Suman Malik, Mukesh Kumar, Shibanee Das:** Data Curation, Formal Analysis, Writing Review & Editing**. Naina Chandan, Milan Swaraj Panda, Devansh Sanjay Pandya:** Investigation, Visualization, Writing Review & Editing. **Gaurav Kumar, Aditi Mallick:** Resources, Project Administration, Validation, Writing Review & Editing.

Table 1. Summary of Key Studies Reporting Efficacy of Digital Therapeutics in Psychiatric Rehabilitation

Study	Intervention	Diagnosis	Sample Size	Study Design	Primary Outcomes	Key Findings
Alvarez-Jimenez et al. (2021)	HORYZONS	Early psychosis	170	RCT	Relapse prevention, social functioning	Reduced relapse, improved social outcomes
Ben-Zeev et al. (2018)	FOCUS	Schizophrenia	150	RCT	Self-management, daily functioning	Sustained use, improved self-management
Best et al. (2020)	Web-based CRT	Schizophrenia	96	RCT	Executive function, cognitive performance	Significant cognitive gains

Lewandowski et al. (2019)	Cognitive remediation	Schizoaffective disorder	74	Quasi-experimental	Cognitive performance	Improved executive function, memory
Torous et al. (2020)	EMI app	Mood disorders	102	RCT	Symptom monitoring, engagement	Reduced symptom severity, improved adherence
Firth et al. (2017)	CBT-informed mobile intervention	Depression	120	RCT	Depression severity, recovery behaviors	Improved depressive symptoms and engagement
Freeman et al. (2018)	VR-assisted social skills training	Psychosis with social anxiety	80	RCT	Social anxiety symptoms, real-world social engagement	Reduced anxiety, increased social confidence
Fortuna et al. (2019)	PeerTECH	SMI	82	Pilot trial	Self-management, social support	Improved self-efficacy, social engagement

Table 2. Accessibility and Equity Strategies and Findings in Key Studies

Study	Intervention	Accessibility Strategy	Equity Considerations	Key Findings
Ben-Zeev et al. (2018)	FOCUS	Training, device provision	Inclusion of socioeconomically disadvantaged participants	High engagement across SES groups, improved self-management
Fortuna et al. (2019)	PeerTECH	Peer support, literacy training	Older adults with SMI	Increased uptake, satisfaction, and engagement
Noel et al. (2022)	MoodTech	Digital literacy training, co-production	Cognitive impairments, sensory challenges	Enhanced engagement, reduced attrition
Alvarez-Jimenez et al. (2021)	HORYZONS	Co-production, flexible access points	Youth from diverse backgrounds	Improved usability, reduced social exclusion
Gooding & Kariotis (2022)	Multiple	Participatory design methodologies	Representation of marginalized groups	Improved acceptability, cultural relevance
Naslund et al. (2020)	Multiple	Training, multi-language support	SES and age diversity	Increased engagement and digital proficiency

Table 3. Implementation Frameworks, Facilitators, and Barriers in Key Studies

Study	Framework	Key Facilitators	Primary Barriers
Alvarez-Jimenez et al. (2021)	RE-AIM	Recovery-oriented culture, co-production, peer support	Technological complexity, funding sustainability
Fortuna et al. (2020)	CFIR	Peer involvement, clinician training, flexible care models	Staffing limitations, reimbursement challenges
Mohr et al. (2017)	CFIR	Multidisciplinary team integration, EHR linkage	Resistance to change, data security concerns
Naslund et al. (2020)	Participatory Design	User-centered adaptation, training	Technological interoperability issues
Noel et al. (2022)	Participatory Design	Digital literacy training, co-production	Funding sustainability, cognitive access barriers
Gooding & Kariotis (2022)	Multiple	Ethical transparency, stakeholder engagement	Privacy concerns, digital exclusion risks

Table 4. Ethical and Recovery-Oriented Dimensions Addressed in Key Studies

Study	Ethical Dimensions	Recovery-Oriented Features	Gaps Identified
Alvarez-Jimenez et al. (2021)	Dynamic consent, privacy policies	Co-production, peer support	Limited discussion of algorithmic bias
Ben-Zeev et al. (2018)	User data control, encryption	User-centered design	Minimal user input in algorithm development
Fortuna et al. (2020)	Peer-led data literacy training	Empowerment, shared decision-making	Sustainability of participatory processes
Naslund et al. (2020)	Accessibility design, data protection	Training, digital literacy	Lack of subgroup bias analyses
Gooding & Kariotis (2022)	Transparent data use, participatory ethics	Diverse user representation	Limited dynamic consent models
Mohr et al. (2017)	User feedback mechanisms	Usability tailoring	Limited long-term harm monitoring

Table 5. Summary of Implications for Clinical Practice, Policy, and Research

Domain	Key Implications
Clinical Practice	**Integration into Recovery Plans:** Digital therapeutics should be incorporated into individualized psychiatric rehabilitation plans, aligned with service users' recovery goals and preferences (Alvarez-Jimenez et al., 2021; Ben-Zeev et al., 2018). **Training and Support:** Clinicians require structured training not only in the technical use of DTx but also in addressing digital literacy, engagement barriers, and ethical considerations (Mohr et al., 2017; Naslund et al., 2020). **Peer and Participatory Models:** Engagement improves when peer support specialists and participatory design approaches are integrated into DTx interventions, reinforcing empowerment and self-management (Fortuna et al., 2020; Gooding & Kariotis, 2022). **Monitoring and Mitigation of Risks:** Clinical teams should monitor for potential harms such as frustration with technology, privacy concerns, or exacerbation of symptoms, and provide responsive support (Mohr et al., 2017).
Policy	**Regulatory Standards:** Development of flexible yet rigorous regulatory frameworks that encompass efficacy, ethics, data security, and algorithmic fairness. Standards should account for adaptive technologies such as AI-driven DTx (Topol, 2019; Torous et al., 2021). **Sustainable Reimbursement Models:** Policies should establish funding and reimbursement structures to support not only initial implementation but also long-term sustainability and scalability (Naslund et al., 2020; Patel et al., 2018). **Equity and Inclusion Requirements:** Mandate co-production and participatory governance processes to ensure cultural and contextual relevance, especially for marginalized populations (Gooding & Kariotis, 2022; Slade et al., 2014). **Digital Inclusion Initiatives:** Investments in digital infrastructure, training programs, and device provision to bridge the digital divide and ensure equitable access across socioeconomic groups (Ben-Zeev et al., 2018).
Research	**Diverse, Longitudinal Studies:** Future research should employ larger, diverse samples and longer follow-up periods, assessing both efficacy and real-world effectiveness across demographic and clinical subgroups (Alvarez-Jimenez et al., 2021; Patel et al., 2018). **Implementation Science:** Increased focus on long-term implementation outcomes, using frameworks like RE-AIM and CFIR to evaluate adoption, sustainability, and scale-up (Proctor et al., 2011; Mohr et al., 2017). **Ethical Evaluation:** Systematic incorporation of dynamic consent models, privacy protection measures, algorithmic bias assessment, and co-produced ethics oversight (Gooding & Kariotis, 2022; Hollis et al., 2015). **Mixed-Methods Approaches:** Utilize qualitative and quantitative methodologies to capture user experiences, clinician perspectives, and contextual factors influencing DTx success or failure (Naslund et al., 2020).

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