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Formative evaluation of the implementation of digital therapeutics for opioids and other substance use disorders in primary care (DIGITS trial)

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Abstract

Background

Substance use disorders (SUDs) result in individual and societal burden. However, most individuals with SUD receive no treatment. Implementing SUD interventions in primary care could address this population's treatment needs. In the USA, reSET® and reSET-O® were the first prescription digital therapeutics (PDTs) for SUDs and opioid use disorder (OUD), respectively. The Digital Treatments for Substance Use Disorder (DIGITS) study tested the effectiveness of practice facilitation and health coaching strategies to support reSET and reSET-O implementation into primary care. A formative evaluation was conducted to monitor implementation, inform adaptations, and learn what promotes PDT sustainment.

Method

The Dynamic Sustainability Framework and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies guided the evaluation. Using rapid qualitative methods, we collected and analyzed observational fieldnotes, key informant interviews, and document sources (e.g., meeting minutes) for synthesis and dissemination to clinical partners and the study team via formative reports. We analyzed the reports to generate evaluation results.

Results

Twenty-four primary care clinics participated. Evaluation data included 98 observational fieldnotes, 16 interviews, and 253 document sources. We produced nine formative reports. The study encountered barriers and facilitators in each DSF domain (ecological system, practice setting, and intervention). In the ecological system, the PDT vendor enabled the study, but the COVID-19 pandemic, laws, regulations, and contracting delayed implementation. In the practice setting, staff shortages and low clinic capacity were implementation challenges, while electronic health record capabilities were both barriers and facilitators. At the intervention level, non-routine workflows, clinician burden, and low patient engagement were barriers despite clinicians' efforts.

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Conclusions

Digital therapeutics are promising SUD and OUD treatments, but integration into primary care requires conducive laws and regulations, organizational capacity, and patient and clinician engagement. Formative evaluation identified important lessons for future PDT implementation.

Plain Language Summary:

Evaluation of the integration of digital treatments for opioid and other substance use disorders in primary care. Most people with substance use disorders (SUDs) receive no treatment. In the USA, two smartphone app-based digital treatments for SUD and opioid use disorders (OUDs) became available by prescription. The Digital Treatments for Substance Use Disorder (DIGITS) study, a randomized implementation trial, tested how best to integrate these digital treatments for SUD and OUD into primary care. Throughout the study, we conducted a formative evaluation to observe progress, recommend implementation improvements, and understand how digital treatments could be offered to patients after the study ended. For this evaluation, we collected qualitative data through observing study meetings and interviewing primary care leaders, clinicians, and clinical and study staff. The data were regularly summarized and reported to our clinical partners and the study team. We used two implementation frameworks to interpret the data: the Dynamic Sustainability Framework and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies. The evaluation revealed factors that helped and hindered implementation. Obstacles from outside the health care system included the COVID-19 pandemic, laws, regulations, and delays in setting up contractual agreements, whereas a partnership with the digital treatment vendor proved helpful. Clinics had difficulties with clinician burden, staff shortages, lack of time and available appointments, and performing new and unfamiliar tasks. The electronic health record system both supported and impended implementation. Last, few patients accepted the offered digital treatment, or used it persistently. Formative evaluation results suggest that digital treatments for SUD and OUD in primary care are promising, however their successful use requires supportive laws and regulations, health system resources, and increased patient and clinician engagement.

Keywords

substance use disorder, mHealth, primary care, implementation science, qualitative research, formative evaluation

Background

Substance use disorders (SUDs) result in individual and societal burden, but only 36% of people with past-year opioid use disorder (OUD) receive treatment and as few as 22% receive first-line medication (e.g., buprenorphine) (Degenhardt & Hall, 2012; Grant et al., 2015; Grant et al., 2016; Jones et al., 2023; SAMHSA, 2023). Treatment utilization for other SUDs including cannabis, stimulant, and alcohol use disorders is even lower (Frost et al., 2024; Grant et al., 2015; Grant et al., 2016; Wu et al., 2017). The National Academy of Medicine and field experts call for preventing and treating SUDs in primary care, which most individuals with SUD prefer (Barry et al., 2016).

In 2017, the U.S. FDA authorized two prescription digital therapeutics (PDTs) for SUDs. Pear Therapeutics reSET® for SUD and reSET-O® for OUD are smartphone-based versions of a computerized cognitive-behavioral SUD treatment with demonstrated effectiveness in specialty care (Bickel et al., 2008; Campbell et al., 2014; Christensen et al., 2014; Maricich et al., 2022; Marsch et al., 2014). They have potential in primary care because they target substance use reductions among people with an active SUD. Further, reSET-O supplements buprenorphine treatment for OUD, which can be prescribed in primary care (Barry et al., 2016).

Healthcare organization uptake of digital SUD interventions remains low (Miller-Rosales et al., 2023). Implementation challenges include persuading care teams to offer digital treatments and patients to initiate them, and ensuring patients receive adequate doses through regular use. The Digital Treatments for Substance Use Disorder (DIGITS) study investigated how to optimally integrate digital therapeutics into primary care clinics. We conducted a rigorous formative evaluation of implementation (Elwy et al., 2020; Stetler et al., 2006) throughout DIGITS, using empirical data from stakeholders to monitor and improve implementation; adapt it to maximize fit to the ecosystem, practice setting, and intervention; and learn what promoted sustainment.

Our formative evaluation can guide pragmatic, multimethod evaluations for timely, trustworthy improvement feedback to researchers and clinical partners throughout implementation. We describe evaluation goals, data sources, analytic methods, evaluation activities, and implementation barriers and facilitators. Methods for sharing evaluation findings with clinical partners and perceived impact on implementation illustrate how centering evaluations on "real-world" concerns informs decision-making in dynamic settings.

Method

Setting

Kaiser Permanente Washington (KPWA) integrates healthcare and coverage for approximately 700,000 members. The more than 30 primary care clinics in Washington State use an integrated mental health (IMH) model, with conditions such as depression and unhealthy substance use treated by primary care clinicians including licensed independent clinical social workers (LICSWs). ("Clinician" indicates qualified clinical practitioners who provide patients' principal care.) (CMS, 2023; Tumulty, 1970).

Research Team and Reflexivity

The lead evaluator was a doctoral-level sociologist and qualitative methodologist with federally funded implementation science training (Palazzo). The bachelor-level evaluator (Dorsey) had experience in qualitative research and contributed to the implementation science literature. Both performed data collection and qualitative analysis and were full-time employees at KPWA Health Research Institute affiliated with KPWA. The study team included clinician scientists (social work, general internal medicine), implementation practitioners (public health), a health economist, project manager, and biostatisticians. Co-investigator clinical partners were leaders in KPWA Mental Health and Wellness (addiction psychiatry, social work). A Steering Committee comprised leaders in addiction, implementation science, and digital therapeutics.

DIGITS Study and Intervention

DIGITS tested the effectiveness of strategies for implementing reSET and reSET-O in primary care to achieve optimal reach, fidelity, and cost effectiveness. Researchers and KPWA leaders partnered to define clinically meaningful objectives and conduct the study.

The digital therapeutics were regulated by the FDA. FDA prescription labeling criteria dictated which patients could be prescribed the therapeutics (Watson et al., 2023). reSET-O was indicated for patients with OUD who were prescribed buprenorphine and reSET for patients with other SUDs (e.g., cannabis) (Maricich et al., 2021, 2022). Patients with a primary OUD not treated with buprenorphine or using alcohol with no other substance were not eligible.

PDTs were treatment adjuncts for patients under clinician care; patients could not download PDTs or use them without clinician assistance. KPWA clinicians trained in reSET and reSET-O, primarily LICSWs, assessed patient eligibility and offered the PDTs in primary care. If patients accepted, clinicians used the vendor's platform to create a new account, sending the patient an access code. Clinicians used the electronic health record (EHR) to prescribe the app by entering a standing order that a physician would co-sign.

reSET and reSET-O were chosen because their effectiveness data and commercial maturity promised sustainability if the health system institutionalized them. The vendor's help desk provided patient and clinician technical support, and a population-management dashboard allowed clinicians to track patients' app initiation and use. The patient-facing app incorporated three evidence-based approaches—contingency management (Lussier et al., 2006), community reinforcement (Lussier et al., 2006; Marsch et al., 2014) (a cognitive-behavioral therapy, delivered in text- and video-based lessons) (Magill & Ray, 2009) and fluency training (Binder, 1996)—to support substance use abstinence or reduction. reSET and reSET-O prescriptions lasted approximately 12 weeks.

Implementation

Three implementation strategies promoted PDT adoption: (1) standard strategy, (2) practice facilitation, and (3) health coaching (Glass et al., 2023; Proctor et al., 2013).

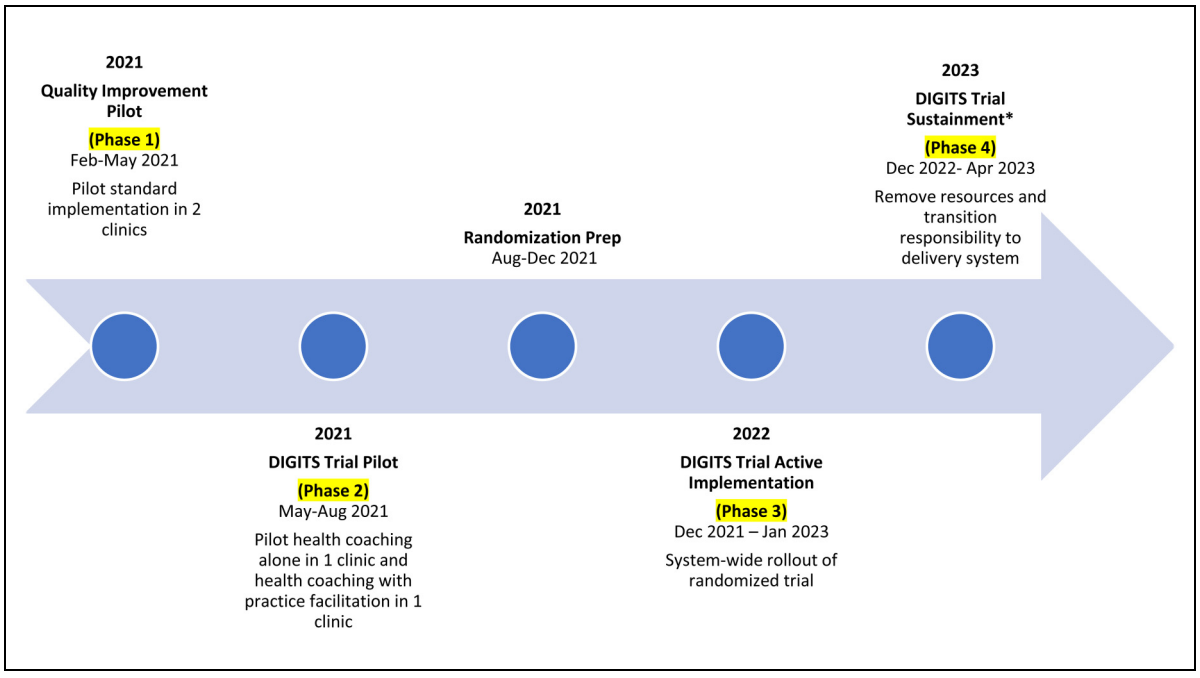
Standard was a package of supports previously employed by KPWA to implement non-prescription digital therapeutics, including live or video-based clinician training from clinical leaders and the PDT vendor, and an implementation toolkit with clinician- and patient-facing materials, such as a clinician job aid about offering the PDTs, patient pamphlets, EHR tools and documentation templates, quality-monitoring performance reports, and marketing materials (e.g., huddle cards). A trained external practice facilitator assisted clinicians, provided audit and feedback, supported plan-do-study-act cycles, and engaged clinic leaders (Ritchie et al., 2017). Health coaching was led by a centralized medical assistant who contacted patients to support engagement, PDT use, and communication with healthcare teams.

DIGITS Phases

The four phases (Figure 1) were (1) quality improvement (QI) pilot (3 months), (2) trial pilot (3 months), (3) active implementation (up to 1 year per clinic), and (4) sustainment (initially planned for up to 1 year per clinic). In the QI pilot, we worked with two clinicians across two clinics to adapt, apply, and monitor use of the standard strategy. In the trial pilot, we observed application of practice facilitation and health coaching alone or in combination in the same 2 clinics (Mogk et al., 2024). In active implementation, 21 participating primary care clinics were cluster-randomized to (1) standard implementation alone, (2) standard + practice facilitation, (3) standard + health coaching, or (4) standard + facilitation and coaching. Sustainment assessed continued intervention reach and viability after reducing study-funded implementation supports.

All KPWA primary care clinics not participating in our two-clinic pilot study were initially eligible for the trial.

Figure 1.
DIGITS Study Phases and Corresponding Key Activities.



Note. *Sustainment was planned for September 2022 through December 2023 but ended in April 2023 due to vendor bankruptcy.

Due to COVID pandemic staffing vacancies, before trial start, we required clinics to have at least one clinician trained to offer the apps.

Formative Evaluation

Qualitative methods used a post-positivist approach (Guba & Lincoln, 1994) to assess implementation strategies, feasibility, real-time implementation, contextual factors and participant responses, and optimize adaptations. Goals included: (1) monitoring and documenting PDT implementation; (2) understanding barriers and facilitators to intervention fidelity, adoption, appropriateness, acceptability, and sustainment; and (3) identifying modifications and adaptations to strategies and/or the intervention. All pilot and trial clinics and study phases were evaluated. Clinical partner needs drove evaluation activities. Mainly evaluators, overseen by Glass, collected and analyzed data.

Dissemination of Findings

Every 1–3 months, evaluators presented to and discussed with clinical partners and the project team as a data-collection point and member-checking opportunity (Birt et al., 2016). Evaluators generated formative reports using resulting data and feedback. Approximately twice annually, the Steering Committee heard selected findings and gave feedback. Reports contained (1) standard sections with key implementation findings (e.g., successes, barriers, recommendations); and (2) special sections on emerging issues (e.g., adaptation outcomes), non-routine events (e.g., supplementary clinician training), or unexpected organizational-level change impact (e.g., departmental restructuring). Flexibility kept the evaluation relevant to a complex health system study.

Guiding Frameworks

The Dynamic Sustainability Framework (DSF) and the Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies (FRAME-IS) guided formative evaluation (Chambers et al., 2013; Miller et al., 2021; Wiltsey Stirman et al., 2019).

DSF comprises three domains—ecological system (practice setting environment), practice setting (intervention context), and intervention (PDTs, associated implementation strategies, clinical interventions)—that change over time.

Successful, sustainable implementation "maximizes fit" of these domains. The DSF is appropriate for PDTs, which are novel for healthcare. Adaptive strategies, including external facilitation were chosen based on the DSF. Before starting, evaluators mapped implementation components to DSF domains and constructs (Table 1). This allowed characterizing overall barriers and facilitators as

Table 1.
DIGITS Implementation Constructs Mapped to the Dynamic Sustainability Framework.

Mapped DIGITS constructs	Definitions
Ecological system domain. *Includes practice settings that influence intervention implementers, the legislative and regulatory environment, the funding environment, characteristics of local, regional, state, and national markets, and population characteristics*	
Laws, policy and regulations	*Legal and regulatory framework for delivering the intervention. Includes FDA, reimbursement, incentives, and HIPAA.*
Market forces	*PDT vendor as an industry actor with market scope and reach, offering products such as reSET and reSET-O. Includes company policies relevant to reSET and reSET-O implementation.*
Population characteristics	*Health (including the presence of substance use disorders) and sociodemographic characteristics of KP members and communities served*
Research funder	*National Institutes of Health and others with resources to study effectiveness and implementation of digital therapeutics*
Steering committee	*External experts advising on reSET and reSET-O implementation and sustainment*
Socio-cultural context	*Social norms and cultural values that provide context for substance use disorder experience and treatment (e.g., stigma, community environment)*
Practice setting domain. *Multilevel context internal to a clinic, the KPWA regional system, and the KP national system*	
Existing digital initiatives	*Health service delivery through digital means other than reSET and reSET-O (e.g., virtual visits, mental health support)*
Existing workflows	*Clinic processes that pre-date or happen outside reSET and reSET-O implementation*
Existing primary care team members and roles	*Clinicians and staff at each level of the setting who contribute to organizational culture and climate*
IT security infrastructure	*IT security infrastructure that prevents and mitigates risks of healthcare activities with technology*
EHR and dedicated EHR tools	*Existing EHR system and dedicated EHR tools and capabilities that facilitate reSET and reSET-O delivery*
Organizational culture and climate across level	*Expectations, historical values, collective experience, norms, and employees' perceptions of their work environment*
Regional and national organizational structure	*KP regional and national organizational structures and integrated care and coverage business model*
Training and supervision	*Training and hierarchical and reporting relationships involving clinicians and clinic staff*
Existing health services for patients	*Health services delivered to patients other than reSET and reSET-O*
Legal and compliance	*Internal governance system for compliance with applicable laws, regulations, policies, and procedures related to KP operations*
Implementation and operations needs and costs	*Level of resources for implementation and ongoing operations, including money, training, education, physical space, and time*
Intervention domain. *Digital treatment delivered through the reSET and reSET-O apps and associated strategies and clinical interventions*	
Intervention content	*CRA, contingency management, CBT, and IMH clinician visits as indicated*
New primary care team member roles and responsibilities	*LICSWs, other primary care clinicians, and other staff whose roles and functions support delivering reSET and reSET-O*
Health coaching and practice facilitation	*Implementation strategies used to increase reach and fidelity of reSET and reSET-O*
Clinical outcomes	*Decreased substance use disorder, increased patient engagement*
Intervention platform (PDT)	*Digital intervention platform, i.e., prescription-based smartphone apps as means of intervention delivery*
PDT-specific clinical pathways and protocols	*Workflows and practical instructions for delivering reSET and reSET-O*
Technical support	*Technical support from the PDT vendor*
Patients using the PDT	*Patients who are eligible, offered, and accept and use reSET and reSET-O*
Support to clinicians for patient onboarding in PDT and follow-up	*Activities to support smooth workflows as clinicians initiate patients to the PDT and follow up on their progress*

Note. CRA = community reinforcement approach; CBT = cognitive behavioral therapy; IMH = integrated mental health; LICSW = licensed independent clinical social worker; PDT = prescription digital therapeutic; KPWA = Kaiser Permanente Washington; KP = Kaiser Permanente; EHR = electronic health record; FDA = U.S. Food and Drug Administration; HIPAA = Health Insurance Portability and Accountability Act; IT = information technology.

arising in ecological system, practice setting, or intervention and helped identify constructs and domains targeted by adaptations.

The FRAME-IS systematically documents modifications and adaptations (respectively, unplanned and planned changes) of evidence-based implementation strategies to improve implementation effectiveness. FRAME-IS captures and organizes content, rationale, decision-making level, and goals of tailoring implementation to fit conditions.

Data Sources

Observational Fieldnotes

Fieldnotes were collected at implementation meetings (internal practice facilitation and health coaching meetings, clinical staff check-ins, clinical partner meetings, clinical education calls), and meetings with the research team, KPWA partners, and primary care clinics (Table 2). Evaluators used a structured fieldnotes template informed by FRAME-IS and recommendations (Proctor et al., 2013) to specify and report implementation strategies by actor, action, action target, temporality, dose, outcomes affected, and justification. Unstructured observations and insights were captured as free text. Evaluators documented strategies, barriers, facilitators, modifications and adaptations, and clinician stories, including about patients. They collected data from virtual practice facilitation meetings with local clinic teams. Throughout the trial, evaluators attended practice facilitation meetings on a rotating basis (five clinics observed at any point), attending at least two per clinic. Meeting participants were aware of evaluators' roles and verbally consented to activities.

Evaluators did not directly observe clinics that implemented standard implementation alone or standard + health coaching but not practice facilitation. To minimize clinic burden under COVID, evaluators attended clinic meetings only if scheduled as part of the trial and led by the practice facilitator (with or without the health coach). Our evaluation plan did not include observing patient encounters with clinicians or the health coach when reSET or reSET-O might be discussed. Data on clinics with standard implementation alone were obtained from trainings, departmental meetings, and from clinical partners. Data on clinics with standard + health coaching were extracted from health coaching implementation meetings.

Key Informant Interviews

Interviews with KPWA employees occurred between trial pilot end and two months into active implementation to explore successes and challenges of app implementation and understand how to adapt implementation strategies for the future. Participants were purposively sampled, including clinical leaders across the healthcare system and clinicians within the two pilot clinics. Interviews were by JM and TEM, overseen by JEG, informed by the DSF and FRAME-IS and asked about interviewees' understanding of PDT implementation, what worked or was challenging. Full data collected and interview guides are published (Mogk et al., 2023) (Additional files in the supplemental material).

Document Sources

Evaluators reviewed implementation materials (e.g., training videos), implementation and other meeting minutes, emails, and online messages, using the observational fieldnotes template to extract data.

Analyses and Reports

Data sources were analyzed for actionable findings for clinical partners and the research team (Figure 2) and summarized in monthly formative reports using qualitative content analysis (Hsieh & Shannon, 2005). Approximately six months into active implementation, evaluators began reviewing reports, developing a coding template for barriers, facilitators, modifications, adaptations, and implementation strategies, and DSF domains and constructs. Evaluators used the template and Atlas.ti 9 (ATLAS.ti, 2023) to code reports, reviewing 10% of coding for quality assurance, and scrutinizing coded text for emerging patterns presented in the final assessment.

Rigor and Trustworthiness

Evaluators triangulated data sources and researcher and care delivery system partners' perspectives, routinely discussing and cross-checking data and findings. During regular evaluation reports, evaluators elicited and incorporated feedback about results validity and accuracy from researchers, delivery partners, practice facilitators, and the health coach (member checking) (Birt et al., 2016), adhering to the Standards for Reporting Qualitative Research (Additional files in the supplemental material) (O'Brien et al., 2014).

Ethics Approval

The KPWA Institutional Review Board reviewed all study activities and granted a waiver of consent and HIPAA authorization to collect individual-level automated electronic medical record data necessary to randomize clinics and to collect information for the analysis. Primary data collection for the formative evaluation was exempt from IRB review.

Results

Implementation Experience

Of 24 participating primary care clinics, two started the QI pilot, each with one trained LICSW. Both entered the trial pilot, but one ended early when the LICSW left. The active implementation phase randomized 21 sites. Across all phases, 38 clinicians (mostly LICSWs) were trained to offer the PDTs. From QI pilot launch to study end, 89 prescriptions were created (68 for reSET), with 46 activated by patients (41 for reSET, Table 3). In April 2023, shortly after all clinics entered the sustainment phase, the vendor filed for bankruptcy, so the sustainment phase ended early.

Table 2.
Data Sources Used in the DIGITS Formative Evaluation.

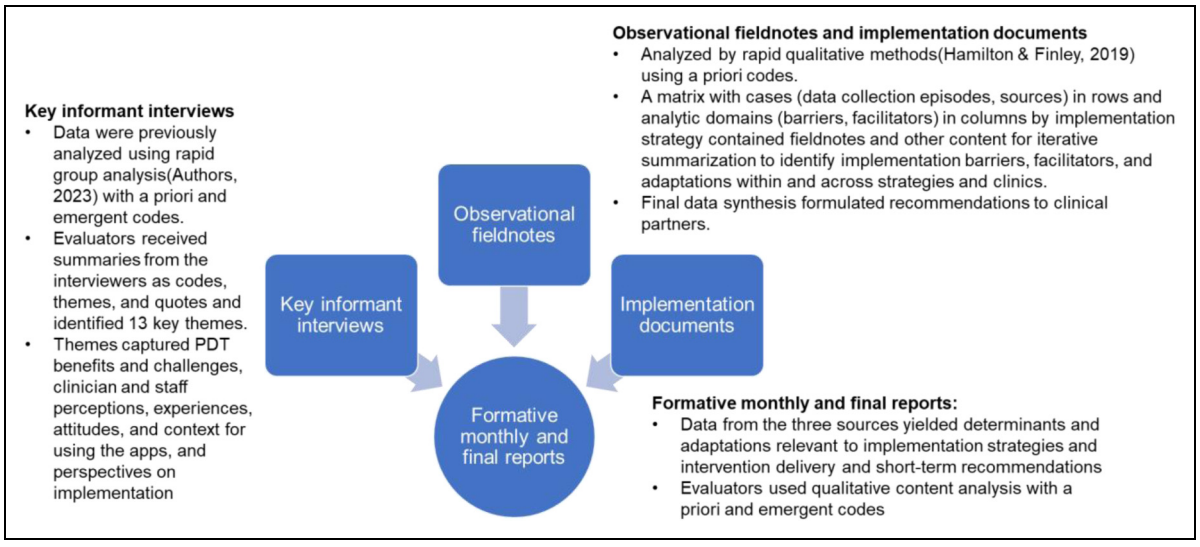
Data source	Description of data collection event	Number analyzed	Framework informing data collection
Observational field notes ($N = 98$)	*Research team meetings*	4	FRAME-IS
	Research team members; one hour twice per month		
	Implementation meetings	57	
	Research team members and clinical partners (one hour twice per month); the heath coaching team (approximately one hour weekly); or the practice facilitation team (one hour, once every two weeks)		
	Clinic-based practice facilitation meetings and associated presentations	22	
	Practice facilitator, health coach (when the health coaching strategy applies), LICSWs, and other care team members; 30–60 minutes monthly		
	Clinical staff check-ins (QI pilot)	4	
	Research team members and pilot clinics LICSWs; bi-monthly, one hour long		
	Trainings	8	
	reSET, reSET-O, and Epic EHR trainings for IMH clinicians		
	Clinical leaders' calls with LICSWs and physicians	2	
	Calls held to discuss SUDs and disseminated reSET and reSET-O		
	Other meetings	1	
	Steering Committee meetings, meetings with KPWA units beyond PC relevant to implementation		
Key informant interviews ($N = 16$)	*Interviews with clinical and implementation stakeholders*		DSF, FRAME-IS
	LICSWs	3	
	Physicians	4	
	MAs	1	
	Implementation team members, clinical leaders, or managers of clinic operations	8	
Implementation documents ($N = 260$)	*Minutes (see above for the description of meetings and trainings)*	125	FRAME-IS
	Research team meetings	23	
	Implementation meetings	45	
	Clinic-based practice facilitation meetings and associated presentations	50	
	Trainings and associated presentations and videos (synchronous and asynchronous reSET and reSET-O training offered to LICSWs and PC clinicians)	7	
	Other meetings	1	
	Online communications	7	
	Emails and chat messages directly relevant to the evaluation	2	
	Other implementation documents		
	Epic build requirements		
Formative reports ($N = 9$)	*Reports to clinical partners*	9	DSF, FRAME-IS
	Generated from ongoing data collection and analysis, presentations and feedback from clinical partners and the project team		

Note. FRAME-IS = Framework for Reporting Adaptations and Modifications to Evidence-based Implementation Strategies; DSF = Dynamic Sustainability Framework; LICSW = licensed independent clinical social worker; QI = quality improvement; IMH = integrated mental health; EHR = electronic health record; SUDs = substance use disorders; KPWA = Kaiser Permanente Washington; PC = primary care; MAs = medical assistants.

Formative Evaluation

Between February 2021 (QI pilot) and March 2023 (early sustainment), we collected observational fieldnotes and meeting minutes. Data were from research team, implementation, and practice facilitation meetings, and events including trainings. Evaluators also analyzed training videos and presentations, and reviewed job aids, huddle cards, and secure messaging

Figure 2.
DIGITS Formative Evaluation Analytic Procedures by Data Source.



scripts. Evaluators directly observed and documented implementation at 13 clinics, indirectly observing remaining clinics via meetings with clinical staff and leaders (Table 2).

Key informant interviews were with eight care team members (LICSWs, physicians, and medical assistants), and eight others (implementation team members, clinical leaders). Interviewees described pros and cons of using reSET and reSET-O and other digital therapeutics in clinical practice, implementation barriers, and mitigation strategies (Table 4).

Evaluators generated nine formative reports across all phases.

Barriers and facilitators. Implementation barriers and facilitators pertained to all DSF domains. They limited, or to a lesser extent supported, the implementation strategies' effectiveness, impacted intervention reach and other outcomes. Barriers in ecological system included COVID-19 pandemic disruptions and population needs; in practice setting, technical problems and adjustments, security and compliance protections, and clinical staffing and communication gaps; in intervention domain, increasing clinician burden, patient eligibility requirements, and challenging intervention features. Implementation facilitators were, in ecological system, PDT vendor cooperation; in practice setting, the EHR system, familiarity with digital tools, and frontline managers' engagement; in intervention, clinician and leadership champions, responsive research teams, and beneficial intervention aspects (Table 5).

Ecological System

Barriers

COVID-19 pandemic disruptions. The pandemic impact delayed the study launch. Pandemic mitigation resulted in clinic closures, staffing losses, and shifts in resource allocations (e.g., to business continuity). These factors reduced the health system's capacity to absorb new digital therapeutics. Implementation was also delayed by state and federal laws that health system administrators interpreted as potentially limiting the small patient financial incentives embedded in reSET and reSET-O as contingency management, a common SUD behavioral motivator. Contracting processes between the health system and the PDT vendor also delayed implementation: "We planned on doing this last year, and the contracting piece sort of dragged on and on" (Table 5, 1.a.1, table has full quotes and attributions). Health system leaders anecdotally reported that delays reduced implementation momentum.

Population Characteristics and Needs

According to LICSWs, despite SUDs' general high prevalence in primary care, few referred patients had SUD, especially in smaller clinics. Some patients needed more specialized or intensive care, limiting LICSWs' interactions with patients with SUD. Some eligible patients were deemed by clinicians to have competing challenges that precluded prescribing the PDT, including unstable housing, mental health crises, or serious medical conditions: [The LICSW said] "there was a patient from [medical center] …he is homeless, needed a crisis plan. He is not doing well mentally or physically" (Table 5, 2.c.2).

Facilitators

PDT Vendor's Cooperation

Regular communication and collaboration with the PDT vendor addressed issues as they arose (e.g., with technical support for patient account creation), aiding the practice facilitators and health coach. The vendor allowed the research team to tailor standard PDT training to accommodate clinicians' time limitations: "Lots of aspects of the product have been customized to support the KPWA team" (Table 5, 3.b). PDT vendor-delivery system collaborations overcame compliance and regulatory concerns.

Practice Setting

Barriers

Information technology capabilities and clinicians' role. Information technology capabilities (largely EHR-related) and LICSWs' role emerged as intersecting barriers. LICSWs were tasked with offering the PDTs, but were not accustomed to creating prescriptions, including in the EHR, which is outside their scope of practice per legal statutes. The research team and mental health leadership facilitated regional changes to institute a standing order policy allowing LICSWs to immediately provision PDTs based on standard eligibility criteria, later obtaining a physician prescriber's approval and signature. The EHR allowed standing order implementation but required that clinicians execute new steps with multiple clicks to complete prescriptions. The novelty of this procedure was emphasized in LICSW training: "an authorized provider needs to co-sign entering an order for reSET. This is a new piece" (Table 5, 4.b.1).

Another EHR-related barrier was lack of integration with vendor information systems so clinicians could set up patient accounts and monitor app use within the EHR versus the vendor's web-based dashboard. Health system information technology leaders would not support two-way communication between the EHR and the vendor systems without experience and a long-term commitment to the products. Thus, during active implementation, workflows were not fully optimized to clinician needs and product capabilities, affecting intervention reach: "EHR integration is critical—we really need to shorten time between offering and the patient being able to use the app" (Table 5, 4. c.1).

Security and compliance protections. Documenting and communicating security and compliance protections about using software-based products to transmit and store protected health information outside the health system's firewall required significant effort. The need to protect patient privacy and the health system's brand and adhere to regulations about use and disclosure of patient data led to rigorous, lengthy, technical risk evaluations. "How do you balance the care provided to patients with the risk?" (Table 5, 5.c.). Risk assessment involved the regional and national health system, research team, and PDT vendor before business leader approval.

Clinical staffing and information gaps. Clinician losses and staffing gaps impeded reach. Several clinics lacking LICSWs who could be trained in the PDTs were excluded from implementation, and nine trained clinicians left during the study: "[two clinics] had social workers that had left their positions and so the social workers that were at [other clinics] ended up having to do a lot of coverage" (Table 5, 6.a.1).

New staffing vacancies coincided with reports of high clinician burden and undermined adoption as LICSWs had difficulties integrating new duties into their schedules. Some perceived their limited capacity was not considered when launching the PDTs: "There isn't a whole lot of consent requested of the team at the clinic, like "hey, we're thinking of starting this—do you have capacity for it?" It's more like "hey, we're starting this—here's the meeting for the orientation." (Table 4, 4.c.1, table has full quotes and attributions). Primary care physicians, physicians' assistants, and registered nurses could refer patients to LICSWs to discuss the PDTs. However, many were not aware of the PDTs. In one example, at a staff meeting about the apps, a physician stated, "*I have no idea what this is about"* (Table 5, 6.b.1).

Others were unaccustomed to referring patients with SUD and OUD to LICSWs for treatment. These barriers affected PDT adoption, while reach was further hampered by few physicians prescribing buprenorphine for OUD, an eligibility requirement for reSET-O. KPWA organizational restructuring during the study changed LICSW staff oversight, enhancing change fatigue and affecting PDT prioritization by LICSWs.

Facilitators

EHR System

The existing EHR supported building dedicated tools to automate clinical processes including ordering, documentation, patient instructions, and population management: "Whether it's working with clinical guides or working with smart phrases but having that information available at a site where I would typically go, that's very helpful" (Table 4, 3.c.1).

Long-standing relationships between research informaticists and delivery system information technology staff were largely responsible for these achievements. Equally critical was working with the PDT vendor and delivery system on compliance and regulatory issues.

Familiarity with Digital Tools

DIGITS was not the only digital initiative at KPWA, with pandemic-motivated shifts to telehealth. Non-prescription depression and anxiety wellness apps

were already available at KPWA. Clinicians reported that simultaneously obtaining access to multiple new digital programs, each with its own purpose and requirements, was sometimes confusing to clinicians and patients (Table 4, 2.c.1). However, it aided PDT implementation by providing process blueprints and familiarity with digital care delivery: "We use apps, frankly, for a lot of other diagnoses here as well—anxiety/depression, which oftentimes go along with substance use disorders…it's a very nice complement" (Table 5, 8.a).

Frontline Managers' Engagement

IMH department restructuring that affected LICSWs' perceived work environment introduced a new administrative layer, but also indirectly supported implementation. LICSW managers expressed interest in DIGITS and their staff's involvement, opening new lines of communication with the research team including a one-page study overview, reSET test accounts, and targeted email updates.

Intervention Domain

Barriers

PDTs' demands on clinicians. Specific requirements for the PDTs, including the detailed patient-eligibility assessment and required prescription, were adoption obstacles. Clinicians often lacked time during appointments to determine eligibility and readiness for the PDT, availability for recommended monthly follow-ups, or time to monitor app use (Table 5, 10.a.1).

Prescribing the PDT and tracking module completion using the vendor's dashboard fell outside routine workflows, in part because of lack of integration into the EHR. These features decreased intervention feasibility.

Patient eligibility requirements. PDT FDA authorization did not include patients with only alcohol use disorder and required patients with OUD to have active buprenorphine prescriptions. Clinician training provided the rationale, but clinicians reported frustration and confusion about these narrow eligibility criteria, limiting the apps' utility in everyday practice (Table 5, 11.b.2).

Challenging intervention features. Clinicians reported low, inconsistent patient engagement with SUD treatment generally and the PDTs, specifically. LICSWs and the health coach frequently could not contact patients who were or could be offered the PDTs. As with many apps, patients often accepted a prescription without activating it or completing learning modules.

Clinicians reported that some patients had technical difficulty installing the app, absorbing the instructional content, or fitting module completion into their schedules. Thus, some clinicians stopped offering the PDTs (Table 5, 12.c.2).

Facilitators

Clinician and Leadership Champions

Some LICSWs committed to supporting PDT implementation, for example by spreading information about the apps in huddles and meetings and primary care clinicians and clinic leaders championed the intervention. A strong evidence base bolstered clinicians' belief about the PDT's benefits and potential to help some patients, motivating their endorsement (Table 5, 13.a.1). Support was not uniform, however. Competing priorities prevented consistent engagement from clinicians and leaders.

Responsive Research Team

Practice facilitators, the health coach, and other research team members answered challenges to intervention delivery with flexibility and responsiveness to local needs, for example, temporarily pausing practice facilitation in understaffed clinics, adapting the facilitation protocol and shortening clinic-based meetings to lessen clinician burden and improve implementation acceptability. A programmer generated reports to help clinicians identify eligible patients in practice facilitation clinics, and the health coach shared successful patient engagement strategies for clinicians (Table 5, 14.b.1). The research team presented at a continuing medical education event and offered PDT training to all clinicians to reduce reliance on LICSWs (manuscript describing adaptations with quantitative implementation results in preparation).

Beneficial Intervention Aspects

According to LICSWs and the health coach, patients who activated accounts and regularly engaged with reSET enjoyed it and were satisfied with the experience. They liked the content, embedded incentives, and lessons such as on building life skills to apply beyond substance use. Some clinicians liked that the PDTs offered "one more tool in the toolbox" that was non-stigmatizing and quickly accessible by patients (Table 5, 15. b.1).

Successes

Successes were mostly with clinicians and patients who had positive experiences with DIGITS and the PDTs. Reflecting on the experience of participation, one LICSW reported increased SUD awareness and confidence in discussing substance use with patients. Practice facilitation clinic clinicians expressed widespread appreciation for practice facilitators, their tools, and resources (e.g., reports, illustrative materials, PDT "elevator speech" for colleagues). Supporting materials formed a toolkit for collaboration and coordination of implementation activities (Additional files in the supplemental material): "I felt like the rollout of reSET was far superior to other initiatives in primary care" (Table 5, 14.a).

Table 3.
reSET and reSET-O activity Activity Across Piloting and the DIGITS Implementation Trial (March 2, 2021, through March 31, 2023).[a]

Clinicians trained by type	38
LICSW	32
PA[b]	1
MD[b]	4
RN	1
Clinics participating in the DIGITS study	24
Pilot clinics	2
Randomized clinics[c]	22
Prescriptions	89
reSET	68
reSET-O	21
Prescriptions activated	46
reSET	41
reSET-O	5

Note. LICSW = licensed independent clinical social worker; PA = physician assistant; MD = medical doctor = RN = registered nurse; PDT = prescription digital therapeutic.
[a]Date of the first and last event related to reSET and reSET-O prescription and activation.
[b]Of the clinicians trained to prescribe the PDTs, one PA and one MD were buprenorphine prescribers.
[c]22 clinics were randomized in 21 randomization units; two clinics were paired because of their geographical proximity and sharing of the LICSW.

Fidelity in strategy delivery by the health coach within an adapted, expanded role was widely praised for helping patients connect with IMH care and engage with PDTs. These efforts identified effective approaches for sustained patient engagement, including stressing the low time commitment for instructional modules, reminding patients about built-in app incentives, and helping them master difficult or intimidating content.

Discussion

DIGITS tested strategies to optimally implement digital therapeutics for SUD and OUD in primary care. Our formative evaluation was critical to improving intervention fit with local contexts and identifying lessons from the implementation experience. It addresses the lack of knowledge on practical considerations to implementing evidence-based digital therapeutics for SUD and OUD that require prescription and clinician oversight. Our multimethod evaluation revealed real-time barriers and prompted rapid adaptations in partnership with the delivery system. We identified project and intervention facilitators to assist others in implementing PDTs. Conceptually grounding the evaluation in the DSF enabled identification of levels where implementation determinants emerged—ecological system, practice setting, intervention—and necessary adjustments.

COVID-19 and its aftermath in the ecological system created opportunities and benefits to digital care by improving access, but disrupted health systems. The impact reverberated across levels, leading to low capacity and staffing challenges in the practice-setting level and widespread clinician burden. These conditions were unfavorable to introducing a first-ever substance use PDT into routine care, despite the need for more and better treatment options. The impact of staffing challenges on implementation of evidence-based SUD interventions aligns with pre-COVID studies (Hagedorn et al., 2014; Rubinsky et al., 2018; Woltmann & Whitley, 2007). In the ecological system, common needs among people with SUD, such as mental health care and housing (Austin et al., 2021; Jones & McCance-Katz, 2019) were competing demands to offering PDTs for clinicians. Legal constraints and compliance issues at the ecological and practice levels delayed implementation. These are important factors for health systems to consider when planning for digital therapeutic adoption. At the intervention level, cumbersome prescribing and PDT use undermined clinicians' and patients' willingness to engage. PDT eligibility criteria precluded use for some with common treatment needs, contributing to poor uptake.

Skillful practice facilitation and health coaching augmented standard implementation strategies, assisting clinicians with workflow concerns. However, many multilevel barriers were outside strategy scope such as low clinic capacity and staffing losses, or workflow hurdles from the lack of EHR-PDT communication. Health coaching to assist patients and minimize clinician burden was hampered by inability to reach patients. The intervention and implementation strategies could not mitigate health or psychosocial conditions beyond SUDs.

A DIGITS goal was gaining insights for future PDT implementation. Our formative evaluation generated lessons and recommendations to improve implementing digital therapeutics in clinical care. First, PDTs versus non-prescription health and wellness apps promise unique benefits but with unique legal and regulatory challenges. This increases administrative tasks for implementors, healthcare administrators, and organizational leaders. The PDT prescription process clashed with clinicians' scope of practice, leading to implementation delays as the research team and clinical leaders spurred institution of new health system policies. Research and implementation teams should know of these issues before selecting PDTs to implement, and thoroughly investigate organizational rules and federal and state laws pertaining to novel intervention features (e.g., monetary incentives). Maintaining connections and good working relationships with clinical leaders and organizational compliance and security officials was critically important to addressing obstacles.

Another lesson is that EHR limitations compound workflow issues. Limited vendor-EHR integration made it burdensome for clinicians to perform reSET and reSET-O implementation tasks, especially when outside their usual role, as supported by prior research

Table 4.
Key Informant Interview Themes and Representative Quotes Relevant to the DIGITS Study.

Domain	Themes	Representative quote
1. Benefits of offering digital therapeutics including reSET and reSET-O	a. Clinicians consider the apps another tool in the care toolbox and like a digital treatment option.	1. "The most positive aspect for me is being able to offer that as an option for patients, because as we know, different things work for different patients…" (Physician)
	b. The evidence base increased the value of the apps.	1. "The nice thing about reSET is that it's…an evidence- based offering" (Implementation team or clinical leader)
	c. Digital therapeutics fit with other existing treatments and may enhance them, while improving patient access and reach.	1. "…I see this as a way to reach more patients, to offer support, and any time I talk about this app and the support that it offers, people get really excited about it, because they just don't know where to send their patients that are presenting with substance use disorders, except for outside of our system." (LICSW)
	d. Digital therapeutics offer a non-stigmatizing treatment that meets patient and clinician needs.	1. "[Physicians and other PC clinicians] appreciate that reSET and reSET-O take a positive approach for patients, which is really important. One of our physicians actually said that's particularly important for patients with opioid use disorder who are on Suboxone,[a] that having a positive augment to ongoing treatment is really helpful." (Implementation team or clinical leader)
2. Challenges of offering digital therapeutics, including reSET and reSET-O	a. Clinicians may lack time, availability, and interest in learning about and connecting patients to digital therapeutics.	1. "I don't know the app content as well as—I mean, we were able to do a 30 day trial period, but I didn't get through all the models because—I don't know, because I didn't (laughs)." (LICSW)
	b. Some patients prefer face-to-face interactions for mental health treatments.	1. "We interact with apps in so many other areas of our life, and it's been surprising to me that people have not been as receptive to this as I would have imagined, for things like a mental health concern or substance use. Some patients, not everyone, really want that face-to-face interaction with a real person. So that's been one thing that I've learned through this." (Implementation team or clinical leader)
	c. Offering multiple apps in one clinic may be confusing for patients and clinical teams.	1. "If we educate and educate, [the patients] can only retain so much information…I don't know how the compliance would be if we offer several apps when maybe we should start with just one, see how a patient deals with it. If they're consistent and active on it, we can add different apps. But I think it's all about, do they really learn what we're telling them?" (MA)
3. Implementation strategies for digital therapeutics including reSET and reSET-O	a. Advertising digital therapeutics to the whole clinic, not only physicians, with a rationale for recommending adoption can foster engagement.	1. "I'm thinking for example of [digital mental health platform], where they had all these email blasts—[physicians and other primary care clinicians] still give us referrals to [digital mental health platform] so we check in with the patient and do an assessment and decide if they would be an appropriate fit for [digital mental health platform]…You just see it everywhere." (LICSW)
		1. "I think the things that work well are making

(Continued)

Table 4.
(Continued)

Domain	Themes	Representative quote
	b. Staff need dedicated time to learn the new app.	sure it's clear on our end, like having the time dedicated to testing it, using it and seeing how it's going to work. Because we don't always have time to do those things." (Physician)
	c. Workflows must be designed to ease clinicians' work burden.	1. "It's very helpful to be able to have information that's easily accessible to share with patients, as well as for me to be able to refer back to easily. I do find one of the frustrations I have as a primary care [physician] is there's lots of different places that information rests and trying to remember where and how to access it—so it's helpful especially for clinical information to have things localized to one place, where I can go and find that information. Whether it's working with clinical guides or working with smart phrases but having that information available at a site where I would typically go, that's very helpful as opposed to having to remember one more place to have to look for things." (Physician)
4. Challenges to implementation of digital therapeutics including reSET and reSET-O	a. Researchers must address the challenge of marketing digital therapeutics to clinical teams	1. "I don't know if they always listen to what we say (laughs), but I feel like if it's coming from someone who's eloquent from the research institute, then maybe that'll help." (LICSW)
	b. Clinicians lack time for implementing and learning new things, making it hard to share information or serve as champions	1. "So one is time, two is like working and learning something new, because then to have the time to enroll another patient—I think right now just in my clinic workflow you're running on negative minutes in every single encounter. There's just no space to add on something else so it's kind of like finding another time to do more stuff." (Physician)
	c. LICSWs have little time for implementation due to staff shortages and turnover but feel unheard in their concerns	1. "There's a couple different pilots going on and as pilots are brought on, what's considered is which clinic would be good for this, just based on patient population but not necessarily based on staffing resource. Which I think is a really huge component…There isn't a whole lot of consent requested of the team at the clinic, to say like "hey, we're thinking of starting this—do you have capacity for it?" It's more sort of like "hey, we're starting this—here's the meeting for the orientation." That is a problem unique to our department and [healthcare system] right now, not necessarily a problem with the actual therapeutic." (LICSW)

Note. MA = medical assistant; LICSW = licensed independent clinical social worker; PC = primary care.[a]Refers to suboxone, buprenorphine, and naloxone.

(Quanbeck et al., 2018). Health system's information technologists refused to integrate the PDT into the EHR without evidence that the intervention would be sustained, creating a "chicken-and-egg" workflow limitation that reduced sustainment likelihood. We iteratively co-designed new workflows with the implementers, considering their needs and preferences, and identifying barriers promptly. Pilot clinicians acknowledged that EHR integration would be beneficial but did not see lack of integration as a major limitation, although our evaluation found it a significant implementation impediment. We recommend involving a broader group of clinicians

Table 5.
Barriers and Facilitators to Implementation by Dynamic Sustainability Framework (DSF) Domain and Data Source.

Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
DSF Domain: Ecological System *Barriers*			
1. COVID-19 pandemic disruptions	*1.a. "The staffing challenges have been so significant, and just how care delivery has been so transformed during COVID-19 and how that's impacted our overall expectations about how we [the research team] were going to implement this. Our standard implementation model is not anywhere near as robust as our enhanced offerings, and our enhanced offerings are also very significantly impacted, not just because of staffing on the social work side but also staffing within primary care and all of that. forever."* (Implementation team, clinical leaders, manager of clinic operations) *1.a.1. "It took forever for the contracts to get signed. On one hand it wasn't as big a deal, just because the delivery system was not as ready as I had anticipated it would be. We planned on doing this last year, and the contracting piece sort of dragged on and on." (Implementation team, clinical leaders, manager of clinic operations)*	*1.b. Barriers to roll out were the situation created by COVID and all the pilots always going on.* (Clinic-based practice facilitation meeting. Clinic C., Dec. 2022. Fieldnotes)	*1.c. From a practice coaching meeting yesterday:* *Immediate changes in daily processes for staff. Good to understand that everything is changing quickly and influx in the clinics.* *If over a certain age being encouraged to not come into clinic* *Another study with practice coaching was cancelled at [clinic]. Some are switching to phone visits. Good to be conscious of the added workload to the clinical staff before asking for anything.* (Research team meeting, Mar. 2020. Minutes).
2. Population characteristics and needs	*2.a. "I've heard from our social workers that often they are seeing patients who may be in a position of really immediate crisis. They may be experiencing suicidal ideation or other challenges, and might not be in a place where they would be ready to start the use of a digital intervention like reSET and reSET-O. So, we've been talking about one of the challenges being having the opportunity to talk with patients when they're in a place where they might be ready to start using an app like this."* (Implementation team, clinical leaders, manager of clinic operations)	*2.b. Known barrier: patients appear eligible for reSET/O in the PF report but have more urgent needs to be addressed, i.e., patient presenting with SUD has acute psychiatric concerns and psychosocial problems.* (Clinic-based practice facilitation meeting, Clinic J, Nov. 2022. Fieldnotes)	*2.c. [The clinic context] is that there is a large elderly population up north in the in the retirement communities. Don't get a ton of warm handoffs [to IMH].* (Clinic-based practice facilitation meeting, Clinic G. Feb. 2022. Minutes). *2.c.1. Initiating[1] Suboxone treatment is ideal when a person is still actively using but ready to change. Meds help manage withdrawal symptoms. This first visit may be 45–60 min, then frequent visits to work on med dosing and side effects, managing withdrawal. Drug screens also need to happen, maybe other lab work. Then visits space out over time. In these cases, may want to wait until later to discuss reSET-O.* (Clinic-based practice facilitation meeting, Clinic A, Aug. 2021. Minutes) *2.c.2. [The LICSW said] "there was a*

(Continued)

Table 5.
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Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
			patient from [medical center] …he is homeless, needed a crisis plan. He is not doing well mentally or physically." [The LICSW] focused on engaging with community services to help get him stabilized and did not even address substance use at the time. (Clinic-based practice facilitation meeting, Clinic E, Sep. 2022. Meeting minutes) *2.c.3. One new patient shows up on the report in August- AUD and positive drug screen- two telephone encounters. [LICSW] sent this patient a message called him twice, didn't offer reSET since the patient hasn't engaged with [LICSW] at all. If the patient does reach back out, he is someone who may be eligible.* (Clinic-based practice facilitation meeting, Clinic C, Sep. 2022. Minutes).
Facilitators			
3. PDT vendor's cooperation	*3.a.* Not mentioned in key informant interviews	*3.b. With [vendor], lots of aspects of the product have been customized to support the KPWA team* (LICSW training, Feb. 2021. Fieldnotes)	*3.c. [Vendor] has approved the training of any new primary care-based clinicians in reSET and reSET-O, even if their clinic has not been randomized [to the study].* (Internal research team email communication, Sep. 2022)
DSF Domain: Practice Setting			
Barriers			
4. Information technology capabilities and clinicians' role	*4.a. "And then also just the tech part of it, trying to familiarize myself as I go, which hopefully will get easier with time, how to prescribe it to them, how to explain the walkthrough to them [is a challenge]. You're also adding that into this brief conversation where you're doing the initial setup."* (LICSW)	*4.b. LICSWs are experiencing technical problems shortly after training: A software error affects enrollment data on vendor's dashboard.* (Research team meeting. Feb. 2021. Fieldnotes) *4.b.1. Documentation [in Epic] is built to be as easy as possible and as similar to [other KPWA digital tool] as possible. But something that is different with reSET: an authorized provider needs to co-sign entering an order for reSET. This is a new piece.* (reSET—reSET-O, Feb. 2021. Fieldnotes).	*4.c. There is a problem that still needs resolution: LICSW is not showing up on the [vendor] website. LICSW had reached out for help with this earlier, but it looks like it isn't fixed. The health coach will write an email explaining the continuing issue.* (Clinic-based practice facilitation meeting, Clinic B, Sept. 2022. Minutes). *4.c.1. [This is] where EHR integration is critical—we really need to shorten time between offering and the patient being able to use the app.* (Implementation meeting, Dec. 2022. Minutes).
5. Security and compliance protections	*5.a* Not mentioned in key informant interviews.	*5.b. Contingency management was a barrier for DIGITS, possible ongoing problem for sustaining the intervention.* (DIGITS Steering Committee meeting, Aug. 2021. Fieldnotes)	*5.c. The Technology Risk Office national review was initiated by us. TRO worked with [vendor's] tech officers to gather information about [vendor's] processes and created the report… Residual level of risk [was found] because of sensitive data stored*

(Continued)

Table 5.
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Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
			outside of KP environment. How do you balance the care provided to patients with the risk? (Implementation meeting, July 2020. Minutes)
6. Clinical staffing and information gaps	*6.a. "Having opportunities to reinforce the information and check back in about what is working and not working, and having some carved-out dedicated time or space to make sure people hear the information and are aware of it, that's challenging in a clinic setting, where people aren't always available at the same time, or may not get a chance to read emails or be part of huddle or whatever."* (LICSW) *6.a.1. "Staff turnover was one of the challenges that we saw. [clinic's name] and [clinic's name] were the two pilot clinics, and in those two clinics we were successful in getting it launched and going, but the thing that impacted care the most was that other positions had social workers that had left their positions and so the social workers that were at [clinic's name] and [clinic's name] ended up having to do a lot of coverage for clinics that had social work gaps in staffing."* (Implementation team, clinical leaders, manager of clinic operations)	*6.b. Clinic A no longer has a LICSW… Loss of a LICSW at Clinic E* (Implementation meeting, Jan. 2022. Fieldnotes) *6.b.1. LICSW presented on reSET and reSET, and one physician was honest and said "I have no idea what this is about."* (Clinic-based practice facilitation meeting, Clinic B, Nov. 2022. Fieldnotes)	*6.c.[LICSW] staffing is good, so far. Expect significant impacts to both LICSWs and [other care team role] as the school closures go on. Looking into options for how they will handle the visits with low staffing.* (Implementation meeting, Mar. 2020. Minutes)
Facilitators			
7. EHR system	*7.a. "I've made [Epic] dot codes, which are like the [Epic] smart phrases to send to people."* (Implementation team, clinical leaders, manager of clinic operations)	*7.b. EHR Integration: Part of the implementation was to get reSET and reSET-O in the providers information systems so it can be at their fingertips, and they can offer it to patients. The team has created a suite of tools using EHR Epic functionality: order set, secure message templates, after visit summary, Population Management, Workbench etc.* (DIGITS Steering Committee meeting, Feb. 2021. Fieldnotes)	*7.c. Purpose/Goal of [Epic] Workbench:* • *Offers functionality to track and monitor patients who are on reSET with an ability to filter the workbench down to clinic and healthcare provider-level information* • *Mental Health Integration LICSWs, the Health Coach, and buprenorphine-waivered prescribers and associated nurses will need this functionality* • *In addition, the Health Coach will monitor their week-to-week health coaching delivered over telephone and secure messaging* • *The workbench would be used to monitor standard care processes of patients using reSET. For instance, it*

(Continued)

Table 5.
(Continued)

Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
			would help flag healthcare providers when patients have missed their appointment and/or have not had a contact for substance use disorder every 30 days. (Reset workbench user requirements. Implementation document. Aug. 2019.)
8. Familiarity with digital tools	*8.a. "I think it's [a] perfect [fit with our approach to SUD]. We use apps, frankly, for a lot of other diagnoses here as well—anxiety/ depression, which oftentimes go along with substance use disorders. So I think it's a very nice complement."* (Implementation team, clinical leaders, manager of clinic operations) *8.a.1. "The social workers do a really great job of saying hey, are you connected to [KPWA app] or [KPWA app] and if not, I'm going to send you instructions on how to do this, or how to set it up for the first time. It's free. So, they're really been doing a great job of selling those other app based services. Prior to that we did [KPWA app] too. [KPWA app] is, I would say, more similar to reSET and reSET-O. It was CBT skills for depression/anxiety, and folks had to have not a prescription, but an access code and we needed to do really more hands on work when we referred somebody to that. So they've had a lot of experience in doing that already."* (Implementation team, clinical leaders, manager of clinic operations)	*8.b. Scripting guidelines are similar to [KPWA digital tools] and familiar to LICSWs…Precedents for reSET are the successes with other digital interventions: [KPWA digital tools].* (reSET-reSET-O training Feb. 2021. Fieldnotes).	*8.c.* Not mentioned in implementation documents
9. Frontline managers' engagement	*9.a.* Not mentioned in key informant interviews.	*9.b. LICSWs management structure changed in late 2020/early 2021, which shifted our initial plans for engaging managers. But [manager] was embarrassed when the LICSWs they manage ask questions about projects and they don't know what's going on. (Managers are expressing desire to be more engaged).*	*9.c. One on one with [LICSW supervisor] to fill her in on DIGITS because she was not a supervisor when we started. We talked about the trial overall and the potential for [LICSW] to complete the training.* *She is supportive and said we could definitely reach out to [LICSW] again and cc her, but that [LICSW] is fairly busy and may just not "bite."* (Clinic-based practice facilitation

(Continued)

Table 5.
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Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
		(Implementation meeting, Jan. 2022. Fieldnotes)	meeting, Clinic D, Nov. 2022. Minutes)
DSF Domain: Intervention *Barriers*			
10. PDTs' demands on clinicians	*10.a. "Yeah, I think providers just have so much on their plates, they're seeing so many different conditions throughout the day, they have a whole list of patients that they're seeing all day long … where I feel like providers have so many demands coming at them at once, that it's hard for them to—I think reSET and reSET-O would be an afterthought to them."* (Implementation team, clinical leaders, manager of clinic operations) *10.a.1. "I just don't have the follow up visits to be able to book people into for the program to run with fidelity. And so that became a challenge as well, to have those check back visits with people."* (LICSW)	*10.b. reSET is different from other [KPWA] apps because it is intended to be used as an adjunct, not a replacement therapy, for patients being evaluated and treated for SUD. It is not a self-serve app, it requires availability of a clinician.* (Meeting with KPWA unit beyond primary care relevant to implementation, Nov. 2022. Fieldnotes)	*10.c. Even if we extended health-coaching level support to all clinics, I am not sure it would address this problem - that "In the moment" support [to patients] for setting up the app would be ideal, and that providers don't have time to support in this way. When the DIGITS trial was designed the hope was that LICSWs could provide in-person, in-the-moment support but with so many visits now occurring virtually and with changes to the LICSWs workflow that is not realistic.* (Internal research team email communication. Oct. 2022)
11. Patient eligibility requirements	*11.a. "If we could maybe roll it out to people who just use alcohol we might have a little bit more people. Because it seems like a lot of people suffer from alcohol use."* (Implementation team, clinical leaders, manager of clinic operations)	*11.b. No new encounters with patients with SUD* (Clinic based practice facilitation meeting, Clinic A. Fieldnotes) *11.b.1. LICSW continues to see patients with AUD only* (Clinic based practice facilitation meeting, Clinic B, Dec. 2023. Fieldnotes) *11.b.2. The LICSW continues to see a lot of patients with AUD only. [The clinician] probes to be sure, but they really are only using alcohol. As a result, [the clinician] has not been able to offer reSET as much as before [the study team clarified eligibility].* (Clinic-based practice facilitation meeting, Clinic G, Oct.2022. Fieldnotes).	*11.c.* (*LICSW) wants to confirm that people with AUD only do not count in this report. (Research team member) "Correct, they do not even show up on the report unless they have something else going on." ·(LICSW): If reSET could be prescribed for people with AUD we would have many more patients to refer to it."* (Clinic-based practice facilitation meeting, Clinic F. Aug. 2022).
12. Challenging intervention features	*12.a. "The feedback I've gotten from patients is that the app is so information heavy that they just get a little bit burned out. Which is sort of like that CBT style, but that people sort of want it to be quicker."* (LICSW)	*12.b. There are issues with the intervention itself: it is not the right approach for everyone, for some people reSET "clicks" but for others it doesn't quite work* (Clinical staff check-in, Apr. 2021. Fieldnotes) *12.b.1.The patient hasn't made it past module 8, [health coach] tweaked [message] a bit to check*	*12.c. [reSET-O] Not as easy to use and offer as apps like [KPWA digital tool] b/c clinicians can't just offer and walk away. We don't have system-wide tech support and health coaching, relying on EHR integration and then having someone immediately help with activation. Without those it requires the clinician to do those extra steps. We could say 'This is an option*

(Continued)

Table 5.
(Continued)

Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
		in about barriers to get a move forward, encouraged 4 modules/ week if possible. No response. Not reading messages/responding. Has 35 days left [in the prescription] as of today. (Health coaching meeting. Oct.2022. Fieldnotes).	*but you would be responsible for ABC to offer it.' [Clinical leader]: "I don't think we can expect a physician to do this. It is not going to happen."* (Implementation meeting, Dec. 2022. Minutes) *12.c.2.The app is not user friendly enough for any of my patients to successfully register. I am no longer recommending it.* (Physician, Oct. 2022. Email communication with the research team)
Facilitators			
13. Clinician and leadership champions	*13.a. "Talking with other clinical partners to get their views and ideas of how something like this might fit into existing work or how an implementation plan for something like this might go is super important….The way we've approached it with reSET and reSET-O has been…working directly with frontline clinical teams but then also involving leaders in the delivery system because I think that can help provide that dual perspective of folks who really know what's going on the ground, but then also leaders who understand the larger level organizational context and who can then potentially be in a position to help troubleshoot as challenges come up. I think having some leadership champions in this work has been really successful for us too."* (Implementation team, clinical leaders, manager of clinic operations) *13.a.1. "[reSET] is something that is evidence based, and that's like Kaiser's emphasis on their approach to substance and alcohol use disorder. That's why it's great, it aligns well."* (LICSW)	*13.b. Clinic leader at [clinic's name] is supportive and engaged with the project.* (Implementation meeting. Fieldnotes)	*13.c. [Clinic director] will share the reSET/reSET-O elevator speech with providers in huddle and in an email update.* (Clinic-based practice facilitation meeting, Clinic E, Feb. 2022. Minutes)
14. Responsive research team	*14.a. "With the rollout of reSET, I felt like I was not only involved with the people from [vendor], but also someone at the research institute who was looking at the data but also trying to understand how it could actually help patients and how to actually get patients to join. So I felt like the rollout of reSET*	*14.b. [What went well?] Quick communication and answers to questions, addressing needs [of frontline clinicians].* Clinical check in, Mar. 2021. Fieldnotes. *14.b.1. "When we don't have meetings, will I get sent who I missed [i.e., the practice facilitation report listing potentially eligible*	*14.c. Elevator Pitch: Suggested language to help you gauge patient interest in app-based treatment:* *"We recently started using an app to help support patients who want to make changes to their substance use. There is no out of pocket costs for you to get or use the app (this is true regardless of insurance coverage). Is*

(Continued)

Table 5.
(Continued)

Barriers and facilitators	Key informant interviews (selected quotes)	Observation fieldnotes (selected excerpts)	Implementation documents (selected excerpts)
	was far superior to other initiatives in primary care." (LICSW)	*patients]? It is always helpful to have a report like that." (LICSW, Clinic based practice facilitation meeting. Clinic* B, Jan. 2023 *Fieldnotes)*	*that something you might be interested in trying? If so, I can connect you to our Integrated Mental Health Specialist who can tell you more about the app and get you set up with it."* (Research team presentation, SUD call with clinicians, Oct. 2022)
15. Beneficial intervention aspects	*15.a. "Right now we do a hybrid mix of face to face care where patients come in the office and virtual care. So for people who really are tech savvy or who do enjoy doing more remote care, or there's logistics challenges where it's a burden to come into an office, I think this is a great option for those patients. So it can really be helpful if we know what type of patient responds best so then we can have it in our arsenal when we come across this type of patient and know it might be more likely to work for them."* (Physician)	*15.b. What helps: Focusing efforts on the patients for whom reSET works* (Clinical staff check-in. Fieldnotes) *15.b.1. "I'm in the midst of working with a patient who is suicidal and she's struggling with alcohol dependence or drugs. none of our other care is that immediate unless I send her to urgent care" (LICSW, Clinical check in. Fieldnotes).*	*15.c. One patient really loves module-based learning and the incentive system and is really liking the app.* (Clinic-based implementation meeting, Clinic A, June 2021. Minutes)

Note. IMH = integrated mental health; LICSW = licensed independent clinical social worker; PDT = prescription digital therapeutic; KPWA = Kaiser Permanente Washington; KP = Kaiser Permanente; EHR = electronic health record; SUD = substance use disorder; AUD = alcohol use disorder; CBT = cognitive behavioral therapy.
[a]Refers to suboxone, buprenorphine, and naloxone.

in piloting, especially those less receptive to technology, to identify constraints before implementation. Benefits of co-design with patients, clinicians, and end-users are documented (Slattery et al., 2020).

Marketing digital therapeutics interventions to clinicians and leaders is essential. We prepared dissemination materials and invited LICSWs to share patient success stories with peers (Parchman et al., 2022) and clinical partners held a medical education session about reSET and reSET-O. This worked in some cases (e.g., with clinicians using our huddle cards). However, a more comprehensive, coordinated communication strategy led by health system leadership may be necessary with novel interventions with multilevel adoption barriers (Aarons et al., 2014).

Relationship building was critical to overcoming implementation obstacles and maintaining partnerships. We forged relationships with informational technologists and delivery system and clinical leaders before DIGITS, maintaining and expanding them to foster frontline managers' engagement. During unavoidable organizational change, involvement of clinical implementation partners from study design to interpreting results will support longstanding and new connections. These efforts are an important investment to ensuring progress and results under difficult circumstances. Ongoing engagement, maintaining relationships, and fostering trust are crucial for implementation (Horton et al., 2018; Rose & Schlichter, 2013).

Sustainment of PDTs ended when the vendor declared bankruptcy and discontinued the apps. Nonetheless, digital interventions continue their promise to address health behaviors and improve patient access and treatment for SUDs and other diseases (Abernethy et al., 2022), although widespread adoption and reach may require contingency planning for sustainability and continuity as digital healthcare grows and evolves. Lessons from DIGITS provide implementation guidance for SUD digital therapeutics and emerging best practices for integrating new interventions into healthcare.

Strengths of our formative evaluation included rigorous, flexible, data collection and analysis to adjust to project and delivery system needs. Multiple data sources and regular member checking validated findings. Limitations included absence of direct patient contact. Patient PDT experiences were from clinicians and the health coach. We did not collect standardized measures of implementation constructs from clinicians (Clinton-McHarg et al., 2016; Fernandez et al., 2018). The COVID-19 pandemic limited our observations; therefore, we did not directly observe clinics randomized to standard implementation

alone and had less information on clinics with health coaching without practice facilitation. We learned about experiences at these clinics through interactions with clinicians during training and department meetings. Vendor bankruptcy precluded identifying facilitators and barriers to sustainment.

Conclusion

The DIGITS formative evaluation offers a unique, close-up look into implementing PDTs for SUD and OUD in primary care. Embedding the evaluation within clinics provided rich context for the challenges of making digital therapeutics a routine care component. It surfaced implementation strengths and lessons to guide researchers and healthcare partners in realizing benefits of digital therapeutics for escalating public health problems.

Availability of Data and Materials

The formative evaluation materials are provided in Additional File 1 in the supplemental material. Additional study materials are available from the last author upon reasonable request. Data used in the current study are not publicly available to protect individual privacy.

Contributions

Palazzo designed and planned the formative evaluation and engaged in all evaluation activities. Dorsey collected and analyzed formative evaluation data and drafted reports. Glass conceptualized and led the study, obtained funding, and approved evaluation activities. All members of the DIGITS study team (Glass,Palazzo, Dorsey, Mogk, Beatty, King, Stefanik-Guizlo, Key, Matson, Shea, Wong, Idu) and clinical partners (Caldeiro, Garza McWethy) enabled data collection and interpretation. Palazzo and Dorsey completed the first manuscript draft. All authors reviewed and approved the final manuscript.

Consent for Publication

Pear Therapeutics was offered the opportunity to review a copy of this manuscript before publication solely to check for disclosures of proprietary content.

Declaration of Conflicting Interests

reSET® and reSET-O® are digital therapeutics for substance use disorder marketed by Pear Therapeutics (US), Inc. that are discussed in this manuscript. During the three-month quality improvement pilot study discussed in this manuscript, Pear Therapeutics (US), Inc. provided digital therapeutic prescriptions at no cost to Kaiser Permanente Washington. Pear Therapeutics (US), Inc. has not provided funding to the authors.

Ethical Approval and Consent to Participate

The Kaiser Permanente Washington Human Subjects Review Office (FWA00002344) determined that the formative evaluation activities are exempt from Institutional Review Board review according to federal regulations, per Category 4 and the clinician interviews are exempt per Category 2. This exempt research was conducted in accordance with the principles of the Belmont Report. All subjects participated voluntarily. Verbal informed consent was obtained from subjects who completed interviews. Staff who attended meetings used for formative evaluation were notified that notes and observations would be used for research purposes. Interviewees received a small compensation. Meeting attendees participated during work hours and did not receive additional compensation.

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Supplemental Material

Supplemental material for this article is available online.

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