Digital treatments for opioids and other substance use disorders (DIGITS) in primary care: A hybrid type-III implementation trial

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STUDY PROTOCOL

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Project Abstract

The DIGITS Trial addresses a critical knowledge gap: How to best implement digital treatments for substance use disorders (SUD) in primary care. We will study implementation of the reSET® and reSET-O® digital therapeutic platforms into primary care to potentially improve care for people with SUD, and as a model for how to sustainably implement digital treatments into real-world healthcare. Digital treatments could extend the reach of SUD therapy to more people and could address a significant barrier to buprenorphine prescribing in primary care: the lack of access to psychosocial treatment. Prior implementation trials found that a digital SUD treatment in primary care was not sustained in part because of workflow and cost burdens so our study design and analytic plans focus on these issues. Our delivery system partners in Kaiser Permanente Washington are committed to collaborating with us to study strategies for implementing reSET and reSET-O throughout the region (approximately 30 primary care clinics in Washington State) to address prior implementation challenges documented in the literature. After piloting in 3 clinics, we will randomize clinics in a 2x2 factorial design to four approaches: (1) "standard implementation," which is an evidence-based implementation strategy previously used by our delivery system partners; (2) "standard implementation with practice facilitation," a clinician-facing implementation strategy; (3) "standard implementation with health coach," a patient-facing implementation strategy using medical assistants to support patient adoption and engagement; and (4) "standard implementation with both." These implementation strategies have some evidence in primary care, but their impact on real-world implementation of a digital treatment has not been evaluated. Specific Aims are to (1) Estimate the effect of clinician-facing (external facilitation) and patient-facing (health coach) implementation strategies in increasing the reach and fidelity of a digital treatment in primary care clinics, and (2) compare the population-level cost-effectiveness of each implementation strategy in increasing reach, fidelity, and abstinence by patients. IMPACT: Researchers and health systems do not know how to reach large numbers of patients with opioid and other SUD. Digital treatments are promising, but health systems lack evidence to guide implementation of digital therapies. This study will estimate and compare the effectiveness of clinician-facing and patient-facing implementation strategies, providing health system leaders with data on how to best implement digital treatments.

Study Phases

The DIGITS Study includes four phases. This protocol outlines the last two phases; piloting procedures are available in a separate document.

1. A 3-month quality improvement (QI) pilot (henceforth "QI Pilot") with the goal of evaluating the implementation and use of reSET/reSET-O in KPWA primary care (2 clinics)
2. A 3-month DIGITS Trial Pilot with the goal of refining the implementation strategies that we will test experimentally in the DIGITS trial and evaluating the feasibility of the research design. The original plan was to carry out the Trial Pilot at 3 clinics. However, we reduced this to the same two clinics as the QI pilot due to LICSW staff departures.
3. A 12-month implementation trial, where implementation strategies are randomized with a factorial design (30 clinics)
4. We planned to complete a 12-month sustainment period, where research funding and support for implementation is scaled back to study sustainment and institutionalization of reSET/reSET-

O. However, the digital treatment vendor filed for bankruptcy early in the sustainment period, so this goal was not accomplished.

Study Background

Implementation context: Kaiser Permanente Washington (KPWA) delivery system

Partnership history. Our trial builds on a partnership of researchers at KPWA Health Research Institute and KPWA delivery system leaders. The partnership solidified in 2015 during integration of behavioral health care in primary care. In collaboration with researchers, KPWA leaders implemented care for cannabis, other drugs, and depression in primary care. Several other studies have followed, including two projects led by the PI to study the design of workflows for offering digital therapeutics in primary care.

General overview of KPWA. KPWA is an integrated health coverage and care system that serves a population of privately insured patients as well as those insured by Medicaid and Medicare. KPWA provides care in urban, rural, and suburban communities. Patient populations of the primary care clinics vary. Approximately 340,000 unique patients visit these clinics annually. *Current care for SUD at KPWA.* Approximately 90% of KPWA primary care patients are screened annually for alcohol, cannabis, and other drug use. Clinics employ licensed independent social workers (LICSWs) who are embedded in primary care teams as mental health and SUD specialists. Many clinics have primary care providers who are buprenorphine prescribers. While many healthcare services are internalized, specialist addiction treatment services, or "rehab programs", are provided through an external contracted care network.

Beginning in May 2020, KPWA began offering a new web and smartphone-based app to all members as a health plan benefit. This app is designed for the management of multiple health behaviors and includes several modules for alcohol and drug use. Since 2017, KPWA has offered another digital treatment for depression to all patients.

DIGITS Trial Summary Overview

The DIGITS Trial will:
(1) conduct a 2x2 factorial trial randomizing KPWA primary care clinics to four implementation approaches for digital treatments in primary care: (a) standard implementation, an evidence-based implementation strategy developed by our delivery system partners to implement a digital depression treatment; (b) standard with practice facilitation, adding a clinician-facing implementation strategy; (c) standard with health coaching, adding a patient-facing implementation strategy to support reSET/reSET-O delivery, and (d) standard with both, adding both the clinician-facing and patient-facing implementation strategies. We will assess impact on two primary implementation outcomes: *reach* and *fidelity*. A secondary *effectiveness* outcome is *substance use*. We will formatively evaluate implementation and use our Steering Committee to promote *sustainability*. We will monitor sustainability as we transfer responsibility of implementation to the delivery system and use mixed methods to evaluate the impact of the intervention, setting, and ecological system on sustainability.
(2) We will compare the population-level cost-effectiveness of each approach in increasing reach, fidelity, and abstinence.

Specific Aims

1. Estimate the effect of clinician-facing (practice facilitation) and patient-facing (health coaching) implementation strategies in increasing the reach and fidelity of a digital therapeutic for SUD in primary care clinics
2. Compare the population-level cost-effectiveness of each implementation strategy in increasing reach, fidelity, and abstinence by patients.

Actual Timeline (overlapping timelines for Pilot and Trial activities are shown)

DIGITS Pilot Activities				
2021			2022	2023
DIGITS QI Pilot Feb - May 2021	**DIGITS Trial Pilot** May - Aug 2021	Randomization Prep Aug - Dec 2021	DIGITS Trial Active Implementation Dec 2021 - Jan 2023	DIGITS Trial Sustainment
Standard Implementation Only (3 mos)	Clinic 1: Standard Implementation + Health Coaching (5/6/21 - 9/8/22)			Pilot Sustainment
Standard Implementation Only (3 mos)	Clinic 2: Standard Implementation + Health Coaching + Practice Faciliation (5/6/21 - 9/8/22)			Pilot Sustainment

DIGITS Trial Activities				
2021			2022	2023
QI Pilot Feb - May 2021	Trial Pilot May - Aug 2021	**Randomization Prep** Aug - Dec 2021	**DIGITS Trial Active Implementation** Dec 2021- Jan 2023	**DIGITS Trial Sustainment** Dec 2022 - Apr 2023
			Rand Group A Clinics: Dec 2021 - Dec 2022	Group A: Dec 2022 - Apr 2023
			Rand Group B Clinics: Jan 2022 - Jan 2023	Group B: Jan 2023 - Apr 2023
			Rand Group C Clinics: Feb 2022 - Jan 2023	Group C: Feb 2023 - Apr 2023
			Clinic D: Feb 2022 - Feb 2023	Clinic D: Feb 2023 - Apr 2023
			Group E: July 2022 - Feb 2023	Group E: Feb 2023 - Apr 2023

Implementation Strategies

Standard Implementation

The research team/delivery system partnership will oversee all implementation strategies, with all clinics receiving standard implementation of reSET/reSET-O led by the delivery system. Our delivery system partners developed standard implementation, which combines several efficacious implementation strategies. First, delivery system leaders will provide 2.5 total hours of mandated training to all LICSWs, by videoconference over two days. Training will cover: current standard of care for SUD and use of health apps, research evidence for reSET/reSET-O, a reSET/reSET-O demo by Pear Therapeutics, description of the implementation toolkit and clinical procedures for using reSET/reSET-O in Primary Care (PC) (35 mins), and general Q&A (10 mins).

After training, LICSWs will receive an implementation toolkit with (1) a job aid with major steps of reSET/reSET-O delivery with the "what", "how", and "why" of each step; (2) patient pamphlets to promote reSET/reSET-O and describe steps for getting started; (3) scripts to help clinicians introduce and enroll patients in reSET/reSET-O, and set expectations for use; and (4) EHR tools including documentation/charting templates and "after-visit-summaries" that reinforce instructions for getting started, summarize the rationale for reSET/reSET-O, describe risks/benefits, and communicate privacy information about reSET/reSET-O (e.g., HIPAA compliance, third-party data hosting). These toolkit items were used successfully for the previous implementation of a digital depression treatment and will

require minor adaptations for reSET/reSET-O. New for this study is (5) an EHR order set so LICSWs can easily access a standing reSET/reSET-O prescription.

Delivery system leaders offer continued support to LICSWs. Leaders review monthly, four-page, text-based performance reports of reSET/reSET-O usage data to help them decide whether to offer 1:1 supervision visits with select clinicians who want additional assistance or who fail to initiate patients in reSET/reSET-O.

Table 2. Clinical Procedures for Using reSET/reSET-O in PC

Initiating a patient on reSET/reSET-O	Support for use of reSET/reSET-O
• Offer via shared decision making (a standard clinical skill) • Enter an electronic order for reSET/reSET-O in the EHR • Provide an enrollment code and patient instructions • Schedule 3 monthly visits during 12-week reSET/reSET-O prescription	• Encourage 4 modules per week • Monitor use of reSET/reSET-O with the clinician dashboard • Identify barriers to using reSET/reSET-O • Review content learned • Encourage practice of skills learned • Consolidate what patients learn and discuss next steps

Practice Facilitation (Clinician-Facing)

Clinics randomized to receive practice facilitation will be offered 12 sessions with a trained facilitator. Practice Facilitation is a clinician-facing implementation strategy designed to overcome workflow challenges by supporting clinicians in tailoring implementation to their local context. It is both a process and a set of strategies designed to build relationships, identify and overcome barriers, and help the clinical team implement the innovation in their clinic. The first facilitation session will take place within the first month after randomization); all visits will be offered by video- or tele-conference.

The facilitators will support the LICSWs in these clinics using four intervention strategies in the context of a supportive relationship:

1. **Education** to augment standard implementation training. The focus of education will be tailored to the needs identified, and may include evidence for the digital treatment, enhanced training on the procedures, or how to communicate with team members about this option for care.
2. **Audit and feedback** strategies to prompt change in practice based on measurable performance goals, and clinic-specific, normed graphical reporting with actionable data and supporting text. The facilitator will share an anonymized report ranking each clinician's performance on reach and fidelity in comparison to others.
3. **Plan-Do-Study-Act (PDSA) cycles**: The facilitator and LICSWs will collaboratively review audit and feedback data, develop an improvement plan for the LICSWs to implement, study the results, and adjust activities for continuous improvement.
4. **Engage others** in change: The facilitator will help the LICSWs identify and engage other clinic stakeholders for the implementation effort, such as leaders, primary care providers, other clinic staff.

Health Coaching (Patient-Facing)

Health coaching is assigned at the clinic level, but the intervention is delivered directly to patients who are enrolled in reSET/reSET-O. The health coach will be responsible for cadenced telephone calls and/or

secure messages to reinforce use of the reSET/reSET-O, encourage skill practice, monitor reSET/reSET-O dashboard, conduct outreach to patients not engaging in reSET/reSET-O, and to monitor patient adherence to visits with LICSWs and encourage patients to see their LICSW. This role is to support people in their use of this digital intervention.

Our trial will employ credentialed medical assistants (MAs) as health coaches (other trials have used a variety of professional roles, credentialed or not). The health coach will be trained in the use of an intervention manual that will act to structure and guide their patient contacts. There are two main sections to the health coach intervention manual; a structured breakdown of support sessions (phone and secure messaging) and conversation guides based on the core lesson within reSET/reSET-O a patient is working on.

At the end of each support session, the manual has a stepped process for handling concerns that may come up during the session (safety, substance use, technical).

The health coach will maintain contact with patients (via telephone and/or secure messaging in the medical record) for the length of the 12-week prescription.

Table 3: Comparison of Standard Implementation to Health Coaching and Practice Facilitation

Standard Implementation (all clinics)	**Standard Implementation plus Facilitation (50% of clinics)**	**Standard Implementation plus Health Coaching (50% of clinics)**
reSET/reSET-O Implementation Toolkit • Pamphlet for patients • Scripting for offering the digital treatment • Step-by-step instructions for offering reSET/reSET-O • Step-by-step instructions for ongoing management of patients prescribed reSET/reSET-O • Huddle cards **Training** • 2.5-hour LICSW training. 3 virtual trainings offered. Video recorded trainings available for those who missed the live trainings. • Evidence for reSET/reSET-O • Demo of reSET/reSET-O • Introduction to procedures and implementation toolkit for reSET • Enrollment via reSET/reSET-O dashboard **Ongoing support** • Performance report provided to LICSW leadership	**Facilitation Strategies** 1. Education: augment standard implementation training (evidence, procedures for delivering the treatment) and how to market to patients and primary care team. 2. Audit and feedback: prompts to change practice based on measurable performance goals, clinic-specific, normed graphical report with actionable data and supporting text. This feedback will be provided monthly to the LICSWs at clinics receiving practice facilitation. Will provide opportunity for self-assessment, ranking individual performance against either aggregate performance at the clinic level or anonymously. 3. Plan-Do-Study-Act cycles: The facilitator and LICSW will review audit and feedback data, make an improvement plan for the LICSW to implement, and study the results	**Health Coaching** • The health coaching is an augment to treatment provided by the LICSW. The goal is to encourage and support patient engagement in their use of the reSET/reSET-O digital intervention (rather than to support them in dealing with their substance use). **Structure** • Health coaching is a patient-facing centralized outreach service, located in and supervised by Mental Health and Wellness Services • Delivered remotely (via telephone or secure messages in the Electronic Medical Record). • Structured (weekly or monthly) • Scripts and templates for outreach, plus “conversation

• Discuss reSET/reSET-O implementation in staff meetings • Delivery-system leaders offer 1:1 help to clinicians as needed **Epic (Electronic Health Record) Integration** • Electronic standing order • Templates for documentation and communication with patients about the program • **Reporting Workbench**: population management tool. Lists all the patients with active reSET/reSET-O prescriptions. Primarily used to identify and prompt outreach to patients due/overdue for required 30-day SUD treatment visits. **Performance Feedback Report** • Referrals, enrollments by month and week • Visits by month • Patient-reported outcome data (baseline/most recent) • Detailed aggregate and individual clinician activity **Basic Technical Support** • As needed (passive) technical assistance if LICSWs request it • Patients and clinicians will have phone # to call Pear patient support center for technical support if needed	and adjust activities for continuous improvement. 4. <u>Engage others in change</u>: The facilitator will help the LICSW identify and engage other clinic stakeholders for the implementation effort, such as leaders, primary care providers, other clinic staff, and the health coach. **Initial virtual visit with randomized clinics - Month 1 of implementation** • Relationship-building • Meet with stakeholders • Education beyond initial standard implementation training • Needs assessment • Identify barriers/facilitators • Site-specific adaptations (post visit planning item, not likely to adapt at that 1st visit) • Introduce/discuss audit/feedback report **Month 2-11 virtual meetings** • Ongoing rapport • Feedback: review audit/feedback report • Identify barriers/facilitators • PDSA improvement cycles: work collectively with LICSWs to develop action plans and evaluate those plans • Enhanced technical support: Assess for technical barriers, problem-solve using available resources and practice facilitation knowledge about reSET/reSET-O.	guide" to support specific reSET/reSET-O modules. **Health Coach activities include** • Monitoring the reSET/reSET-O dashboard and reaching out to patients not engaging in reSET/reSET-O modules. • Reinforce use of the reSET/reSET-O digital intervention. • Encourage skill practice • Monitor adherence to required follow-up and encourage patients to follow-up with their LICSW as recommended.

Combined: Practice Facilitation and Health Coaching

Approximately 25% of Trial clinics will be randomized to receive both practice facilitation and health coaching. This strategy does not incorporate any unique activities, but some components of the two strategies may interact (e.g., the practice facilitator may involve the health coach in facilitation meetings). Combined clinics received components from all three columns of Table 3 above.

Randomization Assignment Procedures

A factorial design (Table 4) will allow us to estimate the main effect of the implementation strategies, compare their effectiveness, and evaluate their interactions. Cluster randomization will be at the clinic level because the implementation approaches target clinics. Details about randomization (e.g., stratification, concealment) are contained in the trial's Statistical Analysis Plan.

Table 4: Random Assignment of PC Clinics to 4 Implementation Approaches (2x2 Factorial Design)

Implementation Strategy	**Approach 1** Standard Only	**Approach 2** Standard + Practice Facilitation	**Approach 3** Standard + Health Coach	**Approach 4** Standard + Both
Standard	YES	YES	YES	YES
Practice Facilitation	NO	YES	NO	YES
Health Coach	NO	NO	YES	YES

Quantitative Evaluation:
The Statistical Analysis Plan is available as a separate document.

Formative Evaluation of Implementation
The purpose of the formative evaluation is to monitor and assess the implementation of the reSET and reSET-O digital treatment for SUD in primary care clinics across Kaiser Permanente Washington. The formative evaluation includes qualitative assessments documented elsewhere.

Economic Evaluation
Aim 2 of the DIGITS Trial was to examine the population-level cost-effectiveness of each implementation strategy in increasing reach, fidelity, and abstinence by patients. Because of the low numbers of patients reached during the trial period we are instead reporting out on implementation, intervention, and operations costs, and we will not do a cost effectiveness analysis.

The economic analysis will draw on several data sources: (1) KPWA's Epic® Clarity® databases for EHR data, (2) KPWA's insurance claims databases, (3) KPWA's Cost Management Database, (4) Pear Therapeutics reSET databases, (5) study records of implementation activities, and (6) public use data on average salaries by occupation. Access to both EHR and claims databases allows us to capture healthcare within and outside the KPWA delivery system. EHR and claims databases log visit characteristics such as patient, provider type, visit type, visit department, procedures, ICD code sets, lab, pharmacy, enrollment, and patient sociodemographic data. The EHR databases specifically include PC clinic, clinician, prescriptions, and screening and assessment results. Claims databases cover contracted care such as emergency, hospital, and specialty addiction treatment visits. The Cost Management Database captures the cost of producing all services used by members incurred by KPWA.

Implementation Costs are defined as the monetary value of time and resources needed to roll out reSET/reSET-O to patients. We will prospectively collect data during piloting, implementation, and sustainment. To derive implementation costs, we will use an activity-based approach to calculate the opportunity cost of time devoted to activities related to reSET/reSET-O implementation. This approach uses microcosting, applying unit costs to the amount of time spent by multiplying the number of hours devoted to activities by the estimated wage rate of a participant. Implementation costs also include the

direct cost of resources to implement reSET/reSET-O (e.g., printing cost of materials to support adoption). We will sum costs associated with activities and resources needed to execute external facilitation, patient coach, and standard implementation strategies, respectively.

Implementation activities will be collected for all participants involved in implementation including delivery system leaders, practice facilitators, health coaches, LICSWs and other personnel involved at the implementation sites. Activities by members of the delivery system will include development of training materials, construction of implementation toolkits, preparation of performance feedback and training sessions, meetings, conference calls, emails, and 1:1 supervision visits. Activities by health coaches will include training, providing phone calls/secure messages to patients and tracking clinician dashboards, conducting patient outreach, monitoring patient visits and communicating with LICSWs.

Using previously employed methods, designated implementation staff will track the date and duration of each implementation activity, the mode of communication (in person, videoconference, phone), and names of individuals involved using structured Excel spreadsheets used in prior research. To reduce documentation burden, we will create a reporting hierarchy so that only one person needs to document activities when multiple individuals are involved. For meetings, duration will be divided into preparation time, travel time, and meeting time. In addition, study staff will collect completed spreadsheets from delivery system leaders following bi-weekly operations meetings and reviewing research specialist notes of organized activities (e.g., initial training).

To estimate time needed for LICSWs to conduct implementation activities outside of meetings (e.g. implementation toolkit use, interpreting performance reports), LICSWs across the KPWA system will be randomized to discrete data collection periods. Specifically, we will survey LICSWs throughout the implementation phase by contacting each LICSW during a random week in the study for a short email-survey followed by a Teams message when necessary to reduce non-response.

To monetize time on implementation activities, we will multiply hours of participation by opportunity cost of time, measured as participant's estimate hourly wage rates. We will inflation-adjust all costs to 2020 constant dollars using the Personal Health Care Index. To calculate hourly wages for all participating staff, we will use aggregate data from the Bureau of Labor Statistics on average wages by area and occupation. In addition to the time spent traveling, we will include direct costs of travel for implementation activities.

Implementation costs will also include the direct costs of materials and resources required to support implementation of reSET/reSET-O. Examples include the printing cost of patient pamphlets, guides and training materials. These direct costs will be ascertained from study budget records.

Operating Costs. Operating costs are dollars spent on regular operation of reSET/reSET-O incurred by the delivery system and patients. Costs include infrastructure/technical resources and staff support such as IT support, reSET/reSET-O fees, and capital equipment.

Direct Intervention Costs. Patient receipt of reSET/reSET-O is expected to affect clinical service costs. Intervention costs include encounters with LICSWs related to the initiation and continued use of reSET/reSET-O. We will identify patient visits with LICSWs during the 12-week reSET/reSET-O prescription period, using EHR data. We will count encounters on the day of and in 12-weeks after the reSET-specific "after-visit-summary" is entered.

Using patient-level encounter records, we will use a KPWA internal cost model that measures actual production costs incurred by KPWA in providing care to members. KPWA's automated information systems capture all services used by members within its integrated practice and contract providers for whom claims are submitted. To determine and allocate costs, KPWA's Decision Information Support Center (DISC) has a model that captures and allocates utilization and costs from the health plan's general ledger for all services. DISC enables standardization of costing data across KPWA and allows for determination of costs for specific encounters and aggregation of costs for individuals over time. All encounter-level costs are identified as a direct care cost (e.g., nurse salaries) or an overhead cost (e.g. facilities). Costs excluded from allocation include those not directly related to delivering health services (e.g., insurance) and patient out-of-pocket costs. Cost data are available to researchers through KPWA Cost Management Database and have been used previously. *Other Indirect Health Care Costs.* We will measure potential change in indirect health care costs attributable to reSET/reSET-O by defining total health care costs at the patient level as the sum of costs for all outpatient encounters (including PC, specialty mental health, specialty medical, ancillary) and dispensed medications expected in this population. We will calculate a patient-level measure of SUD-specific costs (screening, assessment, brief interventions, visits with a SUD diagnosis, SUD medications). We will measure costs of care delivered by KPWA, contracted care, and out-of-network providers recorded in insurance claims data.

Limitations and Strengths

We considered providing smartphones with data plans to ensure that all patients could benefit from the intervention even if they did not own a smartphone (77% of US adults own a smartphone—most but not all). But this would significantly increase costs and therefore could limit adoption and sustainability, as seen in a previous study,[4] and could limit generalizability. Our secondary abstinence outcome will be available only for some patients, because our measures come from EHR data. This is because we based the trial on pragmatic principles which offer an efficient design and avoids a biased sample limited to patients who consent to research.[5] We also considered conducting this study in another health system, but strengths of this system are that we have high universal screening rates for alcohol and drugs (most systems have alcohol only), and we can also capture patient data from inside and outside the delivery system (EHR and claims). This provides a natural laboratory to study the implementation of a digital SUD treatment.

Safety Parameters

IRB Monitoring

The KPWA IRB reviewed and approved all research activities before the beginning of Active Implementation. The IRB will maintain ongoing oversight of the risks and benefits of the study, including annual review of the study and prior review and approval of any changes to the study protocol and materials.

Data and Safety Monitoring

Refer to separate DSMP file dated 08/30/2021

Adverse Event (AE) and Serious Adverse Events (SAE) and Reporting

Refer to IRB files: 1556080, 1743121 and 1794767 for information about how these events will be recorded and reported.

Unanticipated Problems and Reporting

Refer to IRB files: 1556080, 1743121 and 1794767 for information about how these events will be recorded and reported.

Ethics and Protection of Human Subjects

Refer to IRB files: 1556080, 1743121 and 1794767 for information about ethics and protection of human subjects.

Potential Risks and Benefits

Refer to IRB files: 1556080, 1743121 and 1794767 for information about potential risks and benefits.

Inclusion of Populations

Refer to PHS Human Subjects and Clinical Trials Information sections of grant application.

Protocol Violations and Deviations

Refer to IRB files: 1556080, 1743121 and 1794767 for information about how protocol violations and deviations will be recorded.

IRBNet ID	Title
1556080	**DIGITS Secondary Data Analysis**
1743121	**DIGITS Primary Data Collection for Economic Analysis of Implementation Strategies and Time**
1794767	**DIGITS Trial Implementation**

Overview of Main Protocol Changes

Topic	Date	Details of Change
Changes to provision of reSET/O	4/28/2022	Non-social work clinicians began offering reSET and reSET-O.
Changes to provision of reSET/O	7/1/2022	Began allowing reSET and reSET-O prescriptions without requiring follow-up visits.
Changes to provision of reSET/O	8/9/2022	Centralized the administrative tasks of prescribing reSET/reSET-O by allowing clinicians to hand-off the responsibility of creating patient accounts to an administrator.
Economic analysis plans	February 2023	Removed plans for population level cost effectiveness analysis due to the low number of patients reached during the Trial period.
Early end to sustainment phase	4/7/2023	Removed plans for analysis of sustainment phase. Due to the bankruptcy of Pear Therapeutics, sustainment ended early, and we could not study this phase.

Key Roles and Contact Information

Study Team:
Refer to Team Directory located in the KPWHRI G drive: *G:\CTRHS\DIGITS\ADMIN\DIGITS Team Directory*

Steering Committee:
Refer to Steering Committee tab in Team Directory located in the KPWHRI G drive: *G:\CTRHS\DIGITS\ADMIN\DIGITS Team Directory*

Appendix A:

DIGITS Data Safety Monitory Plan is available as a separate file in the KPWHRI study G drive Protocol folder. (DIGITS_DSMP_2021-08-30)

Appendix B:

DIGITS Trial Formative Evaluation Plan is available as a separate file in the KPWHRI study G drive Protocol folder. (Formative evaluation plan_5.23.2022)

References

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