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Increasing timely access to evidence-based treatment for opioid use disorder using novel digital health and system dynamics modelling approaches: a study protocol

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ABSTRACT

Introduction Despite the continued burden of opioid overdose in communities in the USA, effective treatments for opioid use disorder (OUD), such as medication for opioid use disorder (MOUD), remain underused. Motivational interviewing techniques and linkage to MOUD via digital health are innovative practices developed to overcome persistent barriers to accessing MOUD treatment. These practices are merged in a comprehensive digital health platform, *RecoveryPad* (developed by the Center for Progressive Recovery). Our study, 'Using System Dynamics Modeling to Foster Real-time Connections to Care' (NIH Award #: 1R61DA057675-01), is a pilot to assess the feasibility and behaviour change potential of *RecoveryPad* for our target audience of people experiencing OUD.

Methods and analysis This study will recruit 40 participants in Connecticut and New York through online platforms, such as social media and digital advertising, and direct access via quick-response (QR) codes distributed by local community partners. Eligibility assessment and enrolment will be conducted virtually. Individuals reporting symptoms indicating moderate to severe OUD who are at least 18 years of age are eligible for the study, excluding those who are currently receiving MOUD, pregnant or incarcerated. Enrolled participants will interact with an automated chatbot, live recovery coaches and, if desired, be referred to a telehealth MOUD provider via the *RecoveryPad* platform. Participants will have access to the platform for 30 days and will be asked to complete brief surveys to assess MOUD engagement and secondary outcomes at 30 and 90 days. Additionally, system dynamics (SD) models will be developed at the individual level to simulate participant interactions with *RecoveryPad*, and at the community level to improve understanding of the systems affecting OUD and MOUD access.

Ethics and dissemination This project received approval from the Yale University Human Investigation Committee in 2024 (HIC # 2000034414). All participants will complete an electronic consent form with detailed study information and release of information to obtain data related to MOUD appointment attendance. Findings and conclusions from this pilot will be disseminated via peer-reviewed publication, advisory board meetings and meetings with community partners.

Trial registration number NCT05832879.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This pilot study will assess the feasibility of the digital health intervention *RecoveryPad* to link participants to initial appointments for medications for opioid use disorder (MOUD) to inform a larger randomised controlled clinical trial.
⇒ Participants will be recruited from diverse settings in the states of Connecticut and New York, collaboratively with the involvement of multiple local and institutional partners.
⇒ Results from this pilot will be compared with a historical control sample of statistically matched individuals from a non-telehealth MOUD intervention based in the Yale New Haven Health System, potentially limiting the generalisability of study findings.
⇒ Qualitative and quantitative outcome data from this pilot will be analysed using system dynamics modelling to better understand participants' motivations to seek MOUD and identify community-level factors affecting individuals who use opioids.
⇒ No evaluation of the effectiveness of *RecoveryPad* in comparison with treatment as usual will occur during the pilot phase of this study, as all participants will be assigned the intervention with no randomisation.

INTRODUCTION

Fatal overdose remains a significant preventable cause of death in the USA, despite substantial decreases in opioid overdose deaths reported in the past 18 months.[1 2] In efforts to encourage further reductions, federal and state agencies and communities

have taken steps to increase access to medication for opioid use disorder (MOUD). For example, many opioid treatment programmes that dispense methadone have adopted the guidelines from the Substance Abuse and Mental Health Service Administration to provide patients with expanded access to expedient take-home doses.[3 4] Additionally, numerous emergency departments, clinics and syringe services programmes in the Northeast have developed programmes to initiate treatment with sublingual or extended-release buprenorphine injectables.[5–8] Despite evidence that exposure to MOUD reduces the incidence of opioid overdose death compared with non-medication-based treatment,[9 10] enrolment data from Connecticut treatment facilities indicated a less than 5% increase in clients accessing any MOUD from 2017 to 2021.[11]

Digital health approaches, including telehealth and telemedicine,[12] have been used to facilitate linkage to MOUD and reduce gaps in treatment availability.[13–17] These approaches have been employed in community settings to overcome barriers to access, allowing for connection to treatment with minimal disruption to social and professional responsibilities.[18–20] MOUD delivered via digital health has been shown to be equally effective in treatment initiation and retention as traditional in-person approaches.[21–23] Traditional in-person practices that connect patients to MOUD, such as screening, brief intervention, referral to treatment[17 24] and motivational interviewing, are similarly key practices for effective digital health delivery of MOUD.[25] An additional benefit of digital health may be reduced stigma, a potential barrier to treatment when people with OUD seek in-person treatment.[26 27]

Policy changes that suspended requirements for an in-person medical evaluation for buprenorphine have prompted investigators to explore new approaches to linking people who use opioids to MOUD.[28–30] Digital health interventions may assist in expanding treatment, but the benefits may be fewer for specific patient subpopulations, including safety-net populations, incarcerated and formerly incarcerated individuals, and those with limited technological access or acumen.[31] Nevertheless, there is a need for further investigation into the feasibility and effectiveness of MOUD via digital health for specific patient populations.[27] Linkage to MOUD through novel digital health platforms may offer an innovative approach to improving access to care and supporting reduction and/or discontinuation of opioid use.

The digital health treatment platform, *RecoveryPad* (developed by the Center for Progressive Recovery), uses a novel modality and robust evidence-based approaches to promote behaviour change, including MOUD treatment initiation, through interaction with both human recovery coaches and an AI-powered chatbot. Participants can access *RecoveryPad* according to their own schedules, creating a low-barrier environment for individuals to find support for and initiate MOUD. As a novel, on-demand, treatment platform, it can be integrated into existing programmes and practices in a variety of community settings, including those that interface with populations that may not engage frequently with health systems or are reluctant to seek in-person help.

Rationale and aims

This pilot study will test the feasibility of *RecoveryPad* to link eligible participants to initiate MOUD while collecting data to inform ongoing system dynamics (SD) modelling. *RecoveryPad* will be deployed in the states of New York and Connecticut to provide a digital route for people with opioid use disorder (OUD) to access MOUD treatment providers for telehealth initiation of MOUD, or in-person treatment if preferred. By conducting this pilot, we will obtain preliminary outcome data to evaluate the benefits and limitations of deploying *RecoveryPad* to motivate and link participants to MOUD treatment. Data from this pilot phase will inform the design and implementation of a larger randomised controlled trial (RCT) phase of the study and will also be incorporated into SD models that our research team is developing to improve the deployment of *RecoveryPad*. To accomplish this, we will complete the following aims outlined in figure 1.

Outcome data from participating individuals (n=40) will be analysed using SD models developed to assess individual-level interactions with *RecoveryPad*. These models will assist in identifying key factors affecting participant engagement with *RecoveryPad*, such as measures of participants' motivation to engage with MOUD over time. By incorporating intervention data from *RecoveryPad* into our SD models efficiently, we can optimise delivery of the intervention by using findings from the SD model to employ an individualised approach that encourages engagement with *RecoveryPad* and better motivates participants to initiate MOUD treatment. This process will also assist us in effectively scaling the intervention to a larger population during the RCT phase of the study.

METHODS AND ANALYSIS

This is a collaborative study in which enrolment will occur through contact with research team members at Yale University; and protected health information (PHI) resulting from study participation will be collected by the *RecoveryPad* operator, the Center for Progressive Recovery, and stored within a secure, password-protected, cloud-based server. Data will be shared in a deidentified form with research team members at Yale and the City University of New York for analysis. A multistep virtual recruitment and enrolment scheme was developed to allow for engagement with *RecoveryPad* remotely and facilitate linkage to MOUD virtually via the digital health platform. To comply with Yale University IRB requirements, consent and PHI related to study participation will be obtained through encrypted data collection platforms. The protocol for this study was approved by Yale IRB on 7 March 2024.

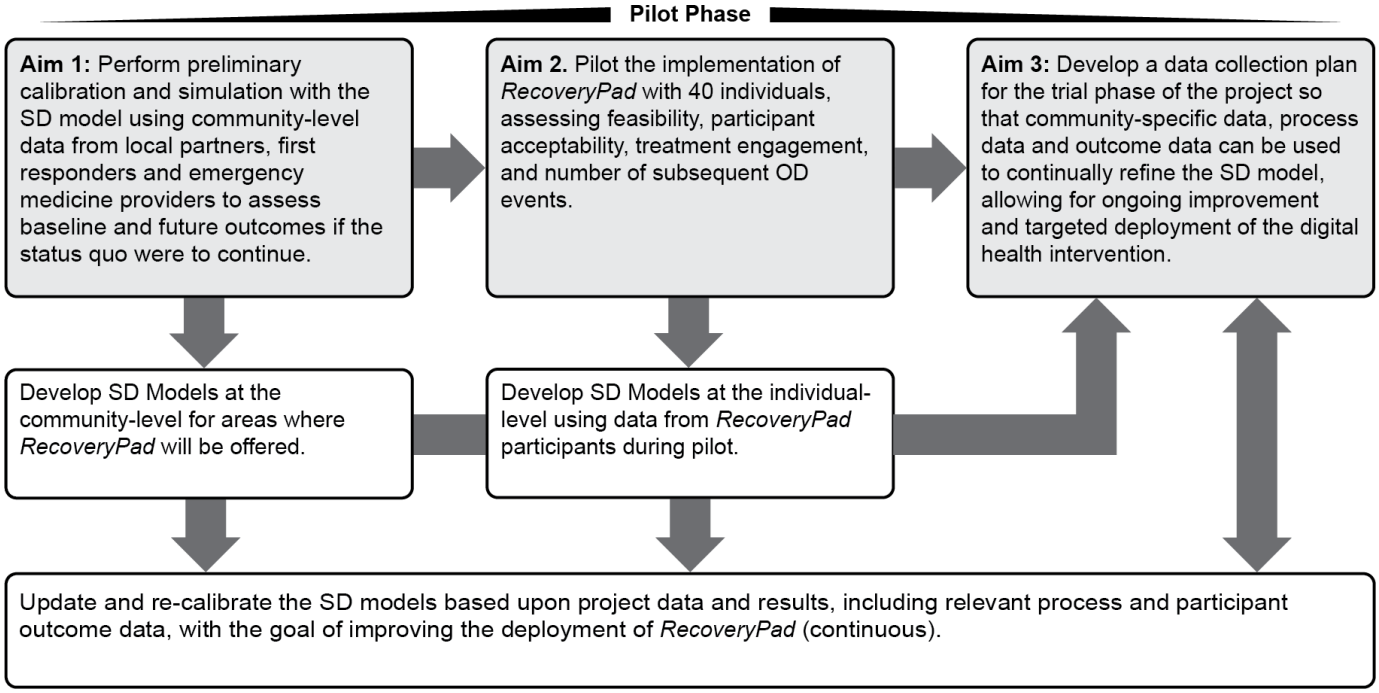

Figure 1 Overview of the specific aims of the pilot phase and supporting SD modelling activities. Arrows represent the flow of data and information between different stages of the project. The protocol described in this report focuses on implementing Aim 2 during the pilot phase and discusses its interrelationship with the system dynamics modelling. OD, overdose; SD, system dynamics.

Participant recruitment

A sample of Connecticut and New York residents (n=40) who have been assessed via an eligibility screener to meet study criteria will be recruited through multiple channels, including through community partner sites sharing information about the study in person, and through online sources such as social media and digital advertising. Recruitment will use QR codes and hyperlinks customised to specific recruitment locations and online sources (eg, social media advertisement) which will link a prospective participant to an online eligibility screener hosted on a secure web portal. All participants must fully complete the self-guided screener to assess study criteria including current OUD symptoms,[32] enrolment in MOUD treatment, city of residence and other status. A prospective participant may also request a guided enrolment through the web portal, in which case a member of the research team will reach out to assist them. Additionally, any inconsistent or missing information identified by the research team during assessment must be clarified or resolved via phone call or email before the prospective participant can proceed with enrolment. Ensuring that the participant has provided accurate information and meets all study criteria is key to our recruitment and enrolment process due to the nature of our digital intervention and the need to prevent multiple enrolments by a single person or use of artificially generated responses. Once the screener is complete, participants will be notified of their eligibility and, if eligible, asked to share contact information, indicate the desired contact method (eg, phone or email), and give consent to be contacted by the research team. If a person is deemed ineligible via the screener, they will be offered a list of treatment options and services in the area, and their data will be deleted from the web portal. All enrolment attempts will be reviewed daily.

If eligibility criteria are confirmed, and the participant has consented to being contacted by the research team, participants will begin the enrolment process by first completing an electronic consent (eConsent) form which provides further information on study activities, duration and participation requirements. Participants are prompted by the research team to carefully review the full requirements before signing the eConsent. Additionally, a release of information (ROI) form will also be obtained from the participant to allow for limited PHI related to appointment attendance for MOUD treatment to be shared with *RecoveryPad* staff, and subsequently with the research team once deidentified. All documents and forms will be sent electronically via hyperlink to a participant's email and completed in Research Electronic Data Capture (REDCap), a secure, web-based software platform designed to support data capture for research studies.[33 34] All signed forms will be reviewed and confirmed by the research team, and all records of the consenting and release of information process will be stored on REDCap. Should a participant need assistance with REDCap, research assistants are trained to explain the study by phone and assist the participant with signing the consent. After eConsent and ROI are obtained, the participant will be considered enrolled and will be contacted by *RecoveryPad* staff to proceed with the study. The study does not require in-person visits, as all activities

are conducted online. In the exceptional circumstance that a participant needs in-person assistance (eg, help obtaining a cellphone, setting up an email), a member of the research team will arrange to meet in person to provide necessary support.

Eligibility criteria

Participants must be 18 years or older; speak, read and write in English; indicate DSM-5 criteria for moderate or severe OUD[32]; reside in Connecticut or New York; and have an internet-accessible device and an email address or be willing to obtain them. Participants are excluded if they are currently receiving MOUD treatment (including methadone and buprenorphine); pregnant; self-reporting risk of suicide; or on parole or incarcerated at the time of enrolment. Although during initial recruitment, eligible participants were required to have one or more overdose events, this criterion was removed, given that many individuals who are at risk of fatal overdose have not yet experienced a non-fatal overdose or fail to recognise that they have had an overdose event.

Sample selection

As the first phase of a larger proposed study, this pilot seeks to enrol a convenience sample of 40 participants to assess the feasibility of the *RecoveryPad* digital health platform while establishing baseline measures related to engagement and key study outcomes. These measures will guide future recruitment strategies and planned statistical analyses of a second phase of the study, in which 470 participants will be recruited as part of an RCT.

Intervention

RecoveryPad is a novel digital health intervention that uses an adaptation of brief motivational interviewing and other evidence-based practices and provides resources for individuals seeking treatment options for OUD. Participants engage with *RecoveryPad* in two stages: an automated brief negotiation interview (BNI) adapted from previous efforts to use evidence-based practices to promote behaviour change,[5 35] followed by person-to-person texting with trained human recovery coaches. An AI-powered chatbot, which is unique to *RecoveryPad*, will deliver the BNI as the first stage of the intervention, with the goal of increasing patient intention to initiate MOUD through reflective listening and evocation of motivational statements (ie, 'change talk'). Chatbot responses will be informed by best practices as identified by the Center for Progressive Recovery consistent with National Institute on Drug Abuse/National Institutes of Health (NIDA/NIH) guidance.[36] During the BNI, the chatbot will guide the participant through a series of questions focused on the following steps which overlap with the key processes of motivational interviewing: (1) establish rapport with the patient/raise the subject (Engaging); (2) provide feedback (Focusing); (3) enhance motivation (Evoking); and (4) negotiate a plan (Planning).[35]

Once the chatbot-led BNI is completed, the participant can proceed to the second stage of *RecoveryPad*: texting person-to-person with a human recovery coach (synchronously or asynchronously) or conducting video chats or voice calls if preferred by participants according to their schedules. During the second stage of *RecoveryPad*, participants can choose to be connected to a buprenorphine prescribing provider or clinic through a referral or receive information about alternative MOUD services that are accessible to them locally or via telehealth. Data specified in the ROI relating to participant engagement with MOUD providers referred to by *RecoveryPad* will be obtained from the provider. In addition, participants will be asked to complete 30- and 90-day post-enrolment surveys to assess MOUD appointment attendance with any provider, including those the participant may choose to use outside of the *RecoveryPad* platform (should the participant choose to use such a provider) and any occurrence of overdose events. Surveys will be conducted via phone by the research team and participants will be given advance notice of each survey date via email in order to arrange for a time that is suitable.

Outcomes

The primary outcome of this pilot is participant attendance at first appointment for MOUD within 30 days of referral from *RecoveryPad*, assessed as a dichotomous variable. We chose first appointment attendance for MOUD as a primary outcome because it is a prerequisite to initiating MOUD. As *RecoveryPad* will primarily seek to refer participants to MOUD telehealth providers, we will consider reported attendance at online 'virtual appointments' to be a sufficient measure of participant attendance. We also anticipate participants may attend traditional in-person appointments, which *RecoveryPad* may also facilitate, and in-person and telehealth attendance data will be assessed together as our primary outcome. Data will be collected via phone surveys with participants conducted by the research team to assess primary and secondary outcomes. Secondary outcomes include engagement in MOUD treatment at 90 days after enrolment and number of OD events within 90 days after enrolment. Additionally, measures of readiness and intention to engage in MOUD treatment and measures of engagement with the *RecoveryPad* chatbot and recovery coaches will be evaluated based on data collected through *RecoveryPad* chatbot and texting and communications with *RecoveryPad* recovery coaches.

Three main categories of data will be collected during the pilot phase of the study: (1) data related to participant appointment attendance for MOUD treatment, reported by *RecoveryPad* providers or collected via phone survey; (2) data related to the study's secondary outcomes collected via phone survey; and (3) supplementary data related to participant engagement with *RecoveryPad* (see table 1 for more information). All of these data sources will be used as inputs for community- and individual-level SD models. Data collection will occur for the entire

Table 1 Data to be collected during pilot phase

Data category	Data	Source/collection method	Analysis
Primary outcome data	Participant attendance at first appointment with MOUD treatment provider within 30 days of study enrolment	30-day survey and/or data reported from *RecoveryPad*	Dichotomous variable (appointment attendance: yes/no)
	Prescription for buprenorphine written by *RecoveryPad*-affiliated prescriber	Data from *RecoveryPad*-affiliated buprenorphine prescriber	Comparison with historical control group
Secondary outcome data	Number of subsequent drug overdose events post-enrolment	30-day survey, 90-day survey	Comparison with historical control group
	Participant appointment attendance with MOUD treatment provider(s) up to 90 days after study enrolment	90-day survey	Comparison with historical control group
	Linguistic data from both the *RecoveryPad* chatbot and texting platform (eg, quantity, frequency, latency, periodicity and quality of participant messages)	*RecoveryPad* chatbot response data, text and communication data from *RecoveryPad* recovery coaches	System dynamics modelling at the individual level to assess measures of motivation and readiness to engage in MOUD Qualitative analysis to identify text utterances associated with change talk identified using DARN-C categories[36]
Supplementary data	Time stamps from use of *RecoveryPad* chatbot texting platform	*RecoveryPad* chatbot response data, text and communication data from *RecoveryPad* recovery coaches	System dynamics modelling at the individual level to assess the latency between initiation of *RecoveryPad* texting and subsequent engagement with platform
	Location of participant during initial enrolment in study	One-time IP address verification via online enrolment portal	System dynamics modelling at the community level to assess participation in different localities in Connecticut and New York

MOUD, medication for opioid use disorder.

duration of the pilot phase in order to facilitate a data-informed approach to implementing our intervention.

Timeline

We are actively piloting the implementation of *RecoveryPad* by recruiting 40 participants and conducting 30- and 90-day follow-up surveys to collect data pertaining to our primary and secondary outcomes (refer to figure 2 for a schedule of enrolment, intervention and assessment activities). Participant recruitment began in April 2024 in Connecticut and in July 2024 in New York. Once recruitment is completed for the pilot phase, we plan to develop a data collection plan for the larger RCT phase of the project. During both the pilot and trial phases, we will collect participant process data (eg, linguistic data from *RecoveryPad*), and outcome data (eg, MOUD engagement at 30 days), as well as community-specific data from key partners that can be used to continually refine the SD model, allowing for ongoing improvement and targeted deployment of *RecoveryPad*. We anticipate the completion of all study activities by September 2025.

Analysis plan

Statistical analysis

Participant data collected after completion of *RecoveryPad* intervention will be analysed using statistical methods including χ^2 tests and analysis of variance procedures to examine the comparability of the pilot group receiving the digital platform to a historical control group of statistically matched individuals (n=40) from a non-telehealth MOUD intervention based in the Yale New Haven Health System.[37] The χ^2 tests will also be used to evaluate statistical significance of the differences in attendance at the first MOUD appointment (ie, engagement in primary outcome). Outcome data from all enrolled participants will be included in analyses, excluding those who are lost to follow-up or choose to discontinue participation prior to data collection. All analyses will involve two-tailed tests of significance and will be performed using CRAN R software, V.4.4.2[38]; p-values less than 0.05 will be considered statistically significant.

SD modelling

We plan to develop community-level SD models for communities where *RecoveryPad* will be offered to identify

		Study Period			
		Day 0	Day 1	Day 30	Day 90
Enrolment	Eligibility screener administered	X			
	Completion of consent form (eConsent) via REDCap	X			
	Completion of release of information form via REDCap	X			
	Participant contact Information shared with *RecoveryPad*	X			
Intervention	Account created in *RecoveryPad*		X		
	Stage 1: BNI conducted with *RecoveryPad* chatbot		●	●	
	Stage 2: person to person communication with recovery coach		●	●	
Assessment	Assessment of participant attendance at first MOUD appointment within 30 days of enrolment			X	
	Assessment of drug overdose events within 30 days of enrolment			X	
	Assessment of participant attendance at MOUD appointment(s) in the past 60 days				X
	Assessment of drug overdose events in the past 60 days				X

Figure 2 Schedule of enrolment, intervention and assessment activities to be completed with study participants by the research team and *RecoveryPad* personnel. MOUD, medication for opioid use disorder; REDCap, Research Electronic Data Capture.

community needs for MOUD access and linkage, and the factors that help or hinder efforts to address those needs. SD models will leverage data from the *RecoveryPad* intervention, our community partners and state-level collaborators to estimate current patterns and future trends for opioid-related overdose and fatality, and identify underlying drivers of opioid use, OUD and MOUD initiation and retention in different communities. SD modelling makes use of algebraic and differential equations to simulate the behaviour of a given system while accounting for the causal pathways and relationships which develop over time.[39 40] SD modelling approaches have been useful towards addressing complex health problems which require coordinated solutions by facilitating collaboration between researchers, community members and other partners to interrogate the dynamics and causes of such problems and build consensus around how to address them.[40–42] SD modelling results are of particular importance to policymakers and decision-makers who may benefit from understanding the causal factors and interactions of the complex systems associated with opioid use, in order to identify policy options and effective solutions to mitigate opioid-related harms.[43–46]

The SD models developed for this project will be calibrated to historical data and used to simulate trends and estimates for outcomes in specific communities or populations. Ventana Systems software Vensim DSS V.10.1.4 will be used to build and calibrate models.[47] These models will then be used to simulate and evaluate trends relevant to the implementation of *RecoveryPad*, such as OUD prevalence in a given community. Understanding these factors will assist the research team in identifying areas in New York and Connecticut where deployment of *RecoveryPad* may be most effective. Additionally, our community-level models can help us generate key data trends to share with partners to help them understand the potential impacts of *RecoveryPad* and encourage continued support for our study as we expand recruitment.

Moreover, measures of participant engagement in *RecoveryPad* and primary and secondary outcome data from the study will be used to inform individual-level SD models which will evaluate the interactions between participants and *RecoveryPad*. By using an SD modelling approach, we can identify insights and data that would otherwise not be available to our research team to refine the *RecoveryPad* intervention during the RCT phase of this study and assist us in scaling the intervention to a larger population. Unique qualitative data from participant engagement with the *RecoveryPad* chatbot and recovery coaches (ie, text data) will be key towards identifying important

factors related to implementation of our intervention such as barriers and facilitators towards motivating participants to initiate MOUD via telehealth.

Patient and public partnership

This project will be conducted in partnership with community, harm reduction, emergency services and substance use treatment organisations in New York and Connecticut who interact and serve those living with OUD. Senior decision makers from partnering entities will participate in advisory board meetings which will occur every 6 months to evaluate progress, discuss current barriers to implementation and plan for strategic methods to promote long-term sustainability. Additional sessions will be held to inform the SD modelling components of this project, with participation from partner organisations involved in our advisory board, and a wider group of community members, including those with lived experience related to OUD or receiving MOUD treatment. These group modelling sessions will allow local perspectives and expertise to be shared to help refine and validate the models using an iterative process. We plan to integrate the community perspectives and findings shared during these sessions to help us develop accurate SD models that are more responsive to community needs.

Ethics and dissemination

Our study has been reviewed and approved by the Yale Human Research Protections Programme IRB covering all aspects of enrolment, participation and participant data protection. Ethical approval by the Yale University Human Investigation Committee was obtained in 2023, with final security review completed by March 2024 (Protocol #2000034414).

Careful consideration was given to determine the best approach to ensuring the security and safety of PHI collected during the study. Participant enrolment data will be collected and stored securely on Yale REDCap for the duration of the study, including the RCT phase, with restricted access and security features enabled including two-factor authentication. Minimal participant contact information and limited PHI, as identified in the ROI form signed by participants, will be stored securely on the *RecoveryPad* platform to facilitate interaction with *RecoveryPad* recovery coaches for the duration of the study. In alignment with FDA regulations which consider digital therapeutics, including digital health software platforms such as *RecoveryPad*, to be medical devices, a risk mitigation plan was adopted for the study to protect prospective participants' data.[48 49] Yale IT Security Office approved *RecoveryPad* as secure in all ways required for such digital therapeutics. Data resulting from participants' interactions with the *RecoveryPad* chatbot will be sequestered from access to non-study personnel and stored securely on an encrypted, firewall-enabled Amazon Web Services server with no third-party access. The content and language of the enrolment form was also reviewed by the Yale Human Research Protections Programme IRB (HIC # 2000034414).

A Data and Safety Monitoring Plan has been developed and will be in place for the duration of the pilot. The multiple principal investigators (MPIs), co-investigators and project managers will review data collection weekly to minimise the risk of adverse events to the participants. While the *RecoveryPad* platform will connect participants to a partner provider of telehealth buprenorphine or to standard ('brick and mortar') MOUD providers, no study personnel will be prescribing or managing any medication treatment.

A Data Safety Monitoring Board (DSMB) will also be convened throughout the duration of the study, consisting of five experts in technology-enabled brief intervention, OUD, SD modelling and study design. The DSMB will meet every 6–12 months to review interim data analyses and any adverse events as needed. In addition, the DSMB will review the study protocol annually and will review/approve any amendments before they are made. Primary investigators will be responsible for alerting relevant parties to any protocol amendments or modifications. As this study was determined to be of minimal risk, we do not anticipate the occurrence of serious adverse effects, and the research team will do everything possible to minimise potential risks. Should an adverse event or unanticipated problem occur, it will be reported within 48 hours to the Yale Human Research Protections Programme and to the funding agency (NIDA) according to current regulations.[50] In the event that a member of the study team is concerned that a participant poses a risk to themself, in which case 911 will be called and the last known location of the participant may be provided. Participants may discontinue the *RecoveryPad* intervention and withdraw from the study at any time through written or verbal communication to the research team or Yale University IRB. Withdrawal from the study will have no impact on clinical care or treatment they were referred to or connected with as part of the study.

Participants will be compensated with a $25 electronic gift card after completing the first interaction with the *RecoveryPad* chatbot, an additional $25 electronic gift card on completion of the 30-day follow-up assessment survey, and a final $50 electronic gift card on completion of the 90-day follow-up assessment survey. Participants who discontinue the study prior to the assessment period will not be surveyed.

Dissemination of data and outcomes from this pilot study will occur through peer-reviewed journal publication and other activities including conference and poster presentations. Additionally, aggregate data and process outcomes from the study will be shared with community-based recruitment partners during advisory board meetings. All study data shared related to participation will be deidentified and aggregated at the regional level to minimise potential participant reidentification. MPIs and study investigators alone will have access to the full pilot dataset. Identifiable participant information will

not be shared with third parties outside of the study team unless required by US or State law as outlined in the informed consent form. All information related to study participation will also be kept private except Food and Drug Administration inspection, or during an audit or programme evaluation by Yale Human Investigation Committee. On completion of the study, all participant datasets will be de-identified and stored in a password-protected database, to which only the MPIs and investigators will have access.

Finally, we will adhere to standard Good Clinical Practice (GCP) and the applicable regulatory requirement(s) around quality assurance measures for subject recruitment, enrolment, enrolment targets and for the validity and integrity of the data. Planned and systematic actions will be established to ensure that the study is performed, and the data are generated, documented, recorded and reported in compliance with GCP and the applicable regulatory requirement(s), as identified by NIDA/NIH clinical research standards.[51 52] Additionally, as per Yale University's IRB requirements, all study personnel will be required to complete GCP training, and all study procedures will be carried out in compliance with the principles and codes set forth in these guidelines.

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Contributors RHec will serve as guarantor. NSS, RHei, MP, GD and RHec designed the study protocol and obtained funding. TC, NSS, RHei, CR, LB, MG, JM, GD and RHec are responsible for the overall logistical and scientific aspects of the study, data collection and analysis, and draft of this manuscript. TC, NSS, RHei, LB, MG, JM and RHec provided administrative and logistical support for the study. TC, NSS, RHei, MP, CR, JM, GD and RHec contributed statistical, scientific and design expertise in the development and planned scientific activities of the protocol. All authors contributed to revisions and gave final approval of the manuscript.

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Competing interests NSS reported receiving grants from the National Institutes of Health outside the conduct of the study. RHei reported receiving grants from the National Institutes of Health, City of New Haven Health Department, Centers for Disease Control Substance Use and Mental Health Services Administration, outside the conduct of the study. RHei reported receiving consulting fees from McCall Behavioral Health and Ledge Light Health District. RHei reported payment for presentations from North Carolina Association of County Commissioners. RHei reported receiving support for attending meetings from North Carolina Association of County Commissioners. MP reported receiving grants from the National Institute of Drug Abuse outside the conduct of the study and having a financial stake in CPR, the makers of RecoveryPad. CR reported receiving grants from the National Institute of Drug Abuse outside the conduct of the study. GD reported receiving grants from the National Institute of Drug Abuse outside the conduct of the study. GD reported payment for presentations outside the conduct of the study for the Northeast NIDA NODE Webinar. GD reports participation on the Naloxone Project Advisory Board. RAH reported receiving grants from the National Institutes of Health outside the conduct of the study. All other authors have no competing interest to declare.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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REFERENCES

1 Connecticut Public Health. Fatal unintentional and undetermined intent drug overdose report. *Connecticut*; 2025. Available: https://portal.ct.gov/-/media/dph/injury-and-violence-prevention/opioid-overdose-data/monthly-death-reports/2019-january-2025_drug-overdose-deaths-monthly-report_connecticut_2-25-2025-final.pdf [accessed 15 Mar 2025]
2 Holtgrave DR, Clear A, McDonald JV. Public health implications of recent declines in fatal drug overdoses in New York State and the United States. *Health Aff Sch* 2024;2:qxae172.
3 Brothers S, Viera A, Heimer R. Changes in methadone program practices and fatal methadone overdose rates in Connecticut during COVID-19. *J Subst Abuse Treat* 2021;131:108449.
4 Substance Abuse and Mental Health Services Administration. Methadone take-home flexibilities extension guidance, 2024. Available: https://www.samhsa.gov/medications-substance-use-disorders/statutes-regulations-guidelines/methadone-guidance [Accessed 15 Apr 2023].
5 D'Onofrio G, O'Connor PG, Pantalon MV, *et al*. Emergency department-initiated buprenorphine/naloxone treatment for opioid dependence: a randomized clinical trial. *JAMA* 2015;313:1636–44.
6 Dooling BCE, Stanley L. Extending pandemic flexibilities for opioid use disorder treatment: authorities and methods. *Minn Law Rev* 2021;106:26.
7 D'Onofrio G, Herring AA, Perrone J, *et al*. Extended-Release 7-Day Injectable Buprenorphine for Patients With Minimal to Mild Opioid Withdrawal. *JAMA Netw Open* 2024;7:e2420702.
8 Jakubowski A, Norton BL, Hayes BT, *et al*. Low-threshold Buprenorphine Treatment in a Syringe Services Program: Program Description and Outcomes. *J Addict Med* 2022;16:447–53.
9 Heimer R, Black AC, Lin H, *et al*. Receipt of opioid use disorder treatments prior to fatal overdoses and comparison to no treatment in Connecticut, 2016-17. *Drug Alcohol Depend* 2024;254:111040.
10 Wakeman SE, Larochelle MR, Ameli O, *et al*. Comparative Effectiveness of Different Treatment Pathways for Opioid Use Disorder. *JAMA Netw Open* 2020;3:e1920622.
11 Navarretta N. Hartford, Connecticut: Department of Mental Health and Addiction Services. State of Connecticut Department of Mental Health and Addiction Services triennial state substance use plan, Available: https://portal.ct.gov/-/media/dmhas/eqmi/2022-triennial-report-final.pdf [Accessed 23 Jan 2025].
12 U.S. Food and Drug Administration. What is digital health?, 2020. Available: https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health [Accessed 23 Jan 2025].
13 Allen B, Nolan ML, Kunins HV, *et al*. Racial Differences in Opioid Overdose Deaths in New York City, 2017. *JAMA Intern Med* 2019;179:576–8.

14 Valdez A, Cepeda A, Frankeberger J, *et al*. The opioid epidemic among the Latino population in California. *Drug Alcohol Depend Rep* 2022;2:100029.
15 Andraka-Christou B. Addressing racial and ethnic disparities in the use of medications for opioid use disorder: study examines racial and ethnic disparities in the use of medications for opioid use disorder. *Health Aff (Millwood)* 2021;40:920–7.
16 Substance Abuse and Mental Health Services Administration National Mental Health and Substance Use Policy Laboratory. Telehealth for the treatment of serious mental illness and substance use disorders, 2021. Available: https://store.samhsa.gov/sites/default/files/pep21-06-02-001.pdf [Accessed 15 Apr 2024].
17 Substance Abuse and Mental Health Services Administration. Screening, brief intervention, and referral to treatment (SBIRT), 2024. Available: https://www.samhsa.gov/sbirt [Accessed 23 Jan 2025].
18 Monnig MA, Clark SE, Treloar Padovano H, *et al*. Access to medication for opioid use disorder supported by telemedicine and healthcare coverage: A web-based survey during the COVID-19 pandemic. *Addict Behav Rep* 2023;18:100515.
19 Boyd J, Carter M, Baus A. Access to MAT: Participants' Experiences With Transportation, Non-Emergency Transportation, and Telehealth. *J Prim Care Community Health* 2024;15:21501319241233198.
20 Sousa JL, Raja P, Huskamp HA, *et al*. Perspectives of Patients Receiving Telemedicine Services for Opioid Use Disorder Treatment: A Qualitative Analysis of User Experiences. *J Addict Med* 2022;16:702–8.
21 Telehealth.hhs.gov. Telehealth for behavioral health care, 2023. Available: https://telehealth.hhs.gov/providers/best-practice-guides/telehealth-for-behavioral-health/tele-treatment-for-substance-use-disorders [Accessed 23 Jan 2025].
22 Walton MR, Kang AW, DelaCuesta C, *et al*. Old tech but not low tech: telephone-based treatment provision for substance use. *Front Psychiatry* 2024;15:1351816.
23 Guillen AG, Reddy M, Saadat S, *et al*. Utilization of Telehealth Solutions for Patients with Opioid Use Disorder Using Buprenorphine: A Scoping Review. *Telemedicine and E-Health* 2021.:tmj.2021.0308.
24 DiClemente CC. Screening, brief intervention, and referral to treatment: an efficacious public health approach to substance use prevention and treatment. In: Cimini MD, Martin JL, eds. *Screen. Brief Interv. Ref. Treat. Subst. Use Pract*. Guide, Washington: American Psychological Association, 2020: 9–29. Available: https://doi.org/10.1037/0000199-002
25 Substance Abuse and Mental Health Services Administration. Enhancing motivation for change in substance use disorder treatment, 2019. Available: https://store.samhsa.gov/sites/default/files/tip-35-pep19-02-01-003.pdf [Accessed 15 Apr 2024].
26 Burke B, Miller E, Clear B, *et al*. A qualitative study to determine perspectives of clinicians providing telehealth opioid use disorder treatment. *Drug Alcohol Depend* 2024;256:111118.
27 Lambdin BH, Kan D, Kral AH. Improving equity and access to buprenorphine treatment through telemedicine at syringe services programs. *Subst Abuse Treat Prev Policy* 2022;17:51.
28 Watson DP, Swartz JA, Robison-Taylor L, *et al*. Syringe service program-based telemedicine linkage to opioid use disorder treatment: protocol for the STAMINA randomized control trial. *BMC Public Health* 2021;21:630.
29 Tookes HE, Oxner A, Serota DP, *et al*. Project T-SHARP: study protocol for a multi-site randomized controlled trial of tele-harm reduction for people with HIV who inject drugs. *Trials* 2023;24:96.
30 Luderer H, Enman N, Gerwien R, *et al*. A Prescription Digital Therapeutic to Support Unsupervised Buprenorphine Initiation for Patients With Opioid Use Disorder: Protocol for a Proof-of-Concept Study. *JMIR Res Protoc* 2023;12:e43122.
31 Davoust M, Bazzi AR, Blakemore S, *et al*. Patient and Clinician Experiences with the Implementation of Telemedicine and Related Adaptations in Office-Based Buprenorphine Treatment During the COVID-19 Pandemic: A Qualitative Study. *Res Sq* 2024.:rs.3.rs-4272282.
32 American Psychiatric Association. Opioid-Related Disorders. Diagn. Stat. Man. Ment. Disord. DSM-5-TR. American Psychiatric Association Publishing, 2022:540–6.Available: https://doi.org/10.1176/appi.books.9780890425787
33 Harris PA, Taylor R, Thielke R, *et al*. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. *J Biomed Inform* 2009;42:377–81.
34 Harris PA, Taylor R, Minor BL, *et al*. The REDCap consortium: Building an international community of software platform partners. *J Biomed Inform* 2019;95:103208.
35 D'Onofrio G, Pantalon MV, Degutis LC, *et al*. Development and implementation of an emergency practitioner-performed brief intervention for hazardous and harmful drinkers in the emergency department. *Acad Emerg Med* 2005;12:249–56.
36 Substance Abuse and Mental Health Services Administration. Chapter 3—motivational interviewing as a counseling style. enhancing motiv. In: *Change Subst Use Disord Treat Updat*. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.
37 D'Onofrio G, Degutis LC. Integrating Project ASSERT: a screening, intervention, and referral to treatment program for unhealthy alcohol and drug use into an urban emergency department. *Acad Emerg Med* 2010;17:903–11.
38 R Core Team. R: a language and environment for statistical computing. 2024.
39 Sterman JD. Learning from evidence in a complex world. *Am J Public Health* 2006;96:505–14.
40 Homer JB, Hirsch GB. System Dynamics Modeling for Public Health: Background and Opportunities. *Am J Public Health* 2006;96:452–8.
41 Minyard K, Smith TA, Turner R, *et al*. Community and programmatic factors influencing effective use of system dynamic models. *Syst Dyn Rev* 2018;34:154–71.
42 Homer J, Wakeland W. A dynamic model of the opioid drug epidemic with implications for policy. *Am J Drug Alcohol Abuse* 2021;47:5–15.
43 Hovmand PS. Community Based System Dynamics. New York: Springer, 2014.
44 Sabounchi NS, Lounsbury DW, Iftikhar P, *et al*. Qualitative System Dynamics Modeling to Support Community Planning in Opioid Overdose Prevention. *Res Soc Work Pract* 2023;33:282–95.
45 Sabounchi NS, Heckmann R, D'Onofrio G, *et al*. Assessing the impact of the Good Samaritan Law in the state of Connecticut: a system dynamics approach. *Health Res Policy Syst* 2022;20:5.
46 Thompson RL, Sabounchi NS, Ali SS, *et al*. Using qualitative system dynamics modeling to understand overdose bystander behavior in the context of Connecticut's Good Samaritan Laws and identify effective policy options. *Harm Reduct J* 2024;21:124.
47 Ventana Systems Inc. Vensim. 2024.
48 U.S. Food and Drug Administration. What is digital health, 2020. Available: https://www.fda.gov/medical-devices/digital-health-center-excellence/what-digital-health [Accessed 18 Feb 2025].
49 U.S. Food and Drug Administration. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions, 2024. Available: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence [Accessed 29 Sep 2025].
50 Yale University Human Research Protection Program (HRPP). Yale University Human Research Protection Program (HRPP) policy and standard operating procedure manual, 2023. Available: https://your.yale.edu/sites/default/files/files/ResearchSupport/HRPP_Policy_and_Standard_Operating_Procedure_Manual_20230724.pdf [Accessed 18 Feb 2025].
51 National Institute on Drug Abuse. Regulations, policies, and guidance, 2016. Available: https://nida.nih.gov/research/clinical-research/regulations-policies-guidance [Accessed 18 Feb 2025].
52 National Institutes of Health. Clinical Trials Stewardship, 2017. Available: https://nida.nih.gov/research/nih-policies-guidance/clinical-trials-stewardship#GCP [Accessed 18 Feb 2025].