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Protocol

Comparing a multicomponent intervention versus a single component intervention for people with co-occurring substance use and mental health disorders: study protocol of a hybrid type I trial

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ABSTRACT

Background: Substance use and mental health are growing public health problems in the United States. People with co-occurring mental health and substance use disorders (COD) often have complex social determinants of health (SDOH) needs and struggle to engage in treatment. Linkage and multicomponent wraparound interventions, including maintaining independence and sobriety through systems integration, outreach and networking (MISSION), have gained popularity as solutions to increase treatment engagement and address behavioral health and SDOH needs of clients with COD. This protocol offers an overview of an effectiveness trial and a process evaluation of MISSION being delivered in a city public health setting.
Methods: This study will use a hybrid type I effectiveness and implementation design with a randomized controlled trial. People with COD will be randomized to one of two treatments: a multicomponent COD intervention (MISSION), or a peer delivered linkage-only intervention (PLS). Secondary aims include the examination of mechanisms of action and a sequential mixed methods process evaluation to inform the sustainability and future implementation of MISSION.
Conclusions: This trial will help determine the effectiveness of MISSION compared to PLS to improve engagement, and reduce substance use and mental health symptoms. This trial is the first to implement MISSION within a public health department setting which has important implications for policymakers and treatment providers within behavioral health fields.
Trial Registration: Trial registration number is NCT05713695, registered on 27 January 2023.

Keywords: Addiction, Mental health, Substance use, Multicomponent interventions, Public health

INTRODUCTION

Addiction is a public health crisis in the United States (U.S.), with 57.2 million Americans reporting illicit drug use and nearly 21 million meeting the criteria for substance use disorder (SUD).[1,2] Those with a SUD have high rates of mortality, with data indicating approximately 841,000 drug overdose deaths since 1999.[3] The COVID-19 pandemic has further intensified the addiction crisis, as overdoses increased by 31% in the U.S. during the pandemic.[4]

Mental health disorders (MHD) are highly prevalent among individuals with SUD, with prevalence rates of any MHD at 49% and comorbidity with a severe MH disorder at 19%.[1] Compared to those with a single behavioral health disorder, individuals with co-occurring MHD and SUD (hereafter called COD) report more substance use relapses, MHD symptom exacerbations, chronic illnesses, infectious diseases, and less social support.[5-9] Individuals with COD also tend to use multiple substances concurrently, which negatively affects treatment access and engagement.[10-12] Among approximately 9 million people with COD in the U.S., only 8% received treatment for both SUD and MHD in 2019, signalling the need to improve access to integrated MHD and SUD care.[1] Poor treatment access is a major concern for individuals with COD as they have complex social determinants of health (SDOH) needs that require multiple service providers. Furthermore, among those who access treatment, engagement rates are as low as 16% as many patients do not follow through on a treatment referral because they are overwhelmed by competing problems and have minimal (if any) support to navigate the treatment landscape.[13-15] Additionally, patients with COD often experience wavering motivation to address their behavioral health and other SDOH needs, thus fuelling a vicious cycle of poor treatment engagement and acute service utilization.[16] Therefore, individuals with COD need more support than those with a single behavioral health disorder to connect successfully with providers and to stay engaged in treatment.

Linkage and wraparound models offer solutions to improve treatment engagement. Linkage models have been used to address patients' behavioral health needs.[17] The most widely used linkage models include patient navigator and community health worker programs. Both types of programs offer referrals and basic care coordination in behavioral health and medical settings to increase access and engagement in care and address other SDOH needs.[18-21] While these programs have improved outcomes, they are less successful for individuals with COD.[22] Given that these individuals often need acute evidence-based treatment and active coordination between multiple providers, many also have individual barriers (e.g., varying motivation) and systemic barriers to care (e.g., transportation issues) that must be addressed.

Multicomponent interventions with linkage-wraparound components, on the other hand, often offer more intensive care coordination than linkage-only models and have shown to be more effective than single component interventions for COD, but they are also more difficult to implement.[23-27]

It is important to better understand implementation issues across a variety of settings. MISSION has demonstrated improved COD outcomes in behavioral healthcare settings, but it has not been tested in a broader public health setting. Implementation of MISSION in a hub run by city public health department could enhance the local recovery ecosystem by offering a bridge to care to support patients with COD, thus reducing system fragmentation and improving outcomes. To further highlight the needs in this setting, Hubs tend to offer limited assertive community outreach for patients with COD, and they do not offer multicomponent hybrid linkage and treatment services such as MISSION.

This paper describes the study protocol (trial registration: NCT05713695) for a randomized controlled trial funded by the U.S. Centers for Disease Control and Prevention (CDC) comparing two psychosocial interventions for people with COD in a city public health department setting.

METHODS

Overview

This study will use a hybrid type 1 effectiveness and implementation design that compares MISSION to a peer linkage support (PLS, a linkage model delivered by peers in recovery). We will compare treatment effects in increasing engagement in care (aim 1a), reducing substance use (aim 1b), reducing risk for overdose (aim 1c), and improving MHD symptoms and functioning (aim 1d). Secondary aims include the examination of mechanisms of action, including mediators (e.g., recovery capital, therapeutic alliance, and receipt of psychiatric medications) and moderators, such as key patient characteristics (e.g., demographics, COD severity, and intravenous (IV) drug use) (aim 2); and a mixed-methods process evaluation to inform sustainability (aim 3) (study logic model in Figure 1).

Design

Study setting

This study will recruit individuals from a city public health setting. MISSION will offer a bridge to care to support patients with a COD who are referred to the Hub following a call to the city's 911 call center. Specifically, this study will operate out of the Hub, a centralized convening program in city hall. Recruitment will be conducted over a period of 20 months from January 2023 through August 2024. An additional 1 year no-cost extension will extend recruitment through September 2025.

Participants

Patients will be eligible for the study if they are 18 or older, have at least one SUD and at least one MHD (including depression, anxiety, trauma related disorders, bipolar, and/or schizophrenia), are in the hub, are not engaged in ongoing treatment for COD with a behavioral health provider or have not seen their provider for at least 3 months. We will exclude those who are acutely psychotic, suicidal with a plan (as measured by the Columbia-suicide severity rating scale [C-SSRS]), or homicidal, and with

concurrent severe alcohol use disorder or high dose benzodiazepine requiring detoxification. For those acutely symptomatic/ acutely suicidal, we will re-approach them when symptoms partially remit. We will use the structured clinical interview for DSM-5 – research version (SCID-5-RV) to confirm MHD and SUD diagnoses and to screen for acute psychosis.[28]

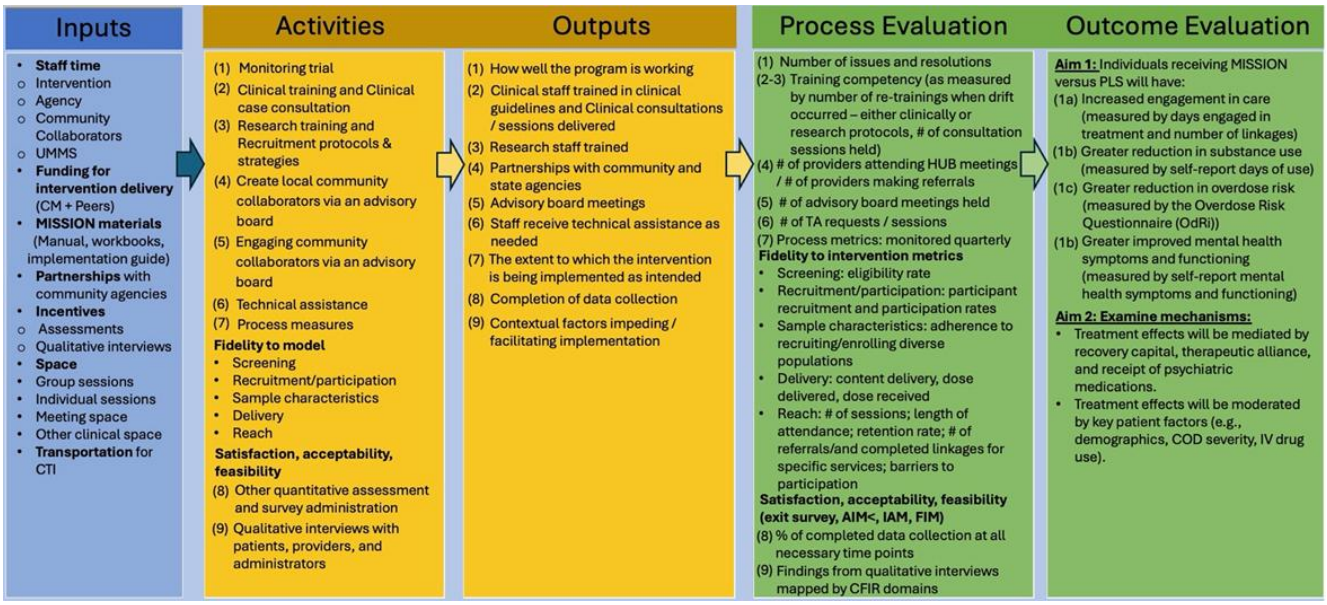

Figure 1: Study logic model: hybrid type 1 design to examine efficiency and implementation.

Participant recruitment for aim 3

Prior to MISSION participants completing a 6-month follow up assessment, our research assistant will be given a sealed envelope prepared by the study project director to support our maximal variation sampling. Upon completion of the follow-up assessment, the assessor will open it. If the participant has been selected for a qualitative interview, the assessor will explain its purpose and nature, invite the participant to take part, and, if the participant agrees, schedule the qualitative interview appointment.

Provider and administrator recruitment for aim 3

This recruitment will occur in the second half of the RCT. In addition to interviewing MISSION providers, the PI will utilize a purposive sampling approach (in consultation with the advisory board (AB)) and invite relevant non-MISSION providers and administrators to participate.[29]

Consent

Possible later invitation to the qualitative interview will be included in the main RCT informed consent procedures. This consent process will be reviewed and renewed verbally, including audio-recording and voluntary participation, when the assessor invites participants to schedule a qualitative interview and again before the interview starts. For provider and administrator interviews, we have obtained IRB waivers for written consent and will emphasize voluntary participation and confidentiality of responses.

Study treatment conditions and staffing

This study involves two conditions MISSION and PLS. MISSION or PLS services are intended to commence within a week of a person calling a Massachusetts city 911 call center and/or being referred to the Hub. MISSION or PLS services will continue for 6 months post-enrollment, and a final follow-up assessment will occur at three months post-treatment completion.

MISSION condition

Participants randomized to MISSION will receive an average of 3 hours of services weekly, delivered by a case manager (CM) and a peer support specialist (PSS) treatment team for 6 months. Table 1 includes the 3 evidenced-based practices delivered through MISSION. The first component of MISSION is critical time intervention (CTI), a time limited form of case management.[30,31] This component is delivered by a CM and PSS team and offers behavioral health linkages as determined by a treatment planning/monitoring tool and a stepdown approach to optimize linkages to support patient needs. In CTI, the CM focuses their linkages on needed clinical and psychosocial resources in the community (e.g., community-based MH and SUD services, housing, vocational support), while the PSS focuses their linkages on recovery activities (e.g., 12-step meetings). The PSS

provides transportation and teaches patients how to navigate resources in the community, facilitating patient engagement in recovery-oriented activities. The second component of MISSION is dual recovery therapy (DRT).[32,33] DRT includes 13 structured sessions delivered by the CM who focus on teaching patients' initial recovery skills to begin their recovery journey and increase motivation for recovery that can be expanded upon and continued as patients' initiate support from community providers.[32,33] The third component of MISSION is peer support groups.[34]

The PSS facilitates 11 structured group sessions to offer initial insights into a life of recovery and how it can be obtained. PSSs also facilitate the use of a MISSION self-help workbook that offers recovery readings and tools for patients to gain a better understanding of their COD.[34] MISSION serves as a bridge to offer initial and time-limited support and also help patients engage in healthcare and social services in an effort to develop a recovery network. As a result, the CTI stepdown approach initially involves weekly outreach sessions through month 3 to link patients to prosocial community supports (e.g., drug-free events), bi-weekly in months 4-5 (when the patient is trying linkages), and one session in month 6. Treatment will include 13 DRT and 11 peer support group sessions (Table 1); each group will be 1 hour per week with rolling admission. PSSs will also work with patients to use the MISSION self-help participant workbook, which offers patients tools to support their own recovery.

MISSION will also include 1 hour of weekly community outreach sessions to link patients to community supports. Caseloads will be about 20 patients per CM/PSS team, allowing for ample assertive outreach as patients will be in varying service delivery intensity.

Peer linkage support condition

The PLS condition will be delivered by a peer with lived experience, who has successfully navigated their own COD recovery. Peers will offer unstructured linkage, community outreach, and transportation support, similar to other unstructured linkage models.[35-38] This condition will focus on addressing patients' broad behavioral health and SDOH needs via linkage only, where peers will provide unstructured recovery support and linkages and help patients navigate any needed services. The core elements of the intervention will not be focused on a specific disease state (e.g., COD) but rather tailored to each patient's needs and geared toward improving overall quality of life. We anticipate that the community outreach and linkages will equate to approximately 2 hours per week for 6 months (not following a CTI stepdown approach). Participants will receive approximately 2 hours of linkage support per week for 6 months.

Caseloads will be approximately 20 patients per peer allowing for ample assertive outreach. Of note, Table 2 highlights the differences between the components in the MISSION and PLS conditions.

Staff training for conditions

At the outset of the study, staff in the MISSION condition will receive training through MISSION University, an online portal developed via National Institutes of Health funding that covers the MISSION curriculum, including how to perform community outreach and provide linkages using a CTI approach, how to run the DRT and peer support group sessions, and how to be trauma-informed in care. Training for the PLS condition will be conducted by a trained physician and will focus on how to: provide linkages in the community; find resources to address SDOH needs; make safety plans for adverse events; and share emergency call line resources for a variety of topics. The trainings will be separate for each condition. Furthermore, MISSION services will be delivered with a MISSION treatment manual to support fidelity to the model, and the PLS condition has a separate treatment manual for peers.

MISSION fidelity

This study will utilize a multi-method approach to objectively assess MISSION fidelity. A MISSION clinical supervisor will observe one DRT and peer support group monthly in the MISSION condition and complete the MISSION fidelity assessment. Regarding CTI (in the MISSION group), a MISSION clinical supervisor and the study project director will select a participant at random and use the CTI fidelity scale to monthly conduct a thorough review of the services tracking sheets. Staff with lower fidelity (below 80%) will meet with a MISSION clinical supervisor to review fidelity and receive additional MISSION training. In addition to fidelity monitoring, CMs and PSSs will have weekly supervision by a MISSION clinical supervisor to discuss patients on their caseload, and once a month, they will discuss fidelity data from that month. Should fidelity drift occur, a MISSION clinical supervisor will provide targeted retraining as needed. We will not use a fidelity measure for the PLS condition as it offers unstructured linkage support, but we will track the number of sessions attended on the treatment services review tracking sheet as part of the measure for aim 1a (see description of fidelity measure below). A MISSION clinical supervisor will also meet with the peer in the PLS condition weekly for supervision. However, it will only focus on linkage supports and will not include a discussion of MISSION.

Management of contamination

In this study, we do not anticipate contamination between conditions as patients typically reside in scattered housing in the community, with little contact with each other. If the study team learns that contamination occurred, participants' records will be flagged, and contamination-adjusted intention-to-treat analyses will be calculated.

Table 1: Components of MISSION (including DRT, peer support groups, details, and the curriculum).

MISSION components	Details and curriculum
Critical time intervention (CTI): A three-stage time-limited, case management (CM) model. Delivered by a master's level CM and the peer specialist (PS), CTI offers assertive outreach, including transportation assistance, and linkages to needed community services to address barriers to service access and broader social determinants of health.[30,31] CTI offers outreach at a "critical time" and linkage support to address behavioral health and social determinants of health needs of the patient. Moreover, CMs offer linkages to such things as MOUD/MAT, Rx appointments, housing, entitlements, and other formal treatments; whereas the PS offers linkages to 12-step meetings and other recovery activities such as sporting events. Furthermore, using CTI, CMs and PSs provide linkages to other social determinants of health needs such as vocational and trauma informed services.	Stage 1 (months 1-3): rebuilding community bridges - the CM, PS, and patient develop an individualized treatment plan to identify resource needs (e.g., primary care, and housing supports), and meet in the community weekly to establish linksto community services. Stage 2 (months 4-5): try-out - community supports used during Stage 1 are tested and adjusted during bimonthly meetings. CMs/PSs identify support needs and adjust the Tx plan. Stage 3 (months 6): transfer of care - one sessionis delivered, and community linkages are finalized with any needed adjustment prior to termination.
Integrated dual disorders treatment via dual recovery therapy (DRT): DRT is a 13-session motivation-based, manualized relapse prevention group approach also delivered by the CM.[32,33] DRT helps patients: develop initial skills for recovery from substance use and mental health issues; understand relationships between substance use and mental health problems; and increase understanding that substance use and mental health issues must be addressed together and that motivation to change can differ for each. DRT helps patients maintain recovery and manage both their mental health and substance use issues. These one-hour weekly sessions are facilitated by the CM for the first 13 weeks.	Onset (lifetime SUD and MH symptoms), life problem areas affected by COD, motivation, confidence and readiness for change, developing a personal recovery plan, decisional balance, communication skills development, 12-step orientation and recollections, anger management and prosocial skills, relapse prevention, interpersonal relationships, changing unhealthy thinking patterns, changing irrational beliefs, and activity scheduling
Peer support groups (led by peer specialists) (PS): PSs have lived experience and are in recovery from a COD (at least 2 years). PSs deliver an 11-weekly 1-hour group recovery session curriculum. The curriculum is designed to offer a framework, roadmap, and tools for the patient to engage in recovery, while receiving input from the PS based on their own recovery journey.	Willingness, self-acceptance and respect, gratitude humility, dealing with frustration, handling painful situations, significance of honesty, courage, patience, medicine maintenance, and making a good thing last

Table 2: Comparison of mission (M) and linkage only (LO) intervention conditions.

Component of care	Component scope by intervention condition and staff role	
	MISSION	**Linkage only**
Treatment planning	Structured assessment to prioritize and address linkage needs (including an SDOH informed assessment). Bi-monthly clinical review of needs based on progress. – Case manager and peer specialist	Peers offer an unstructured plan based on general recovery needs without formal monthly review. – Peer
Integrated mental health and substance use treatment (DRT)	13 DRT/prosocial curriculum exercises (focus on COD and promoting prosocial attitudes, behaviors, and connections). – Case manager	None (occurs through linkage only). – Peer
Linkages to address behavioral health and SDOH needs	Case managers focus on linkages to mental health, employment, education, trauma, and other SDOH needs, whereas the peer support specialist focuses on 12-step and other recovery activities. Both staff use a structured assessment and framework for linkage support and provide transportation support. – Case manager and peer specialist	Focus on linkages to mental health, employment, education, trauma and other SDOH needs, and provide transportation support but without a structured assessment to benchmark progress nor a stepdown approach. – Peer
MISSION workbook (self-help recovery exercises and tools)	Supports the use of the self-help materials (e.g., self-help recovery exercises and tools). Includes readings on recovery, and symptom checklists. – Peer specialist	None – Peer

Data collection and analytic plan

Measures

Data used for aims 1 and 2 will be collected at baseline and follow-up assessments (3-, 6-, and 9-months post-baseline) as well as collected at other time points (e.g., weekly treatment fidelity) via REDCap. Deidentified data will be imported into STATA MP 18 for all quantitative analyses. Assessments include a battery of measures (Table 3). These measures include lifetime and current information on substance use, psychiatric symptoms and diagnoses, medical history, social support, health functioning, healthcare utilization, and quality of life.

The process evaluation metrics for aim 3 (Table 3) will include fidelity measures, program acceptability/ appropriateness, feasibility, and satisfaction (aligning with the study logic model, Figure 1). Measures of fidelity include five core components that focus on MISSION being implemented within the hub (Table 1). To measure acceptability and appropriateness, we will use the acceptability of intervention measure (AIM) and the intervention appropriateness measure (IAM). To measure feasibility, we will collect the feasibility of intervention measure (FIM) at treatment completion. AIM, IAM, and FIM tools are essential for monitoring and evaluating the success of implementation efforts. Higher scores denote higher perceived acceptability, appropriateness, and feasibility of the intervention. Lastly, we will measure treatment satisfaction via an exit survey at treatment completion.

Second, as part of aim 3 (Table 3), we will conduct qualitative interviews guided by the CFIR among 45 MISSION participants and providers/administrators to examine implementation.[39] The CFIR characterizes contextual determinants of implementation across five domains and allows us to explore multilevel barriers and facilitators impacting MISSION sustainability and equitable implementation, as well as the likelihood for broader dissemination in other healthcare systems and settings. The CFIR aligns with the social-ecological model (SEM; Figure 2).[39] The SEM also considers the influence of multilevel factors on effective policy implementation but expands the contextualization of individual characteristics and behaviors to include interpersonal interactions, community interactions, and community infrastructure. Figure 2 aligns the CFIR domains within the SEM to make explicit the domains that may support or impede implementation.

Data for aim 3 regarding implementation barriers and facilitators will be assessed via semi-structured qualitative interviews with open-ended questions addressing CFIR domains as they relate to individuals' experiences with MISSION to inform sustainability and future equitable implementation.

Table 3: Study aims and measures.

Study aim	Outcomes	Measures and timepoints*
1. MISSION versus PLS on treatment effects	Patient characteristics and diagnoses	Addiction severity index (ASI) – B, DSM-5 symptoms – B, SCID-5-RV – S, B[28]
	Engagement in treatment	Modified treatment service review (TSR) – B, F, fidelity logs and scales – W, M, alcohol anonymous inventory (AAI; adapted for other substances) – B, F
	Reduction in overdose risk	Overdose risk questionnaire (OdRi) – B, F, timeline follow back (TLFB) – B, F
	Mental health	BASIS-24 – B, F, PCL-5 – B, F, World Health Organization disability assessment (WHODAS 2.0) – B, F, WHO quality of life brief version (WHOQOL-BREF) – B, F
2. MISSION mechanisms of action	Mediators	SCID-5-RV – B, working alliance inventory (WAI) – B, F, brief assessment of recovery capital (BARC-10) – B, F[28]
	Moderators	From ASI (e.g., age, race/ethnicity, marital status, gender, education) – B, F, psychosocial supports (e.g., employment and housing) – B, F
3. Mixed-methods process evaluation	Inform sustainability	Quantitative: acceptability of intervention measure (AIM) – B, F; intervention appropriateness measure (IAM) – B, F; feasibility of intervention measure (FIM) – F; treatment satisfaction survey – F. Fidelity logs – W: screening (eligibility rate among people referred to RA during recruitment period); recruitment/ participation (i.e., uptake; participant recruitment/participation rate – until the recruitment of the last participant.); same characteristics (adherence to recruitment of diverse population); delivery (content delivered, dose delivered, and dose received); reach (# of sessions; length of attendance; retention rate; # of referrals/completed linkages for specific services; barriers to participation). Consolidated framework for implementation research (CFIR) to guide qualitative interviews[39]

S=Screening assessment, B=baseline assessment, F=follow-up assessment, D=data extracts, W=weekly MISSION staff reports, M=monthly MISSION staff reports

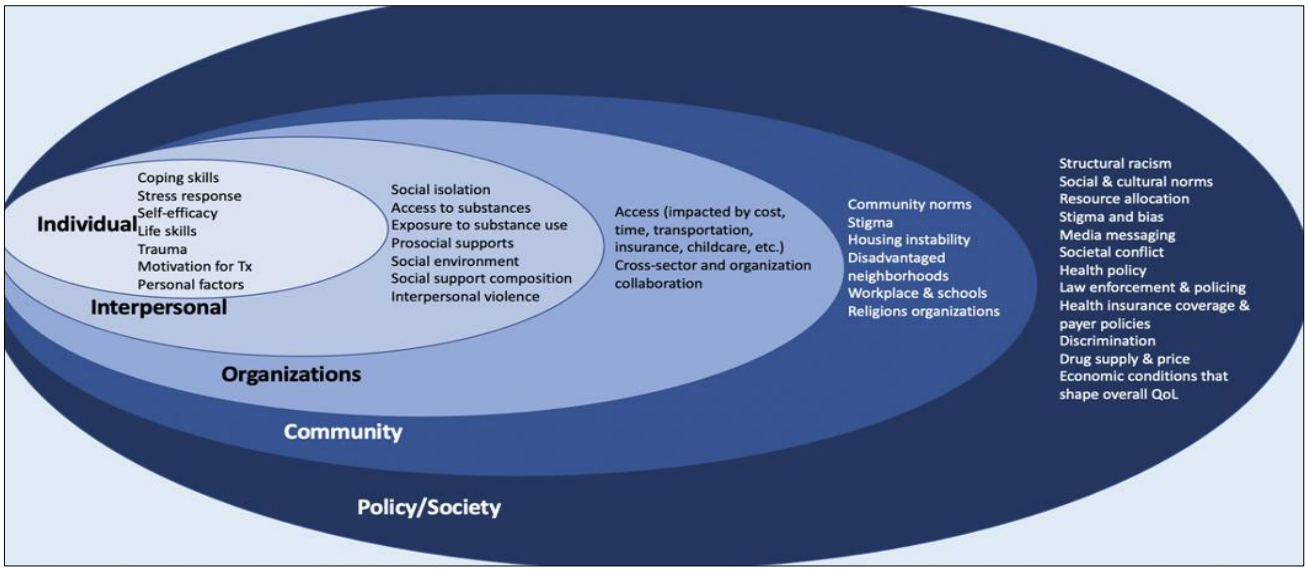

Figure 2: SEM for supporting treatment and recovery through linkage support (STAR-LS), aligns the CFIR domains within the SEM to make explicit domains that may support or impede implementation.

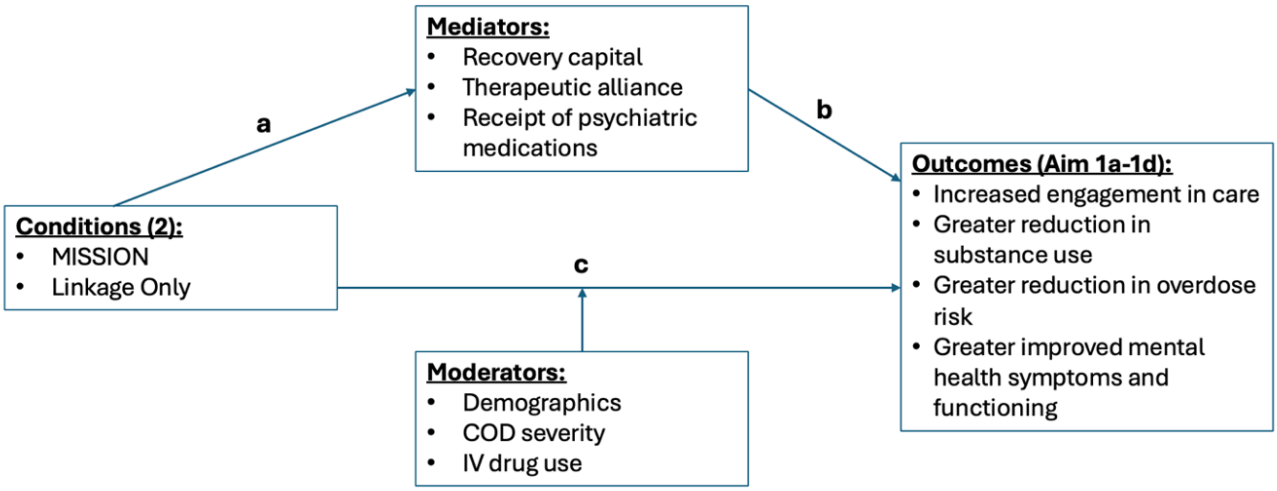

Figure 3: Mediators, moderators, and hypothesized outcomes of the treatment effects of MISSION versus linkage only.

CFIR domains include intervention characteristics of relative advantage, complexity, and adaptability (e.g., what changes would improve?); outer setting which include broader social, political, and economic context (e.g., how well does MISSION meet your needs/the needs of people with COD?); inner setting in which the clinical intervention is implemented including structural characteristics, relationships, and implementation readiness (e.g., how do an agency's values and beliefs impact the implementation of MISSION?); characteristics of Individuals involved in implementation such as knowledge, efficacy, and skill about the intervention (e.g., how prepared were you to implement MISSION?); and the final domain to assess is the implementation process which includes strategies or tactics that might influence implementation (e.g., did the project engage the appropriate individuals in the implementation and use of MISSION?). As reflected in CFIR interview guides, interviews will be tailored to study participant versus provider roles to allow exploration of contextual drivers of potential disparities identified in aim 3.

Qualitative interviews for aim 3 will be conducted in person or virtually, will last 30-60 minutes and be audio recorded. MISSION participants, providers, and administrators will be paid $50 for the interview. Due to organizational policies, some administrators may not be able to accept study incentives. All qualitative data will be stored on a secure university server and in locked cabinets at university offices with access restricted to the study team only. Interview audio files will be transcribed by a HIPAA and IRB approved service.

Analytic plan

For aim 1, we will use generalized linear mixed models (GLMMs) to compare the MISSION and PLS conditions on increased engagement (greater number of days engaged in treatment and number of linkages); greater reduction in substance use (measured by self-report days of use via the TLFB); greater reduction in overdose risk (measured by the OdRi); and greater improved MHD symptoms and functioning (measured by self-report MHD symptoms via the BASIS-24 and MHD functioning and impairment via the WHODAS 2.0) over the study period. For each outcome, we will estimate a GLMM model that specifies the appropriate distribution of the outcome variable in the regression model (normal, binomial, Poisson) and uses the appropriate link and variance functions. We will assess the effectiveness of the intervention using a treatment x time interaction term, which will estimate the change in the outcome measure of interest across the four assessment points for the MISSION condition as compared to the PLS condition and will be adjusted for baseline characteristics to increase the precision of intervention effect estimates.

For aim 2, we will conduct structural equation models and difference-in-coefficients tests using simultaneous estimation methods. These analyses will assess what proportion of the effect for outcomes 1a-1d for each condition (MISSION and PLS) can be explained by the mediators as outlined in Figure 3 (i.e., indirect effects, path a+b). With the difference-in-coefficients approach, we will first fit a GLMM to estimate the outcomes 1a-1d per condition while adjusting for common covariates (i.e., direct effects, path c). Second, we will fit a GLM/GLMM to estimate the effects of MISSION and PLS on aims 1a-1d adjusting for both mediators (Figure 3) and the same set of covariates. Third, we will then use the simultaneous estimation models to compare coefficients (effects) of MISSION and PLS on aims 1a-1d, based on likelihood ratio tests (i.e., a+b compared to c). Statistically significant attenuation of the coefficients of MISSION and PLS towards null signals a possible mediation effect (mediators noted in Figure 3) on the effects of MISSION and PLS.

Further, we will calculate the extent of mediation as (1 – effects of MISSION and PLS adjusted for mediators/the effects without adjustment) × 100%). Then, we will use structural equation models to test the mediation effects (e.g., Sobel test).[40] To examine moderating effects of key patient static factors, GLM/GLMMs similarly defined in aim 1 will be used to examine interactions of indicators of MISSION and PLS by potential key patient factors (moderators in Figure 3), while adjusting for other patient factors. Statistically significant interaction terms signal possible modifications of intervention effects by patient factors. If an interaction is present, we will report the intervention effects stratified by these factors. Patient factors may modify the effect of MISSION and/or PLS on mediators and subsequently modify the effects on aims 1a-1d. Such information may help identify patients most or least likely to benefit from MISSION or PLS and form the basis for future directions and studies.

For aim 3, study staff will use *NVivo* qualitative data analysis software via both inductive and deductive approaches. Using the a priori CFIR domains of interest (i.e., templated coding), while also allowing for emergent factors (open coding), the team will code several interviews in parallel to develop the initial codebook, then refine it iteratively during analysis of all interviews.

Then, in keeping with thematic analysis, we will organize codes into broader categories and cross-cutting themes as analysis progresses, both within the CFIR domains and allowing for any emergent themes, for final data interpretation.

Our proposed process evaluation (study logic model in Figure 1) includes a sequential mixed methods design. Quantitative data will be used to inform the qualitative portion of the aim. Data for aim 3 will be collected before the RCT and across the study via inputs, activities, and outputs. Once both portions of data collection for aim 3 are complete, both data types will be used to jointly assess the implementation of MISSION including fidelity process metrics; acceptability and appropriateness; feasibility; satisfaction (1-4 assessed quantitatively); and (5) implementation barriers and facilitators (assessed qualitatively). Collectively these findings will inform sustainability and future equitable implementation of MISSION for diverse subpopulations.

A complementary approach to mixed methods research (combining qualitative and quantitative data) is a common methodology for integrating study findings. This approach allows for further clarification and depth of the results from the quantitative method (e.g., surveys assessing acceptability), and can be gathered and contextualized with the results from the qualitative method (e.g., qualitative interviews). Ultimately, this provides a more complete, unified explanation than either single approach.

DISCUSSION

This hybrid type I study includes a RCT that will evaluate MISSION compared to PLS for increasing linkage engagement, reducing overdose risk, and improving behavioral health outcomes. We will also examine mechanisms of outcomes to understand under what circumstances and for what set of patients MISSION or PLS works best. Finally, this study includes a sequential mixed methods process evaluation, which focuses on diverse subpopulations and AB input to inform sustainability and future MISSION implementation.

The qualitative interviews are critical and will help support sustainability and guide subsequent implementation trials of MISSION (e.g., hybrid type 2 and 3 designs) by explaining the societal, system, provider, and patient level barriers (and how to address them) and facilitators to

equitable implementation of MISSION. In addition, findings from aim 3 will identify perceptions about why MISSION is successful at achieving better outcomes and factors, such as health care financing, to support the sustainability of MISSION in the absence of a funded research project and how to achieve this goal.

If aim 1 hypothesis are not supported, the interviews will help to determine the reasons why (i.e., questions posed to staff and patients will solicit information on barriers associated with the delivery of MISSION during the RCT and what modifications could be made to MISSION to maximize effectiveness). Aim 3 interviews may also add depth to aim 2 analyses for both moderators and mediators by strengthening the understanding of facilitators and barriers.

While this proposed study aims to examine the efficacy and implementation of MISSION versus PLS, it also importantly tests how these two interventions work to engage a very vulnerable population in a public health setting who often otherwise fall through the cracks. The proposed study is unique as it is testing the interventions delivered through the Hub in a public health department setting.

CONCLUSION

Thus, this study is ultimately examining how these interventions can be positioned within a recovery ecosystem (e.g., through a city health department) to engage people with COD, link them to services, and improve health outcomes.

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Conflict of interest: None declared
Ethical approval: This study was approved by the Institutional Ethics Committee

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