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Research Paper

Peer recovery specialist-delivered, behavioral activation intervention to improve retention in methadone treatment: Results from an open-label, Type 1 hybrid effectiveness-implementation pilot trial

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ABSTRACT

Background: Despite the efficacy of methadone to treat opioid use disorder (OUD), retention is an urgent priority, particularly among low-income, minoritized populations. Peer recovery specialists are well-positioned to engage vulnerable patients, particularly when trained in an evidence-based intervention to promote retention. This hybrid effectiveness-implementation pilot trial aimed to demonstrate the proof of concept of a peer recovery specialist-delivered behavioral activation and problem solving-based approach (*Peer Activate*) to improve methadone retention.

Methods: Implementation outcomes included feasibility, acceptability, and fidelity. Feasibility and acceptability were defined by the percentage of participants who initiated the intervention (≥75%) and completed ≥75% of core sessions, respectively. Fidelity was assessed via independent rating of a randomly selected 20% of sessions. The primary effectiveness outcome was methadone retention at three-months post-intervention vs. a comparison cohort initiating methadone during the same time period. Secondary outcomes included methadone adherence, substance use frequency, and substance use-related problems.

Results: Benchmarks for feasibility and acceptability were surpassed: 86.5% (32/37) initiated the intervention, and 81.3% of participants who initiated attended ≥75% of core sessions. The mean independent rater fidelity score was 87.9%, indicating high peer fidelity. For effectiveness outcomes, 88.6% of participants in *Peer Activate* were retained in methadone treatment at three-months post-intervention—28.9% higher than individuals initiating methadone treatment alone in the same time period [$\chi^2(1) = 10.10$, $p = 0.001$]. Among *Peer Activate* participants, urine-verified methadone adherence reached 97% at post-intervention, and there was a significant reduction in substance use frequency from 48% of past two-week days used at baseline to 31.9% at post-intervention [$t(25) = 1.82$, $p = .041$]. Among participants who completed the core *Peer Activate* sessions ($n = 26$), there was a significant reduction in substance use-related problems [$t(21) = 1.84$, $p = 0.040$].

Conclusion: Given the rapid scale-up of peer recovery specialist programs nationwide and the urgent need to promote methadone retention, these results, although preliminary, have important potential clinical significance. The next steps are to conduct a Type 1 hybrid effectiveness-implementation randomized trial with a larger sample size and longer-term follow-up to further establish the implementation and effectiveness of the *Peer Activate* approach.

Introduction

The opioid use disorder (OUD) crisis has been considered an "epidemic of poor access to care" (Wakeman & Barnett, 2018) that disproportionately affects low-income, racial/ethnic minoritized individuals (Mitchell et al., 2012; Saloner & Cook, 2013; Samples et al., 2018; Stahler & Mennis, 2018). The COVID-19 pandemic has exacerbated this divide, with the greatest increases in opioid-related overdoses occurring

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among Black/African American individuals living with OUD (Friedman & Hansen, 2022; Khatri et al., 2021; Patel et al., 2021). Efforts to identify gaps in OUD care using a cascade of care framework (Williams et al., 2018, 2019) have highlighted the need to improve OUD treatment retention, especially for medications for OUD (MOUD), where six-month retention is often below 50% (Williams et al., 2017) and even lower for low-income, racial/ethnic minoritized individuals (Manhapra et al., 2017; Samples et al., 2018; Stahler & Mennis, 2018; Weinstein et al., 2017). OUD treatment retention is highly predictive of future relapse, functioning, quality of life, and mortality (Hser et al., 2007; Stotts et al., 2009; Timko et al., 2016), and thus an important treatment target. There is an urgent need to develop and evaluate innovative strategies to address barriers to MOUD retention for low-income, racial/ethnic minoritized individuals.

Intervention delivery by peer recovery specialists (PRSs)—trained and typically certified individuals with their own lived experience with substance use and recovery—is a promising implementation strategy to improve MOUD retention for low-income, racial/ethnic minoritized individuals. PRS-delivered interventions offer a flexible approach to address barriers to MOUD retention, including stigma, challenges navigating services, housing instability, and other structural and psychosocial factors (Bassuk et al., 2016; Jack et al., 2018). The rapid increase in the use of PRSs nationwide demonstrates the appeal of employing PRSs as a potentially sustainable solution to support the behavioral treatment needs of individuals in OUD care. Yet, few evidence-based interventions have been evaluated for PRS delivery to promote MOUD retention. Prior research has largely been inconclusive regarding evidence-based psychosocial interventions to support MOUD retention (Carroll & Weiss, 2017; Timko et al., 2016). To date, reinforcement-based approaches, such as contingency management, have empirical support for improving MOUD retention, yet typically low adoption in community settings due to organizational and provider barriers, including cost, especially in medically underserved areas (Carroll, 2014; Timko et al., 2016). Prior research suggests the relevance of reinforcement-based approaches to improve MOUD retention but will require approaches that are feasible and sustainable for underserved populations (Dunn et al., 2013; Timko et al., 2016).

Behavioral activation may be a feasible, scalable, reinforcement-based approach for improving MOUD retention for low-income, racial/ethnic minoritized individuals with OUD. Behavioral activation, originally developed as an efficacious treatment for depression (Lejuez et al., 2011), aims to increase positive reinforcement by promoting engagement in value-driven, substance-free activities to increase experiences of enjoyment and mastery in one's environment. By targeting increases in positive reinforcement, behavioral activation has also been found to be effective for improving substance use treatment retention (Magidson et al., 2011) and preventing future relapse (Daughters et al., 2018; Mimiaga et al., 2012, 2019) among low-income, minoritized individuals with substance use. Further, when combined with problem-solving behavioral interventions, behavioral activation has improved medication adherence (i.e., for HIV) among low-income, minoritized populations with substance use (Daughters et al., 2010; Magidson et al., 2014, 2021; Tull et al., 2018). From an implementation perspective, behavioral activation is highly feasible using lay counselor delivery (Magidson et al., 2015, 2021; Nadkarni et al., 2017b) and is likely to be cost-effective (Ekers et al., 2011; Nadkarni et al., 2017a; Richards et al., 2016). Following from this prior research, behavioral activation may be an ideal evidence-based intervention for improving MOUD retention using a PRS-delivered model.

Building upon our team's formative work based on key stakeholder input (Satinsky et al., 2020), this study aimed to demonstrate the proof of concept for a PRS-delivered behavioral activation approach ("*Peer Activate*") to support retention for low-income, largely racial/ethnic minoritized individuals in OUD treatment. Guided by Proctor's model for defining implementation outcomes (Proctor et al., 2011), we conducted a Type 1 hybrid effectiveness-implementation open-label pilot trial to establish the feasibility, acceptability, and PRS fidelity of *Peer Activate* and evaluate preliminary effectiveness for methadone retention (primary), methadone adherence and substance use outcomes, including substance use frequency and related problems (secondary).

Methods

Setting

Recruitment took place at a community-based opioid treatment program (OTP) in Baltimore City. Baltimore is a prime location to test innovative strategies to combat the OUD crisis, as its overdose fatality rate is among the highest in the US, particularly for low-income Black/African Americans (Baltimore City Health Department, 2018; Maryland Department of Health, 2018). The OTP program is certified by the Maryland Department of Health Commission on Accreditation of Rehabilitation Facilities and currently serves approximately six hundred active patients receiving methadone treatment. Greater than 95% of all individuals who receive services at this OTP are on Medicaid and approximately 80% report incomes of less than $15,000 in the past year.

Recruitment

Patients receiving *Peer Activate* were recruited through word-of-mouth, flyers left at methadone dosing, on-site recruitment tables (outdoor and indoor), and staff referral. We screened all patients newly enrolling in the methadone treatment program who consented to be contacted for research, as well as patients who indicated interest in being contacted for research after intake. This included systematic screening of their methadone dosing records to determine date of treatment initiation and dosing history. Interested and potentially eligible patients were invited to complete a baseline assessment to determine eligibility. Inclusion criteria were: (1) ≥18 years of age; and (2) initiated treatment in the methadone program and/or demonstrated challenges with methadone adherence in the past three months. Challenges with methadone adherence were defined based on stakeholder input and included: (1) at least one missed methadone dose in the past three months; (2) counselor/provider report of methadone nonadherence; (3) at least one missing methadone take-home bottle; (4) urine toxicology negative for methadone; and/or (5) move from extended methadone take-homes to daily dosing due to concerns regarding adherence. Exclusion criteria were: (1) pregnant at study enrollment; (2) untreated or undertreated psychosis or mania that would interfere with study participation; and/or (3) inability to provide informed consent in English.

Design and procedures

All participants in the open-label trial condition received the study intervention content (*Peer Activate*, described below), alongside usual care at the OTP. An intent-to-treat approach was used such that participants could continue assessments regardless of treatment continuation. Assessments were administered at baseline and at three months post-intervention. The majority of study assessments took place in a private space at the OTP. When participants were not able to travel to the OTP, study procedures could take place on-site elsewhere or by phone. Participants received $25 gift cards for assessments. To avoid assessment fatigue, participants were given the option to complete assessments over two days within a two-week period. Recruitment began in October 2020 and ended in August 2021. All primary data collection (i.e., follow-up assessments) were completed in October 2021. Final chart extraction of medical record data was completed in January 2022.

Comparison cohort. A comparison cohort ($n = 119$) of individuals receiving methadone at the study site during the same timeframe was created retrospectively by extracting monthly retention rates for patients with intake dates on or after October 1, 2020. The timeframe of the comparison cohort was matched to the study sample due to COVID-related

Table 1
Demographic data and baseline characteristics.

	Intent-to-Treat *N*=37	Completer* *n*=26	Comparison cohort for primary outcomes** *n*=119
Race †			
Black or African American	61.3%	65.4%	49.6%
White	41.9%	38.5%	50.4%
American Indian/Alaska Native	6.5%	11.5%	
Other	6.5%	3.8%	
Gender			
Male	58.1%	69.2%	67.2%
Female	41.9%	30.8%	32.8%
Mean age, years (*SD*)	48.81 (9.24)	48.65 (8.89)	46.24 (11.97)

Note. * Completers were defined as completion of at least 75% of the core sessions (i.e., first five sessions), which equaled ≥ four sessions.
** Methadone retention was compared to a cohort of individuals initiating methadone at the study site during the same timeframe (i.e., on or after October 1, 2020, through May 2021).
†Participants were allowed to select more than one option.

programmatic changes (i.e., extended take home medication options during this time). Data from this group were used to evaluate differences in methadone retention over three months. Demographic data for both the active and comparison samples are reported in Table 1.

All study procedures were approved by the University of Maryland, College Park IRB with an IRB Authorization Agreement approved by the University of Maryland, Baltimore. The trial was registered on Clinicaltrials.gov on January 30th, 2020 (ClinicalTrials.gov Identifier: NCT04248933).

Peer Activate intervention

Peer Activate is a behavioral activation-based intervention aimed at increasing substance-free, positive reinforcement in one's environment. Behavioral activation leverages individual values and self-identified activities, and is brief and flexible, increasing its potential for implementation in a range of clinical and community contexts. Prior work has demonstrated the effectiveness of behavioral activation, adapted for substance use, in improving substance use treatment retention (Magidson et al., 2011) and sustained abstinence (Daughters et al., 2018) compared to a contact-time matched control condition (i.e., supportive counseling). Following this work, our team further adapted behavioral activation for PRS delivery (Satinsky et al., 2020) and for OUD treatment specifically (Kleinman et al., 2020). Specifically, in formative work leading up to this trial (Kleinman et al., 2020), we received feedback from stakeholders (N = 32), including OTP staff at the study site, representing a range of roles in patient care and program administration, PRSs working in Baltimore City (n = 12), and patients currently enrolled in methadone treatment at the study site (n = 20). Patients were purposefully sampled to represent those who were both successfully engaged in treatment as well as those who were struggling with methadone treatment retention (Kleinman et al., 2020). Guided by stakeholder input, we combined the adapted behavioral activation approach with problem-solving strategies to improve medication adherence (i.e., Life-Steps, originally developed to improve adherence to HIV treatment; Safren et al., 1999), which also follows from our team's prior work integrating behavioral activation and Life-Steps for HIV medication adherence (Magidson et al., 2014, 2021, 2022).

Peer Activate includes up to 12 weekly sessions, with the first five being the core treatment sessions and content, and the subsequent seven designed to reinforce core content. The core treatment components of *Peer Activate* include: (1) Life Steps for medication adherence (Safren et al., 1999), adapted for methadone (i.e., discussion of problem-solving strategies across barriers to methadone retention, including transportation and housing); (2) psychoeducation regarding the behavioral cycle of substance use, patterns of reinforcement, and the rationale for increasing substance-free, positive reinforcement as a strategy to reduce substance use; (3) behavior monitoring, including monitoring of daily activities, their enjoyment, importance, and associated cravings levels, and identifying areas for increasing value-driven activities; (4) identifying individualized values across a range of life areas; (5) and scheduling value-driven, substance-free activities. Additional sessions are used to reinforce the initial five-core session content, including continued scheduling of value-driven, rewarding, substance-free activities; balancing productive and enjoyable activities; building social support; relapse prevention and planning for anticipated challenges for methadone retention and substance use; and reviewing lessons learned throughout the intervention and opportunities for continued skill practice. Each *Peer Activate* session begins with a brief check-in on substance use and methadone adherence. Identified barriers to methadone adherence guide an individualized discussion about needs and barriers to methadone treatment retention. Problem-solving strategies are used to support patients to identify solutions for barriers to retention, such as transportation and housing. Additionally, the PRS interventionist provides traditional PRS support as needed, including linkage-to-care and case management-type services, alongside the structured intervention. Throughout the intervention, the PRS is encouraged to share his/her own lived experience with substance use and recovery to support participant engagement with intervention content, reduce stigma, and provide motivation.

The duration of each session is approximately 30-60 minutes, depending on participant availability, preference, and mental status (i.e. recent substance use, methadone side effects, or other difficulty concentrating). All intervention sessions were audio-recorded for fidelity monitoring. The majority of intervention sessions took place in a private space at the OTP. When participants were not able to travel to the OTP, sessions could take place by phone or in a private space off-site.

PRS interventionist training and supervision

Peer Activate in this pilot study was delivered by one PRS with a deep knowledge of the community and available resources who is an Internationally Certified Peer Recovery Specialist, a Maryland State Certified Peer Recovery Specialist, and a Registered Peer Supervisor through the Maryland Addictions and Behavioral Health Certification Board. He identifies as a Black/African American male and has lived experience of OUD and recovery in Baltimore City. The PRS interventionist was hired by the study team based on his relevant personal experiences, prior training, and openness to multiple pathways to recovery. For this study, he was based full-time at the OTP. He provided active input

in adapting the intervention materials (treatment manual and supplementary handouts). In addition to his state certification and training, intervention-specific training included approximately three days of one-on-one didactic sessions and role-plays of intervention content, followed by weekly supervision that included ongoing role plays, booster trainings and intervention content review as needed (particularly for Life-Steps and mindfulness exercises). *Peer Activate* training and supervision were conducted by a clinical psychologist with training in OUD treatment, behavioral activation, and Life-Steps. Supervision was conducted weekly for one hour. The supervisor also conducted a weekly review of audio-recordings of sessions to monitor potential drift, although fidelity was very high. Further, an ongoing focus on one's own self-care, wellness, and recovery is essential in supervision of PRSs. As such, each weekly supervision session began with a self-care check-in and support in addressing any personal barriers to wellness or maintenance of recovery supports, as well as regular check-ins regarding role boundaries.

Outcome measures

Implementation outcomes

Implementation outcomes were guided by Proctor's model's recommendations for early- or mid- implementation phases, and included feasibility, acceptability, and fidelity, defined below (Proctor et al., 2011).

Feasibility and acceptability

Feasibility and acceptability were defined *a priori* based on *Peer Activate* session attendance (i.e., the percentage who initiated the intervention, and session attendance respectively). Feasibility was defined as ≥75% of patients initiating *Peer Activate*, and acceptability as ≥75% of patients completing ≥75% of the core *Peer Activate* intervention sessions.

We also used a validated quantitative measure of feasibility and acceptability, the Applied Mental Health Research Group implementation outcome assessment (Haroz et al., 2019), which has been used to evaluate the implementation of peer- and lay health worker-delivered interventions and was designed to be adapted for different resource-limited settings globally (Magidson et al., 2021; Moore et al., 2021). This measure has separate subscales for feasibility and acceptability, with ratings on a four-point scale: 0 = "not at all"; 3 = "a lot". We adapted wording of this measure for the OTP context and peer-delivered intervention (e.g. "Do you believe people in your community could seek help for alcohol or drug problems from sessions with a peer without fear of how others would view them?").

Fidelity

Fidelity was assessed by coding a randomly selected 20% of audio-recorded sessions by a trained, independent rater using a checklist of five to eight elements of the *Peer Activate* approach. Specific elements of *Peer Activate* were assigned to each intervention session (per treatment manual), guided by prior trials of behavioral activation and problem-solving approaches for substance use (i.e., Daughters et al., 2018; Magidson et al., 2022). Based on these checklists, fidelity was determined based on the delivery of each component as intended. The PRS self-reported fidelity using the same checklist of intervention components at each session. We *a priori* defined high fidelity as ≥75% of components delivered as intended as rated by the independent coder. The independent coder also rated common factors (i.e. verbal communication, self-disclosure, normalization, empathy) using the ENhancing Assessment of Common Therapeutic factors (1 to 3 rating scale; Kohrt et al., 2015), a cross-cultural competency measure of lay health worker skill in delivering a behavioral intervention.

Effectiveness outcomes

Methadone treatment retention

Methadone retention was assessed using chart extraction of methadone dosing data. Dosing at the treatment site is monitored and documented through an electronic health record (Methasoft, Netalytics, Greer, SC), which captures all dosing information and missed doses. We used the OTP definition of dropout (30 days or more without a dose), measured dichotomously at the three-month follow-up study assessment (primary endpoint)—approximately three months following *Peer Activate* intervention initiation. If a participant transferred to another treatment program, we requested methadone dosing data from outside programs with participant consent, which was considered as being retained in treatment. Secondarily, we also examined methadone retention at one- and two-months post-intervention, examining whether participants had one or more documented methadone dosing dates for each 30-day period. Depending on length of time in treatment, urine toxicology results, and COVID-19-response protocols, patients may receive up to 28 days of take-home bottles; therefore, treatment retention was assessed as engagement with the treatment site (dosing/ picking up take-home bottles) at the month level and not based on number of missed doses. For the comparison cohort, methadone retention was assessed using the same approach at one-, two-, and three-month intervals following methadone treatment initiation.

Urine toxicology of methadone adherence and substance use

Methadone adherence was assessed via urinalysis, extracted from the medical record within 30 days of baseline and post-intervention assessments. At the OTP, urine toxicology is assessed routinely for eight substances, including methadone, amphetamines, benzodiazepines, cannabinoid, cocaine, opiates, oxycodone/oxymorphone, and fentanyl. Results are binary (i.e., yes/no) indicating the presence of methadone and other substances.

Substance use frequency and severity

Substance use, including opioid and non-opioid use, was also assessed via self-report. Substance use frequency was assessed at baseline and post-intervention using the Timeline Followback, capturing frequency and quantity of use across each substance separately in the past two weeks for non-prescribed substances (Sobell & Sobell, 1992). Problems and negative consequences associated with substance use were assessed at baseline and post-intervention using the revised Short Inventory of Problems (SIP-R), which measures problems across five domains: interpersonal, intrapersonal, physical, impulse control, and social, over the past three months (Kiluk et al., 2013).

Data analytic plan

Primary outcomes

Descriptive statistics were used to characterize the sample, including implementation outcomes. We defined benchmark milestones *a priori* for successful implementation: ≥75% of patients participating in the first *Peer Activate* session (feasibility); ≥75% of patients completing ≥75% of the core *Peer Activate* sessions (acceptability); and PRS fidelity ≥75% as rated by an independent coder. Methadone retention was examined using descriptive and inferential analyses. Differences between rates of methadone retention for *Peer Activate* participants and the clinic-based comparison sample were evaluated using chi-square tests, assessed at one-, two-, and three-month follow ups (post-intervention for *Peer Activate* participants, and post-methadone initiation for the comparison cohort).

Secondary outcomes

Methadone adherence assessed via urinalysis was evaluated by comparing the proportion of participants who tested positive for methadone at baseline and post-intervention using a McNemar test. Secondary substance use outcomes included the frequency and severity of overall substance use and opioid and non-opioid use. For urinalysis results, substance use was evaluated by examining the proportion of individuals who tested positive for non-prescribed substances on urinalysis toxicology at baseline and post-intervention. Reductions in self-reported

substance use frequency (assessed using the Timeline Followback) and substance-related problems were examined using single-sided paired-samples *t*-tests given *a priori* hypotheses regarding the direction of the effect. Substance use outcomes were analyzed in both the intent-to-treat sample ($N = 37$), as well as a sub-sample of participants who were *a priori* defined as "completers" ($n = 26$). Treatment completers were determined *a priori* based on completing at least 75% of the core treatment sessions. This cut-off was selected based on the core content of the intervention being introduced in the first five sessions, with subsequent sessions (6-12) being used to reinforce the core content. Thus, we defined "completers" as those who completed at least 75% of core sessions, or ≥ four sessions)."

Results

Participants

Fig. 1 depicts the study CONSORT diagram. Thirty-seven individuals were enrolled in the open-label trial (intent-to-treat sample), with the goal of reaching a minimum of $n = 24$ completers (i.e., defined as completing ≥ four *Peer Activate* sessions). Of the $N = 37$ intent-to-treat sample, 26 participants completed at least four *Peer Activate* sessions and were defined as the "treatment completer" group. Characteristics of the intent-to-treat and completer sample are presented in Table 1. The characteristics of the comparison group used for the primary effectiveness outcomes (methadone retention) are also included in Table 1. In the intent-to-treat sample ($N = 37$), 32.4% (12/37) initiated methadone in the past three months, and 67.6% (25/37) were eligible for study participation due to challenges with methadone adherence. The majority of participants (73%) indicated heroin was their primary substance, followed by fentanyl (24.3%), and cocaine (21.6%; participants were allowed to select more than one choice). The majority of participants (75.7%) reported prior MOUD treatment attempts; 21.6% reported prior attempts at the study OTP site, and 59.5% reported prior or current additional treatment from another substance use treatment program. No participants were legally mandated to engage in treatment, but 89.2% reported prior incarceration.

Implementation outcomes

Feasibility and acceptability

All *a priori* benchmarks for measuring feasibility and acceptability were surpassed: 86.5% of the total sample (32/37) initiated the intervention, and 81.3% of participants who initiated the intervention (26/32) attended ≥75% of the core five intervention sessions. Participants completed an average of 7.7 sessions ($SD = 5.0$) with an average of 8.8 days between sessions ($SD = 6.3$) and average 71.1 days of total intervention engagement ($SD = 38.2$). The quantitative assessment of feasibility and acceptability also indicated high levels of feasibility ($M = 2.04$, $SD = 0.43$) and acceptability ($M = 2.92$, $SD = 0.19$).

Fourteen participants opted to have at least one intervention session conducted by phone. Of those participants, the median proportion of total sessions conducted by phone was 0.13 ($IQR = 0.083$). One participant elected to have all intervention session conducted by phone. Though it was an option for all participants, no intervention sessions took place in-person at a location other than the OTP.

Fidelity

The mean independent rater fidelity score was 87.9% ($SD = 18\%$) across the randomly selected 20% of sessions. The mean PRS-reported fidelity score was 93.8% ($SD = 14.7\%$) across all sessions. The mean score on the ENhancing Assessment of Common Therapeutic factors scale was 2.99 ($SD = 0.09$), indicating very high PRS competence across all domains assessed (i.e., verbal communication, self-disclosure, normalization, empathy). The PRS shared self-disclosures related to his recovery and/or substance use a mean of 1.54 times per session ($SD = 1.90$), with total self-disclosures per session ranging between 0-9 disclosures.

Effectiveness outcomes

Methadone retention

Verification of methadone retention at the study site and/or outside methadone treatment programs was able to be established for 94.6% of participants (35/37) at monthly intervals (one, two, and three months post-intervention). Two participants were coded as missing, as we were unable to verify their status at an outside treatment program after being transferred.

At three-months post-intervention (primary endpoint), 88.6% (31/35) of participants in *Peer Activate* were retained in methadone treatment, compared to 59.7% (71/119) at three-months post-methadone treatment initiation for the comparison cohort—a 28.9% retention rate difference that was statistically significant between the groups [$\chi^2(1) = 10.10$, $p = 0.001$]. At one-month post-intervention, all participants in *Peer Activate* (100%) were retained in methadone treatment, compared to 79.8% (95/119) in the comparison sample at one-month post-methadone initiation. At two-months post-intervention, 94.3% (33/35) of participants in *Peer Activate* were retained in methadone treatment, compared to 70.6% (84/119) at two-months post-methadone initiation in the comparison group [$\chi^2(1) = 8.32$, $p = 0.004$].

Methadone adherence

Verification of methadone urinalysis toxicology was able to be established for 94.6% of participants (35/37) at baseline and 89.2% (33/37) at post-intervention. Of the two individuals missing urine toxicology results at baseline, $n = 2$ did not have urine toxicology results available during the baseline assessment window due to pandemic-related interruptions to typical toxicology intervals. Of the four individuals missing urine toxicology results at post-intervention, two transferred to another program, and two discontinued treatment at the clinic; none had urine toxicology results available during the post-intervention assessment window (all four of these individuals were *Peer Activate* "non-completers").

Based on urine toxicology results, 82.9% (29/35) tested positive for methadone at baseline. This increased to 97.0% ($n = 32/33$) at post-intervention. A McNemar's test suggested significant increases in methadone positive results from baseline to post-intervention ($p = 0.045$).

We also conducted a sensitivity analysis to account for six participants' baseline urinalysis tests that were conducted at methadone treatment intake, and thus may not have reflected methadone adherence. For these participants, if a urinalysis result was available after intake, the first available result was imputed for baseline ($n = 3$). Otherwise, participants were excluded from the sensitivity analysis. In the sensitivity analysis subsample ($n = 32$), we found a baseline methadone urinalysis positivity rate of 87.5% (28/32), and a non-significant increase from baseline to post-intervention ($p = 0.083$).

Substance use outcomes

Urinalysis. Verification of substance use from urine toxicology results was able to be established for 34/37 participants at baseline and 33/37 at post-intervention; 100% (34/34) of participants with baseline urine toxicology results available tested positive for at least one non-prescribed substance. On average, participants used 2.53 ($SD = 1.11$) non-prescribed substances at baseline, with the most common being fentanyl (85.3%; 29/34) and cocaine (70.6%; 24/34). At post-intervention, 84.8% (28/33) of the intent-to-treat sample continued to use at least one non-prescribed substance [80.8% of completers (21/26) and 100% of non-completers (7/7)], using an average of 2.06 ($SD = 1.34$) substances. Fentanyl (72.7%; 24/33) and cocaine (57.6%; 19/33) continued to be the most commonly used substances at post-intervention.

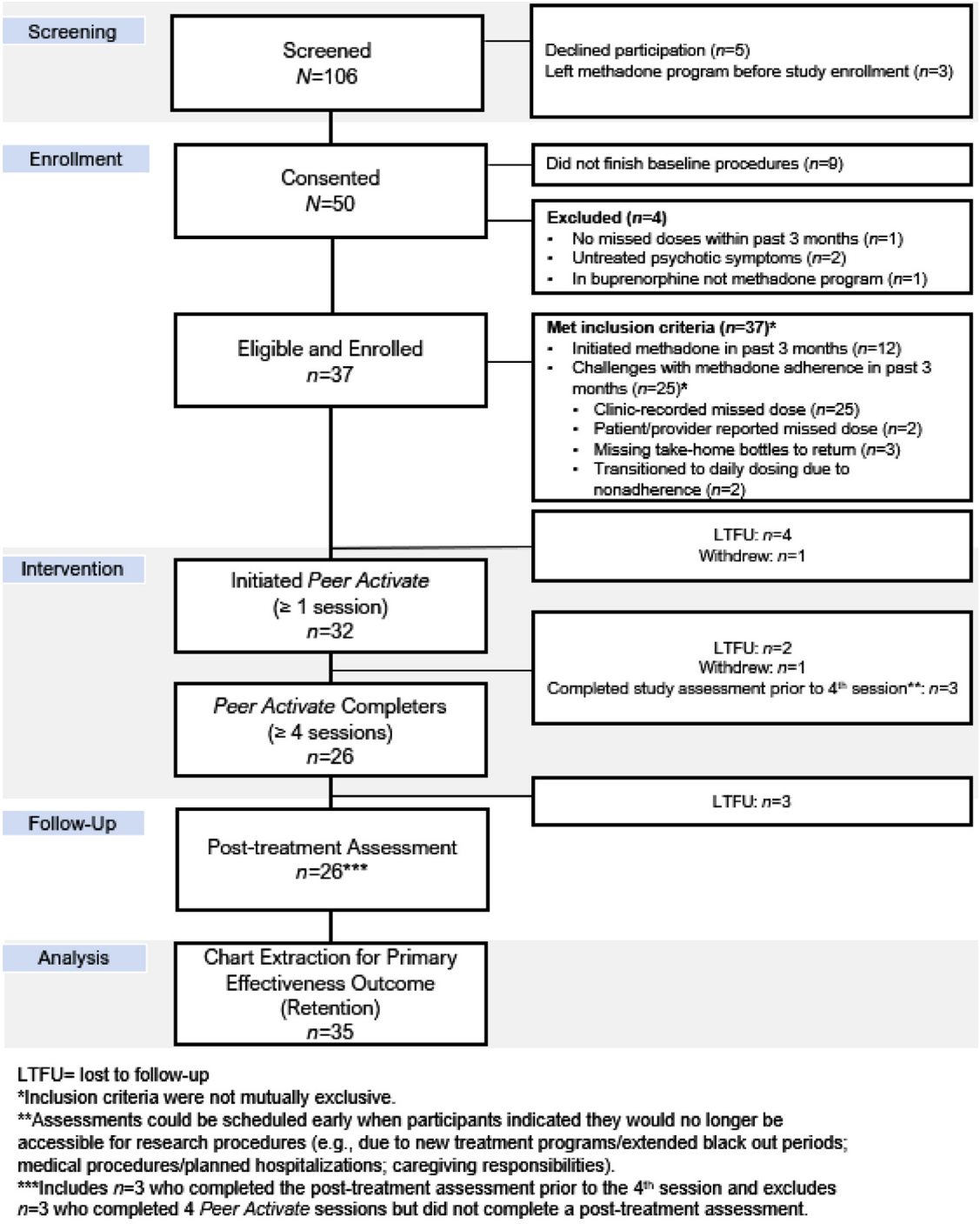

Fig. 1. Study consort diagram.

Self-report (TLFB). In the intent-to-treat sample ($N = 37$), participants reported using substances, on average, 48.0% of days in the past two weeks. At post-intervention, use was reduced to an average 31.9% of days in the past two weeks. A paired-samples *t*-test suggests a significant reduction in self-reported substance use frequency from baseline to post-intervention [$t(25) = 1.82$, $p = 0.041$].

In the *Peer Activate* completer subgroup ($n = 26$), participants reported an average of 44.4% of days used at baseline, which reduced to 28.1% of days used at post-intervention, a statistically significant reduction [$t(22) = 1.86$, $p = 0.038$].

Self-report (SIP-R). Results suggest non-significant decreases in total problems associated with substance use from baseline ($M = 27.03$, $SD = 13.91$) to post-intervention ($M = 20.96$, $SD = 13.83$) [$t(24) = 1.62$, $p = 0.059$] in the intent-to-treat sample. Significant reductions were found in the intrapersonal [$t(25) = 1.97$, $p = 0.030$] and impulse control [$t(25) = 2.21$, $p = 0.018$] subscales. Non-significant reductions were found in the physical problems subscale [$t(25) = 1.67$, $p = .054$].

In the *Peer Activate* completer subgroup ($n = 26$), there was a significant decrease in total problems associated with substance use [$t(21) = 1.84$, $p = 0.040$]. There was a similar pattern of results for subscales for the completer group, with significant decreases in physical problems subscale scores [$t(22) = 2.21$, $p = 0.0019$]; interpersonal problems [$t(22) = 2.14$, $p = 0.022$]; and impulse control problems [$t(22) = 1.92$, $p = 0.034$].

Discussion

This Type 1 hybrid effectiveness-implementation pilot trial demonstrated the feasibility, acceptability, fidelity, and preliminary effectiveness of a PRS-delivered behavioral intervention to improve methadone treatment retention. There are few evidence-based interventions that have been tailored specifically for PRS delivery and evaluated for both implementation and effectiveness. This study is novel in that we tested PRS delivery of a structured evidence-based intervention, behavioral activation, that has previously been demonstrated to improve substance use treatment retention in other non-OTP contexts (Magidson et al., 2011) and reduce the severity of other substance use (Daughters et al., 2018). Results demonstrated high levels of methadone treatment retention among *Peer Activate* participants, with approximately 89% of individuals being retained in methadone treatment three months following starting *Peer Activate*, compared to a comparison cohort receiving methadone at the same site that had approximately 60% retention three months after initiating methadone treatment. Findings also demonstrated that all *a priori* benchmarks for measuring feasibility, acceptability, and fidelity were surpassed, with 87% of the total sample initiating the intervention, 81% of participants who initiated the intervention attending ≥75% of core intervention sessions, and 88% PRS fidelity rated by an independent rater. Further, in our assessment of fidelity, we not only evaluated the delivery of specific evidence-based intervention components, but also the quality of PRS delivery and incorporation of one's own lived experience into the intervention (Anvari et al., 2022).

The *Peer Activate* intervention was developed and adapted based on several lines of formative work that captured stakeholder perspectives to inform the adaptation of the PRS-delivered intervention (Kleinman et al., 2020; Satinsky et al., 2020). The approach was also informed by the field of global mental health, which has put forth robust evidence for the feasibility, acceptability, and effectiveness of "task sharing" evidence-based interventions with non-specialist delivery (Singla et al., 2017; Verhey et al., 2020). Although there is strong empirical support in low- and middle-income countries for task shared delivery of evidence-based interventions, such as behavioral activation and problem solving (Magidson et al., 2021; Singla et al., 2017; Verhey et al., 2020), task sharing specific evidence-based interventions (vs. providing general support) with peers has been more limited in high-income contexts. This may be in part due to stricter boundaries around clinical roles and licensure/certification requirements (i.e., there are formal training and certification programs for peers in the US, which are more limited or non-existent in many low- and middle-income countries; Satinsky et al., 2021). However, given the severe shortages of trained behavioral health providers that also exist in high-income contexts, including the US, and the massive gaps in receiving substance use treatment services—with only 6.5% of individuals who were in need receiving substance use care in the last year in the US (Substance Abuse and Mental Health Services Administration, 2021)—urgent efforts are needed to expand access not only to services but to evidence-based, high-quality services. Peer-delivered models of evidence-based interventions, such as the approach we tested, may help address this gap.

In addition to our primary implementation and effectiveness results focused on retention, results demonstrated promising secondary outcomes related to urine-verified methadone and substance use toxicology, and self-reported frequency and severity of opioid- and other substance use. Results demonstrated increases in urine-verified methadone toxicology, with positivity reaching 97% at post-intervention, which is meaningful given the increased provision of take-home methadone during the COVID-19 pandemic. There were also significant reductions in the frequency of substance use, and among participants who completed the core *Peer Activate* sessions, significant reductions in problems associated with use. The next step from this work is to evaluate longer-term retention and other substance use and functional outcomes using a randomized design with a comparison condition, larger sample size, and longer-term follow-up. Further, given that behavioral activation was originally developed as an intervention for depression, there are also future implications for extending this model to other mental health outcomes, such as depression, which is highly comorbid with substance use. These efforts would also include training the robust workforce of PRSs who are more focused on mental health vs. substance use care.

Findings must be interpreted in the context of study limitations inherent in an open-label pilot feasibility trial. First, as a hybrid effectiveness-implementation pilot study, we prioritized eligibility criteria that would reflect real-world conditions for future implementation of the intervention; thus, we elected to include individuals who were both newly initiating methadone treatment, given challenges with early retention (Williams et al., 2019), as well as other patients demonstrating challenges with adherence, regardless of how long they had been in treatment. This decision was responsive to stakeholder feedback to broaden availability of the intervention, especially in the context of the COVID-19 pandemic causing new challenges for many patients in methadone treatment. However, we recognize that this also brings variability into our sample, particularly in how to interpret retention outcomes, which will be important to further investigate in the subsequent larger trial. Second, although a comparison cohort was able to be created at the OTP that was matched on timeframe given COVID-related programmatic changes and other considerations, not all study inclusion criteria (i.e., challenges with adherence) were able to be extracted for the comparison cohort, and only methadone retention outcomes were available in the comparison cohort. Further, we were not able to obtain records for patients in the comparison group who may have transferred to another program. Additionally, the cohort was not matched on other factors (i.e., race/ethnicity, time in treatment) and may have included individuals who were approached for the pilot study but did not follow up for participation. These differences must be considered when interpreting differences across our sample and the comparison cohort. As such, this comparison does not substitute the need for a randomized comparison condition in future work. However, it did provide an initial benchmark for comparison for our primary effectiveness outcome of methadone retention. Finally, we relied on clinic-administered urine toxicology results, which was a greater challenge during the COVID-19 pandemic when urine toxicology testing was not as consistently administered. Future work will include researcher-administered assessments of urinalysis results. Additionally, there was little variability in urine-verified substance use to allow for statistical comparison of changes over time.

Proctor's model (Proctor et al., 2011) guided our approach to defining and measuring implementation outcomes, with a focus on outcomes early in the process of implementation. Although our sample size was reasonable for examining early implementation outcomes (i.e., feasibility, acceptability, fidelity), which is the primary purpose of pilot work (Thabane et al., 2010), a larger sample size is needed in future work to provide sufficient power to examine the effectiveness of *Peer Activate* in comparison to a control condition across all outcomes, including longer-term retention (i.e., at least six months; Williams, 2021; Williams et al., 2018, 2019). Larger sample sizes will also be important to allow comparison across participant characteristics, especially treatment status (e.g. new to treatment, demonstrating challenges with adherence, receipt of take-home medication). Longer-term implementation outcomes should also be evaluated, including adoption and sustainability, and capturing implementation outcomes at multiple levels (e.g., peer/provider, organizational) in a subsequent trial with additional PRS interventionists and treatment sites. Finally, this project took place with substantial involvement from a PRS interventionist. It will be important in future quantitative and qualitative work with more than one PRS interventionist and larger sample size to understand how PRS characteristics (e.g., demographic, interpersonal, other background characteristics, including incarceration history) may affect treatment outcomes for different types of patients.

Conclusions

This pilot demonstrated the proof of concept for a PRS-delivered behavioral activation-based approach to improve methadone treatment retention. Preliminary results show promise for both the implementation and effectiveness of PRS-delivered behavioral activation to improve retention in methadone treatment. By improving retention in methadone treatment, an efficacious treatment for OUD, there is the potential to improve important clinical outcomes, including patient functioning and quality of life, and reduce subsequent risk of relapse and/or death (Hser et al., 2007; Stotts et al., 2009; Timko et al., 2016). Given the rapid scale-up of PRS programs nationwide, which suggests the potential for sustainability and wide-scale dissemination, as well as the urgent need to promote retention in MOUD programs among low-income, racial/ethnic minoritized populations (Stahler & Mennis, 2018), these results, although preliminary, have important potential clinical significance. Further, demonstrating that it is feasible, acceptable, and potentially sustainable for PRSs to deliver an evidence-based intervention to reduce the behavioral health treatment gap may also promote the long-term sustainability, reimbursement, and funding of the PRS role. Throughout this process, it will be crucial to maintain the support, supervision, and respect for the boundaries of the PRS role if evidence-based intervention delivery by PRSs is expanded, including ongoing attention to self-care. Our team is actively launching a larger Type 1 hybrid effectiveness-implementation trial (NCT05299515) using a randomized design, larger sample size, and longer-term follow-up to further establish the implementation and effectiveness of this approach.

Ethics approval

The authors declare that they have obtained ethics approval from an appropriately constituted ethics committee/institutional review board where the research entailed animal or human participation.

All study procedures were approved by the University of Maryland, College Park IRB (#1531148) with an IRB Authorization Agreement approved by the University of Maryland, Baltimore.

The trial was registered on Clinicaltrials.gov on January 30th, 2020 (ClinicalTrials.gov Identifier: NCT04248933).

Declarations of Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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