

# Using recovery management checkups for primary care to improve linkage to alcohol and other drug use treatment: a randomized controlled trial three month findings

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## Abstract

**Background and Aims:** Recovery management checkups (RMC) have established efficacy for linking patients to substance use disorder (SUD) treatment. This study tested whether using RMC in combination with screening, brief intervention, and referral to treatment (SBIRT), versus SBIRT alone, can improve linkage of primary care patients referred to SUD treatment.

**Design:** A randomized controlled trial of SBIRT as usual ( $n = 132$ ) versus SBIRT plus recovery management checkups for primary care (RMC-PC) ( $n = 134$ ) with follow-up assessments at 3 months post-baseline.

**Setting:** Four federally qualified health centers in the United States serving low-income populations.

**Participants:** Primary care patients ( $n = 266$ , 64% male, 80% Black, mean age, 48.3 [range, 19–53]) who were referred to SUD treatment after SBIRT.

**Interventions:** SBIRT alone (control condition) compared with SBIRT + RMC-PC (experimental condition).

**Measurement:** The primary outcome was any days of SUD treatment in the past 3 months. Key secondary outcomes were days of SUD treatment overall and by level of care, days of alcohol and other drug (AOD) abstinence, and days of using specific substances, all based on self-report.

**Findings:** At 3-month follow-up, those assigned to SBIRT + RMC-PC ( $n = 134$ ) had higher odds of receiving any SUD treatment (46% vs 20%; adjusted odds ratio = 4.50 [2.49, 8.48]) compared with SBIRT only, including higher rates of entering residential and intensive outpatient treatment. They also reported more days of treatment (14.45, vs 7.13;  $d = +0.26$ ), more days abstinent (41.3 vs 31.9;  $d = +0.22$ ), and fewer days of using alcohol (27.14, vs 36.31;  $d = -0.25$ ) and cannabis (19.49, vs 28.6;  $d = -0.20$ ).

**Conclusions:** Recovery management checkups in combination with screening, brief intervention, and referral to treatment are an effective strategy for improving linkage of primary care patients in need to substance use disorder treatment over 3 months.

**KEYWORDS**

Federally qualified health centers (FQHC), Linkage to treatment, Primary Care, recovery management checkups (RMC), screening brief intervention and referral to treatment (SBIRT), substance use disorders

## INTRODUCTION

Substance use accounts for 11% of the total health burden, globally [1,2]. In a recent study from 26 countries, only 7% of individuals received minimally adequate substance use treatment [3]. In the United States (US), over 20 million people had a past-year substance use disorder (SUD), including 14.5 million with an alcohol use disorder and 8.3 million with a drug use disorder [4]. Among primary care patients, the majority report past-year substance use, and half meet criteria for a past-year SUD. The identification and management of unhealthy alcohol and other drug use in primary healthcare settings has been a decades-long public health priority [2–4].

Unfortunately, SUDs have the largest gap between diagnosis and treatment received, with only 10% receiving past-year treatment [4]. There are a multitude of practical and attitudinal barriers that prevent some individuals from receiving or accessing care, particularly for underrepresented populations.

Federally qualified health centers (FQHCs) are primary healthcare providers in the United States that increase access to treatment at reduced rates [5]. FQHCs are required to serve an area and/or population with low rates of private insurance, offer sliding scale fees, provide comprehensive services, and have an ongoing quality assurance program. As such, their patient populations include a disproportionate number of low-income individuals and people of color who typically experience more barriers to SUD treatment access [6–8]. Like other primary care settings, FQHCs can play an important role in identifying individuals with SUD and referring them to appropriate treatment options [9].

Paramount to achieving and sustaining recovery is successful linkage to SUD treatment from primary health care settings. Screening, brief intervention, and referral to treatment (SBIRT) is a public health approach for identifying and addressing SUD among patients in primary healthcare settings [10,11] and has been widely disseminated in the United States and internationally [12–16]. SBIRT is a three-step process that involves (i) screening patients and using clinical judgement to assess the severity of substance use, (ii) having staff provide brief intervention when potentially problematic use is identified, and (iii) providing a referral to SUD treatment when needed. Although early studies with SBIRT among post-hospitalization or emergency room visits showed an increase in treatment initiation from 5% to over 50% [17–19], these results were not replicated in primary care settings. In a recent scoping review of SBIRT in primary healthcare settings, the majority of studies focused on alcohol use, with limited

evidence of its efficacy for individuals using other drugs [20]. Further, few SBIRT studies in primary healthcare have shown effects on successful referral to SUD treatment [20]. Therefore, the identification of more effective linkage models is a priority within addiction health services.

Models of ongoing monitoring and early reintervention occupy a central role in the long-term management of numerous chronic medical conditions [21,22]. Recovery management checkups (RMCs) may be a solution to increasing linkage to treatment services among patients seen in FQHCs. RMCs are designed to improve SUD treatment linkage, engagement, and long-term treatment retention by (i) a fixed schedule of face-to-face quarterly checkups to assess need for SUD treatment, (ii) personalized feedback based motivational interviewing to increase treatment motivation, (iii) problem solving around barriers to treatment access and retention, and (iv) assistance with scheduling and linkage to treatment. The efficacy of RMC has been demonstrated in multiple clinical trials. In the first community-based trial [23,24], participants assigned to the RMC condition following SUD treatment completed 94% of their quarterly checkups over 2 years and were more likely to enter SUD treatment following a relapse episode, re-enter treatment at any time, and stay in treatment longer. In the second trial [25], participants assigned to a modified RMC protocol, which included a retention component, completed 95% of their quarterly checkups over 4 years. Moreover, RMC participants reported more total days of abstinence and fewer past-month SUD symptoms over 48 months—with effects increasing with repeated checkups over time. In preparation for the present study, the research team conducted a quasi-experimental pilot test of RMC, modified for FQHC/primary care (RMC-PC). Results indicated that those assigned to RMC-PC were more likely to attend treatment and reported greater reductions in alcohol and other drug use.

## Current study

The current study evaluated 3-month results from phase 1 of a randomized controlled trial (RCT) of FQHC/primary care-based SBIRT-only versus SBIRT + RMC-PC. We hypothesized that individuals receiving RMC-PC would report greater odds of self-reporting the receipt of any past 90-day SUD treatment (primary outcome) at the 3-month follow-up. We also hypothesized that the addition of RMC-PC would have an effect on a number of secondary outcomes. These included number of days receiving treatment in the past 90 days

(broken down by residential, intensive outpatient, outpatient, medication-assisted, and other treatment). Other secondary outcomes included past 90-day abstinence, as well as days of using alcohol, cannabis, stimulants, opioids, and other drugs, and a composite measure assessing days of use across all substances and problems stemming from substance use.

## METHODS

### Study design and participants

#### Participants and procedures

Participants were recruited from four FQHC agencies in Chicago, Illinois (IL) from July 2017 through March 2020. As part of regular practice, the participating FQHCs already screened patients at least once a year to identify alcohol and drug problems. Those who screened for probable SUD (via 5+ on the Alcohol Use Disorder Identification Test [AUDIT] [26] or 3+ on the Drug Abuse Screening Test [DAST] [27]) or were referred to brief or regular treatment were approached about participating in the study. Participants were screened for study eligibility and completed informed consent if they agreed to be part of the study. All participants completed SBIRT as part of standard practice at the FQHC before being randomized to the control (SBIRT-only) or experimental condition (SBIRT + RMC-PC). Those assigned to SBIRT + RMC-PC received multiple checkups with a linkage manager (see Interventions section). All SBIRT procedures were conducted by FQHC staff before randomization. RMC-PC procedures were conducted by Chestnut Health Systems research staff after randomization and only for the subset ( $n = 134$ ) assigned to the experimental condition.

For the baseline assessment, all participants completed an interview and urine test with the aid of research staff (average time, 43.7 [SD = 19.6] minutes). Three months after enrollment/randomization, all participants completed a follow-up interview and urine test to measure outcomes (average time, 45.7 [SD = 17.8] minutes). Participants were paid \$25 for each assessment. Of note, the primary end point for this RCT is 12 months after randomization. The present study reports results at the 3-month follow-up. Study assignment was open (i.e. not blind) as participants in the experimental condition worked directly with linkage managers. This study is registered at [clinicaltrials.gov](https://clinicaltrials.gov) (ID: NCT03746756).

#### Planned and actual sample size

The planned sample size was 300 and designed to have at least 99% power to detect a moderate effect size (e.g. OR = 1.5) for the primary outcome of any SUD treatment. Recruitment was stopped prematurely at 266 because of a combination of the coronavirus disease 2019 (COVID-19) epidemic and racial unrest in Chicago in 2021. Together, these events limited FQHC services to only those

most critical, and SBIRT, which was viewed as a prevention service, was suspended. Substance use treatment was still being provided, so we continued with the 12-month linkage and engagement components using the existing sample. Although the overall model still has over 99% power, the effective power dropped to 70% for random assignment to RMC-PC 'term' in the model using our final sample of 266.

### Participant characteristics

Participants were predominately male (65%), were African American (81%), had an average age of 48.3 years (SD = 11.9; range, 19–53), and had a high school degree or equivalent (58%) (Table 1). Consistent with the focus of FQHC on underserved populations, only 46% of participants had been employed in the past year, and 45% had been homeless in the past year. Clinically, 90% reported weekly substance use before intake and 78% self-reported symptoms consistent with past 90-day SUD (68% alcohol, 35% cannabis, 35% stimulant, 24% opioid, and 8% other disorders). Based on screening at the FQHC for probable alcohol or drug use disorder on either the AUDIT (AUDIT scores of 5+) or DAST (DAST scores of 3+), 35% were referred to brief treatment, and 65% were referred to regular SUD treatment. See Table 1 for more details.

### Inclusion and exclusion criteria

Inclusion criteria were (i) receiving SBIRT from one of the participating FQHCs; (ii) scoring in the moderate to high range on the AUDIT (scores of 5+) or DAST (scores of 3+) referred as part of SBIRT to brief or regular SUD treatment; and (iii) were not already in SUD treatment. Participants could screen for more than one SUD and remain eligible. For logistical reasons, individuals were deemed ineligible if they (i) currently lived outside Chicago, or planned to live outside of Chicago during the next 12 months; (ii) expected to be in jail, prison, or another setting that would prevent their participation; (iii) were under age 18; (iv) were mandated by a court to SUD treatment because of a driving under the influence offense; (v) required an interpreter or language other than English to participate; or (vi) self-reported ever been told by a doctor that they schizophrenia or bipolar disorder.

### Randomization and masking

The project manager randomly assigned participants with urn randomization using a computer program called GRandom version 1.1 [28]. A base rate of 50% per condition was set and using Bayesian probability to optimize balance on the following participant characteristics: sex (woman vs other), race (African American vs other), referral type (regular SUD treatment vs brief treatment), FQHC site (four sites), and age (under 26 vs other) [29]. Prior work supports

**TABLE 1** Participant characteristics and services before randomization

| <i>Characteristics at or during the 90 days before enrollment and randomization</i> | <i>Total (n = 266)</i> | <i>Randomly assigned group</i> |                                 |
|-------------------------------------------------------------------------------------|------------------------|--------------------------------|---------------------------------|
|                                                                                     |                        | <i>SBIRT only (n = 132)</i>    | <i>SBIRT + RMC-PC (n = 134)</i> |
| Female (%)                                                                          | 35                     | 31                             | 39                              |
| Race/ethnicity (%)                                                                  |                        |                                |                                 |
| African American                                                                    | 81                     | 80                             | 82                              |
| Caucasian                                                                           | 9                      | 10                             | 8                               |
| Hispanic                                                                            | 4                      | 4                              | 4                               |
| Other/mixed                                                                         | 7                      | 7                              | 7                               |
| Age mean (SD)                                                                       | 48.3 (11.9)            | 46.8 (11.4)                    | 49.6 (12.2)                     |
| Age groups (%)                                                                      |                        |                                |                                 |
| 18–25                                                                               | 6                      | 7                              | 6                               |
| 26–39                                                                               | 17                     | 20                             | 14                              |
| 40–49                                                                               | 22                     | 23                             | 20                              |
| 50+                                                                                 | 55                     | 50                             | 60                              |
| High school graduate or GED (%)                                                     | 58                     | 62                             | 55                              |
| Employed in the past year (%)                                                       | 46                     | 50                             | 43                              |
| Homeless in the past year (%)                                                       | 45                     | 45                             | 45                              |
| Weekly tobacco use (%) <sup>a</sup>                                                 | 78                     | 76                             | 81                              |
| Weekly substance use (%) <sup>a</sup>                                               | 90                     | 87                             | 93                              |
| Any past 90-day substance use (%)                                                   |                        |                                |                                 |
| Disorder (SUD) <sup>b</sup>                                                         | 78                     | 73                             | 82                              |
| Alcohol use disorder <sup>c</sup>                                                   | 68                     | 65                             | 72                              |
| Cannabis use disorder <sup>d</sup>                                                  | 35                     | 32                             | 38                              |
| Stimulant use disorder <sup>e</sup>                                                 | 35                     | 42                             | 38                              |
| Opioid use disorder <sup>e</sup>                                                    | 24                     | 23                             | 25                              |
| Other drug disorder <sup>e</sup>                                                    | 8                      | 9                              | 7                               |
| Mean number of SUDs (%)                                                             | 1.7 (1.3)              | 1.6 (1.3)                      | 1.8 (1.2)                       |
| Mental health problems (%) <sup>f</sup>                                             | 81                     | 76                             | 85                              |
| Physical health problems (%) <sup>f</sup>                                           | 74                     | 73                             | 74                              |
| Stress problems (%) <sup>f</sup>                                                    | 66                     | 62                             | 69                              |
| Risk/victimization problems (%) <sup>f</sup>                                        | 61                     | 61                             | 61                              |
| Crime/violence problems (%) <sup>f</sup>                                            | 18                     | 19                             | 17                              |
| Mean number SUD/other problems (SD) <sup>g</sup>                                    | 4.4 (2.3)              | 4.3 (2.4)                      | 4.6 (2.1)                       |
| FQHC site (%)                                                                       |                        |                                |                                 |
| A                                                                                   | 30                     | 33                             | 28                              |
| B                                                                                   | 53                     | 52                             | 54                              |
| C                                                                                   | 9                      | 8                              | 9                               |
| D                                                                                   | 8                      | 7                              | 9                               |
| AUDIT groups (%)                                                                    |                        |                                |                                 |
| Screening only                                                                      | 30                     | 27                             | 32                              |
| Brief intervention                                                                  | 14                     | 13                             | 16                              |
| Brief treatment                                                                     | 13                     | 15                             | 11                              |
| Referral to treatment                                                               | 42                     | 44                             | 41                              |
| DAST groups (%) <sup>h</sup>                                                        |                        |                                |                                 |
| Screening only                                                                      | 22                     | 23                             | 21                              |
| Brief intervention                                                                  | 5                      | 7                              | 4                               |
| Brief treatment                                                                     | 33                     | 32                             | 34                              |
| Referral to treatment                                                               | 39                     | 38                             | 41                              |

(Continues)

**TABLE 1** (Continued)

| <i>Characteristics at or during the 90 days before enrollment and randomization</i> | <i>Total (n = 266)</i> | <i>Randomly assigned group</i> |                                 |
|-------------------------------------------------------------------------------------|------------------------|--------------------------------|---------------------------------|
|                                                                                     |                        | <i>SBIRT only (n = 132)</i>    | <i>SBIRT + RMC-PC (n = 134)</i> |
| SBIRT assignment based on max of AUDIT/DAST (%)                                     |                        |                                |                                 |
| Brief treatment                                                                     | 35                     | 35                             | 34                              |
| Referral to treatment                                                               | 65                     | 65                             | 66                              |
| Mean days from SBIRT screening to random assignment (SD)                            | 10.8 (27.9)            | 7.4 (34.5)                     | 14.2 (18.7)                     |
| Days in a controlled environment (e.g. jail, hospital)                              | 3.86 (11.15)           | 4.45 (12.79)                   | 3.27 (9.27)                     |
| Baseline values of primary outcome (%)                                              |                        |                                |                                 |
| Any substance use disorder treatment <sup>a</sup>                                   | 16                     | 20                             | 13                              |
| Baseline values of secondary outcomes (%) <sup>a</sup>                              |                        |                                |                                 |
| Any residential treatment                                                           | 6                      | 7                              | 4                               |
| Any intensive outpatient treatment                                                  | 3                      | 4                              | 3                               |
| Any outpatient treatment                                                            | 6                      | 9                              | 3                               |
| Any medication-assisted treatment                                                   | 4                      | 5                              | 3                               |
| Any other treatment                                                                 | 3                      | 3                              | 3                               |

AUDIT, Alcohol Use Disorder Identification Test; DAST, Drug Abuse Screening Test; FQHC, federally qualified health centers; GED, General Educational Development Test; RMC-PC, recovery management checkups for primary care; SUD, substance use disorder; SBIRT, screening, brief intervention, and referral to treatment; SDSr, substance disorder screener.

<sup>a</sup>During the 90 days before randomization.

<sup>b</sup>Any SUD based on self-report of two or more symptoms on the SDSr and any days of alcohol or drug use in the past 90 days.

<sup>c</sup>Alcohol use disorder based on self-report of two or more symptoms on the SDSr and either any days of intoxication or 3 to 90 days of alcohol use—each in the past 90 days.

<sup>d</sup>Cannabis use disorder based on self-report of two or more symptoms on the SDSr and 3 to 90 days of cannabis use—each in the past 90 days.

<sup>e</sup>Stimulant, opioid or other drug use disorder based on self-report of two or more symptoms on the SDSr and any days of use for a given drug class.

<sup>f</sup>Specific problems require two or more symptoms on the each screener and any days of reported problems—each in the past 90 days.

<sup>g</sup>Based on the count of estimated individual substance use disorders and the other problem areas: mental health, physical health, stress, risk behaviors, and crime/violence.

<sup>h</sup>Scores on the DAST were broken into groups of 0 = screen only, 1–2 = brief intervention, 3–5 = brief treatment, 6+ = referral to treatment.

stratification by age given that most alcohol and illicit drug use is initiated and peaks by age 25 and have the lowest treatment completion rate [4]. Participants, linkage managers, research assistants conducting follow-up assessments, and statistical analysts were not blind to assignment.

## Interventions

### SBIRT (control and experimental conditions)

All participants completed the full SBIRT procedures conducted by FQHC staff as part of standard practice before referral, consent, and randomization. Depending on each of the four FQHC's site-specific practices, initial participant screening to determine need for referral to alcohol or other drug treatment was conducted by a medical assistant, medical provider, or behavioral health staff with training in screening instrument administration. Brief interventions and referrals were conducted by a certified or licensed behavioral health staff member, with those patients in need of brief treatment being referred internally to a masters-level clinician and those in need of more intensive treatment being referred to external services.

### RMC-PC (experimental condition only)

Participants randomized to the experimental group received SBIRT and the RMC-PC intervention (i.e. SBIRT + RMC-PC). RMC-PC started immediately after randomization and continued over the 3-month period reported here. Under this protocol, a linkage manager (i) provided personalized feedback to participants about their substance use, problems, motivation, and barriers to treatment; (ii) helped participants resolve ambivalence about their substance use and facilitate a commitment to change by accessing additional care; (iii) scheduled an assessment; and (iv) facilitated re-entry and engagement. The linkage manager also contacted patients two to three times per week for an additional 2 weeks to ensure patients both initiated and remained engaged in treatment (fidelity data are in the Results section).

The content of each checkup varied depending on the participants' substance use and treatment participation in the prior 30 days. For those who reported no substance use and may or may not be in treatment, the meeting focused on reinforcing their recovery. For those who continued to use, but remained in treatment, the linkage manager focused on reducing their use and supporting their treatment participation. For those not in treatment and using, the checkup

focused on treatment linkage. As part of the checkup, linkage managers used motivational interviewing to provide feedback, cultivate change talk, soften sustain talk, develop a sense of partnership with participants, and express empathy. All sessions were digitally recorded. There were no specific educational requirements for linkage managers; however, each completed extensive training, achieved a specific level of competency with motivational interviewing, and maintained this level throughout the trial. Training and quality assurance reviews of digital recordings were conducted by an independent trainer from the Motivational Interviewing Network of Trainers. This process included reviewing 100% of the sessions until the linkage manager was certified as competent and then 10% of the linkage sessions per month thereafter to monitor fidelity.

## Data collection

The primary data source for the data reported here was participant responses to standardized interviews conducted with the GAIN-Q3 [30,31]. This instrument screens for nine of the most common problem areas including school, work, physical health, sources of stress, risk behaviors, internalizing disorders, externalizing disorders, and crime and violence, and SUDs. The GAIN-Q3 is able to estimate the severity and clinical decision cut points that would be identified using the full GAIN [30]. All measures, below, were derived from the GAIN-Q3.

## Primary outcome

Our primary outcome of interest was 'Any days of SUD treatment' in the past 90 days. Participants were asked at the 3-month follow-up interview about the days of receiving specific types of SUD treatment, which were combined into days of any treatment and then dichotomized for the primary outcome (e.g. 0 or 1+ days). Based on our prior research [32], this dichotomized 'Any days of SUD treatment' variable has excellent reliability (test-retest  $\kappa = .81$ ).

## Secondary outcomes

### Days of SUD treatment

Participants were asked about the number of days they received treatment in the 90 days following randomization overall and by level of care (i.e. residential, intensive outpatient, outpatient, medication-assisted, and other treatment). Our prior research found this measure to have a test-retest rho of 0.93 [23].

### Days of abstinence and substance use

Participants reported (i) the days of abstinence from alcohol and other drugs during the past 90 days and (ii) the days using alcohol, cannabis,

stimulants (including crack, cocaine, methamphetamines, and other amphetamines), opioids (including heroin, fentanyl, and other opiates), and other drugs in the past 90 days. The validity of self-report was strengthened by conducting urine tests on site with CLIA-waived QuikScreen cups using an immunochromatographic assay for rapid qualitative results (2–5 minutes), providing the results before the self-report questions, and probing any inconsistencies per our prior protocol [33]. The resulting false negative rate for self-report compared to all available sources of data was 2% ( $\kappa = 0.84$ ), with no significant difference by condition.

## Substance frequency scale

The scale is based on the average days (in the past 90) of any alcohol or other (AOD) use, alcohol use, cannabis use, heroin/opioid use, cocaine/stimulant use, and other drug use, as well as days of being drunk/high all day and days with problems caused by AOD use. The average is divided by 90 and multiplied by 100 to obtain a score from 0 (complete abstinence) to 100 (use of all substances, to intoxication/high every day, and problems every day). From prior research [23], the substance frequency scale (SFS) has a test-retest  $\rho$  of 0.95; in this sample, it has a Cronbach's  $\alpha$  of 0.70 and an interclass correlation coefficient (ICC) over time of 0.47.

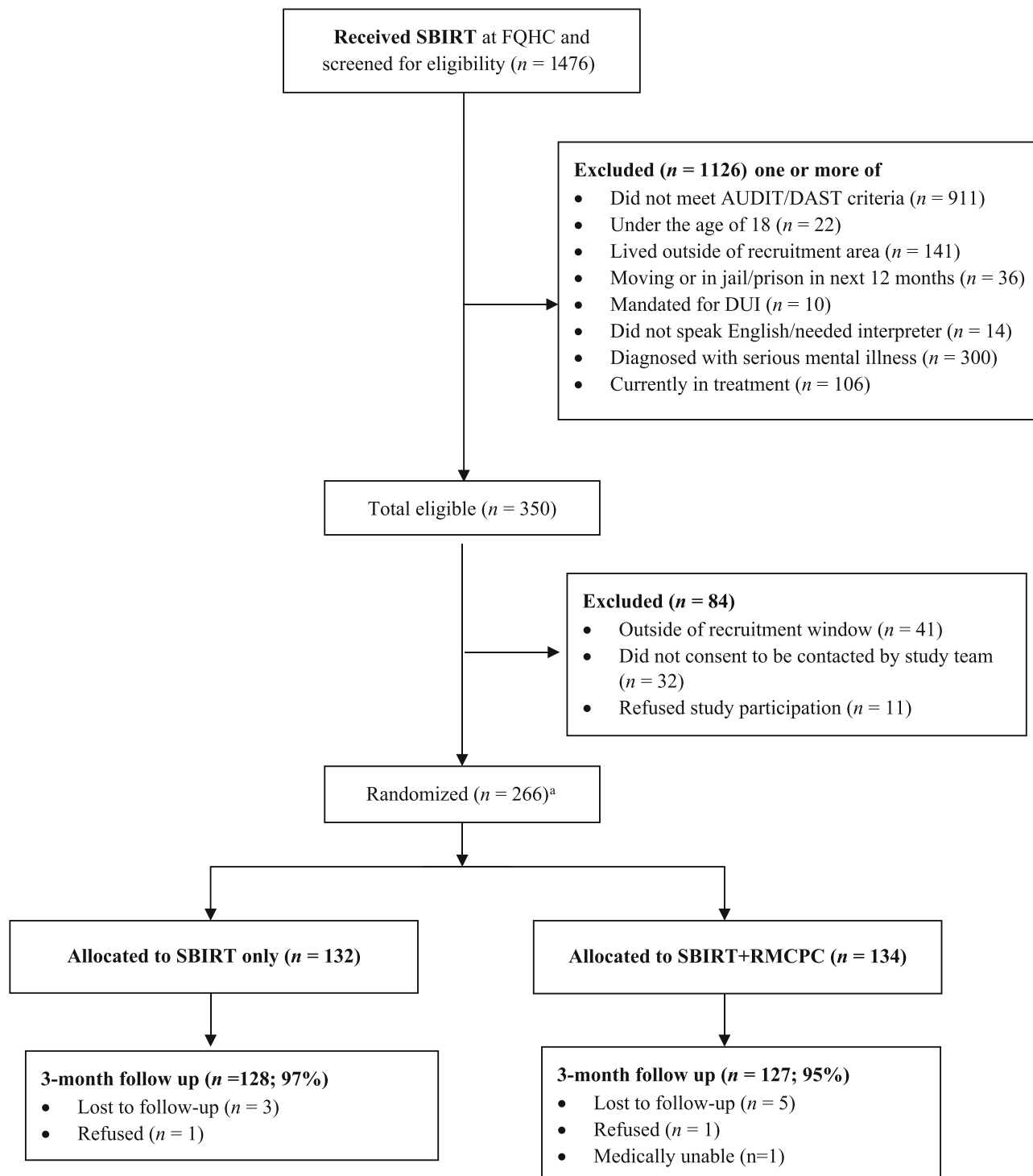
## Analytic plan

We evaluated the effects of adding RMC-PC to SBIRT on receiving any SUD treatment (H1, primary outcome) through a  $\chi^2$  test of independence and logistic regression. As a secondary outcome, we also evaluated effects of RMC-PC on SUD treatment across levels of care (residential, intensive outpatient, outpatient, medication-assisted, and other) using  $\chi^2$  test of independence and logistic regression. The adjusted odds ratio (AOR) was used as the effect size, with AOR of more than 1.0, meaning the likelihood for SBIRT + RMC-PC was greater than the likelihood for SBIRT-only, and less than 1.0, meaning SBIRT + RMC-PC's likelihood was relatively lower. Our cut points for interpreting AOR in these two directions are 1.2+/0.8 for small, 1.5/0.67 for moderate, and 2.0/0.5 for large.

We also evaluated the effects of SBIRT + RMC-PC on secondary outcomes including past 90 days of SUD treatment, days of treatment by level of care, days of abstinence, days of substance use, and a composite measure of substance use/problems (H2, secondary outcomes). All secondary analyses were analyzed with analyses of covariance (ANCOVAs). We report the estimated marginal means and statistics on the adjusted effect of SBIRT + RMC-PC on each outcome. We interpret the effect size for these secondary outcomes with Cohen's  $d$ , where a positive (+)  $d$  indicates that receiving SBIRT + RMC-PC resulted in higher means compared to SBIRT only and a negative (–)  $d$  indicating that SBIRT + RMC-PC resulted in lower relative means. We interpreted all calculated Cohen's  $d$  effect sizes as  $|d| = 0.2$  as small, 0.4 as moderate, and 0.8 as large.

All models controlled for baseline values of the respective primary or secondary outcome as well as the mean of the maximum days in a controlled environment (e.g. jail, hospital). Using analysis

of covariance, the partial  $\eta^2$  reported in the table represents the effect of condition after controlling for covariates. Although we report the total model  $R^2$ , the present study focuses on the effects



**FIGURE 1** Recovery management checkups for primary care (RMC-PC) study consort diagram. <sup>a</sup>Small amount (3%–5%) of missing follow-up data replaced with the baseline value for the same individual in the intent-to-treat (ITT) analysis. All participants received screening, brief intervention, and referral to treatment (SBIRT), as part of routine procedures at the federally qualified health centers (FQHC), before randomization. Baseline interview was completed before randomization. The 3-month follow-up as well as baseline interview included assessments for primary outcome (any substance use treatment) and secondary outcomes (any treatment and days of treatment by level of care, days of abstinence, days of substance use, and a composite measure of substance use/problems).

associated with random assignment. Finally, given the present study included multiple treatment centers, we tested an interaction between treatment center and treatment assignment. There was no evidence of an effect of treatment center in our model predicting our primary outcome; therefore, it was dropped from treatment comparison models.

## Missing data

All participants were included in this analysis using an intent-to-treat model, with the baseline value within participant used to replace the small amounts of missing data. Therefore, predictor and outcomes used here are not missing at the individual level. This is effectively a form of missing not at random (MNAR) (i.e. those who did not respond were more likely to have continued their prior behavior).

## RESULTS

### Pre- and post-inclusion case flow

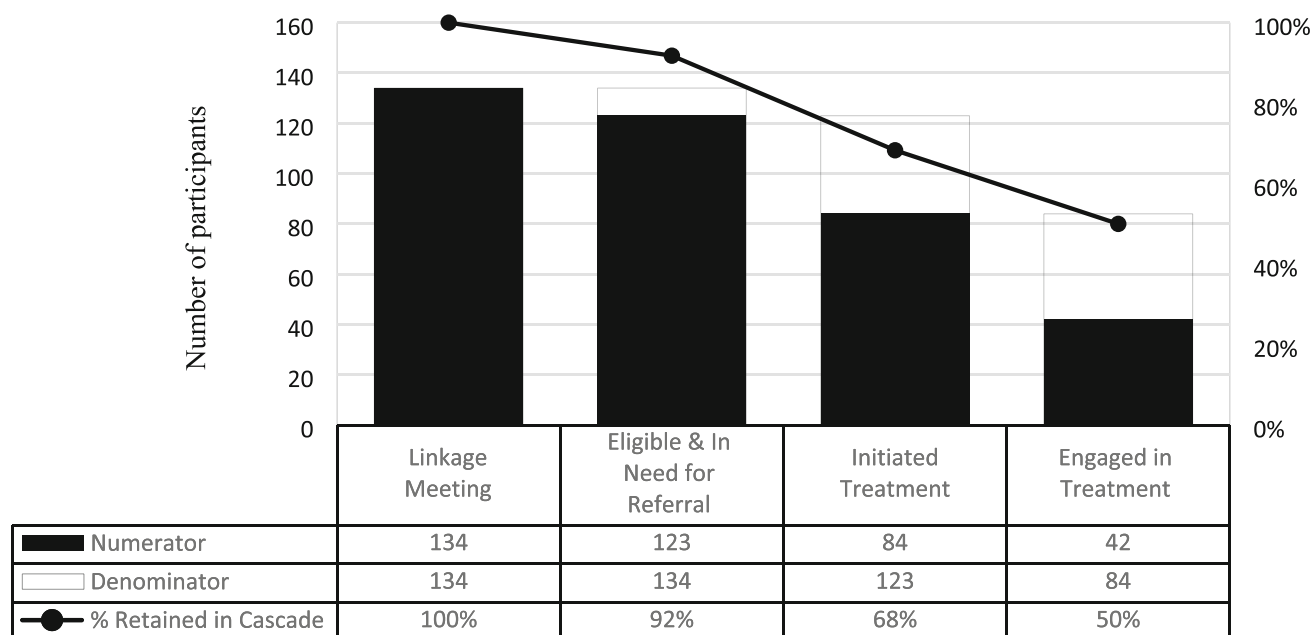
Figure 1 shows the study CONSORT diagram. Of the 1476 patients screened by FQHC staff, 350 (24%) needed a referral to SUD treatment and were eligible for the study, with reasons for exclusion detailed in Figure 1. Of the 350 FQHC participants who completed SBIRT and were considered potentially eligible, 91% agreed to be

contacted and screened by the study team—other reasons for exclusion included on the right of Fig. 1. Of those who agreed to be contacted/screened, 91% agreed to participate in the experiment and were randomized into the SBIRT-only ( $n = 132$ ) and SBIRT + RMC-PC ( $n = 134$ ) conditions. Of those randomized, 96% ( $n = 255$ ) completed their 3-month follow-up interview. The intent-to-treat analysis reported here uses everyone who was randomly assigned, replacing the small amount of missing observations (four in SBIRT only, seven in SBIRT + RMC-PC) with the values from their baseline interview.

Figure 2 shows the extent to which RMC-PC participants were successfully retained along the desired service cascade based on staff service logs. Of participants assigned to RMC-PC, 100% attended the initial linkage meeting, and 92% were found to be eligible and in need of SUD treatment linkage assistance. Of these, 68% initiated SUD treatment, and 50% engaged in treatment two or more additional times within the month (e.g. counseling session, residential treatment, or medication).

### Effect of RMC-PC on any treatment access overall and by type of treatment

Table 2 shows the rate of receiving any SUD treatment (primary outcome) in the first 3 months after randomization overall and then by type of treatment for descriptive purposes. Panel A on top provides unadjusted rates and odds ratios. Panel B on bottom provides AOR. Because the results are similar, here, we focus on the AOR. Relative



**FIGURE 2** Retention along the desired service cascade for recovery management checkups for primary care (RMC-PC) participants after enrollment and randomization to RMC-PC ( $n = 134$ )

**TABLE 2** Any substance use disorder treatment access at 3 months by condition

| <b>A. Unadjusted ORs</b>                          |                      |                           |                               |          |         |                                                    |
|---------------------------------------------------|----------------------|---------------------------|-------------------------------|----------|---------|----------------------------------------------------|
| Type of treatment <sup>a</sup>                    | Total<br>(n = 266) % | SBIRT only<br>(n = 132) % | SBIRT + RMC-PC<br>(n = 134) % | $\chi^2$ | P       | OR (95% CI) <sup>b</sup>                           |
| Primary outcome                                   |                      |                           |                               |          |         |                                                    |
| Any substance use disorder treatment <sup>b</sup> | 33                   | 20                        | 47                            | 22.03*   | <0.001* | 4.95 (1.97, 5.89)*                                 |
| Secondary outcomes <sup>c</sup>                   |                      |                           |                               |          |         |                                                    |
| Residential                                       | 10                   | 6                         | 14                            | 4.81*    | <0.05*  | 3.68 (1.08, 6.08)*                                 |
| Intensive outpatient                              | 7                    | 2                         | 11                            | 8.39*    | <0.01*  | 4.53 (1.53, 9.19)*                                 |
| Outpatient                                        | 10                   | 8                         | 12                            | 1.44     | 0.23    | 2.36 (0.72, 3.79)                                  |
| Medication-assisted                               | 8                    | 6                         | 10                            | 1.21     | 0.27    | 2.05 (0.67, 4.16)                                  |
| Other treatment                                   | 8                    | 8                         | 7                             | 0.25     | 0.62    | 0.93 (0.32, 1.98)                                  |
| <b>B. AORs<sup>c</sup></b>                        |                      |                           |                               |          |         |                                                    |
| Type of treatment <sup>a</sup>                    | Total<br>(n = 266) % | SBIRT only<br>(n = 132)   | SBIRT + RMC-PC<br>(n = 134)   | Wald     | p       | Adjusted odds ratio<br>(AOR) (95% CI) <sup>d</sup> |
| Primary outcome                                   |                      |                           |                               |          |         |                                                    |
| Any substance use disorder treatment              | 33                   | 20                        | 46                            | 23.74*   | <0.001* | 4.59 (2.48, 8.48)*                                 |
| Secondary outcomes <sup>c</sup>                   |                      |                           |                               |          |         |                                                    |
| Residential                                       | 10                   | 6                         | 14                            | 6.07*    | <0.05*  | 3.31 (1.28, 8.57)*                                 |
| Intensive outpatient                              | 7                    | 2                         | 11                            | 7.52*    | <0.01*  | 6.40 (1.70, 24.1)*                                 |
| Outpatient                                        | 10                   | 8                         | 12                            | 1.65     | 0.20    | 1.76 (0.74, 4.18)                                  |
| Medication-assisted                               | 8                    | 6                         | 10                            | 2.60     | 0.11    | 2.47 (0.82, 7.41)                                  |
| Other treatment                                   | 8                    | 8                         | 7                             | 0.15     | 0.69    | 0.83 (0.33, 2.09)                                  |

AORs, adjusted odd ratios; ORs, odd ratios; RMC-PC, recovery management checkups for primary care; SBIRT, screening, brief intervention, and referral to treatment.

<sup>a</sup>Treatment data based on self-report.

<sup>b</sup>OR compares RMC-PC to control.

<sup>c</sup>Lower power comparisons by type of treatment provided for descriptive purposes.

<sup>d</sup>AOR models controlled for baseline values of the outcome as well as number of days in a controlled environment (jail) during the treatment period.

\* $\chi^2$ , ORs, and P-values indicate  $P < 0.05$ .

to participants in the SBIRT-only group, those who also received the SBIRT + RMC-PC intervention had significantly greater odds of access to any kind of treatment in the first 3 months (20% vs 46%; AOR = 4.59). This included greater odds of any residential treatment (6% vs 14%; AOR = 3.31) and intensive outpatient treatment (2% vs 11%; AOR = 6.40). No differences emerged for outpatient, for medication-assisted treatment, or for other treatment.

### Secondary effects of RMC-PC on days of treatment, abstinence, and substance use

Table 3 shows the days of SUD treatment and days of substance use at 3-month follow-up by condition. Relative to those who received SBIRT only, the participants who received the SBIRT + RMC-PC intervention reported twice as many days of any SUD treatment in the first 3 months (7.13 vs 14.45 days,  $P < 0.01$ ; Cohen's  $d = 0.26$ ), including more days of residential treatment ( $d = 0.25$ ). There were no differences in days of outpatient treatment, medication-assisted treatment, or other treatment.

Relative to the participants in the SBIRT-only group, participants who received SBIRT + RMC-PC reported more days of abstinence during the 3-month follow-up (41.31 vs 31.9,  $P < 0.01$ ;  $d = 0.22$ ) and larger increases from baseline to 3 months in the days of abstinence (across any substance;  $d = 0.35$ ). This was primarily driven by reductions in the days of alcohol ( $d = -0.25$ ) and cannabis use ( $d = -0.20$ ). Receiving SBIRT + RMC-PC was not associated with differences in the days of opioids, stimulants, or other drug use. Relative to the SBIRT-only group, participants in the SBIRT + RMC-PC group reported lower summary scores on the SFS (26 vs 21,  $P < 0.05$ ;  $d = -0.17$ ).

## DISCUSSION

The primary purpose of this study was to evaluate the effect of following existing SBIRT practices in primary care with RMC-PC to increase linkage of patients in need to SUD treatment. In line with our primary hypotheses, our results indicate improved linkage to SUD treatment and more days in SUD treatment for participants

**TABLE 3** Mean days of treatment and days of substance use at 3 months by condition

| Secondary outcomes                     | Condition | Est. marginal mean | SD    | Effect of condition |        |         |           |                  | Total model R <sup>2</sup> |
|----------------------------------------|-----------|--------------------|-------|---------------------|--------|---------|-----------|------------------|----------------------------|
|                                        |           |                    |       | F                   | d.f.   | P-value | Cohen's d | Partial $\eta^2$ |                            |
| Days of any SUD treatment              | SBIRT     | 7.13               | 24.01 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 14.45              | 23.96 | 6.15                | 1, 262 | <0.01*  | 0.26*     | 0.02             | 0.08                       |
| Nights in residential                  | SBIRT     | 1.33               | 11.26 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 4.51               | 11.34 | 5.26                | 1, 262 | <0.02*  | 0.25*     | 0.02             | 0.04                       |
| Days in intensive outpatient           | SBIRT     | 1.33               | 11.26 | 3.66                | 1, 262 | 0.06    | 0.23*     | 0.01             | 0.05                       |
|                                        | RMC-PC    | 3.97               | 11.69 |                     |        |         |           |                  |                            |
| Number of times in outpatient          | SBIRT     | 2.18               | 9.08  |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 1.78               | 9.14  | 0.13                | 1, 262 | 0.72    | -0.02     | 0.00             | 0.20                       |
| Days in medication-assisted treatment  | SBIRT     | 1.97               | 13.10 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 3.69               | 13.08 | 1.14                | 1, 262 | 0.29    | 0.11      | 0.00             | 0.09                       |
| Days in other treatment                | SBIRT     | 1.47               | 6.20  |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 0.64               | 6.25  | 1.16                | 1, 262 | 0.28    | -0.13     | 0.00             | 0.01                       |
| Days of AOD abstinence                 | SBIRT     | 31.90              | 30.33 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 41.31              | 30.33 | 6.35                | 1, 262 | <0.01*  | 0.22*     | 0.02             | 0.16                       |
| Days of alcohol use                    | SBIRT     | 36.31              | 27.80 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 27.14              | 27.78 | 7.23                | 1, 262 | <0.01*  | -0.25*    | 0.03             | 0.32                       |
| Days of cannabis use                   | SBIRT     | 28.58              | 22.52 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 19.49              | 22.46 | 10.86               | 1, 262 | <0.001* | -0.20*    | 0.04             | 0.57                       |
| Days of heroin or other opioid use     | SBIRT     | 11.23              | 17.23 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 8.15               | 17.25 | 2.11                | 1, 262 | 0.15    | -0.10     | 0.01             | 0.51                       |
| Days of cocaine or other stimulant use | SBIRT     | 12.10              | 19.88 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 12.90              | 19.91 | 0.11                | 1, 262 | 0.75    | 0.17      | 0.00             | 0.34                       |
| Days of other drug use                 | SBIRT     | 1.29               | 7.70  |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 1.33               | 7.76  | 0.00                | 1, 262 | 0.97    | -0.01     | 0.00             | 0.17                       |
| Substance Frequency Scale (SFS)        | SBIRT     | 26                 | 14.94 |                     |        |         |           |                  |                            |
|                                        | RMC-PC    | 21                 | 15.05 | 5.82                | 1, 262 | <0.05*  | -0.17     | 0.02             | 0.23                       |

AOD, alcohol or other drug; Est, estimated; d.f., degrees of freedom; RMC-PC, recovery management checkups for primary care; SBIRT, screening, brief intervention, and referral to treatment; SUD, substance use disorder; SFS, substance frequency scale. SBIRT (only) = control condition; (SBIRT+) RMC-PC, experimental condition.

Estimated marginal means represent the means of outcomes controlling for the mean of the baseline value of the same variable as well as the mean of the maximum days in a controlled environment (e.g. jail, hospital). Analysis of covariance variance statistics and partial  $\eta^2$  on the right represent the effect of condition after controlling for above covariates. The total model R<sup>2</sup> includes the variances explained by condition, baseline variable and days in jail/a controlled environment.

\*P < 0.05 or Cohen's |d| ≥ 0.20. All days variables can range from 0 to 90. Days of abstinence is based on the days without using alcohol, cannabis, heroin or other opioids, cocaine or other stimulants, or other drugs (including medication misuse). The SFS is based on the average of the days in 3 months of any alcohol or other drug use, being drunk/high all day, alcohol use, cannabis use, heroin/opioid use, cocaine/stimulant use, and other drug use; this average is then divided by 90 and multiplied by 100 to get a score from 0 to 100.

who received SBIRT plus RMC-PC. These results are promising, especially given the study was conducted in primary care settings designated as FQHCs that target groups with higher rates of SUD, including people who are below the federal poverty line, are unemployed, are in public housing, are homeless, and are typically underserved. Although FQHCs only serve about 6% of the total US population, they are responsible for nearly 15% of uninsured patients and nearly 30% of those who use some form of public insurance [34–36]. With recent work noting the low efficacy of SBIRT alone on linking individuals in primary care settings to SUD treatment

[11,37,38], our results provide evidence on the feasibility of adding RMC-PC to SBIRT procedures and relative effectiveness of doing so by approximately doubling the rates of treatment linkage and days of treatment.

The current study also demonstrates the benefit of adding RMC-PC to SBIRT in terms of secondary outcomes, including increased days of abstinence from alcohol and other drugs (mainly reduced alcohol use and cannabis use). Numerous reviews and meta-analyses on the screening and brief intervention portion of the model note reductions in alcohol consumption [10,39,40], but fewer show support across

other drugs. Results from the current study provide continued support for reductions in alcohol use and extend support to reductions in cannabis use and the study's summary measure of polysubstance use/problem use (i.e. substance frequency scale). Similar to other studies assessing SBIRT models, we did not find statistically or clinically significant differences across opioids, stimulants, or other drugs. However, in a quasi-experimental pilot trial testing the RMC-PC intervention, 6-month follow-up results indicated fewer drug-using days, primarily driven by a reduction in opioid use [41]. It is also possible that effects on other drugs may take longer and/or require additional reintervention, both of which are being tested in phase 2 of the current trial.

Another compelling result from the current study is the high rates of retention along the entire service cascade for those receiving SBIRT plus RMC-PC, with a notable 68% initiating treatment following the linkage meeting and 50% of these individuals engaging in treatment. This demonstrates the feasibility of RMC-PC to engage publicly insured and low-income patients within FQHCs in SUD treatment, likely because the RMC approach does not rely on participants to seek help. Many individuals treated in FQHCs lack the support to actively negotiate healthcare systems to overcome barriers in accessing SUD treatment, but RMC combats these barriers through regularly scheduled face-to-face quarterly checkups, quarterly assessments, and personalized feedback for participants on the status of their recovery. RMC also uses motivational interviewing, problem solving, and assertive linkage, which includes ongoing contact to ensure patients engage in treatment and follow through on continuing care recommendations. Given the limited time most physicians and healthcare workers spend with patients in FQHCs (~10 minutes per visit), our results show how vital it is for these healthcare settings to implement recovery management protocols to improve linkage to SUD treatment services.

Taken together, results from the current study provide support for including RMC as a robust initial linkage model for patients who screen positive for SUD in primary care settings. The original RMC model was based on the theory that long-term monitoring through regular checkups and early reintervention will facilitate early detection of relapse, reduce the time to treatment re-entry, and, consequently, improve long-term outcomes [24,42]. The hallmark of managing chronic conditions is to recognize that less expensive care delivered early can be offset by reductions in more expensive hospitalization or emergency care [43]. Both SBIRT and RMC are potential avenues to cost-effective approaches for monitoring patients and identifying a need for formal SUD treatment [44].

## Limitations

This study is not without limitations. First, the majority of data were self-reported, giving rise to potential recall bias and shared variance issues [45]. We validated substance use results with urine analysis screenings and treatment engagement with clinical records, therefore, increasing our confidence in some of our outcomes of interest.

Further, RMC-PC was provided by research staff; FQHCs or SUD treatment partners may need dedicated staff and/or additional resources to incorporate it into routine practice. Our results may also not be generalizable given the majority of participants were 50+ years old and high severity.

In addition, when we broke out the effects on SUD treatment by level of care, the effects were strongest for residential and intensive outpatient, and there were only trends (based on clinical, but not statistical significance) for outpatient and medication-assisted treatment. Similarly, the effects of abstinence were also evident when broken out by drug for alcohol and cannabis, but not opioids, stimulants, or other drugs. To impact these other levels of care and substances may require additional or longer RMC-PC intervention and are currently being tested in phase 2 of the trial.

## CONCLUSION

This study demonstrated the effectiveness of adding RMC-PC to SBIRT in increasing SUD treatment within four FQHCs that provide primary care to underserved populations. Adding RMC-PC was associated with significant increases in abstinence from all substances, and specifically in reduced alcohol and cannabis use as well as substance use-related problems. The current study is one of few to show improved treatment referral and treatment engagement following initial screening and brief interventions within a primary care setting. As this is an ongoing study, the present results will be followed up and replicated at 12-month post-baseline focused on treatment access (e.g. days of treatment) as a mechanism of behavior change. Our 12-month follow-up analysis will also allow us to determine the effect of reintervention on long-term outcomes. In conclusion, results from the current study indicate promise for those most in need of substance use services by providing continued care throughout the service cascade.

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## DECLARATION OF INTERESTS

None.

## AUTHOR CONTRIBUTIONS

**Christy K. Scott:** Conceptualization; funding acquisition; investigation; methodology; project administration; supervision. **Michael Dennis:** Data curation-lead; formal analysis-lead; investigation-supporting;

methodology-lead; software-lead; validation-lead; visualization-lead; writing – review & editing-equal. **Christine E. Grella:** Conceptualization; funding acquisition; investigation. **Dennis P. Watson:** Validation. **Jordan P. Davis:** Formal analysis; validation; visualization. **M. Kate Hart:** Data curation; formal analysis; validation; visualization.

## CLINICAL TRIAL REGISTRATION

Clinical trial registration ClinicalTrials.gov ID: NCT03746756.

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