

The Implementation & Sustainment Facilitation Strategy improved implementation effectiveness and intervention effectiveness: Results from a cluster-randomized type 2 hybrid trial

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Abstract

Background Substance use disorders (SUD) among people with HIV are both prevalent and problematic. In 2014, the Substance Abuse Treatment to HIV care (SAT2HIV) Project was funded to test the team-focused Implementation & Sustainment Facilitation (ISF) strategy as an adjunct to the staff-focused Addiction Technology Transfer Center (ATTC) strategy for integrating a motivational interviewing-based brief intervention (MIBI) for SUD within HIV community-based organizations (CBOs). This article presents the main findings from the project.

Methods Using a cluster-randomized, type 2 hybrid trial design, 39 HIV-CBOs were randomized to either: 1) ATTC (n = 19); or 2) ATTC+ISF (n = 20). HIV-CBOs identified two staff to be prepared to implement the MIBI (N = 78 MIBI staff). Subsequently, during the implementation phase, HIV-CBOs in each condition randomized client participants (N = 824 client participants) to one of two intervention conditions: 1) usual care (UC; n = 415); or 2) UC+MIBI (n = 409). Both staff-level outcomes and client-level outcomes were examined.

Results The ISF strategy had a significant impact on implementation effectiveness (i.e., the consistency and quality of implementation; $\beta = 0.65$, $p = .01$), but not on time-to-proficiency ($\beta = -0.02$) or level-of-sustainment ($\beta = 0.09$). Additionally, the ISF strategy was found to have a significant impact on intervention effectiveness (i.e., the effectiveness of the MIBI), at least in terms of significantly decreasing the odds (odds ratio = 0.11, $p = .02$) of clients using their primary substance daily during follow-up.

Conclusions The ATTC strategy was sufficient for the preparation of HIV-CBO staff to implement a MIBI for SUDs, yet the ISF strategy was found to be an effective adjunct to the ATTC strategy in terms of implementation effectiveness and intervention effectiveness. Based on these findings, it is recommended future efforts to integrate the project's MIBI for SUD within HIV-CBOs use the ATTC+ISF strategy. However, given the ISF strategy did not have a significant impact on level-of-sustainment, which was similarly low in both implementation conditions, implementation research testing the extent to which the ATTC+ISF strategy can be significantly enhanced via effective sustainment strategies is warranted.

Trial registration: ClinicalTrials.gov: NCT02495402. Registered 7/6/2015. ClinicalTrials.gov: NCT03120598. Registered 4/18/2017, retrospectively registered.

Contributions To The Literature

- The Addiction Technology Transfer Center (ATTC) strategy was found to be an effective strategy for helping prepare individuals to implement a motivational interviewing-based brief interventions (MIBI) for substance use disorders.
- The Implementation & Sustainment Facilitation (ISF) strategy was found to be an effective adjunct to the ATTC strategy in terms of impact on implementation effectiveness (i.e., the consistency and quality of implementation) and intervention effectiveness (i.e., the effectiveness of the MIBI for improving client-level outcomes).

- Underscoring the significant challenge of sustainment, level of sustainment was similarly poor for both the ATTC strategy and the ATTC + ISF strategy.

Background

Substance use among people with HIV (PWH) is a significant public health issue given it has been found to be associated with increased psychiatric problems (1), poorer HIV viral suppression (2-4), poorer HIV medication adherence (5-8), and increased likelihood of engaging in risk behaviors that result in infection transmission to others (9-11). Increasing its public health significance further, research suggests approximately half of PWH have a substance use disorder (SUD) (12).

Complementing HIV primary care, HIV community-based organizations (CBOs) provide medical and nonmedical case management services (e.g., retention in care, medication adherence, referral to social services and specialty treatment) and are a major source of care for PWH (13). Thus, in 2014, as part of its multipronged effort to help improve the integration of substance use services within HIV service settings, the National Institute on Drug Abuse (NIDA) funded the Substance Abuse Treatment to HIV care (SAT2HIV) Project to help advance generalizable knowledge about how best to integrate SUD services within HIV-CBOs across the United States. The primary aim of the SAT2HIV Project was to test the team-focused Implementation & Sustainment Facilitation (ISF) strategy as an adjunct to the staff-focused Addiction Technology Transfer Center (ATTC) strategy for helping HIV-CBOs and their staff integrate a motivational interviewing-based brief intervention (MIBI) for SUDs (14). However, given the importance of context (15, 16) and given research on the effectiveness of MIBIs for SUDs with HIV settings was relatively limited (17-19), the SAT2HIV Project also examined the impact of the ISF strategy on intervention effectiveness (i.e., the effectiveness of the MIBI on improving client-level outcomes (20-24)). Written in accordance with both the Consolidated Standards of Reporting Trials (CONSORT) guidelines for cluster-randomized trials (25) (see Additional File 1 for checklist) and the Standards for Reporting Implementation Studies (StaRI) guidelines (26) (see Additional File 2 for checklist), this article presents the main findings from the SAT2HIV Project.

Rationale for Trial Design

Consistent with the primary objective of NIDA's funding opportunity (27), the SAT2HIV Project's primary aim was to test the team-focused ISF strategy as an effective adjunct to the staff-focused ATTC strategy for helping integrate a MIBI for SUDs within HIV-CBOs. We used a cluster-randomized design (HIV-CBOs were the unit of randomization) to minimize the likelihood of contamination across the project's two implementation conditions and because cluster-randomized designs had been noted as being preferred over other designs, including stepped-wedge designs (28-30). However, beyond the use of a cluster-randomized design, we used a type 2 hybrid trial design given Curran et al.'s (31) recommendation of it as an innovative design "in support of more rapid translation" and to "provide more valid estimates of potential clinical effectiveness." Recently, Landes et al. (32) highlighted the SAT2HIV Project as a "dual-randomized trial" and noted it as a "rarer" type 2 trial design. However, given that randomization was

sequential (i.e., HIV-CBOs and their staff randomized during the preparation phase; HIV-CBO client participants randomized within HIV-CBOs during the project's implementation phase), the SAT2HIV Project may also be considered a type of sequential multiple assignment randomized trial (33) or a multilevel 2 x 2 factorial trial (34).

Rationale for Testing a MIBI for SUDs as an Adjunct to Usual Care Within HIV-CBOs

As highlighted by DiClemente et al. (35), multiple reviews have supported the efficacy and effectiveness of MIBIs for reducing alcohol use (36-39) and cannabis use (37, 40-42). However, supporting our rationale for integrating a MIBI for SUDs within HIV service settings was research conducted within HIV service settings and found MIBIs can be effective for reducing alcohol use (17, 19) and the use of other substances (18).

To help maximize the external validity of the project and its findings, we aimed to examine the effectiveness of the project's MIBI for SUD as an *adjunct* to usual care (UC) within HIV-CBO (i.e., UC+MIBI compared to UC only). Regarding UC within HIV-CBOs, we found standardized substance use screening was rare, with it being even rarer for HIV-CBOs to employ staff adequately trained to address substance SUDs. Rather, we found UC for SUDs within HIV-CBOs was primarily referral to treatment. Thus, although most HIV-CBOs could possibly be considered as implementing the last component of screening, brief intervention, and referral to treatment (SBIRT), there was a clear need for research to identify effective strategies for helping HIV-CBOs integrate the brief intervention component of SBIRT.

Rationale for Testing the ISF Strategy as an Adjunct to the ATTC Strategy

The combination of staff training, performance feedback, and coaching has been found to be one of the most effective strategies for helping *prepare* individuals to implement motivational interviewing-based interventions with proficiency (43-49). The ATTC Network (50), which is one of the oldest and largest intermediary/purveyor organizations in the United States (51), has long used this multifaceted strategy to help addiction treatment organizations improve the integration of motivational interviewing for SUDs. As such, the ATTC strategy was identified as one of the most promising strategies for helping HIV-CBOs and their staff integrate the project's MIBI. However, given implementation and sustainment are acknowledged as multilevel processes (16, 52), the staff-focused ATTC strategy was hypothesized to be a necessary, but not sufficient, strategy (14). Thus, building upon research that identified facilitation (i.e., process of interactive problem solving and support that occurs in a context of a recognized need for improvement and a supportive interpersonal relationship) as a promising strategy (53-63), we aimed to test the team-focused ISF strategy as an effective adjunct to the staff-focused ATTC strategy (14).

As detailed by Garner et al. (14) the ISF strategy is a multifaceted strategy with facilitation as the overarching discrete strategy, encompassing six additional discrete strategies (i.e., develop tools for quality improvement; organize implementation team meetings; identify and prepare champions; assess for readiness and identify barriers; conduct local consensus discussions; conduct cyclical small tests of change). Grounded in the theory of implementation effectiveness (20-23), the ISF strategy seeks to

improve implementation effectiveness (i.e., the consistency and quality of implementation of the clinical intervention) and intervention effectiveness (i.e., the clinical intervention's effectiveness in terms of improving client outcomes) via improving implementation climate (i.e., the extent to which implementation is expected, supported, and rewarded). However, guided by the Exploration-Preparation-Implementation-Sustainment (EPIS) framework (16), we sought to expand the theory of implementation effectiveness in two ways. Specifically, by examining the extent to which the ISF strategy would help decrease staff time-to-proficiency (the project's preparation phase outcome) and increase staff level-of-sustainment (the project's sustainment phase outcome) (14). In addition to being grounded in the theory of implementation effectiveness, the ISF strategy was grounded in motivational interviewing principles (64), which is similar to how Kauth et al. (56) employed motivational interviewing techniques as part of their multifaceted facilitation strategy for improving implementation of cognitive behavioral therapy within 20 Department of Veteran Affairs clinics. Thus, as part of each ISF strategy meeting, the ISF facilitator attempts to: (1) engage the implementation team, (2) help focus the implementation team on the project's key goal(s), (3) help evoke from the implementation team pros and cons related to the project's key goal(s), and (4) help the implementation team *plan* how best to achieve the project's key goals and sustain those achievements over time.

Primary Aims and Hypotheses

The primary aim of the SAT2HIV Project was to test the ISF strategy as an effective adjunct to the ATTC strategy for helping HIV-CBOs and their staff integrate a MIBI for SUDs. Guided by the theory of implementation effectiveness (20-23) and the EPIS framework (16), we hypothesized that the ISF strategy would have significant impacts on three staff-level outcome measures (i.e., decreasing time-to-proficiency, increasing implementation effectiveness, and increasing level-of-sustainment; see Figure 1). However, as detailed by MacKinnon (65) integrating moderators into research design is important to understand generalizability by examining the extent to which there are any differential effects that would impede interpretation of a main effect. Thus, we further hypothesized (see Figure 1) that the impact of the ISF strategy on these staff-level outcomes would be moderated by components of the Consolidated Framework for Implementation Research's (CFIR) (15) inner setting domain (i.e., implementation readiness, implementation climate, leadership engagement, tension-for-change) and characteristics of individuals domain (i.e., motivational interviewing experience, personal recovery status). Guided by implementation effectiveness theory (20-23) and Curran et al.'s suggestions regarding advantages of type 2 hybrid trials (31), we also hypothesized (see Figure 1) that the ISF strategy would impact (i.e., moderate) the effectiveness of the MIBI (i.e., intervention effectiveness) in terms of improving client outcomes (e.g., decreasing days of primary substance use, decreasing times engaging in risky behaviors, decreasing days of missed HIV medication).

Methods

Trial Design

The trial design was a cluster-randomized, type 2 hybrid trial. Following an exploration phase in which HIV-CBOs were recruited, HIV-CBOs (and their staff) were randomized to one of two strategies: 1) the ATTC strategy; or 2) the ATTC+ISF strategy. Following randomization, the trial was deployed using a multiphase design that included three 6-month phases corresponding to the preparation, implementation, and sustainment phases of the EPIS framework (16). During the implementation phase, HIV-CBOs recruited and randomized client participants to one of two clinical intervention conditions: 1) UC, or 2) UC+MIBI. Institutional review board (IRB) approval and oversight of all research activities were provided by RTI International's IRB.

Context

HIV-CBOs, located in 23 states and the District of Columbia within the United States, provided the context for the SAT2HIV Project.

Participants

HIV-CBO staff participants. To be eligible to participate, an HIV-CBO was required to: (a) serve a minimum of 100 individuals living with HIV per year; (b) have at least two staff willing and able to be prepared to implement a MIBI for SUDs; and (c) have at least one leadership staff (e.g., supervisor, manager, director) willing to help ensure MIBI staff were given sufficient time to participate. There were no exclusion criteria. Each collaborating HIV-CBO identified two staff to be prepared to implement the MIBI as part of the project's implementation phase and to be recruited for participation in staff surveys. Each HIV-CBO also identified 1-3 leadership staff to be recruited for participation in staff surveys. Staff completed surveys prior to randomization (i.e., before the preparation phase), after the implementation phase (month 13), and after the sustainment phase (month 19), and received a \$25 e-gift card per survey. For more details, see the study protocol paper (14).

HIV-CBO client participants. Client eligibility was assessed by HIV-CBO staff via the project's standardized screener. Eligibility criteria included: (a) having been diagnosed with HIV; (b) being 18+ years of age; and (c) acknowledging use of at least one substance in the past 28 days with self-reported endorsement of two or more of the 11 *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) criteria (66) for SUD for that substance during the past 12 months. An exclusion criterion was not being able to speak English, which was due to the project's research staff and MIBI proficiency raters being monolingual. Clients who met eligibility criteria were recruited for study participation by one of several trained HIV-CBO staff. However, it was one of the two MIBI staff from each HIV-CBO who was trained to administer the baseline assessment, follow-up locator form, and open the randomization envelope with client participants. Each HIV-CBO was provided compensation to cover staff time to complete these research-related activities. Clients randomized to the UC+MIBI condition received the MIBI at no cost. Clients received a \$20 gift card for completing the baseline assessment, as well as \$20 for completing a 4-week follow-up assessment administered by research staff blinded to all condition assignments.

Implementation Strategies

Complementing the comprehensive descriptions provided as part of our study protocol paper (14), Table 1 highlights: (a) the 10 discrete strategies in the ATTC strategy, (b) the 7 discrete strategies in the ISF strategy, and (c) the phase that each strategy was made available. For the ATTC strategy, the HIV-CBO's two MIBI staff were given the opportunity to receive 12 months of MIBI training and technical assistance: (a) training (5-hour online didactics, 2-day in-person workshop), (b) performance feedback (standardized feedback on 1-3 MIBIs during the preparation phase, standardized feedback on all MIBIs during the implementation phase), and (c) consultation (1-2 individual consultation calls during the preparation phase, monthly 1-hour group consultation calls during the implementation phase). For the ISF strategy, the HIV-CBO's MIBI staff and leadership staff were given the opportunity to additionally receive 18 months of external facilitation led by one of the project's ISF facilitators (monthly virtual team meetings lasting 30-60 minutes, 1-2 in-person meetings lasting approximately 4 hours). To maximize the extent to which the ISF strategy was implemented with consistency and quality, the project's lead developer of the ISF strategy (BG) trained each ISF facilitator, reviewed randomly selected ISF session recordings (each virtual ISF facilitation meeting was video recorded for quality assurance purposes), and regularly supervised the ISF facilitators (no less than monthly, usually weekly). For more details see the study protocol paper (14).

Clinical Interventions

UC consisted of referral to formal addiction treatment, mutual-help services, or both. Clients randomized to UC+MIBI received the project's 20-30-minute MIBI for SUD provided by one of the HIV-CBO's prepared/trained MIBI staff. The MIBI was designed to motivate individuals living with HIV who have an SUD to change their substance use by (a) examining their reasons for change, (b) receiving feedback about common negative interactions of substance use and HIV-related health issues, (c) further developing importance or confidence to reduce or stop their primary substance use, and (d) making a plan for change. For more details, see the study protocol paper (67).

Outcome Measures

Organized by phase (i.e., preparation phase, implementation phase, and sustainment phase), Table 2 details the staff-level outcome measures (i.e., time-to-proficiency, implementation effectiveness, level-of-sustainment) and client-level outcome measures (i.e., days of primary substance use, number of substance-related problems, times engaging in risky behaviors, days of substance use treatment, days of medication non-adherence) collected.

Moderator Measures

Table 3 details the staff-level measures (i.e., implementation readiness, implementation climate, leadership engagement, tension-for-change, motivational interviewing experience, personal recovery status) hypothesized to moderate the impact of the ISF strategy on the staff-level outcomes.

Targeted Sample Size

The targeted sample size was estimated via power analyses with Optimal Design Software (68). For analyses of staff-level outcomes, it was estimated that 78 MIBI staff nested within 39 HIV-CBOs would provide 80% power to detect a statistically significant ($p < .05$) difference for effect sizes .67 or greater (14). For analyses of client-level outcomes, it was estimated that 1,872 clients, nested within 78 MIBI staff, nested within 39 HIV-CBOs would provide 80% power to detect a statistically significant difference for effect sizes .20 or greater (24).

Randomization Sequence Generation

For randomization of HIV-CBOs (i.e., the clusters), each HIV-CBO was allocated to one of two implementation strategy conditions (ATTC; ATTC+ISF) via an urn randomization process (69). Specifically, using survey data collected during the exploration phase from HIV-CBO staff, seven organizational-level factors (i.e., importance of substance use screening, importance of brief intervention for substance use, innovation-value fit, implementation strategy-value fit, implementation climate for MIBI, implementation readiness for MIBI, and implementation effectiveness for MIBI) were entered into an urn randomization program (70) that optimized the balance of the two implementation strategy conditions on these factors.

During the project's implementation phase, HIV-CBOs randomized client participants to one of two intervention conditions (UC; UC+MIBI) via a blocked randomization sequence (blocking size of 6) generated via a blocked randomization program (71). Within each participating HIV-CBO, each MIBI staff had a lock box containing 36 sequentially numbered tamper-evident security envelopes containing a randomization slip indicating condition assignment. The randomization envelope was opened in front of the client participant. Staff updated a centralized recruitment tracking log monitored multiple times per week by research staff.

Blinding

It was not possible to blind HIV-CBOs and their staff to the assigned implementation strategy condition, but the project's ATTC strategy staff and Independent Tape Rater Scale (ITRS) raters were blinded to implementation strategy condition assignment. Additionally, it was not possible to blind HIV-CBOs, their staff, or client participants to clinical intervention condition assignment, but the project's research staff who conducted the follow-up assessments were blinded to all condition assignments.

Statistical Methods

Statistical analyses were conducted using an intention-to-treat approach. Staff-level outcomes were approximately normal and within-site variation was close to zero. A series of multilevel adjusted analyses was conducted, each of which controlled for project cohort and was weighted via a propensity score weight derived by regressing implementation strategy condition assignment on staff characteristics. The interaction between implementation strategy condition assignment and each hypothesized moderator was examined first, with main effects examined as appropriate.

Client-level outcomes had strong floor effects (e.g., 0 of 28 days) and/or strong ceiling effects (e.g., 28 of 28 days), which led to bimodal u-shaped, j-shaped, or inverted j-shaped distributions. Given these non-normal distributions, linear regression analyses were not appropriate. Rather, these types of distributions are appropriately addressed using zero-and-one inflated beta (ZOIB) regression after data are transformed to a proportion scale (i.e., 0 to 1). The ZOIB model is a mixture model with three parts: (a) a prediction of the probability of the ceiling effect vs. other values (i.e., the ceiling effect), (b) a prediction of the mean for values in between, but not including, the floor and ceiling effect (i.e., non-ceiling/non-floor effect), and (c) a prediction of the probability of the floor effect vs. other values (i.e., the floor effect). We fit three-level multilevel ZOIB models to account for nesting of client participants within MIBI staff and MIBI staff within HIV-CBOs using the R package developed by Liu (72). Each ZOIB model was adjusted for the baseline value of the respective outcome measure, client characteristics (i.e., age, White, male, heterosexual, transgender, married, high school or higher, alcohol as primary substance, engagement in HIV care), project cohort, randomization to ATTC+ISF condition, randomization to UC+MIBI condition, and the cross-level interaction between ATTC+ISF condition and UC+MIBI condition.

Results

Participant Flow and Recruitment

For study feasibility, HIV-CBOs were recruited in three cohorts, each lasting 20 months from the randomization of HIV-CBOs to the final data collection. The first cohort, in the central United States, occurred January 2015 through August 2016, and resulted in the recruitment of 14 HIV-CBOs, 28 MIBI staff, and 191 client participants. The second cohort, in the western United States, occurred January 2016 through August 2017, and resulted in the recruitment of 11 HIV-CBOs, 22 MIBI staff, and 300 client participants. The third cohort, in the eastern United States, occurred January 2017 through August 2018, and resulted in the recruitment of 14 HIV-CBOs, 28 MIBI staff, and 333 clients. Figure 2 details the flow of HIV-CBOs, MIBI staff, and client participants through the project's preparation, implementation, and sustainment phases.

Baseline Characteristics

Table 4 presents baseline characteristics for MIBI staff participants for the overall sample (N = 78) and each condition (ATTC = 38; ATTC+ISF = 40). Overall, MIBI staff participants were/had: 25-34 years of age (46%), female (71%), Caucasian/White (62%), a graduate degree or higher (50%), 12 months or less tenure with current HIV-CBO (35%), and intermediate motivational interviewing experience or higher (53%).

Table 5 presents baseline characteristics for client participants for the overall sample (N = 824) and each condition (ATTC & UC = 134; ATTC & UC+MIBI = 130; ATTC+ISF & UC = 281; ATTC+ISF & UC+MIBI = 279). Overall, clients were/had: male (76%), African American/Black (54%), heterosexual (42%), a high school graduate or higher (70%), and engaged in HIV care (95%). Primary substance use for the overall sample was: alcohol (37%), cannabis (23%), cocaine/crack (18%), methamphetamine (17%), heroin (2%), and other (3%). On average, client participants reported using their primary substance 16 days during the past

28 days (57% of days). However, 222 (27%) of client participants reported using their primary substance daily during the past 28 days (i.e., ceiling effect; see Figure 3).

Outcomes

Table 6 summarizes results of analyses focused on testing the extent to which the ISF strategy (ATTC+ISF strategy compared to ATTC strategy) had an impact on the staff-level outcomes. Consistent with our hypotheses, results of each moderator analysis are presented first, with a main effect analysis reported as appropriate.

For time-to-proficiency, none of the hypothesized moderators were found to be significant. Further, the ISF strategy was not found to have a significant main effect on decreasing time-to-proficiency ($\beta = -0.02$; 95% confidence interval [CI] = -0.41, 0.37). On average, time-to-proficiency was 12.35 weeks ($SD = 3.18$) for MIBI staff in the ATTC condition and 11.44 days ($SD = 4.87$) for MIBI staff in the ATTC+ISF condition.

For implementation effectiveness, none of the hypothesized moderators were found to be significant. However, the ISF strategy was found to have a significant main effect on increasing implementation effectiveness ($\beta = 0.65$; 95% CI = 0.25, 1.05, $p < .01$). On average, the sum number of MIBIs implemented during the implementation phase (the consistency dimension of staff-level implementation effectiveness) was 3.34 ($SD = 4.19$) for MIBI staff in the ATTC condition and 6.92 ($SD = 5.49$) for MIBI staff in the ATTC+ISF condition. On average, the sum quality score of MIBIs (the quality dimension of staff-level implementation effectiveness, was 558 ($SD = 777$) for MIBI staff in the ATTC condition and 1310 ($SD = 1053$) for MIBI staff in the ATTC+ISF condition.

For level-of-sustainment, none of the six hypothesized moderators were found to be significant and there was not a significant main effect for the ISF strategy ($\beta = 0.09$; 95% CI = -0.42, 0.60). On average, the number of MIBIs implemented during the sustainment phase was 3.42 ($SD = 6.31$) for MIBI staff in the ATTC condition and 3.18 ($SD = 8.33$) for MIBI staff in the ATTC+ISF condition.

Table 7 summarizes results of analyses focused on testing the extent to which the ISF strategy (ATTC+ISF strategy compared to ATTC strategy) had an impact on the effectiveness of the MIBI to improve client outcomes (i.e., intervention effectiveness). Consistent with our hypotheses, the cross-level interactions between implementation condition and clinical intervention condition (i.e., ATTC+ISF x UC+MIBI) are presented first, with the other key terms (i.e., ATTC+ISF, UC+MIBI) presented below.

For days of primary substance use (see Figure 4 for the distribution at follow-up), the ISF strategy had a significant impact on the effectiveness of the MIBI, at least in terms of significantly decreasing the odds (odds ratio [OR] = 0.11, 95% CI = 0.08, 0.15, $p = .01$) of clients using their primary substance daily during the 28 day follow-up period (i.e., ceiling effect). To help interpret the size of this effect, an OR of 0.11 is equivalent to an OR of 9.09 ($1 / 0.11 = 9.09$), which is considered a large effect (73). The ISF strategy increased the odds (OR = 1.51) of clients being completely abstinent from their primary substance at follow-up, but this small effect was not statistically significant. Complementing the results shown in

Table 7, Figure 5 helps visualize the cross-level interaction (ATTC+ISF x UC+MIBI) between implementation condition (ATTC+ISF compared to ATTC) and intervention condition (UC+MIBI compared to UC) on days of primary substance use.

The ISF strategy was not found to have a significant impact on the effectiveness of the MIBI (i.e., intervention effectiveness) for the other client outcome measures. However, there were significant effects for the ATTC+ISF strategy on clients' endorsement of problems related to their primary substance (i.e., problem recognition), which is important, yet distinct from the effectiveness of the MIBI (i.e., intervention effectiveness). Specifically, the ATTC+ISF strategy increased (a) the odds of client participants endorsing that their primary substance was associated with each of the 11 DSM-5 symptoms (i.e., ceiling effect; OR = 6.68, 95% CI = 5.39, 8.28, $p = .01$) and (b) the number of the 11 DSM-5 symptoms endorsed for client participants without a ceiling/floor effect (OR = 1.36, 95% CI = 1.09, 1.68, $p = .01$).

Discussion

We used a cluster-randomized, type 2 hybrid trial to simultaneously test the impact of the ISF strategy (as an adjunct to the ATTC strategy) on: (1) the integration of a MIBI for SUDs within HIV-CBOs across the United States, and (2) the effectiveness of the MIBI (as an adjunct to UC within HIV-CBOs). Contributing to the growing literature on the effectiveness of facilitation-based strategies (74-82) and the effectiveness of MIBIs for SUD within HIV service settings (18, 83-88), we found at least two findings of significance. First, we found evidence that the ISF strategy had a significant impact on improving the integration of the MIBI for SUDs, at least in terms of significantly improving the consistency and quality of MIBI implementation during the implementation phase (i.e., implementation effectiveness). Second, we found evidence that the ISF strategy had a significant impact on improving the effectiveness of the MIBI (i.e., intervention effectiveness), at least in terms of significantly decreasing the likelihood that client participants were using their primary substance daily during the follow-up period. However, our main findings also included null results. Indeed, we did not find support for our hypotheses that staff-level measures of the inner setting domain (i.e., implementation readiness, implementation climate, leadership engagement, tension-for-change) and characteristics of individuals domain (i.e., motivational interviewing experience, personal recovery status), two of the key CFIR domains (15), moderated the impact of the ISF strategy. Additionally, we did not find support for our hypotheses that the ISF strategy would significantly decrease time-to-proficiency and significantly increase level-of-sustainment. Organized in chronological order along the EPIS continuum (16), below we discuss the limitations, generalizability, and implications of our findings (25, 26).

In terms of time-to-proficiency, which was the project's preparation phase outcome, we did not find evidence supporting our hypotheses. However, we believe the potential for the ISF strategy to decrease time-to-proficiency was limited by requiring MIBI staff to demonstrate proficiency before they were allowed to help implement/test the project's MIBI for SUDs and/or instructing MIBI staff to demonstrate MIBI proficiency *sometime* before the beginning of the project's implementation phase, rather than as soon as possible. As such, our findings may or may not generalize to: (a) contexts in which

demonstration of MIBI proficiency is required before staff are allowed to implement with clients *and* there is a stronger justification for staff demonstrating MIBI proficiency as soon as possible (e.g., fee-for-service contexts), and/or (b) contexts in which demonstration of MIBI proficiency is not required before staff are allowed to implement with clients. In terms of implications, our findings advance knowledge regarding the preparation of staff to implement a MIBI for SUDs, as well as highlight the need for research experimentally testing the extent to which strategies minimize the time to complete key activities (89) and the extent to which the impact of these strategies is significantly moderated by one or more constructs hypothesized to be important (e.g., implementation readiness, implementation climate, leadership engagement) (15).

Consistent with our time-to-proficiency findings, we did not find evidence to support our moderation-focused hypotheses regarding the impact of the ISF strategy on implementation effectiveness (i.e., the consistency and quality of implementation). We did, however, find evidence that the ISF strategy significantly improved the average level of implementation effectiveness achieved by MIBI staff. A potential limitation of this finding is that MIBI staff were asked to limit the number of MIBIs implemented to three per month. This was done to help increase the likelihood that the monthly performance feedback and group consultation provided as part of the ATTC strategy could have an impact on MIBI quality, which is important given that implementation effectiveness is defined as the both the *consistency* (e.g., the number of MIBIs implemented) and *quality* (e.g., the adherence and competence to the MIBI protocol) of implementation (14, 20, 21). Although we believe this approach was well-justified, our finding may not generalize to less controlled contexts and/or contexts in which the quality component of implementation effectiveness is not using the ITRS to measure MIBI quality. Nonetheless, a key implication of this finding is that the ISF strategy was a promising adjunct to the ATTC strategy, at least for improving the implementation of our project's MIBI for SUDs within HIV-CBOs. Thus, it is recommended that intermediary/purveyor organizations seeking to improve the integration of a MIBI for SUD within HIV-CBOs, such as the AIDS Education & Training Center (AETC) network (90), consider use of the ATTC + ISF strategy for such efforts.

Consistent with prior research highlighting that implementation matters (91)(92) we found that in addition to significantly improving implementation effectiveness, the ISF strategy significantly improved intervention effectiveness. Notwithstanding the importance of this finding, it is important to note the ISF strategy's impact on the effectiveness of the project's MIBI for SUDs was limited to a single client outcome, days of primary substance use. Relatedly, days of primary substance use, as well as the other client outcome measures (e.g., times engaging in risky behaviors, days of missed HIV medication), were based on client self-report and limited to a 4-week follow-up period. We believe, however, blinding follow-up staff to all condition assignments and blinding client participants to HIV-CBO condition assignment helped minimize the extent to which biases associated with these limitations differ between conditions. To the best of our knowledge, we are the first to have experimentally tested the impact of an implementation strategy on intervention effectiveness, which is distinct from our prior implementation research that tested the impact of an implementation strategy on client outcomes (93). Thus, the generalizability of our findings may need to be limited to contexts similar to our current study. Similar to

the implication associated with the impact of the ISF strategy on implementation effectiveness, the key implication of this finding is that future efforts to improve the integration of MIBIs for SUDs within HIV-CBOs, both implementation research and implementation practice (e.g., efforts conducted by the AETCs), should consider use of the ATTC + ISF strategy. Finally, Foy et al. (94) noted “If studies evaluating the effects of implementation intervention are to be of relevance to policy and practice, they should have end-points related to evidence-based processes of care, patient outcomes or population outcomes.” Thus, another implication of our finding is the need for more type 2 hybrid trials that enable tests of impact on intervention effectiveness (i.e., the effectiveness of the clinical intervention), which is arguably one of the most relevant end-points of all.

Although level-of-sustainment is not possible without some level of implementation effectiveness occurring first, level-of-sustainment is another end-point of significant relevance (95-97). Thus, it is significant to note that: (a) we did not find support for our hypotheses related to level-of-sustainment (the ISF strategy would have an impact on level-of-sustainment, with its impact being moderated by one or more staff-level measures), and (b) the average level-of-sustainment was not only similar between conditions, but was relatively low (i.e., only 3 MIBIs during the 6-month sustainment period). The key limitation associated with this finding is level-of-sustainment was based on self-report from MIBI staff. Although it does not appear that self-report led to MIBI staff overestimating their level-of-sustainment, our level-of-sustainment measured also was limited by not being able to measure the extent to which MIBIs were implemented with quality, which may have been possible given the ISF strategy’s impact on implementation effectiveness during the project’s implementation phase. Conservatively, the generalizability of our findings should be limited to efforts to testing the impact of the ISF strategy as an adjunct to the ATTC strategy and/or the level-of-sustainment of a MIBI for SUDs within HIV-CBOs. However, we believe our finding generalize more broadly to research that has advanced knowledge regarding sustainment (98, 99). Arguably, sustainment is one of the most important outcomes to identify effective strategies for, especially given that the lack of sustainment minimizes the return-on-investments for resources expended during prior phases along the EPIS continuum (e.g., exploration phase, preparation phase, implementation phase) (16). Thus, a key implication is that future research is needed to test strategies that can significantly improve both the relative effectiveness of the ATTC+ISF strategy on level-of-sustainment, as well as the extent to which the ATTC+ISF strategy improves the absolute level-of-sustainment.

Conclusions

Although the ATTC strategy was found to be sufficient for the preparation of HIV-CBO staff to implement a MIBI for SUDs, the ISF strategy was found to be an effective adjunct to the ATTC strategy in terms of both implementation effectiveness (i.e., the consistency and quality of implementation during the implementation phase) and intervention effectiveness (i.e., the effectiveness of the MIBI for SUDs). Based on these findings, we conclude that future implementation research and practice focused on integrating a MIBI for SUD within HIV-CBOs should consider use of the ATTC+ISF strategy. However, given the ISF strategy did not have a significant impact on level-of-sustainment, which was similarly low in both

implementation conditions, we also conclude that future efforts should seek to enhance the ATTC+ISF strategy via strategies focused on improving level-of-sustainment during the sustainment phase.

Abbreviations

AETC	AIDS Education & Training Center
ATTC	Addiction Technology Transfer Center
CBO	community-based organization
CFIR	Consolidated Framework for Implementation Research
EPIS	Exploration-Preparation-Implementation-Sustainment
IRB	institutional review board
ISF	Implementation & Sustainment Facilitation
ITRS	Independent Tape Rater Scale
MIBI	motivational interviewing-based brief intervention
NIDA	National Institute on Drug Abuse
PWH	people with HIV
SAT2HIV	Substance Abuse Treatment to HIV care
SBIRT	screening, brief intervention, and referral to treatment
SUD	substance use disorder
UC	usual care
ZOIB	zero-and-one inflated beta

Declarations

Ethics Approval and Consent to Participate

The current study was conducted under the auspices of RTI International's institutional review board.

Consent for Publication

Not applicable.

Availability of Data and Material

Upon reasonable request, which should be made to the corresponding author, study data or materials may be made available.

Competing Interests

None.

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Authors' Contributions

Conception and design of the work: BG, HG, MC, SM, JF, KS, DV, EB, AT, and ST. Acquisition, analysis or interpretation of data: BG, HG, MC, SM, JF, MR, KS, DV, MB, EB, AT, and ST. Creation of new software used in the work: BG, CG, EB, and AT. Drafted the work or substantively revised it: BG, HG, MC, SM, JF, MB, EB, AT, and ST. In addition to having approved the submitted version, all authors have agreed to (a) be personally accountable for the author's own contributions and (b) ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Tables

Table 1. Discrete Strategies Included Within the ATTC Strategy and the ISF Strategy

	Discrete Strategies	Preparation Phase	Implementation Phase	Sustainment Phase
ATTC Strategy	Centralized technical assistance	<input type="checkbox"/>	<input type="checkbox"/>	
	Develop educational materials	<input type="checkbox"/>		
	Develop and organize quality monitoring system	<input type="checkbox"/>		
	Develop tools for quality monitoring	<input type="checkbox"/>		
	Distribute educational materials	<input type="checkbox"/>		
	Conduct educational meetings	<input type="checkbox"/>		
	Make training dynamic	<input type="checkbox"/>		
	Audit and provide feedback	<input type="checkbox"/>	<input type="checkbox"/>	
	Provide ongoing consultation	<input type="checkbox"/>	<input type="checkbox"/>	
	Create a learning collaborative		<input type="checkbox"/>	
ISF Strategy	External Facilitation	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Develop tools for quality improvement	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Organize implementation team meetings	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Identify and prepare champions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Assess for readiness and identify barriers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Conduct local consensus discussions		<input type="checkbox"/>	<input type="checkbox"/>
	Conduct cyclical small tests of change		<input type="checkbox"/>	<input type="checkbox"/>

Note: ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation. See the study protocol paper(14) for detailed descriptions of each discrete strategy.

Table 2. Outcome Measures

Measure Name	Measure Description
(Phase)	
1. Time-to-proficiency (Preparation Phase)	A staff-level measure of the number of weeks between MIBI staff completing the in-person training and demonstrating proficiency in the project's MIBI for SUDs. Developed for this project based on research by Saldana (89). Proficiency was determined by one of the project's MI experts, who rated audio recordings of MIBI practice sessions using the Independent Tape Rater Scale (ITRS) (100). The ITRS is used to rate 10 MI-consistent items for adherence and competence along 7-point scales. MIBI proficiency was demonstrated when a single MIBI session had half the items rated at the mid-point or higher for both adherence and competence items.
2. Implementation effectiveness (Implementation Phase)	A staff-level measure of the overall consistency and quality of MIBI implementation during the project's implementation phase. Developed for this project based on research by Klein (21). P PPPFirst, the cumulative number of MIBIs implemented was summed and standardized for each MIBI staff (MIBI consistency). Second, the MIBI proficiency scores were summed and standardized for each MIBI staff (MIBI quality). Proficiency of each MIBI session was assessed by the project's cadre of raters who were trained, calibrated, and supervised by one of the project's MI experts. A quality score was calculated for each MIBI session by multiplying the corresponding adherence rating (ranged from 1 - 7) and competence rating (ranged from 1 - 7) and summing for all 10 of the MI-consistent items (ranged from 10 - 490). Finally, MIBI consistency and MIBI quality scores were summed and standardized.
3. Intervention effectiveness (Implementation Phase) regarding:	
3.1. Days of primary substance use	A client-level measure of the number of days client participants self-reported using their primary substance during the past 28 days and measured using a modified version of the Addiction Severity Index.(101) Client's primary substance was identified at baseline by asking: "Of the substances that you have used in the past 4 weeks (not including tobacco), which one has been the biggest problem for you OR caused you the most problems?" At follow-up, client participants were reminded of the substance they had indicated was their primary substance.
3.2. Number of substance-related problems	A client-level measure of the number of the 11 DSM-5(66) substance use disorder symptoms client participants self-reported recognition of regarding their primary substance and during the past 28 days. At follow-up, client participants were reminded of the substance they had indicated was their primary substance.
3.3. Times engaging in risky behaviors	A client-level measure of the number of times client participants self-reported engaged in unprotected sex, injection drug use, or needle sharing during the past 28 days, which was developed for this project based on the Addiction Severity Index.(101)
3.4. Days of substance use treatment	A client-level measure of the number of days client participants self-reported having attended residential treatment, outpatient treatment, or self-help group meetings during the past 28 days, which was developed for this project based on the Addiction Severity Index.

Measure Name	Measure Description
(Phase)	
3.5. Days of HIV medication non-adherence	A client-level measure of the number of days client participants self-reported having missed at least one dose of their HIV medications during the past 28 days, which was developed for this project based on the on the Addiction Severity Index.(101)
4. Level-of-sustainment	A staff-level measure of the number of MIBIs delivered during the project's 6-month sustainment phase and measured via MIBI staff self-report as part of the project's sustainment phase survey.
(Sustainment Phase)	

Note: BI = brief intervention; MIBI = motivational interviewing-based brief intervention. Intervention effectiveness was assessed in terms of the impact of the ISF strategy on each of the client outcome measures.

Table 3. Staff-level Moderator Measures

Measure Name	Measure Description
Motivational interviewing experience	A baseline measure of MIBI staff perception of their motivational interviewing experience. Measured by having MIBI staff select one five response options (i.e., none, beginner, intermediate, advanced, or expert).
Personal recovery status	A baseline measure indicating if MIBI staff considered themselves to be in recovery from alcohol/drugs (0 = no; 1 = yes).
Implementation readiness	A baseline measure representing MIBI staff perception regarding their organization's readiness for implementing a brief intervention for SUDs. Measured using the average of 12 items developed by Shea (102). Each item (e.g., staff working on this project want to implement this change; staff working on this project are committed to implementing this change; staff working on this project will do whatever it takes to implement this change) was measured on a 5-point scale (1 = Disagree, 2 = Somewhat Disagree, 3 = Neither Agree nor Disagree, 4 = Somewhat Agree, 5 = Agree). Coefficient alpha = .95.
Implementation climate	A baseline measure representing MIBI staff perception regarding the extent to which implementing brief intervention for SUDs is expected, supported, and rewarded within their organization. Measured using the average of the 6 items developed by Jacobs (103). Each item (e.g., staff working on this project are expected to use brief intervention for substance use with a certain number of clients; staff working on this project get the support they needed to use brief intervention for substance use with eligible clients; staff working on this project receive recognition for using brief intervention for substance use with eligible clients) was measured on a 5-point scale (1 = Disagree, 2 = Somewhat Disagree, 3 = Neither Agree nor Disagree, 4 = Somewhat Agree, 5 = Agree). Coefficient alpha = .91.
Leadership engagement	A baseline measure representing MIBI staff perception regarding the extent to which their HIV-CBOs leadership is committed, involved, engaged, and accountable for implementing brief intervention for SUDs. Measured using 4 items developed for this project based on the leadership engagement construct described by Damschroder (15). Each item (i.e., to what extent was the leadership of this organization <i>committed</i> to the implementation of brief intervention for substance use; to what extent was the leadership of this organization <i>involved</i> in the implementation of brief intervention for substance use; to what extent was the leadership of this organization <i>engaged</i> in the implementation of brief intervention for substance use; to what extent was the leadership of this organization <i>accountable for</i> the implementation of brief intervention for substance use) was measured on 7-point scale (0 = not at all to 6 = highest extent possible). Coefficient alpha = .94.
Tension-for-change	A baseline measure representing MIBI staff perception regarding the extent to which implementing a brief intervention for SUDs is important, needed, and desired. Measured using 3 items developed for this project based on the tension-for-change construct described by Damschroder (15). Each item (i.e., to what extent do staff working on this project believe implementation of brief intervention for substance use is important; to what extent do staff working on this project believe implementation of brief intervention for substance use is needed; to what extent do staff working on this project believe implementation of brief intervention for substance use is desired) was measured on 7-point scale (0 = not at all to 6 = highest extent possible). Coefficient alpha = .92.

Note: MIBI = motivational interviewing-based brief intervention.

Table 4. Staff Characteristics at Baseline

	Overall		ATTC		ATTC + ISF	
	(n=78)		(n=38)		(n=40)	
	n	%	n	%	n	%
Age						
18-24	3	3.8	2	5.3	1	2.5
25-34	36	46.2	12	31.6	24	60.0
35-44	16	20.5	9	23.7	7	17.5
45-54	14	17.9	9	23.7	5	12.5
55-64	9	11.5	6	15.8	3	7.5
Biological Sex						
Female	55	70.5	26	68.4	29	72.5
Male	23	29.5	12	31.6	11	27.5
Hispanic or Latino	16	20.5	11	28.9	5	12.5
Race						
African American/Black	27	34.6	14	36.8	13	32.5
Asian	3	3.8	1	2.6	2	5.0
Caucasian/White	48	61.5	23	60.5	25	62.5
Graduate degree or higher	39	50.0	16	42.1	23	57.5
Experience in current profession						
12 months or less	14	17.9	6	15.8	8	20.0
13-24 months	10	12.8	2	5.3	8	20.0
25-60 months	15	19.2	7	18.4	8	20.0
81-120 months	18	23.1	10	26.3	8	20.0
121+ months	21	26.9	13	34.2	8	20.0
Tenure at current organization						
12 months or less	27	34.6	17	44.7	10	25.0
13-24 months	20	25.6	6	15.8	14	35.0
25-60 months	15	19.2	6	15.8	9	22.5
81-120 months	9	11.5	4	10.5	5	12.5
121+ months	7	9.0	5	13.2	2	5.0
Moderator measures						
Intermediate MI experience or higher	41	52.6	22	57.9	19	47.5
In recovery for alcohol or drugs	11	14.1	8	21.1	3	7.5
Readiness for implementing change [mean (SD)]	78	2.9 (1.4)	38	3.3 (1.4)	40	2.6 (1.4)
Implementation climate [mean (SD)]	78	2.8 (1.1)	38	3.0 (1.1)	40	2.7 (1.1)
Leadership engagement [mean (SD)]	78	3.7 (1.7)	38	3.8 (1.6)	40	3.5 (1.7)
Tension-for-change [mean (SD)]	78	4.4 (1.4)	38	4.5 (1.3)	40	4.4 (1.4)

Note: ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; MI = motivational interviewing.

Table 5. Client Characteristics at Baseline

	Overall (n = 824)		ATTC & UC (n = 134)		ATTC & UC + MIBI (n = 130)		ATTC + ISF & UC (n = 281)		ATTC + ISF & UC + MIBI (n = 279)	
	n	%	n	%	n	%	n	%	n	%
Age										
18-24	46	5.6	5	3.8	3	2.3	16	5.7	22	7.9
25-34	138	16.8	27	20.3	25	19.2	46	16.4	40	14.3
35-44	179	21.7	24	18.0	24	18.5	69	24.6	62	22.2
45-54	287	34.9	51	38.3	43	33.1	99	35.2	94	33.7
55-64	156	19.0	24	18.0	31	23.8	49	17.4	52	18.6
65+	17	2.1	2	1.5	4	3.1	2	0.7	9	3.2
Biological Sex										
Male	627	76.1	99	73.9	91	70.0	220	78.3	217	77.8
Female	197	23.9	35	26.1	39	30.0	61	21.7	62	22.2
Gender Identity										
Male	575	69.9	91	67.9	87	66.9	203	72.5	194	69.5
Female	203	24.7	35	26.1	38	29.2	65	23.2	65	23.3
Transgender	45	5.5	8	6.0	5	3.8	12	4.3	20	7.2
Hispanic or Latino	109	13.2	22	16.4	17	13.1	37	13.2	33	11.8
Race										
African American/Black	447	54.2	77	57.5	72	55.4	161	57.3	137	49.1
American Indian/Alaska Native	23	2.8	1	0.75	2	1.5	6	2.1	14	5.0
Asian	4	0.5	0	0.0	0	0	3	1.1	1	0.4
Caucasian/White	298	36.2	48	35.8	50	38.5	96	34.5	104	37.6
Native Hawaiian/Other Pacific Islander	10	1.2	0	0.0	1	0.8	2	0.7	7	2.5
More than one	20	2.4	2	1.5	2	1.5	7	2.5	9	3.2
Sexual Orientation										
Heterosexual	347	42.1	60	44.8	70	53.8	97	34.6	120	43.2
Homosexual, gay, or lesbian	315	38.3	51	38.1	40	30.8	124	44.3	100	36.0
Other	160	19.5	23	17.2	20	15.4	59	21.0	58	20.8
Married	109	13.2	16	11.9	26	20.0	36	12.8	31	11.1
Highschool graduate or higher	576	70.4	94	71.8	86	66.7	203	72.2	193	69.7
Engaged in HIV care	778	95.2	127	95.5	122	94.6	260	93.5	269	97.1
Primary Substance										
Alcohol	304	36.9	56	41.8	54	41.5	99	35.2	95	34.0
Cannabis	186	22.6	35	26.1	37	28.5	57	20.3	57	20.4
Cocaine/Crack	145	17.6	23	17.2	15	11.5	52	18.5	55	19.7

	Overall (n = 824)		ATTC & UC (n = 134)		ATTC & UC + MIBI (n = 130)		ATTC + ISF & UC (n = 281)		ATTC + ISF & UC + MIBI (n = 279)	
	n	%	n	%	n	%	n	%	n	%
Methamphetamine	143	17.4	12	9.0	14	10.8	59	21.0	58	20.8
Heroin	20	2.4	2	1.5	6	4.6	7	2.5	5	1.8
Other	26	3.2	6	4.5	4	3.1	7	2.5	9	3.2
	n	mean (SD)	n	mean (SD)	n	mean (SD)	n	mean (SD)	n	mean (SD)
Outcome measures										
Days of use	823	15.9 (9.7)	134	16.3 (9.8)	130	16.9 (9.9)	280	15.6 (9.7)	279	15.4 (9.5)
Problem recognition	824	7.3 (3.1)	134	6.9 (3.1)	130	7.0 (3.2)	281	7.4 (3.2)	279	7.4 (3.1)
Risky behaviors	818	3.8 (9.8)	132	2.8 (10.7)	130	3.4 (7.5)	279	4.2 (11.2)	277	4.1 (8.7)
Engagement in SUD treatment	822	2.4 (7.1)	133	3.2 (8.5)	129	2.0 (6.5)	281	2.1 (7.5)	279	2.5 (6.2)
Days of missed HIV medication	740	3.8 (6.3)	126	3.6 (6.2)	120	3.5 (5.8)	240	4.1 (6.4)	254	3.8 (6.4)

Note: ATTC = Addiction Technology Transfer Center; ISF = Implementation & Sustainment Facilitation; MIBI = motivational interviewing-based brief intervention; UC = usual care

Table 6. Moderator-first analyses of the impact of the ISF strategy on time-to-proficiency, implementation effectiveness, and level-of-sustainment

	Time-to-Proficiency			Implementation Effectiveness			Level of Sustainment		
	(ICC = .22)			(ICC = .06)			(ICC = .001)		
	Estimate	SE	p	Estimate	SE	p	Estimate	SE	p
	(95% CI)		value	(95% CI)		value	(95% CI)		value
MI Experience									
ATTC+ISF	-0.35	0.30	0.24	0.70 (0.10,1.30)	0.30	0.03	0.34	0.39	0.39
	(-0.93,0.23)						(-0.42,1.10)		
MI experience (intermediate plus)	-0.02	0.29	0.95	0.20	0.30	0.50	0.18	0.38	0.64
	(-0.58,0.54)			(-0.38,0.78)			(-0.56,0.92)		
ATTC+ISF x MI experience	0.63	0.39	0.11	-0.07	0.41	0.86	-0.47	0.52	0.37
	(-0.14,1.40)			(-0.87,0.73)			(-1.49,0.55)		
Personal Recovery Status									
ATTC+ISF	0.09	0.21	0.67	0.70 (0.27,1.13)	0.22	0.01	0.26	0.28	0.34
	(-0.33,0.51)						(-0.28,0.80)		
In recovery	0.35	0.38	0.35	-0.01	0.39	0.98	0.64	0.49	0.20
	(-0.39,1.09)			(-0.77,0.75)			(-0.33,1.61)		
ATTC+ISF x In recovery	-0.90	0.58	0.13	-0.58	0.60	0.33	-1.36	0.76	0.08
	(-2.04,0.24)			(-1.75,0.59)			(-2.84,0.12)		
Implementation Readiness									
ATTC+ISF	0.43	0.49	0.38	-0.06	0.50	0.90	-0.40	0.65	0.54
	(-0.53,1.39)			(-1.03,0.91)			(-1.67,0.87)		
Implementation Readiness	0.15	0.11	0.16	-0.20	0.11	0.06	-0.08	0.14	0.58
	(-0.06,0.36)			(-0.41,0.01)			(-0.35,0.19)		
ATTC+ISF x Implementation Readiness	-0.13	0.15	0.36	0.21	0.15	0.16	0.16	0.19	0.41
	(-0.41,0.15)			(-0.08,0.50)			(-0.22,0.54)		
Implementation Climate									
ATTC+ISF	0.20	0.58	0.73	0.68	0.59	0.26	-0.56	0.75	0.46
	(-0.93,1.33)			(-0.48,1.84)			(-2.04,0.92)		
Implementation Climate	0.02	0.14	0.86	-0.05	0.14	0.71	-0.15	0.18	0.41
	(-0.25,0.29)			(-0.33,0.23)			(-0.50,0.20)		
ATTC+ISF x Implementation Climate	-0.08	0.18	0.67	-0.02	0.19	0.93	0.21	0.24	0.37
	(-0.43,0.27)			(-0.38,0.34)			(-0.25,0.67)		
Leadership Engagement									
ATTC+ISF	0.18	0.51	0.72	0.04	0.52	0.94	-0.53	0.67	0.43
	(-0.82,1.18)			(-0.98,1.06)			(-1.84,0.78)		

	Time-to-Proficiency			Implementation Effectiveness			Level of Sustainment		
	(ICC = .22)			(ICC = .06)			(ICC = .001)		
	Estimate	SE	p	Estimate	SE	p	Estimate	SE	p
	(95% CI)		value	(95% CI)		value	(95% CI)		value
Leadership Engagement	0.02	0.09	0.84	-0.12 (-0.3,0.06)	0.09	0.21	-0.03	0.12	0.82
	(-0.16,0.20)			(-0.26,0.20)					
ATTC+ISF x Leadership Engagement	-0.06	0.13	0.66	0.16	0.13	0.22	0.17	0.16	0.31
	(-0.31,0.19)			(-0.09,0.41)			(-0.15,0.49)		
Tension-for-Change									
ATTC+ISF	0.20	0.74	0.79	0.08	0.76	0.91	-0.30	0.97	0.76
	(-1.25,1.65)			(-1.40,1.56)			(-2.21,1.61)		
Tension-for-Change	-0.01	0.12	0.93	-0.01	0.12	0.91	-0.10	0.16	0.54
	(-0.24,0.22)			(-0.25,0.23)			(-0.40,0.20)		
ATTC+ISF x Tension-for-Change	-0.05	0.16	0.76	0.12	0.16	0.44	0.08	0.21	0.69
	(-0.36,0.26)			(-0.19,0.43)			(-0.32,0.48)		
Main Effect									
ATTC+ISF	-0.02	0.20	0.91	0.65 (0.25,1.05)	0.20	0.00	0.09	0.26	0.74
	(-0.41,0.37)			(-0.42,0.60)					

Note: ICC = intraclass correlation; ATTC = Addiction Technology Transfer Center; CI = confidence interval; ISF = Implementation & Sustainment Facilitation; MI = motivational interviewing.

Table 7. Cross-level Interactions Examining the Impact of the ISF Strategy on the Intervention Effectiveness of the MIBI

	Days of Primary Substance Use (ICC = .07)		Number of Substance-Related Problems (ICC = .06)		Times Engaging in Risky Behaviors (ICC = .03)		Days of Substance Use Treatment (ICC = .03)		Days of HIV Medication Non-Adherence (ICC = .01)	
	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value	OR (95% CI)	p value
Ceiling Effect										
UC+MIBI x	0.11	0.02	0.26	0.16					•	
ATTC+ISF	(0.08,0.15)		(0.20,0.36)							
ATTC+ISF	4.11	0.04	6.68	0.01					2.50 (2.07,3.02)	0.50
	(3.25,5.19)		(5.39,8.28)							
UC+MIBI	1.87	0.39	1.50	0.62					0.36 (0.29,0.45)	0.13
	(1.44,2.42)		(1.18,1.91)							
Non-Ceiling/ Non-Floor Effect										
UC+MIBI x	1.03	0.87	0.86	0.33	0.62	0.10	1.39	0.25	1.18 (0.90,1.55)	0.23
ATTC+ISF	(0.74,1.43)		(0.64,1.16)		(0.36,1.08)		(0.79,2.44)			
ATTC+ISF	1.02	0.86	1.36	0.01	1.02	0.93	0.95	0.81	1.09 (0.90,1.32)	0.36
	(0.81,1.29)		(1.09,1.68)		(0.66,1.56)		(0.65,1.40)			
UC+MIBI	1.09	0.53	1.05	0.72	1.26	0.35	0.72	0.17	0.88 (0.70,1.10)	0.25
	(0.84,1.41)		(0.82,1.33)		(0.78,2.05)		(0.45,1.15)			
Floor Effect										
UC+MIBI x	1.51	0.58	1.51	0.73	0.91	0.86	0.82	0.62	0.89 (0.68,1.17)	0.75
ATTC+ISF	(1.09,2.10)		(1.12,2.03)		(0.52,1.59)		(0.47,1.44)			
ATTC+ISF	2.00	0.20	0.85	0.85	0.59	0.15	1.40	0.26	1.23 (1.01,1.48)	0.45
	(1.58,2.53)		(0.68,1.05)		(0.39,0.91)		(0.95,2.05)			
UC+MIBI	1.05	0.94	0.93	0.94	1.08	0.87	1.10	0.78	1.14 (0.91,1.43)	0.68
	(0.81,1.37)		(0.74,1.19)		(0.66,1.74)		(0.69,1.74)			

Note: ATTC = Addiction Technology Transfer Center; CI = confidence interval; ICC = intracluster correlation; ISF = Implementation & Sustainment Facilitation; MIBI = motivational interviewing-based brief intervention; OR = odds ratio; UC = usual care. • indicates variable removed to allow model to converge. Ceiling effects were excluded for outcomes without a ceiling effect. Times engaging in risk behavior has no theoretical ceiling. Past 28 days substance use treatment does have an actual ceiling at 28, but it was so infrequently observed in the data that a ceiling effect did not result.

Figures

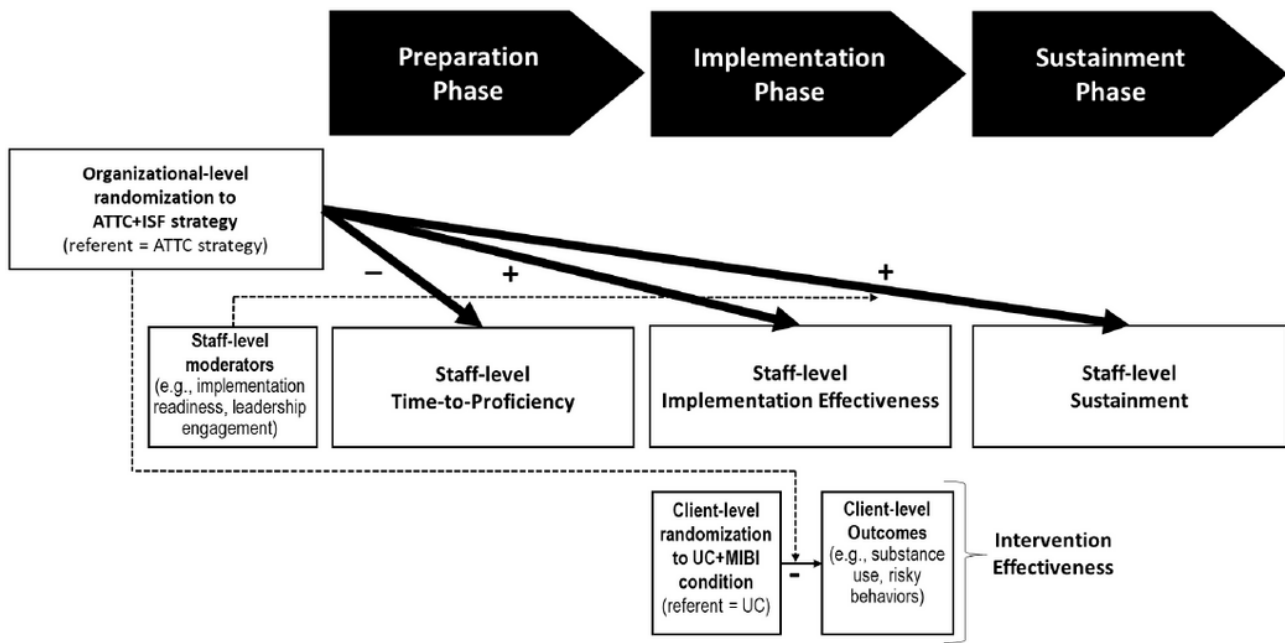


Figure 1

Aims and Hypotheses Note: ATTC = Addiction Technology Transfer Center; ISF Implementation & Sustainment Facilitation; MIBI = motivational interviewing-based brief intervention; UC = usual care. Bolded lines indicate primary aim and hypotheses; thin line indicates other aim; dashed lines indicate hypothesized moderators.

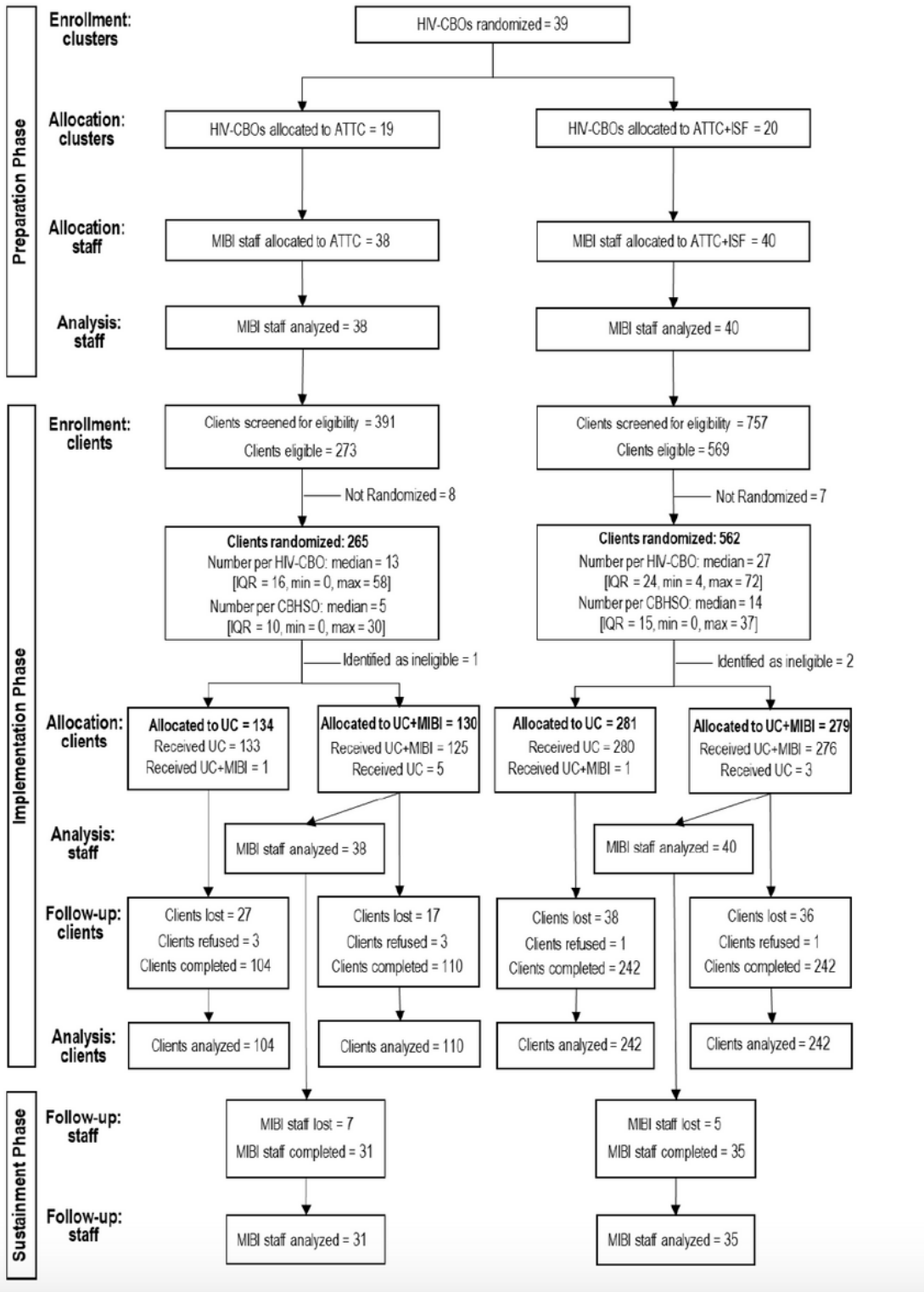


Figure 2

Participant Flow Note: ATTC = Addiction Technology Transfer Center; IQR = interquartile range; ISF Implementation & Sustainment Facilitation; MIBI = motivational interviewing-based brief intervention; UC = usual care.

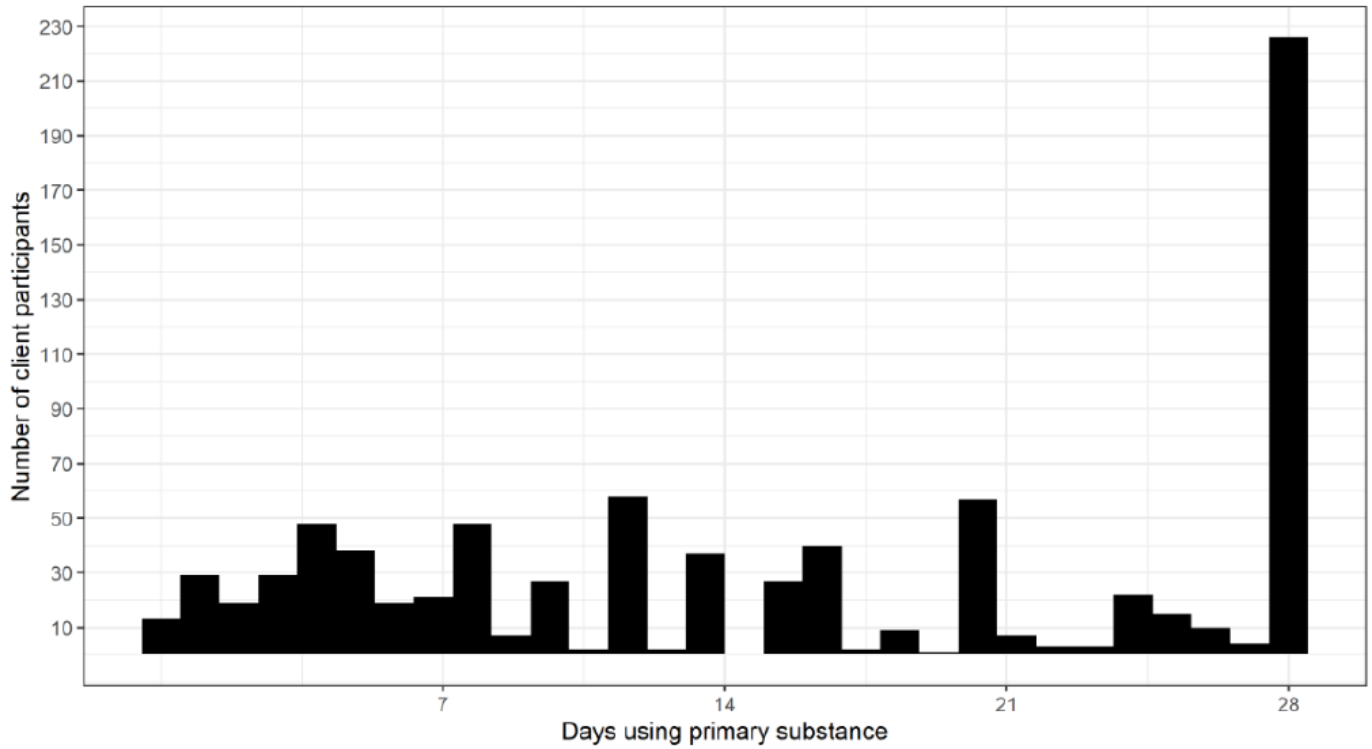


Figure 3

Baseline Distribution for Client's Days of Primary Substance Use

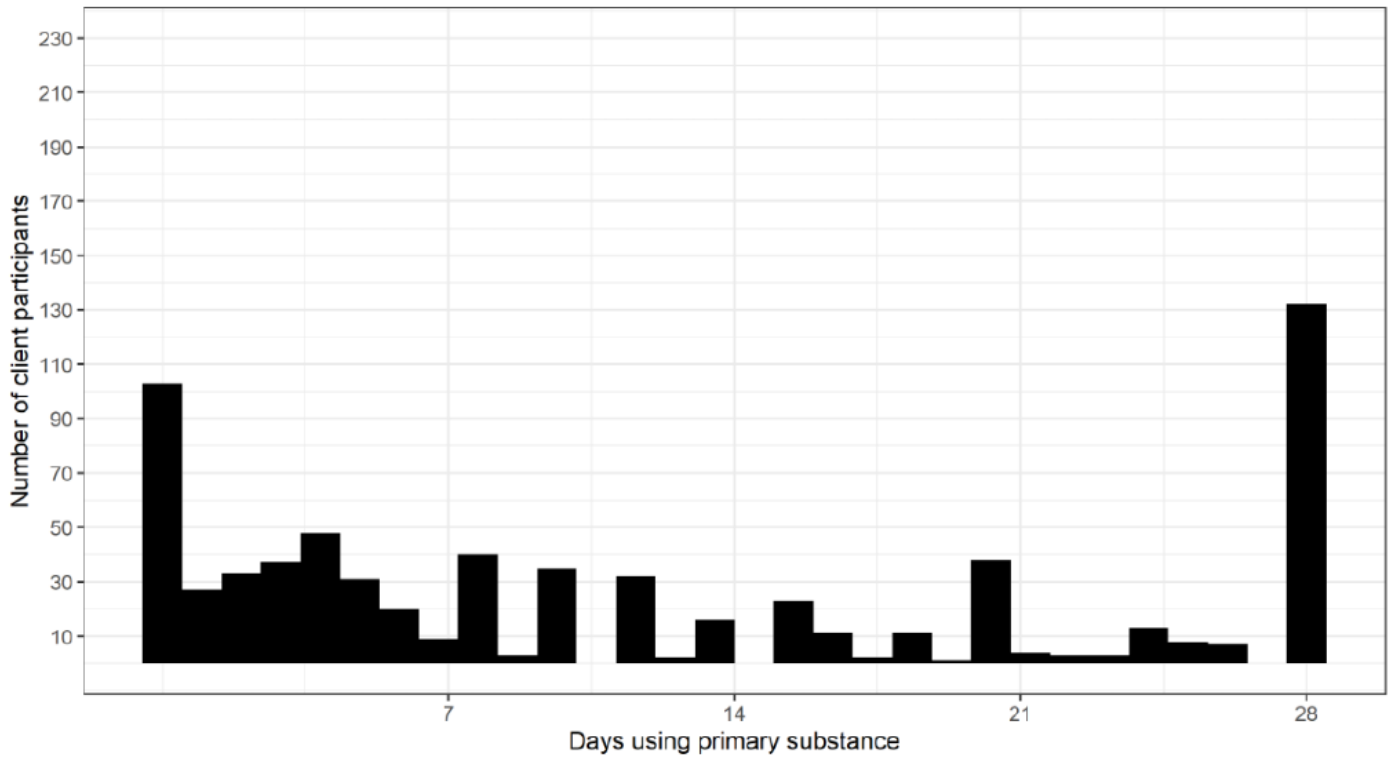


Figure 4

Follow-up Distribution for Client's Days of Primary Substance Use

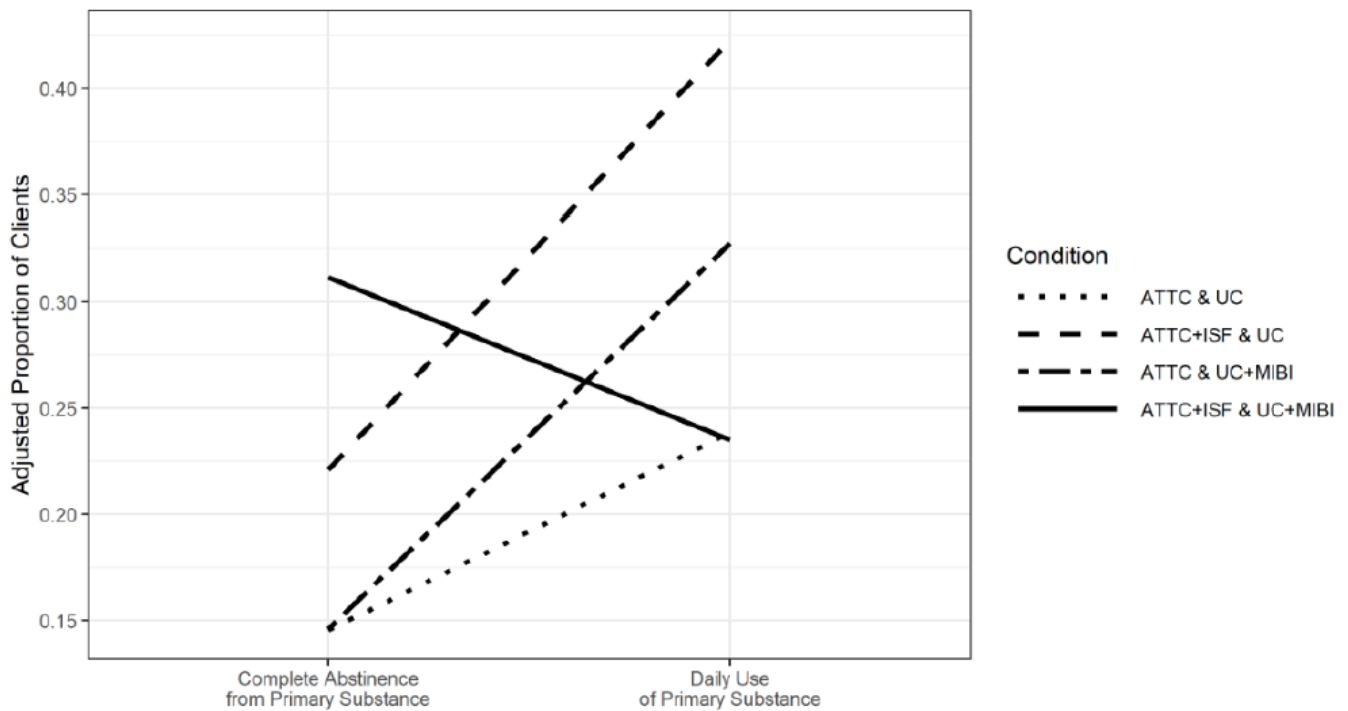


Figure 5

The Impact of the ISF Strategy on Intervention Effectiveness

Supplementary Files

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