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Motivational tools to improve probationer treatment outcomes

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Abstract

Background—Motivational interviewing (MI) is a promising practice to increase motivation, treatment retention, and reducing recidivism among offender populations. Computer-delivered interventions have grown in popularity as a way to change behaviors associated with drug and alcohol use.

Methods/Design—Motivational Assistance Program to Initiate Treatment (MAPIT) is a three arm, multisite, randomized controlled trial, which examines the impact of Motivational Interviewing (MI), a Motivational Computer Program (MC), and Supervision as Usual (SAU) on addiction treatment initiation, engagement, and retention. Secondary outcomes include drug/alcohol use, probation progress, recidivism (i.e., criminal behavior) and HIV/AIDS testing and treatment among probationers. Participant characteristics are measured at baseline, 2, and 6 months after assignment. The entire study will include 600 offenders, with each site recruiting 300 offenders (Baltimore City, Maryland and Dallas, Texas). All participants will go through standard intake procedures for probation and participate in probation requirements as usual. After standard intake, participants will be recruited and screened for eligibility.

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Trial status

Recruitment for this trial is ongoing and expected to end by December 2015.

Clinical Trial registration: NCT01891656.

Competing Interests

The authors declare that they have no competing interests.

Authors' Contributions

FST and STW are co-principal investigators of the study, drafted the study protocol and study materials, and obtained approval from their respective Human Subjects Review Boards and the National Institute on Drug Abuse to conduct the study. LBS is involved in quality checks of the data. JL and MR are project managers of the study for their respective sites. All authors contributed to the manuscript and approved the final version.

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Discussion—The results of this clinical trial will fill a gap in knowledge about ways to motivate probationers to participate in addiction treatment and HIV care. This randomized clinical trial is innovative in the way it examines the use of in-person vs. technological approaches to improve probationer success.

Trial Registration—NCT01891656

Keywords

MAPIT; motivational interviewing; computer-delivered interventions; criminal behavior; substance use; HIV risk; e-health

Background

Addiction treatment has a well-documented positive effect on drug use, criminal behavior, and other related outcomes [1–6]. Addiction treatment can serve as the main vehicle to address the sheer number of people on probation or parole who have substance use disorders and other related health conditions such as infectious disease [7,8] while also serving to reduce recidivism [9]. Despite the overwhelming evidence in support of treatment, over 3.5 million of the nearly 6 million individuals under community corrections (probation and parole) fail to receive adequate treatment. [10,11]. Of those individuals meeting the criteria of substance use disorders, less than half actually participate in treatment [12]. There are numerous challenges that inhibit individuals from accessing services, including individual motivation for treatment [4,10,13,14,15].

Pre-treatment motivation is a good predictor of treatment engagement and retention [16,17,18] with clinical research reinforcing the importance of the behavior change process to increase retention and effectiveness [19]. Unfortunately, relatively few treatment programs in the criminal justice system have early phases that specifically address motivation [20]. In addition, many “action-oriented” treatment programs are a poor match for clients who have not yet decided that substance use is a problem (pre-contemplators) or those who have not decided what they want to do about their substance use (contemplators).

Motivational interviewing (MI) and brief automated technologies are recent advances that specifically target motivation to enter treatment as a precursor to clinical services. MI has a strong evidence base for increasing treatment readiness in general populations of substance users [19,21] and shows promise at improving motivation, treatment retention, and reducing recidivism among offenders as well [22]. More recently, brief computer interventions have shown similar findings regarding improved treatment readiness and decreased substance use, particularly when grounded in theoretical frameworks such as MI and cognitive behavioral therapy [23–31]. Unfortunately, most of this research has been conducted on non-offender populations; very little research has been conducted in criminal justice settings where the need for treatment services is great. This paper discusses a multi-site, randomized controlled trial examining the impact of in-person MI versus an automated motivational program on probationer treatment initiation and retention, recidivism, and other risky behaviors.

Motivational Interviewing (MI)

MI is a client-centered, directive method for increasing motivation and commitment for change [32]. MI focuses on eliciting client speech about desire, ability, reasons, need or commitment to change [33,34]. MI, normally delivered in one or two sessions, can be implemented as a stand-alone intervention, a prelude to other treatments, or combined with other elements, such as personalized feedback.

Decades of research demonstrate the versatility of MI in a number of behavior change areas such as drug and alcohol use, medication compliance, and HIV risk behaviors. A recent review of 119 studies found that MI had a significantly better effect than no-treatment groups in terms of drug/alcohol use and engagement in treatment, and an equivalent effect when compared to other active (but typically more lengthy) treatments [21]. Another review of MI in health settings concluded that MI had a “significant and clinically relevant” effect in three of four studies, and outperformed traditional advice-giving 80% of the time [35]. Some evidence suggests that adding MI components to the beginning of a treatment sequence increases treatment effects [19, 36–39]. In addition, when MI is used alongside personalized feedback, individuals respond more positively to treatment seeking and readiness (see the “Check-Up” format discussed by [40]). These personalized feedback reports typically include information from the client’s baseline assessment, such as a comparison to population norms, identification of risk factors, and perceived or experienced negative consequences of the behavior [40,41].

Computer-Delivered Interventions

In recent years, there has been increasing interest in developing computerized interventions for behavior change, including some that target drug and alcohol use [42–45] and treatment initiation [23]. Automated interventions hold several potential advantages over face-to-face interventions, such as cost effectiveness, transportability, and improved fidelity of treatment delivery [46].

Computerized interventions for drug and alcohol use vary greatly in their format and delivery style. Interventions range from relatively simple formats, such as assessment with tailored feedback [31,47], to complex formats that involve interactive assessments, goal setting, skills practice, and self-monitoring [43]. Specific to alcohol use, a systematic review found that computer-based alcohol interventions were successful in reducing the quantity, frequency, and peak intoxication periods compared to control (standard treatment) conditions [48]. Regarding illicit drug use, another review found that computer-based interventions led to decreased substance use, increased motivation and treatment retention, and a greater retention of information, compared to treatment as usual [24]. In some cases these outcomes were superior to in-person counseling using cognitive behavioral therapy, community reinforcement approach, or cognitive rehabilitation [24].

The potential benefits of computer-based interventions are well established. In a study of adult drinkers, Hester and colleagues tested a computer-based “Check-Up” that included assessment, personalized feedback, and decision-making components [28]. Problem drinkers reported significantly less drinking after receiving the program, and maintained these

reductions throughout a 12-month follow-up. Riper and colleagues and Carroll and colleagues found significant effects on drinking and drug use, respectively, as a result of participation in web-based interventions using cognitive behavioral principles [30,27]. Finally, specific to treatment engagement, Lieberman and Massey found that a computerized motivational program significantly increased interest in seeking treatment [23]. To our knowledge, no individual study has directly compared in-person versus automated formats for increasing treatment engagement and retention among people involved in the justice system.

Methods and Design

The present study will test the efficacy of a 2-session MI intervention or a 2-session motivational computer program (MC), compared to standard probation intake (Supervision as Usual; SAU) to improve addiction treatment initiation, engagement, and retention among people on probation. Primary and secondary objectives for this study include the following:

1. Primary: develop two intervention formats (MI and MC) for increasing motivation to initiate and engage in addiction treatment and (if applicable) HIV testing and care;
2. Secondary: test the efficacy of MI versus MC on 2 and 6-month addiction treatment initiation and engagement, drug/alcohol use, probation progress, recidivism and HIV/AIDS testing and treatment, as compared to SAU among 200 probationers in each project site (400 total)¹;
3. Evaluate probationer characteristics (e.g., risk level, gender, ethnicity, motivation) as potential moderators of the intervention effect(s); and
4. Assess the relative cost and cost-effectiveness of MI and MC on addiction treatment and/or linkage to or participation in HIV testing/care, supervision outcomes, recidivism, and substance abuse.

The last two study aims are not primary objectives to the study but are of interest to the research team.

Setting

The study will take place in two large probation agencies: Baltimore City, MD (general population of 620,000), and Dallas County, TX (general population of 2.5 million). Baltimore is the largest office of the Maryland Department of Public Safety and Correctional Services, supervising over 18,000 offenders each year. Dallas County Community Corrections and Supervision (like other Texas counties) is organized at the county level, and supervises approximately 30,000 offenders each year. In terms of ethnicity, 90% of Baltimore clients are African American; 37% of Dallas clients are African-American, 36% are non-Hispanic white, and 26% are Hispanic. In both sites, approximately half of

¹Initially the study design included 300 probationers per site (600 total), however challenges in recruitment (e.g., lower numbers of probation intakes at sites) led to re-examining the necessary sample size. Power analysis using 2 month data on primary study outcome of treatment initiation determined sufficient power with only 200 probationers per site (400 total).

offenders are court ordered to drug or alcohol treatment services, with the specific placement generally determined by a clinical interview at the start of probation.

The two study sites bring strengths to the project as well as important differences that will help to determine whether intervention effects are likely to generalize to other probation agencies. Baltimore is part of a state probation system with direct allocation of treatment slots from the city's treatment system, while Dallas is a county-administered probation system that outsources most of its treatment placements.

In both sites (as with most probation departments around the country), the purpose of the intake is to review probation conditions, administer assessments, and determine appropriate treatment recommendations. Dallas uses a pre-trial assessment process for felony offenders to define the sentence and supervision characteristics. Baltimore, on the other hand, assesses only probationers who already have judicially-ordered treatment conditions, which is about one-third of offenders. In both sites, offenders may be reassessed if it is found that they are using illicit substances during probation.

Eligibility Criteria

To be eligible for the clinical trial, participants must be: 1) 18 years of age or older; 2) currently on probation; 3) able to provide informed consent; 4) able to communicate in English; 5) sentenced to a court date for probation or released from a short (i.e., less than 1 year) jail stay within the last 30 days; and 6) report any illicit drug use and/or any instance of heavy alcohol use (5 or more drinks for men; 4 or more drinks for women in a single occasion) in the last 90 days. If clients are in treatment at the time of the baseline interview, they are allowed to be in the study to measure continued engagement and retention in treatment, which should affect positive outcomes. The eligibility criteria are intentionally broad to assess the impact of the different approaches on a variety of probationers. Since continued substance use tends to increase the risk of probation violation, the study examines the role of motivating probationers to participate in treatment to prevent poor probation progress.

Recruiting Participants

Research staff recruit potential study participants using a number of methods. These methods include: 1) face-to-face contact; 2) word of mouth; 3) flyers and brochures; and 4) referrals from probation office staff (e.g., assessors, probation officers). Recruitment varies based on differences in intake procedures. Data will be collected on why subjects do not agree to participate in the study.

In Baltimore, after their court appointment, probationers report to a central intake office for processing and assignment to their probation officer. At intake, probationers receive an addiction treatment assessment if the court has ordered a treatment condition. The probationer then reports to a field office for individual visits with their probation officer. To recruit participants in this system, research staff post flyers at the various field probation offices, the central intake office, and community organizations. Research staff recruit one-on-one in the waiting areas of the central intake and various field offices. Project staff administer the screening questionnaire on a touchscreen laptop in waiting areas.

In Dallas, most probationers receive a substance abuse screening and (if appropriate) a treatment recommendation prior to their final court hearing. Once sentenced, the probationer reports to their respective field office for an orientation session. Recruitment is targeted in three probation field offices during orientation. To clients who express interest, staff administer the screening questionnaire on a touchscreen laptop after orientation, or over the phone at a later date. Staff also reach out to other field offices and distribute advertisement material for dissemination.

Procedures and Interventions

The study will use a computer-assisted interviewing system where all instruments are housed in a web-based study management software². Screening of potential participants will occur in-person or via phone. The screening questionnaire will include the eligibility criteria questions listed above. If someone is screened eligible, the research assistant (RA) administers a criminal justice screener to determine level of recidivism risk based on static risk (e.g., prior number of arrests). Block randomization is allocated by static criminal justice risk level (i.e., low/moderate versus high risk). Therefore, recruitment within either risk level will cease once approximately 100 participants per site are recruited within each respective risk level. If the potential participant is unable to complete the baseline assessment the day of the screening, then he or she is scheduled to return within a week to complete the baseline and (if necessary) Session 1 intervention. The potential participant has 30 days to return for their baseline assessment after their screening.

Prior to the baseline assessment, the RA will obtain informed consent from the participant. The RA will review the informed consent with the client, explains the study, and answers any questions. Once the participant signs the consent form, the RA will collect locator information from the client (e.g., phone numbers, addresses). Prior to randomization, an approximately 2-hour baseline assessment is completed. Information collected during the baseline assessment includes measures such as: demographics, substance use history, addiction treatment history, physical and mental health history, employment/education history, sexual risk behaviors, HIV testing and care, trauma, criminal cognitions, and motivation for treatment. Randomization occurs within the study management software upon the submission of the baseline assessment, placing participants into one of three arms (i.e., MI, MC, or SAU). If the participant is placed in one of the intervention groups (i.e., MI or MC), he or she is asked to complete the 45-minute first intervention session. Participants randomized to SAU receive their incentive (i.e., gift card) and an appointment time for the 2-month follow-up before leaving.

Supervision as usual (SAU)

Participants randomized to the SAU group will receive the standard agency intake process as well as baseline and follow-up research interviews, but no additional intervention as part of the study. Referrals to treatment programs happen as per the normal routine within each jurisdiction.

²DatStat study management software is used for this study (www.datstat.com).

Motivational Interviewing (MI)

Participants randomized to the MI group will receive the standard agency intake process, complete the baseline and follow-up research interviews, and receive two 45-minute MI sessions focused on motivation to initiate and engage in treatment [49]. These sessions happen approximately 3–4 weeks apart. The protocol for the counselor-delivered MI mimics the computerized intervention. The MI sessions will be provided by masters level clinicians who are employees of the study and clinical oversight is provided by the PI (SW).

In the MI session, counselors will utilize open-ended questioning, reflective listening, affirmation, and summarization aimed at exploring ambivalence and eliciting “change talk” [32]. Counselors follow the directive aspects of a motivational interview, such as attending to and reinforcing self-motivational statements. The format of the interview includes: 1) orienting the participant to the session and the limits of confidentiality; 2) exploring the participant’s substance use and related problems; 3) presenting the participant’s personalized feedback report (similar to that generated by the MC condition); 4) utilizing the “Readiness Rulers” to explore importance and confidence to engage in addiction treatment; 5) discussing treatment engagement in the hypothetical or concrete; and (if appropriate) 6) providing suggestions and assistance with identifying treatment options that might fit the person’s schedule, budget, or transportation situation. The goal of these sessions is to increase motivation to make changes in substance use, including initiating or engaging in substance use treatment. Participants are given a list of treatment programs, including location and phone number. For a full description of the MI protocol, see [49].

Motivational Computer Intervention (MC)

Participants randomized to the MC group will receive the standard agency intake process, complete the baseline and follow-up research interviews, and participates in two 45-minute computer interventions focused on motivation to initiate and engage in treatment. The program length varies based on participant choices and the speed at which participants complete the program. The computer system (i.e. network, programs, hardware, etc.) are provided by the study team. The study does not use the probation agency’s computer system to prevent any confidential information being accessible to the probation staff. These sessions will happen approximately 3–4 weeks apart. The MC program applies the same concepts as the MI study arm, but delivers through an automated format. Participants “interact” with the computer through selecting goals, answering questions, and providing responses to information. A text-to-speech engine allows the program to pull thousands of word combinations based on the information the participant provides not only during the baseline assessment, but also during the MC session itself. Research assistants are available to assist clients who have difficulty using the program. For a full description of the MC protocol, see [50].

Follow-up procedures

After completing the baseline research assessment and randomization, participants randomized to MI or MC will complete the first 45-minute session immediately (or on a subsequent day if they cannot stay). Before leaving the initial appointment, the RA or counselor provide an appointment card for both the 2-month follow-up phone assessment

and the intervention Session 2 (scheduled approximately 3–4 weeks later). Four days following the completion of the MI or MC Session 1, the research staff sends a thank you letter to the participant. The SAU participants follow the same procedures, but only receive an appointment card for the 2-month follow-up phone interview.

A staff member will send an email or letter 14 days before the second MI or MC visit. Three days before the session, the counselor sends a text, followed by a phone call the day before the appointment (Figure 2). Emails will be sent directly to the participant; none of these emails are available to the probation staff. The probation agency will not be aware that the research team is using emails or text messaging and therefore there should be minimal risk of loss of confidentiality due to these follow-up strategies. Procedures to ensure that correspondence is secure are similar to mail and phone correspondence in that there is no reference to being on probation or that the person is in a study. If the participant opts not to receive texts or emails, then phone calls are made in the place of these reminders. Four days following the completion of the MI or MC Session 2, the counselor sends a thank-you letter to the participant.

The participant must complete the MI or MC Session 1 within 60 days post-baseline and MI or MC Session 2 within 60 days post-Session 1. This timeframe ensures that the data provided to the participant is current. If the participant fails to show for their scheduled MI or MC appointment, the counselor and/or RA initiates tracking procedures (e.g., phone calls, letters, street tracking) to locate the participant.

Two follow-up research interviews will be conducted by the RA occur at 2- and 6-month post-baseline assessment. The 2-month interview, approximately 30–40 minutes, is a phone interview. The 6-month interview, approximately 90 minutes, normally takes place in-person at a neutral location in the community (e.g., library). The RA offers to meet the participant outside of the probation office to complete the 6-month interview so that the probationer feels more comfortable discussing their probation and treatment experiences. A series of reminder letters, phone calls, text messages, and emails are sent to participants as reminders for upcoming appointments. Figure 3 provides details about the reminders that occur prior to the 6-month research interview. These procedures mimic those that occur for the 2-month interview.

Since some study participants will be likely to be reincarcerated in local jail and/or prison during the study period, the research team will use traditional follow-up procedures. Research assistants will contact the local jail and/or prison, use Victim Information and Notification Everyday (<https://www.vinelink.com/vinelink/initMap.do>), or check the probation records to identify if the person is incarcerated, and at which facility. A letter will be sent asking an administrator at the facility to allow us to conduct an interview in the jail. This letter includes notification that the individual has given us permission to contact them while incarcerated but does not state the nature of the study. The letter will be mailed, faxed, or emailed to a contact person at the jail/prison. If permission is granted, then a research assistant will conduct the interview at the facility. However, no cheek swabs will be taken at the facility.

Participant compensation

Participants receive a \$40 gift card for each in-person interview and a \$10 gift card for the telephone interview. If randomized to MI or MC, the participant receives an additional \$20 gift card for completing the second intervention session. Participants may collect \$90 to \$110 for completing all parts of the study.

Statistical Analysis Plan

Primary and secondary outcome variables

The primary outcomes will be treatment initiation, engagement and retention using the Timeline Follow-back Interview (TLFB) and Timeline Follow-back Supplemental (TLFBS) questions at the 2- and 6-month follow-up interviews. These outcomes are selected because they are theoretically related to the intervention, and significant predictors of probation outcome. Treatment initiation refers to whether the individual commences formal treatment (i.e., self-help groups are not included) or any type of treatment. Formal treatment refers to outpatient care, inpatient, medication assisted therapies, and correctional treatment. Medication therapies are identified if the individual uses opioids or alcohol. A fuller range of treatment options that is also collected includes self-help group, medications, faith based counseling, and other services that the participants perceive as treatment. The fuller range of treatment options are collected to allow the study to measure participation in support or recovery services as well as formal treatment. Consideration is also given to HIV/AIDS treatment. Treatment initiation will be measured as a dichotomous variable (yes/no) or the length of time from randomization in the experiment to first treatment appointment (continuous). Treatment engagement refers to involvement in at least two sessions of treatment within the first 30 days of starting treatment. Treatment retention refers to having participated in at least four treatment services within 30 days of initiating treatment for substance abuse or for three months of HIV/AIDS care, and/or using medications for HIV/AIDS within the first month. Retention will be measured both as a dichotomous outcome (retain/not), as well as a continuous outcome (percentage of sessions attended). The primary source for the data is self-report from the TLFB, supplemented by administrative data where available for participants who have a treatment requirement.

Secondary outcomes will include: drug/alcohol use, probation progress, recidivism and HIV/AIDS testing and treatment. Drug/alcohol use refers to self-reported use by the probationer and results from a cheek swab test administered during the baseline and six-month interviews to corroborate self-report. Probation progress refers to having no official judicial revocations during the follow-up period. Recidivism refers to rearrest for any crime. Recidivism will be measured both as a dichotomous measure (i.e., yes/no) and a continuous measure (i.e., length of time to arrest). Finally, HIV/AIDS testing refers to whether the probationer has been tested for HIV/AIDS and is aware of his or her test results. Treatment progress, administrative data, drug use, and the cost measures come from different sources. The 6-month assessment captures treatment progress. Management information systems from the states of Maryland and Texas will provide administrative data on study participants including progress on probation and rearrest rates. Treatment progress will include whether any treatment conditions were met during the period of supervision. Some cost data will be

collected from the research interviews, but a larger portion comes from ongoing instruments completed by the research and clinical staff to cover time spent on various activities. All other variables not mentioned will be measured as nominal or continuous variables.

Sample size

We will use arrest to determine the power analyses because it is a readily available variable and there is more information accessible on this measure. Even though the primary outcomes will be treatment initiation, there is no readily available information on initiation patterns among probationers. Arrest is a more conservative measure than treatment initiation since it is harder to achieve a statistical significance difference in research studies. Prior to beginning the study, researchers performed power calculations using the *Repeated Measures with Attrition* (RMASS2) program developed by Hedeker and colleagues [51]. Initially the study included a 12-month follow-up assessment, which resulted in four repeated measurements (baseline, 1, 6 and 12 months) and an estimated 15% attrition rate. The RMASS2 calculations assume two different correlations among the repeated measures (.1 and .2), an alpha of .05, historical effect sizes, and two sites with block randomization. The calculations assume tests of differences between two independent groups on a central recidivism measure (mean number of rearrests) using conventional assumptions of power at .80, Type I error (alpha) at .05, and the standard deviation observed (1.23) based on prior research on probationers [52]. Assuming a moderate effect on subsequent arrests (.35, amounting to a difference of .28 mean arrests), the study needs 39 subjects in each group to detect the hypothesized difference. (Note: due to a 26 percent decrease in grant funding provided by NIH during the grant cycle, the 12 month interview was altered to be a 6 month interview. Power assessments were done to assess this change using the same procedures as well as examining the first year's data.)

Interim data analysis plan

The interim data analyses plan will examine data at scheduled intervals (when 25%, 50%, and 75% of data are collected) for monitoring purposes of the Data and Safety Monitoring Board (DSMB) to determine if there are any integrity issues or adverse events. The data used for these analyses include: 1) number of subjects recruited at each site by month; 2) important characteristics (e.g., gender, race, substance abuse); 3) number of subjects in each study group (to ensure random assignment); 4) number of follow-up assessments collected by site (to calculate follow-up rates); 5) percent of missing items; and 6) missing data and logic errors by site and interviewer. Researchers continuously update CONSORT reporting to monitor recruitment progress.

Preliminary Analyses

Preliminary analyses will be conducted prior to the examination of the experimental conditions include such information as scale psychometrics and descriptive statistics. Many of the measures included in the interviews require psychometric analyses to assess reliability of the various measures. Researchers will also complete descriptive analysis to describe the samples in the experimental conditions, including the participants and staff participating in the study. Such variables include rates of assessment, placements, referrals, and length of

treatment stay, program completion rates, and demographic variables (e.g., race, gender, age). Research staff will examine frequency distributions and comparisons of means to describe each variable for the MI, MC, and SAU as well as the distribution of all outcome variables for the study. Preliminary analyses will inform the primary analyses for the study.

Planned Analyses

This three-arm study will be viewed as the following: Assignment (MC, MI, or SAU) X 2 Risk Levels (High vs. Low/Moderate) block design where offenders are randomly assigned. Assignment and risk will be crossed with each other, and both will be considered fixed factors. (The study blocked on risk level to assess whether any study condition is more likely to produce positive outcomes for various types of probationers.) Due to the nature of the design, the only estimable interaction effect is assignment and risk. The hypotheses will be tested for each site separately, as well as pooled across study sites. The main hypotheses are: 1) MI or MC will result in a shorter period of time to initiate treatment than SAU, more engagement in treatment, and more retention in treatment; 2) MI or MC interventions will be more effective for higher-risk probationers in terms of initiating, engaging, and retaining in treatment than SAU; 3) Lower-risk probationers assigned to MC will have better outcomes; and 3) MI or MC interventions will result in reduced recidivism compared to SAU, particularly for high-risk probationers.

Planned Contrasts

A series of contrasts will directly test different hypotheses. Contrast 1 will compare the two conditions (MI and MC) pooled, to the SAU condition, while Contrast 2 will compare MI to MC. These two comparisons will answer the question of whether either intervention is superior to the traditional intake process or to each other on the various study outcomes.

The randomization process by risk level will use mixed model analyses that takes into account the independent impact of risk level, and the potential interaction between risk level and assignment. A mixed model approach will account for several factors in each of the analyses, including the main effects of assignment, the impact of risk level, and the interaction between risk level and assignment. The mixed model approach will use ACOVA and survival models (for time variables) with different dependent variables, such as the presence of and length of time to initiation treatment, engaging in treatment, and retention in treatment. Other outcomes that will be measured are rearrest; presence and length of time to positive drug tests; continued drug use; stable employment; stable residence, and treatment progress. For example, to test the hypothesis that the MI impacts treatment initiation rates, our outcome measure is interval and we will use a simple mixed model analysis (Hays, 1981). The same model of analysis (which includes terms for assignment, risk group, and the interaction between assignment and risk) will be applied to a number of different dependent variables (e.g., addiction treatment initiation, engagement, retention and rearrest, continued substance abuse, treatment progress) depending on the research question examined. For static models that include binary dependent variables, we will use logistic rather than ANOVA procedures. We will use survival models to examine rates of failure across time. As suggested above, the measurement family will assist in determining the statistical techniques. We can estimate whether MI or MC can enhance treatment

participation or delay technical violations, rearrest, or drug use, even if it they not change overall recidivism or relapse rates during the follow-up period. We will also be able to estimate whether the rates of failure are likely to differ after the censoring date, or last date of follow-up in our analyses.

Cost and cost-effectiveness analysis

The study will include a cost and cost-effectiveness analysis. This analysis takes the criminal justice perspective, including the costs to all agents in the criminal justice system. A micro-costing method is being used to collect data and estimate start-up and implementation costs [53,54]. The estimation protocol distinguishes between research costs (covering resources used solely for the research study) and intervention costs (covering resources actually used to administer the intervention). To estimate costs, we will first develop a taxonomy of resources for each intervention arm, which includes the resources needed to implement each intervention. For example, delivering MI requires counselor time, office space, and supplementary materials, such as manuals and literature. Upon completion of the trial, we will gather information on unit costs. Information on time taken to assess and deliver MI comes from a survey of counselor and research staff participating in the study. To estimate the average cost of each intervention, we will multiply the cost per unit of service by the number of units. To obtain the average cost per participant, the average cost of each resource will be estimated across participants within each intervention.

The cost-effectiveness analysis will include a calculation of the incremental cost-effectiveness ratio for each outcome, estimated cost-effectiveness acceptability curves (CEACs), and sensitivity analyses. The results will allow decision-makers to understand how much it costs to achieve a specific gain in effectiveness (i.e., treatment initiation, treatment engagement, and recidivism). *The incremental cost-effectiveness ratio (ICER)* is the incremental cost of obtaining an improvement in effectiveness. This analyses will follow standard methods to estimate the ICER [55,56,53] that have been implemented by Zarkin and colleagues among others [57]. Comparing two interventions j and k , the ICER is: $ICER = \text{cost} / \text{effectiveness} = (\text{Average Cost } j - \text{Average Cost } k) / (\text{Average Outcome } j - \text{Average Outcome } k)$ where j and k represent any two of the three interventions. To calculate the numerator, cost, the difference between the average cost of intervention j and the average cost of intervention k will be calculated. The denominator is the difference between the average outcome for intervention j and the average outcome for intervention k . The estimate for effectiveness will come directly from the efficacy results of the main study (above). The ICER will be used to determine the more cost-effective intervention arm.

Calculating CEACs accounts for the inherent variability that arises from using estimates in the analysis. CEACs show the probability of an intervention's cost-effectiveness as a function of the stakeholder's intrinsic appraisal or willingness to pay for the outcome [58–60]. Sensitivity analyses will investigate the degree to which conclusions change when assumptions made in the course of analyses vary [61]. A one-way sensitivity analyses (that varies one parameter at a time) and n-way sensitivity analyses (that varies several assumptions) will be calculated.

Treatment Fidelity

Adherence and fidelity are important features of clinical trials. This study will track adherence and fidelity to study protocols using audio recordings in both the interview and MI sessions. Research staff review and code a random sample of the interview recordings. Upon review of the interview session recordings, researchers will provide the interviewer with immediate feedback about the congruence rate between their own responses and the interviewer's data entry as well as a completed interview feedback sheet. The project managers (JL or MR) address any deficiencies heard on the recordings immediately with the appropriate staff member. Similarly, the principal investigator (SW) reviews counselor MI session recordings and provides the counselor with feedback about the session's adherence to the intervention protocol. These recordings provide a way for continual training of staff throughout the project. Analysis of these recordings post-study will provide measures of implementation. For instance, MI session recordings will be coded using the Motivational Interviewing Treatment Integrity coding system [62] while interview recordings will be coded using a qualitative data analysis program (e.g., Atlas.ti).

Discussion

This study will examine two different strategies to improve addiction treatment initiation and engagement among people in the probation system. We designed these interventions to be compatible with the existing system of care in other probation agencies. While the study has a number of strengths, there are also some design limitations: (1) the two selected sites are not representative of all probation settings; (2) the needs of the population in these two sites may be different in some way unanticipated in the intervention's design; and (3) the study conducts one phone and two face-to-face interviews, which are additional services not provided by probation agencies. The results of this clinical trial will fill a critical knowledge gap about ways to motivate people in the criminal justice system to engage in treatment and make changes in substance use. If effective, our interventions may provide innovative tools to criminal justice agencies seeking new technologies that improve offender success.

Limitations of this Study

This three-arm randomized trial is designed to assess the relative efficacy of different motivational interventions to accelerate participation in treatment for probationers with substance use disorders. The setting is a probation office. Baseline research interviews are conducted at the probation office and follow-up interviews are in the field. Most data from the study are from interviews with probationers (self-reports) with administrative data to verify probation conditions, arrests, and drug testing results, if available. Treatment initiation, engagement and retention data will primarily come from study participants since there are no available data sets to verify the information and it would be too costly to contact the myriad of treatment providers in the two communities. It is not expected that there will be problems with this self-report data since study subjects will not be aware that the primary study outcomes will be related to treatment processes. A second limitation is that the study subjects will be compensated at slightly different rates based on study condition. While we do not expect this to be a problem it is a possible imbalance among the arms that we cannot

control. We do not expect this differential payment to impact the control arm (supervision as usual) since many probationers tend to prefer less intrusive probation requirements. The payment of subjects to attend the MI or MC intervention visits are may have a slight differential impact on participation rates which we cannot measured in this study. Finally, the check swab technology will allow us to verify drug use only within a narrow window. Overall, the study design will test the efficacy of two different motivational interventions as ways to enhance positive outcomes such as treatment participation, which has been found to reduce drug use and negative probation outcomes.

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List of Abbreviations

MAPIT	motivational assistance program to initiate treatment
MI	motivational interviewing
HIV	human immunodeficiency virus
MC	motivational computer program
SAU	supervision as usual
ACASI	audio computer-assisted self-interviewing
RA	research assistant
TLFB	timeline follow-back interview
TLFBS	timeline follow-back supplemental
RMASS2	repeated measures with attrition
DSMB	data and safety monitoring board
CONSORT	consolidated standards of reporting trials
CEACs	cost- effectiveness acceptability curves
ICER	incremental cost-effectiveness ratio

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Figure 1.
Study Design

Figure 2.
Follow-up and Reminders for Interventions

Figure 3.
Follow-up and Reminders for 6 Month Assessment