PrEP Readiness Interventions for Supporting Motivation

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Feasibility. In this pilot SMART, we examined several indices of feasibility. We report randomization rates, completion of MI and CM sessions, fidelity ratings of MI sessions, and follow-up rates over six months.

Acceptability. After the 6-month assessment, participants were given the opportunity to sit for a one-on-one, semi-structured qualitative exit interview via Zoom. The staff member conducting exit interviews was not involved in the primary study procedures to avoid bias. Participants were given an overview of the activities they completed during PRISM (e.g., two MI sessions, CM incentives, and three surveys) and asked about their experiences. Interview guides were tailored to each participant's study arm (MI, CM, or MI+CM) and whether they had filled a PrEP prescription during the intervention (ie., responders versus non-responders). Exit interviews were approximately 30 minutes and participants received a $50 incentive.

Qualitative interviews were analyzed using a rapid qualitative analytic approach as a guide (Hamilton, 2020; Harkness et al., 2022). Interviews were first transcribed verbatim and reviewed for quality assurance. Transcriptions were then used to develop a matrix summary of participant' responses, including participant number, intervention arm, PrEP status, and responses to each domain of interest. The research team, consisting of a graduate student research assistant, a doctoral level interviewer and a doctoral level project manager, reviewed and discussed the matrix to identify emerging themes, data consistency and matrix accuracy. Illustrative quotes were then extracted to highlight relevant themes. Finally, the manuscript authors reviewed the matrix, themes, and illustrative quotes as well as agreed upon the accuracy of the findings.

Scalability. The cost analysis was framed from the provider perspective to reflect the resources required to plan and implement the PRISM telehealth motivational enhancement interventions in a community-based setting (e.g., STI clinic). Cost data were collected from the study's financial records and interviews with the investigative team. We created a structured data extraction template to organize cost data and summarize key results including start-up costs (i.e., one-time investments required to implement the strategies), total intervention costs, and participant incentive payments. Resources were tracked across three stages of the intervention: baseline, first-stage intervention (three months), and second-stage intervention where applicable (six months). Total incentive payments for each intervention stage were calculated by multiplying the number of participants engaged in each strategy by the payment amounts for each intervention stage. We excluded purely research-related expenses such as study recruitment efforts and outcome assessments. We focused on identifying the essential costs required to replicate the interventions outside of a research environment. Expense categories comprised personnel (including wages and benefits), consultants, clinical assessments, and incentives. Fixed expenses like infrastructure (e.g., buildings and facilities), utilities, transportation, and equipment were not applicable since all interactions were conducted remotely via Zoom and data organized in REDCap. The only direct expenses were for supplies (i.e., HIV tests, shipping, and computers).

PRISM primary and secondary outcomes. Adaptive interventions that are embedded in a SMART can be compared via the Weighted and Replicated (W&R) method (Nahum-Shani et al., 2012). However, given the feasibility and acceptability nature of this study we instead descriptively compared three groups by aggregating across the first-stage and second-stage randomizations (see Figure 1): MI-only (arms D and E), CM-only (arms A and B), and MI+CM (arms C and F). Specifically, our efforts to examine the primary and secondary outcomes proceeded in four steps. First, demographic characteristics and meth use severity were stratified by first-stage randomization status (i.e., MI versus CM) to ensure randomization was successful (see Table 1). Second, intervention assignment was collapsed into the three groups described above. Third, because pilot trials do not provide reliable effect size estimates (Kraemer & Kupfer, 2006), we did not conduct statistical tests or comment on the magnitude of CM, MI, or MI+CM effects. Instead, we provide descriptive statistics for primary and secondary outcomes at six months stratified by intervention assignment. Fourth, we examined correlates of verified PrEP use (versus no PrEP use) over the 6-month follow-up, irrespective of first- or second-stage randomization status.

Figure 1. Pilot SMART procedures