Mopati: A Pilot HIV Treatment Partner Intervention in Botswana (R34MH121229)

NCT04796610

Study Protocol and Statistical Analysis Plan

August 12, 2023

STUDY PROTOCOL

Low-cost, scalable interventions are essential to support people living with HIV to adhere to antiretroviral therapy (ART) and remain in care. One such intervention is the use of treatment partners, which are recommended by HIV treatment guidelines worldwide. Specifically, national HIV policies of several countries, including Botswana, recommend that healthcare providers encourage patients initiating ART to identify an individual who can provide support, accompany patients to appointments, and provide medication reminders. Although a large body of work indicates the key role of social support in promoting adherence, research on treatment partners' effectiveness has shown mixed results. Thus, research is needed to determine how support from treatment partners can be better harnessed. We propose to pilot test the effects of the *Mopati* program ("partner" in Setswana, the official language of Botswana), a multi-level intervention that guides healthcare providers and patients about treatment partner selection, and trains treatment partners on provision of effective support. The Specific Aims are: (1) To develop a multi-level treatment partner intervention with input from community and healthcare provider stakeholders in Botswana; and (2) To conduct a pilot test of the feasibility, acceptability, and preliminary effects on viral suppression of a multi-level treatment partner intervention.

Intervention Pilot Test. We will recruit 60 people living with HIV who are not virally suppressed and their 60 treatment partners in 1 matched-clinic pair (30 dyads/clinic) in Gaborone, Botswana. We will obtain updated data on 7 satellite clinics in the Greater Gaborone area, and match satellite clinics on number and type of staffing, number of patients total, and number of unsuppressed patients by calculating Euclidean distances between all possible pairs to determine the best (closest) matches, and then selecting one pair of matched intervention and control clinics. Clinics will be randomly assigned to standard of care or a healthcare provider guidance and treatment partner training intervention. In the randomly selected clinic over a 9-month period, (1) clinic healthcare providers will offer guidance around treatment partners to patients who are unsuppressed, in addition to patients who are initiating treatment (although we will only assess intervention effects among those who are not suppressed); and (2) the clinic will offer monthly, open treatment partner training sessions, and request that treatment partners of unsuppressed patients attend ≥2 sessions, one within a month after baseline, and one within 3 months after baseline. Patients and treatment partners will be asked to attend two sessions together, so that they can practice role-plays with each other: one within a month after the baseline interview, and one ~3 months later (as a booster session). To better fit with clinic flow and the way in which the sessions would ultimately be disseminated and implemented into clinics, the sessions will be open to all treatment partners (regardless of study enrollment) and run monthly for 9 months (during the length of time that the intervention is tested in the clinic). Each one-hour monthly open treatment partner group training session will consist of the same three components: (1) basic HIV treatment education (e.g., names and descriptions of medications and how they work, why adherence is important, how to manage side effects); (2) introduction to Motivational Interviewing (MI), why well-meaning partners can sometimes be unhelpful, how MI strategies (open questions, reflective listening) can be used to better support patients' motivation, and psychoeducation with examples of different types of treatment partner support activities that may be helpful in addition to adherence reminders; and (3) role-plays between patients and treatment partners of different types of challenging situations,

All patients and treatment partners will be surveyed at baseline and 3-months post-baseline, and patients' viral loads will be extracted from medical records from baseline to 6-months post-baseline. We will obtain viral load suppression rates for the intervention and control clinic at baseline and 12-months post-baseline. We will conduct an implementation process evaluation of acceptability and feasibility in the intervention clinic, using semi-structured interviews with patients and treatment partners about their experiences with attending the sessions, and healthcare providers about their experiences with intervention implementation, and suggestions for improvement.

Patients will eligible if they (1) are 18 years of age or older; (2) are on ART and initiated ART at least 6 months prior (to have sufficient time to confirm viral load); (3) are not virally suppressed (at least two viral loads ≥ 400 cp/ml within prior 12 months at time of enrollment) and do not show viral resistance in the past 6 months. Viral

load and time from ART initiation will be confirmed with clinic records before enrollment. We will recruit 80 patients (20 per clinic; half men and half women) and their 80 treatment partners. Patients will not be eligible if they screen positive for HIV-related dementia (from clinic records) and if they have not been tested for viral resistance as part of standard of care (all patients failing second-line ART and some patients failing first-line ART are undergo resistance testing). A study nurse will pre-screen patient charts and place study fliers in eligible patients' charts to remind providers to mention the study during the appointment. Interested patients will be told that they can meet with an interviewer in a private clinic space before or after the appointment or at another convenient time for an eligibility screening. Participants can be interviewed immediately after the screening or make an appointment for another time by phone or in person.

Treatment partners will be eligible if they (1) are 18 years-old or older and (2) were selected to be the PLWH's treatment partner. Based on our pilot, we expect that some treatment partners will also be HIV-positive, and if so, patients and treatment partners may select each other as their treatment partners. For the purposes of study design, we will consider the first patient recruited to be the patient, and the patients' treatment partner to be the treatment partner (regardless of whether the treatment partner is also a patient). After patient and treatment partner participants in the intervention clinic complete the baseline interview, they will be asked to attend the next treatment partner training session (in the next month after the baseline interview), as well as in three months.

STATISTICAL ANALYSIS PLAN

Consistent with R34 guidelines, our primary purpose is to collect preliminary data on feasibility, acceptability, and outcomes; conducting formal tests of outcomes for a measure of effect size is not justified with limited sample size. Thus, the proposed analyses are meant to be exploratory, to help plan for a full RCT. We do not expect to have sufficient statistical power to adequately examine effects. We will calculate descriptive statistics and conduct bivariate analyses of intervention-control differences in change. We will use logistic regression to examine changes in viral suppression (% suppressed at follow-up, % adherent to at least 95% of doses) among enrolled patients in intervention and control clinics. We will use linear regression to examine changes in other survey outcomes (e.g., dyadic relationship support).