




The Treatment Ambassador Program: A Highly Acceptable and Feasible Community-Based Peer Intervention for South Africans Living with HIV Who Delay or Discontinue Antiretroviral Therapy

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Abstract

We conducted a novel pilot randomized controlled trial of the *Treatment Ambassador Program (TAP)*, an 8-session, peer-based, behavioral intervention for people with HIV (PWH) in South Africa not on antiretroviral therapy (ART). PWH (43 intervention, 41 controls) completed baseline, 3- and 6-month assessments. *TAP* was highly feasible (90% completion), with peer counselors demonstrating good intervention fidelity. Post-intervention interviews showed high acceptability of *TAP* and counselors, who supported autonomy, assisted with clinical navigation, and provided psychosocial support. Intention-to-treat analyses indicated increased ART initiation by 3 months in the intervention vs. control arm (12.2% [5/41] vs. 2.3% [1/43], Fisher exact p-value = 0.105; Cohen's h = 0.41). Among those previously on ART (off for > 6 months), 33.3% initiated ART by 3 months in the intervention vs. 14.3% in the control arm (Cohen's h = 0.45). Results suggest that *TAP* was highly acceptable and feasible among PWH not on ART.

Keywords Engagement in care · South Africa · ART initiation · Motivational interviewing · Peer-based intervention · Behavioral intervention · Differentiated service delivery

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Introduction

South Africa currently provides treatment for nearly 60% of the 7.9 million people with HIV (PWH) in the country. While this is over a two-fold increase in the past decade [1], it is still far from achieving UNAIDS 90–90–90 targets [2]. Significant attrition from the care cascade has been documented consistently throughout the region, despite sweeping changes made to increase access to and availability of antiretroviral therapy (ART) [3–7]. A recent prospective cohort study of 500 PWH presenting for testing in Soweto and Gugulethu townships adds to these data, showing that 62% of treatment-eligible PWH initiated ART, but only 25% had evidence of an undetectable HIV-1 plasma RNA (< 50 copies/ml) within 9 months of testing [8, 9].

Prior research has shown PWH encounter individual, social, and structural barriers to initiating care, such as fear of side effects, HIV-associated stigma, and long clinic waiting times [10]. For those who delay or decline treatment, the perceived risks of disclosing one's status and experiencing HIV-associated stigma may outweigh the life-saving benefits of ART [11]. Conversely, those who start treatment and achieve viral suppression do so through a combination of adaptive coping and support from key partners. These findings are consistent with other studies showing that PWH who have non-judgmental, nonconfrontational support are more likely to be engaged in care [12, 13].

While prior research has focused on how to better engage individuals who fail to initiate ART, few studies have developed interventions targeting individuals who were previously on ART but discontinued treatment [7, 10]. Differentiated service delivery models, client-centered approaches that simplify and adapt HIV services to reflect the preferences, expectations, and needs of individual PWH, while reducing unnecessary burdens on the healthcare system, are critical in engaging this population in care [8, 14, 15]. Behavioral research can inform the feasibility and acceptability of differentiated care models for optimizing ART initiation and adherence. In particular, research focused on increasing resilience, or individuals' capacity to overcome adversity and stress to achieve health and well-being [16–18], may be especially helpful for identifying modifiable strength-based factors that can promote healthy outcomes [11, 19, 20].

Interventions promoting adaptive coping may be associated with acceptance of a new HIV diagnosis by fostering problem solving and emotional expression, while mitigating the perceived risk associated with starting treatment [7, 21]. In addition, enhancing social support, including comfort and/or assistance from others, has been shown to be associated with better HIV-related health symptoms

among PWH, possibly because it buffers people from the negative effects of stressors on physical health [19, 20]. For this reason, peer-delivered interventions may be successful in improving engagement in care for PWH by increasing levels of social support as well as providing patients with information on how to best navigate HIV-services [12, 22–28].

In this study, we developed and tested a new intervention, called the “*Treatment Ambassador Program (TAP)*,” a client-focused, peer-based differentiated care strategy for addressing individual, social, and structural level barriers to ART initiation, in order to promote early and enduring treatment uptake by PWH [29–31]. Given its focus on reducing individual barriers to starting ART, promoting social support, and enhancing linkages to the healthcare system, we hypothesized that the Treatment Ambassador Program would be highly acceptable and feasible among PWH who faced challenges initiating or staying on ART in South Africa [32, 33].

Methods

Study Design

The study was a pilot randomized controlled trial of an intervention targeting PWH in Gugulethu Township, South Africa. We assessed acceptability and feasibility, along with fidelity to the intervention by peer interventionists, called “Treatment Ambassadors.” Eighty-four participants completed structured surveys at baseline; follow-up assessments occurred at three and 6-months post-baseline. Participants were randomly assigned at a 1:1 ratio to intervention ($n=41$) or control ($n=43$) arms at baseline. We also conducted an evaluation of the different intervention components and their implementation using semi-structured exit interviews with 30 randomly selected participants (25 from the intervention arm and 5 from the control arm) upon completion of the intervention [34]. All study visits (for intervention and assessment sessions) took place in a neutral non-clinical space (e.g., a church or community center) that was convenient for participants.

Description of the Treatment Ambassador Program

The Treatment Ambassador Program was iteratively developed in partnership with a Community Advisory Board, a group of key stakeholders in the Gugulethu community, who provided crucial contextual expertise and guidance in the development of the intervention. Specifically, the research team met with the Community Advisory Board three to four times per year, beginning in the pre-pilot phase, and through the end of the study to solicit feedback, and provide progress reports. Core intervention components included one-on-one

client-centered counseling sessions and patient navigation. The intervention development was based on prior research [7, 35, 36] and findings from a large systematic review focused on understanding why PWH delayed or discontinued treatment in low- and middle-income countries [6]. Building on the Theory of Triadic Influence (TTI) [37], this intervention was designed to address *individual-, social-, and structural-level* barriers to ART initiation (see Fig. 1). TAP was hypothesized to work through several mechanisms and levels as framed by the TTI: (1) *individual-level factors*, including attitudes and beliefs about treatment, by building the knowledge base and trust of treatment for participants, while promoting self-efficacy and effective coping strategies; (2) *social-level factors* through social interactive processes that address HIV-related stigma and the need for disclosure; and (3) *structural-level factors* through facilitating engagement with clinic providers.

The intervention was tailored for the South African context using content and strategies from Motivational Interviewing (MI)-enhanced interventions that were developed and tested in the U.S [38–40]. As shown in Table 1, the full intervention consisted of eight sessions over 8–14 weeks for PWH who had not initiated treatment within 6 months of testing or had previously initiated ART, but been off treatment for over 6 months. MI strategies were used to create collaborative, goal-oriented communication focused on enhancing intrinsic motivation for behavior change by helping individuals to identify discrepancies between their stated goals and values, and current behavior [41]. Treatment Ambassadors helped clients to develop problem-solving skills to overcome key individual- and social-level barriers. Interventions using MI have demonstrated acceptability, feasibility, and fidelity in research in South Africa [42, 43].

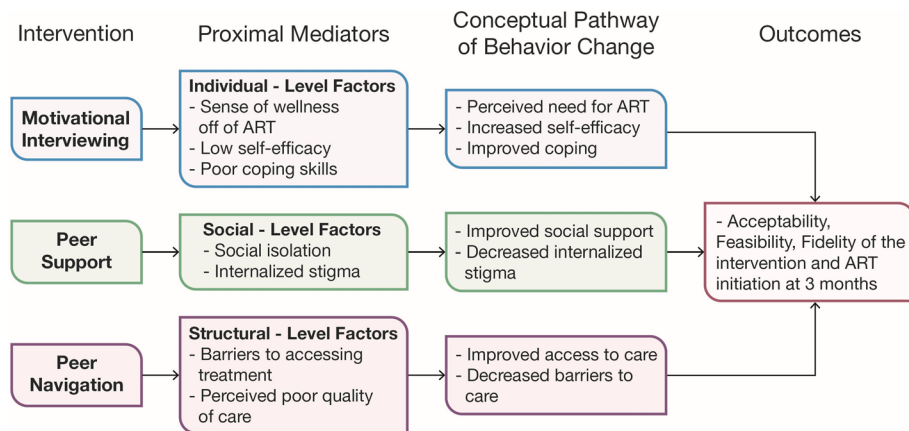
Two Treatment Ambassadors were identified by study staff from a group of PWH previously selected from among the 2500 PWH in care at Gugulethu Community Health Centers to be trained as clinic counselors [44]. The

Treatment Ambassadors underwent two rounds of three full days of intensive training over 6 months in MI techniques and TAP intervention content and structure. Consistent with the client-centered counseling approach, TAP counselors tailored session content to individual participants’ needs, focusing on improving treatment knowledge, promoting self-efficacy and coping skills, and supporting perceptions of treatment benefits. Treatment Ambassadors conveyed stories about their own experiences with these issues to participants, in order to act as role models for ART initiation. Each session involved goal setting and review of the participant’s personal treatment plan. Treatment Ambassadors offered to accompany participants to their preferred treatment center and served as a liaison with healthcare providers. They also provided information about how to link to services and encouragement to link to other services (e.g., substance use/mental health), as well as practical tips for navigating through clinic, including reviewing a detailed map of the steps required to initiate care in a standard public facility.

Participants

Participants (n = 84) were recruited between January and December 2017 in Gugulethu using a community-based hybrid approach comprised of targeted sampling in community-based organization and peer-to-peer recruitment through snowball sampling in Gugulethu township, and distributing fliers in the community describing the study with contact information provided. The study protocol and data collection instruments were approved by Human Subjects Committees at Partners Healthcare and the University of Cape Town Human Research Ethics Committee. All participants provided written informed consent. Study data were collected and managed using a secure, web-based, Research Electronic Data Capture (REDCap) tool [45]. The study was registered with Clinicaltrials.gov (NCT03099707). This study was designed as a feasibility and acceptability trial,

Fig. 1 Conceptual model of Treatment Ambassador Program



* Based on our Explanatory Framework of ART Refusal

Table 1 Psycho-social components of the Treatment Ambassador Program

Sessions	Focus and goals	Content description
Session 1: Welcome session	Focus: Building rapport and understanding of participant Goal: Elicit participant's beliefs and concerns about ART and treatment	Treatment Ambassador (TA) introduces self, explains study highlighting autonomy and supportive approach TA elicits participant's beliefs about ART and treatment and why s/he has chosen not to take ART With permission, TA offers information—address knowledge deficits or misconceptions TA reflects participant's reasons against/for taking ART and asks for thoughts TA offers educational materials for participant to review/consider before next visit
Session 2: Enhancing motivation and confidence	Focus: Enhancing motivation and confidence Goal: Elicit participant's treatment readiness	TA reviews participant's thoughts about last session TA evaluates ART readiness TA explores participant's beliefs about importance of taking ART using Importance Ruler* TA explores participant's confidence in their ability to take ART using Confidence Ruler* TA explores link between not taking/taking ART and participants values using Values Clarification Card TA/Participant develop a written action plan for one health-related goal (e.g., reduce alcohol use, disclosure, start ART) TA provides summary of session and asks for thoughts
Sessions 3–8: Supporting motivation, confidence, and skills For each session, participant selects most relevant topic from list	Focus: Supporting motivation, confidence, and skills to address common barriers Goals: Enhance positive attitudes, increase skills and support to address barriers with the goal of increasing treatment readiness	TA reviews participant's thoughts about last session and evaluate ART-readiness TA re-explores participant's beliefs about importance of and confidence for taking ART using rulers Participant selects session content from options below: 1. <i>Addressing barriers</i> : Elicit barriers to starting ART (e.g., anticipated stigma, social isolation, disclosure, structural barriers) and identify possible solutions 2. <i>Personal support and disclosure</i> : Identify people who can provide support and encourage disclosure; role plays 3. <i>Dealing with stigma</i> : Elicit thoughts/worries and experiences, highlight external and internalized stigma, explore link to health/goals and coping strategies 4. <i>Steps to take to start treatment</i> : Explore why participant originally got tested, their awareness of steps necessary to start ART, interest in accompaniment 5. <i>Addressing concerns about side-effects</i> : Elicit concerns about treatment side-effects, with permission offer information and develop plan to address concerns TA/Participant develop a written action plan for one health-related goal TA provides summary of session and asks for thoughts

*Importance and confidence rulers are used as a tool to evaluate the importance an individual assigns to a given task (e.g., “On a scale of 0–10, ranging from not at all important to extremely important, how important is it for you to start ARVs this week?”) and the confidence they have to execute it (“e.g., On a scale of 0–10, ranging from not at all confident to extremely confident, how confident are you that you could start ARVs this week?”)

rather than an effectiveness trial. As such, the sample size was not determined by power analysis to detect an effect size. Rather, the sample size was the largest that was feasible in the context of a small study of a novel intervention.

Eligibility Criteria

Inclusion criteria included people who: (1) were living with HIV; (2) were of 18 years of age or older; (3) had not initiated ART within 6 months of learning their status or were off treatment for at least 6 months; (4) lived within 60 km of the testing center; and (5) were English- or isiXhosa-speaking. All people living with HIV were eligible for treatment under current South African guidelines, including peer-based treatment preparedness sessions [46]. Participants were excluded if they were unable to provide informed consent, if they had been on ART within the last 6 months, or if they were women who reported current pregnancy at the time of consent (since they qualified for intensive adherence support under current South African guidelines). ART laboratory data were obtained from the South African National Health Laboratory Service (NHLS) database [47–49]. Researchers screened 133 potential participants. Of these, 26 did not meet enrollment criteria due to an inability to sign informed consent (one individual) or recent ART use within the last 3 months (25 individuals). An additional 23 were withdrawn by the Principal Investigator due to not meeting inclusion criteria, with three individuals ultimately found to be HIV-negative, and 20 others appeared to be actively or recently on treatment based on data from NHLS (Fig. 2). Ultimately, 84 participants were successfully enrolled.

Randomization

Participants were randomized by the study's principal statistician in a 1:1 ratio to the intervention or control arm after the baseline assessment was completed. Those in the control

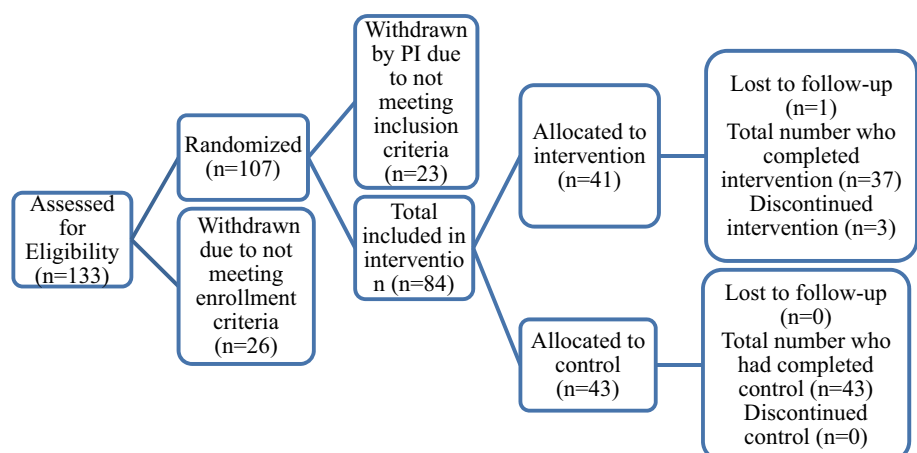
arm received no intervention, beyond engagement with study staff for the assessments at designated times. All participants had access to free comprehensive HIV care and services in community-based settings. Field staff worked with the principal statistician to develop a randomization assignment, and assignments were stored in a password-protected file only available to the principal statistician. Staff and participants were not blind to intervention arm assignment, however, researchers were blinded during consent and the baseline survey, prior to randomization, so that the baseline measures were not biased by foreknowledge of conditions. In addition, team members assessing clinical outcomes in NHLS were blinded to the study arms of the participants during data collection. Of the 84 participants enrolled, 43 were allocated to the control arm and 41 to the intervention arm (Treatment Ambassador Program).

Assessment Procedures

Overview

Eligible individuals provided signed informed consent for study participation and accessing NHLS data. They participated in structured, 60-min baseline and follow-up surveys conducted in person with a bilingual (English and isiXhosa) research assistant. Baseline and follow-up surveys used the same measures; follow-up assessments were conducted at Time 2 (T2; 3 months post-intervention, focused mainly on the past 3 months) and Time 3 (T3; 6 months post-intervention, focused mainly on the past 6 months). Participants received Rand 100 (roughly \$8 U.S.) for each baseline and follow-up assessment for their time and fare for local public transportation, and a bonus of Rand 200 (roughly an additional \$16 U.S.) for completing all three surveys. Participants in the intervention arm received Rand 20 (roughly \$1.50 U.S.) for each session to cover transportation to and from the venue.

Fig. 2 Study enrollment—CONSORT diagram



NHLS Data

We assessed ART initiation within 3 months after study enrollment. While the follow-up assessments were conducted at three and 6 months post-intervention, treatment initiation was measured only at 3 months to capture the importance of early treatment initiation, which is associated with better long-term outcomes [50, 51]. ART initiation was assessed using NHLS data, based on a measure of creatinine that was performed prior to initiation of tenofovir (part of the standard first-line ART regimen in South Africa). ART workup blood tests as recorded in NHLS have been previously validated as an accurate measure to impute dates of treatment initiation among South African PWH who are receiving public-sector HIV care [52]. All treatment initiation was verified with prescription data and pill bottle visualization, in which participants brought their medications to a visit with the Treatment Ambassador, to show them they had initiated treatment.

Survey Instrument

Survey measures were administered at baseline and follow-up to assess psychosocial characteristics, as well as

sociodemographic and medical characteristics potentially related to behavior at baseline and at follow-up in both arms of the study to evaluate the moderators and mediators of intervention effects (see Table 2). The TTI states that health related behaviors are shaped by individual-, social-, and structural-level factors and thus, the survey attempted to analyze barriers at these three levels. Individual-level factors included self-perceived health and wellness, as well as coping and mental health. These factors were measured using the *Short Form-8* questionnaire to capture general health perceptions, the *AUDIT scale* to measure alcohol and recreational drug use, the *Brief COPE* to assess how participants deal with stressors, and the *Patient Health Questionnaire* to measure depression, anxiety, and somatic complaints [53–58]. The social-level factors included perceived social support, measured using the *Medical Outcomes Study Social Support Survey*, HIV-associated stigma (internalized, enacted, and anticipated), measured using the *Internalized AIDS-Related Stigma Scale* and the *HIV stigma framework*, and disclosure concerns, measured using *HIV stigma scale* [59–62]. Structural-factors included barriers to accessing ART and trust in ART efficacy, measured by assessing competing needs and barriers to care in the past 6 months and a scale

Table 2 Behavioral survey measures

Individual-level factors	
Attitudes and beliefs	Self-perceived health and wellness (1) General health perceptions were measured using the <i>Short Form-8</i> questionnaire, which indicated personal ratings of health status, and how physical health problems affected usual activities and mood (0.87) [53, 54] (2) A modified <i>AUDIT</i> scale was used to measure alcohol and recreational drug use (frequency of use of alcohol and a variety of other substances ($\alpha=0.88$) [55]
Capabilities	Coping and mental health (1) <i>Brief COPE</i> was used to assess for differences in how participants cope with stressors, including how often people engage in certain behaviors post-diagnosis of HIV, including denial, self-blame, substance use, behavioral disengagement, self-distraction, and venting (15-items; ($\alpha=0.86$) [56, 57] (2) Depression and anxiety symptoms and somatic complaints were measured using the 9-item <i>Patient Health Questionnaire</i> (PHQ) ($\alpha=0.76$) [58]
Social-level factors	
Social interaction processes	Perceived Social Support: <i>Medical Outcomes Study (MOS) Social Support Survey</i> (α for all subscales greater than 0.91) [59] HIV-associated internalized, enacted, and anticipated stigma: Internalized stigma was measured using the <i>Internalized AIDS-Related Stigma Scale</i> ($\alpha=0.75$) [60] Enacted and anticipated stigma (α between 0.87–0.89 for all subscales) was measured using the <i>HIV stigma framework</i> [61] Disclosure concerns: Concerns were measured with a psychometric assessment of the <i>HIV stigma scale</i> ($\alpha=0.96$) [62]
Structural-level factors	
Barriers to Accessing ART	Barriers and competing needs were assessed by asking participants whether they had experienced each of 13 problems when medical care was needed in the past 6 months (e.g. not knowing where to find care, affordability of medications or transportation) [63] The count of each participant's "yes" responses to these 13 yes/no items was taken as their score
Perceived quality of Care	Trust in ART efficacy: Scale based on the <i>RAND HIV Cost and Services Utilization Study (HCSUS)</i> (Cronbach's $\alpha=0.71$) [64, 65]

based on the *RAND HIV Cost and Services Utilization Study*, respectively [63–65].

Intervention and Assessment Feasibility: Study Participant Tracking Records and Fidelity Ratings Assessment of intervention feasibility measures included participation withdrawal and retention rates for the intervention and study assessments. We used the following benchmarks to assess feasibility of the intervention: $\leq 10\%$ withdrawing from the intervention arm, $\geq 50\%$ enrollment of eligible participants, $\geq 80\%$ completion of 3-month and 6-month outcome assessments [66]. Sessions were recorded and scored to assess Treatment Ambassador's *fidelity* to the intervention content and MI style using established procedures [40, 67, 68]. Trained independent isiXhosa raters coded the extent to which Treatment Ambassadors addressed key session content as presented in the manual and training. Fidelity to key content delivery was measured using a checklist, rated as "yes" (1), "no" (0), "partially" (0.5), or "N/A" (excluded). Scores for each content item were summed to create a total score for each session. The overall average content fidelity for all sessions was then calculated by averaging all the individual total session scores, with a 1 indicating perfect fidelity to the manualized session content. Fidelity to the MI strategies presented in the manual and training (i.e., reflective listening, asking permission, open ended question, expressing empathy, summaries, and overall quality) was assessed using a modified version of the Motivational Interviewing Treatment Integrity (MITI) Code [22] which is scored on a 7 point scale. An overall average of 5 and above indicates excellent adherence to MI style throughout sessions.

Intervention Acceptability: Qualitative Data Semi-structured exit interviews were performed after completion of the intervention with a random subset of 30 participants (25 intervention, 5 control; 100% Black African; 96% females). While the focus of these semi-structured interviews was to understand the acceptability of the intervention, we also chose to interview a small number of control participants to provide a comparison to intervention participants to understand perceived barriers to and facilitators of ART initiation in the absence of the intervention [29]. Interviews were conducted in isiXhosa or English, at participant's preference and audio-recorded, transcribed, and translated as required. Qualitative data were entered into NVivo 10[®] (QSR International Pty Ltd 2014) software.

Data Analysis

Data analysis focused on characterizing perceived acceptability (extent to which people receiving an intervention consider it to be appropriate), which was operationalized in

terms of attitudes toward and perceptions of the intervention and its components [23]. Sample questions to assess perceived acceptability included questions regarding the structure of the sessions, comfort with the Treatment Ambassador, cultural sensitivity, and the content and length of the survey. Using an inductive approach based upon grounded theory, categories were constructed to name, define, and illustrate content themes [69]. We searched interview data for key concepts that pertained to intervention acceptability and displayed the text in matrices to identify patterns. Patterns of content appearing repeatedly in the data formed the basis for thematic categories. Coding began with a provisional start-list of themes based on prior research. Twenty percent of the interviews ($n = 6$) were independently read and new themes were iteratively generated based on identifying themes that were not present in the start-list, which resulted in a codebook. The team members coded 20% additional interviews ($n = 6$) to calibrate the methods of evaluation, and one individual, using the standards established, coded the remaining interviews (Cohen's Kappa = 0.82). For each of the seven survey measures, we compared responses at 6 months by computing the mean response for each arm, a 95% bootstrap confidence interval for the between-arm difference in means, and a permutation test p-value for the between-arm difference in means adjusted for each participant's baseline score. To assess preliminary efficacy, rates of ART initiation at 3 months for the two arms were compared by computing the relative "risk" of initiation and testing for an association between arm and initiation rate using Fisher's exact test.

Results

Participants

At enrollment (Table 3), participants' median age was 34 (IQR 29, 43) years. Over three-quarters of the participants were female, and the majority were unemployed (88% in the control arm and 98% in the intervention arm). The median time since taking a diagnostic HIV-test was 33 (IQR 21, 53) months. Over half of the participants reported testing last for HIV due to "feeling sick" (51% in the control arm and 54% in the intervention arm). Across both arms, participants' self-perception of health was good, very good, or excellent in the month prior to the intervention (86% in the control arm and 90% in the intervention arm); however, participants indicated challenges with coping (median 1 on a scale of 1 to 4), and over 90% reported food insecurity. There were no statistically significant differences at baseline between those assigned to the intervention and control arms on psychosocial, sociodemographic, and medical characteristics.

Table 3 Socio-demographic and health characteristics at baseline

	Control (n=43) (Median, IQR)	Intervention (n=41) (Median, IQR)	Total (n=84) (Median, IQR)
Age at screening	34 (30, 43)	34 (27,43)	34 (29, 43)
Months since dx test	43 (23, 62)	30 (21, 48)	33 (21, 53)
Number of times participant tested for HIV	2 (1, 3)	2 (2, 3)	1 (1, 2)
CD4 at last HIV test	400 (340, 555)	460 (378, 546)	410 (375, 555)
Female	77%	88%	82%
Parent	86%	71%	79%
Employed	12%	2%	7%
Completed high school	93%	98%	95%
Most common reason for last HIV test	51% felt sick	54% felt sick	53% felt sick
Most common reason for not starting ART	45% not ready	44% not ready	45% not ready
Perceived general health			
Overall rating of health as good, very good, or excellent in past 4 weeks	86%	90%	88%
Substance use			
Drink alcohol four or more times per week	14%	22%	18%
Ever smoke cigarettes	42%	63%	51%
Ever used other recreational drugs	12%	12%	12%
Coping (ability to cope) 2-item scale (min 1, max 4)	1 (1, 1)	1 (1, 1)	1 (1, 1)
Belief in ARV efficacy 8-item scale (min 1, max 4)	3 (2.9, 3)	3 (3, 3)	3 (2.9, 3)
Most common reason to go without healthcare, money needed for...	93% food	90% food	92% food

Feasibility and Fidelity

The intervention was highly feasible, with 90% of the 41 participants randomized to the intervention arm participating in the full intervention (three voluntarily withdrew before the intervention started and one voluntarily withdrew prior to completing the intervention). All 38 participants who started the intervention completed both the 3 and 6-month follow-up surveys. There were no adverse or unintended effects reported during the intervention or follow-up assessments.

The intervention counselors maintained high levels of fidelity. All eight sessions delivered to the 38 intervention participants who completed the full intervention were recorded, totaling in 256 recorded MI sessions. Roughly 25% were chosen at random to assess session content and MI style fidelity. Of 73 sessions (29%) randomly selected to assess content fidelity, the median score was 0.90 (IQR 0.81–0.95), with a score of 1 indicating that all content described in the manual was delivered in the session. Of 71 sessions (28%) randomly selected to assess MI style, the median intervention session score was 4.3 (IQR 3.6–5.0) indicating strong use of MI strategies during counseling sessions.

Intervention Acceptability—Qualitative Data

The exit interview data indicated that all 25 intervention participants interviewed found the intervention to be highly

acceptable. Acceptability clustered around five primary themes: (1) support from an “ideal” partner promoting self-reflection; (2) support of autonomy and intrinsic motivation while promoting disclosure; (3) assistance with navigating a challenging clinical environment; and (4) the need to unpack barriers, including myths and misinformation, anticipated and internalized stigma, and denial. Table 4 summarizes results from our qualitative interviews. Individuals who engaged in the intervention but did not start ART reported several barriers to ART initiation that were not addressed by the intervention, including: structural challenges getting to clinic and waiting to be seen; competing needs and priorities; and social isolation. Suggestions to improve the intervention from participants included: direct delivery of ART by nurses outside of a clinic setting; strategies to improve self-efficacy; and ongoing education regarding safety of ART usage (especially if using alcohol). See Table 5.

Survey Results

There was little evidence of difference between arms at 6 months on the survey measures, including ARV efficacy, social support, internal stigma, disclosure concern, and barriers (see Table 6). The exception was the depression measure (PHQ9). On average, intervention participants reported better (lower) scores (mean 0.32, SD 0.24) than control participants (mean 0.61, SD 0.56) (95% CI for difference in

Table 4 Acceptability of the Treatment Ambassador Program—mechanisms of action (n=25)

Support from an ideal partner	Quote from participant
Gaining medical knowledge through the Treatment Ambassador Program	Well, sisi, they were not long, they were not short – [as] we were benefitting, getting educated. Being educated about things that are happening here in – in our bodies and in our journey. Because I wasn't the kind of person who would use a condom. But now I've learned a lot. I am using the condom.
Social support	
Social support from family or friends	The person that I have already informed, the first one is my boyfriend, my life partner. He knows. He once said to me, as I'm about to go to the clinic on the first week of December, 'I can go with you, if they didn't call me to work – [then] I will go with you to the thingamajig.' [Thanks] to you. So, [thanks] to you guys, actually.
Social support from TAP	[The Treatment Ambassador] was telling me himself – about himself too, understand? So, he told that I should not be worried, I should be free. Well, I then became free as well – if he can tell me about – about his [HIV] status, so, perhaps I can be able to chat with him – about mine.
Support of autonomy and intrinsic motivation	Quote from participant
Intrinsic motivation	There's nothing that people are going to do for you. You have to live for your children, that's all – and for your family.
Self-efficacy	The study, it has helped me – the first thing that I can tell you. It's got me out of problems. Even that issue of sleeplessness – I do sleep now. Because I didn't know who I am. I don't want to lie, sisi. I didn't know whether, who am I? Even if I'm worried, I throw everything on this problem that I'm in. But it is not a problem – It [used] to be a big problem. Now I am saying – today, since I'm attending the study, 'It isn't a problem. I am human, you know. I am alive.'
Disclosure	It's my boyfriend. [I previously worried] what's he going to be like? But, man, I just became free, then I told him. He said he had been afraid to tell me himself first, for a long [time].
Assistance with navigating a challenging clinical environment	Quote from participant
Challenges with the clinic	
Challenges with patient/provider communication	Interviewer: Which session did you [guys] perhaps discuss in, whereby you felt that you were becoming comfortable? Participant: I can say, session – the session – the session – I think, the session about going to the clinic. You see? At the clinic, how to – perhaps going to the reception and enquiring; how to handle the nurses. Yes. So, I would say, if the nurses ridicule you, you go to the superior, you see? Yeah, I would – I would say so. Interviewer: So, how did you feel about that discussion then? Participant: Yeah, ok, in that discussion I left with the information that I didn't have. You see? Yeah. I am someone who likes going to the clinic. So, I left with the information that I didn't have [before]. So, I learnt a lot about the right thing.
Challenges with Disclosure due to Clinic Structure	The reason I was not able to go to take the treatment is because they will be talking about me. Because if you are there at the the Day Hospital, they watch which door you're at. You find that in this queue, at this door, someone who lives with you gets to see you. He/she gets to the township and says, 'Well, so-and-so is also like this. I saw her at a certain door.'
Unpacking persistent barriers	Quote from participant
Myths and misinformation	In starting the treatment, I used to be afraid because I saw it from my cousin, that it is bad. It made pimples appear on her – and a rash on her body. She became itchy, it left black spots on her. That's why I was afraid in the beginning. But [the Treatment Ambassador] taught me that, no, it depends on the body's parts, whether what are they like inside. But now that fear has left me.
Stigma	
Anticipated stigma	I: So, when you say that, perhaps is it the way – How were you feeling in the past? P: I used to think – I didn't see myself being – being able to – I didn't consider myself human among [other] humans. I: What was causing that? P: The guilty conscience I had about myself. It's how I [felt] about myself.

Table 4 (continued)

Unpacking persistent barriers	Quote from participant
Internalized Stigma	Back then I was afraid of – perhaps of – dis - discrimination, you see? Yes, I was afraid of that, getting judged. That perhaps I brought it upon myself; and it's my fault – that I'm like this. Things like that – just some negative comments.
Denial	At that time I heard some fear. I – I – I had thoughts that, no, probably they – they've made a mistake. You know? It – It – It can't be inside me. It's a disease that can perhaps happen to other people. You know. It's not – I think I hadn't accepted it yet or I hadn't heard a lot – about it, I'd say so.
Hierarchy of needs	The reason that now I still haven't gone to the treatment – for, I am ready to take it – it's just that I'm finishing writing [the exams] next Monday. So, after I've finished writing [the exams] next week, that's when I'm going to just get up – Because I was stressed due to – it's the study, on the [other hand] it's the treatment, and then on the other it's school, it requires – a lot from me. So, now that I'm going to finish writing, it's only now that I am going to start the treatment – the treatment, I will get up – and go to the clinic.

means = -0.48, -0.09; permutation test p-value, controlling for baseline scores = 0.002).

Preliminary Efficacy

Rates of confirmed ART initiation by 3 months in the intervention and control arms were 12% (5/41) and 2% (1/43), respectively (Fisher exact p-value = 0.105; Cohen's $h = 0.41$). Relative "risk" of ART initiation was 5.2 (95% CI 0.6–43.0). Rates of confirmed ART initiation by 3 months among those who were previously on ART in the intervention and control arms were 33% (5/15) and 14% (1/7), respectively (Fisher exact p-value = 0.616; Cohen's $h = 0.45$, indicating a meaningful effect size). Relative "risk" of ART initiation for this subgroup was 2.3 (95% CI 0.3–16.4). This exploratory study was not powered for definitive null hypothesis significance testing, but the first test of this new intervention was designed to explore preliminary efficacy.

Discussion

In this manuscript, we report on a novel behavioral intervention targeting a population at high-risk for poor health outcomes: PWH from a hard-to-reach population in South Africa who were aware of their status but were not taking ART nor engaged in care. These participants, all recruited through peers and other community members, were diagnosed with HIV on average 3 to 4 years prior to enrolling in the study. The Treatment Ambassador Program was shown to be highly acceptable and feasible as a tool to improve initiation among a highly disenfranchised population. In addition, participants in the intervention arm reported improvements in symptoms of depression

as compared to the control arm. Peers, whom we identified as Treatment Ambassadors, delivered the intervention with a high degree of fidelity, despite having no formal advanced degree or counseling training. Our promising findings demonstrate the potential for peer-delivered interventions and provide support for an approach that is both acceptable and feasible.

The use of peers as counselors is based on a substantial literature that supports linking participants with peer supporters to promote HIV-related behavior change, with effect sizes generally comparable to provider-led interventions [24–26, 35, 70, 71]. Participants enrolled in the Treatment Ambassador Program cited gaining medical knowledge, social support, self-efficacy, support with disclosure, and overcoming challenges with stigmatizing health systems as critical aspects of the program. Among those initiating ART, intrinsic motivation, disclosing to a trusted friend or family-member, and an ability to overcome barriers appeared to be essential mechanisms of action. These findings are consistent with literature demonstrating that peer supporters can be credible role models and challenge negative peer norms about care and ART [27, 72–75]. Moreover, support with clinical navigation has been shown to improve engagement and retention of low-income PWH in HIV care [76], including in sub-Saharan Africa [13, 28, 77]. This component was based on the Health Resources and Service Administration HIV System Navigation model [78], and informed by prior research in South Africa [79], focusing on a strengths-based approach [80]. The individuals initiating ART in our sample described that the level of support provided by the Treatment Ambassadors was largely missing from their daily lives, supporting prior research that showed that

Table 5 Barriers to uptake and suggestions for the TAP Intervention

	Theme	Excerpt
<i>Barriers</i>		
1	Structural challenges getting to clinic and waiting to be seen	“[Traveling to acquire medication] will still [cost] transport fare. The money won’t always be there, of course, for you to be travelling to take the pills. You see?” Female participant
2	Competing needs and priorities	The reason that now I still haven’t gone to the treatment – for, I am ready to take it – it’s just that I’m finishing writing [the exams] next Monday. So, after I’ve finished writing [the exams] next week, that’s when I’m going to just get up – Because I was stressed due to – it’s the study, on the [other hand] it’s the treatment, and then on the other it’s school, it requires – a lot from me. So, now that I’m going to finish writing, it’s only now that I am going to start the treatment – the treatment, I will get up – and go to the clinic. Female participant
3	Social isolation among participants	“... It’s fear of people. Like, you haven’t disclosed to your family; you haven’t disclosed to anyone else. Then if you are to go to the clinic, one of them is going to see you. So, then it is going to fill the community.” Female participant
<i>Suggestions</i>		
1	Direct delivery of ART	“I think the one that might be a good plan is that of people bringing [medication] to us..” Female participant
2	Promoting self-efficacy	“Interviewer: We would like to make it bigger, so it’s good – as you are also praising it. What would you perhaps advise us to add, like, to this programme that we are conducting? Participant: In this programme that I’m in, I wished that – as I also – as I was attending here, I do have some people whom I would like to get knowledge about this programme that you are doing, whom I could bring along, who don’t have knowledge. So, we can help them, so they can also be free. Because they are also affected the same way that I was affected.” Female participant
3	Ongoing education regarding safety of ART usage	“[I would like to learn] how you should live, in order to live a long life... And how you should ‘eat’ — you should ‘eat’ the treatment and the things that you perhaps see appearing on your [body], then advice — ask for advice; seek knowledge, perhaps.” Female participant

Table 6 Comparison of 6-month scores for control and intervention participants

Scale	Control (n = 38)		Intervention (n = 43)		95% CI ^a for difference	p ^b
	Mean	SD	Mean	SD		
COPE (2 items)	1.53	0.85	1.24	0.57	−0.59, 0.05	0.078
ARV efficacy	2.93	0.34	3.00	0.24	−0.07, 0.19	0.356
Social support	4.22	0.64	4.39	0.65	−0.10, 0.46	0.233
PHQ9	0.61	0.56	0.32	0.24	−0.48, −0.09	0.002
Internal stigma	2.61	1.50	2.30	1.26	−0.92, 0.30	0.460
Disclosure concern	3.47	1.72	3.81	1.61	−0.39, 1.02	0.221
Barriers	4.55	2.50	3.91	2.17	−1.65, 0.39	0.405

^a95% bootstrap confidence interval for difference between means

^bPermutation test p-value for between-arm difference, controlling for baseline scores

PWH struggle to trust family and friends due to concerns about stigma and discrimination [81].

Given that South Africa has the highest burden of HIV/AIDS but a shortage of trained health care workers, task-shifting and sharing of health service responsibilities are essential for a treatment model to be sustainable and scalable in this setting [27, 74, 75, 82]. Peer-delivered, community-based interventions, such as the Treatment Ambassador Program, present both a scalable and sustainable solution to improving treatment for high-risk populations of PWH who struggle to engage in care. The feasibility and acceptability of this intervention suggest that there

is untapped value in leveraging community resources to better engage these key populations. Peer interventions have potential for high-impact in low resource settings, as they reduce the burden on health care workers and strained health systems. Despite concerns that peer supporters could fail to deliver interventions with a high degree of fidelity, the Treatment Ambassadors in this study demonstrated that peers can be trusted to deliver interventions and should be leveraged in settings with shortages of health care workers. While past studies have primarily evaluated the impact of interventions focused on improving ART adherence [39, 79] and engagement in HIV

primary care [83, 84], or promoting early ART initiation within the context of “treatment for all,” [85] few behavioral interventions have been designed for PWH who have delayed, declined, or discontinued ART [51].

This intervention showed high levels of feasibility and acceptability amongst a population that had remained out of treatment for, on average, 33 months since initial testing. This demonstrates the promise of differentiated service delivery models in engaging populations who have delayed or declined ART for an extended period, especially highly disenfranchised populations such as the one identified in this study. This is consistent with previous research that has found that peer supporters have a unique ability to access hidden populations that may have limited interactions with the health care system [86]. Individuals in this population described persistent barriers to accessing care, such as structural challenges in getting to the clinic, competing needs and priorities, and social isolation. In the study population, individuals experienced high levels of food insecurity and reported that needing money for food was the most common reason to delay or decline health care. Given that food insecurity is commonly cited as a reason for poor clinic attendance and poor ART uptake and adherence, it is important to address this competing need in order to improve adherence in this population [87]. While this intervention shows considerable promise and potential in reaching these individuals, modifications to the intervention are needed for the next phase of this research program to address persistent barriers, and future studies with a longer follow-up period and a study of intervention mediators may shed light on whether the impact can be augmented.

Several key limitations in our study should be considered. First, this is an exploratory study with a modest sample size. Data on effects of psychosocial factors in the pilot study were generally inconclusive. For example, while participants who initiated ART reported disclosure to others as a critical step to initiation, this sample was small and thus, these results do not necessarily imply that disclosure is a necessary step in ART initiation. Studies with a larger population and a longer follow-up may provide more detail on specific mechanisms of action in this population. In addition, participants in our study were diagnosed with HIV for, on average, 3 years before enrolling. Prior data collected at this site show that the longer PWH wait from the point of testing to initiate ART, the less likely they are to ever engage in care [83]. These data are supported by other studies in sub-Saharan Africa [84, 85]. Therefore, the Treatment Ambassador Program has the potential to be more efficacious if offered closer to the time of HIV testing. Further, participants highlighted persistent challenges with initiating treatment, such as structural challenges in getting to the clinic, competing needs and priorities, and social isolation, despite the acceptability and feasibility of

this intervention. Future research is necessary that builds upon this intervention by incorporating the solutions to these barriers suggested by participants, such as direct delivery of ART, enhanced channels of social support, and ongoing education about the safety of ART usage.

Conclusions

There is an urgent need for interventions to improve rates of ART initiation among the 40% of South Africans living with HIV who are not on treatment. The present intervention was found to be highly acceptable and feasible, providing a potential strategy to engage a highly disenfranchised population who are not traditionally represented in standard healthcare settings. The model presented here shows a promising pathway to harness the power of peers in delivering interventions, while maintaining a high degree of fidelity. Beyond this, it identifies several promising intervention components that merit further study.

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