

# Development and pilot testing of an intervention to promote care engagement and adherence among HIV-positive Kenyan MSM

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**Objectives:** In many African settings, MSM are a stigmatized group whose access to and engagement in HIV care may be challenging. Our aim was to design a targeted, culturally appropriate intervention to promote care engagement and antiretroviral therapy (ART) adherence for MSM in coastal Kenya, and describe intervention safety, feasibility, and acceptability based upon a small pilot study.

**Design:** Based on qualitative work including in-depth interviews with HIV-positive MSM and focus groups with providers, we developed a tailored intervention and conducted a pilot test to refine intervention materials and procedures.

**Methods:** The *Shikamana* intervention combines modified Next-Step Counseling by trained providers, support from a trained peer navigator, and tailored use of SMS messaging, phone calls, and discrete pill carriers. Providers, including counselors and clinicians, work together with peer navigators as a case management team.

**Results:** Forty HIV-positive MSM aged 19–51 participated in intervention development and testing. Six counselors, three clinical officers, and four MSM peers were trained in intervention procedures. Of 10 ART-naïve participants who enrolled in the pilot, eight completed follow-up with no adverse events reported. One participant was lost to follow-up after 2 months and another failed to initiate ART despite ongoing counseling. No adverse events were reported. Staff feedback and exit interviews rated the intervention as feasible and acceptable.

**Conclusion:** This adherence support intervention tailored for Kenyan MSM was well tolerated, feasible, and acceptable in the pilot phase. A randomized controlled trial of a scaled-up programme to estimate intervention efficacy is ongoing.

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Introduction

Although MSM are at high risk for HIV/AIDS globally, this group has only recently become an important focus of HIV prevention programmes in sub-Saharan Africa, the region hardest hit by the HIV-1 epidemic [1,2]. Overall, African MSM have 2–4 times higher HIV prevalence than the general male population [1,3,4]. In coastal Kenya, HIV prevalence among MSM has been estimated at 24.5%, compared with 4.4% among men in general [5,6]. A 2009 modes of transmission study estimated that 15% of HIV infections in Kenya are attributable to male–male sex [7], and recent data suggest that MSM, especially MSM who sell sex, play an important role in the Kenyan epidemic [8,9]. The development of innovative, effective interventions for primary and secondary prevention in this population is an urgent research priority.

Unfortunately, MSM are stigmatized by prevailing attitudes and laws against male–male sex in many African countries [10]. As a result, they have poor access to care and may lack trust in providers [11,12]. In a small cohort on the Kenya coast, we found that MSM struggled with antiretroviral therapy (ART) adherence and had worse clinical outcomes compared with other high-risk individuals, including female sex workers and men with multiple sex partners [13]. Targeted interventions to promote care engagement and ART adherence among MSM could significantly decrease HIV transmission and improve clinical outcomes, both among MSM and on a population level [14]. However, best practices for this group are not established.

Based on preliminary work showing healthcare disparities and adherence challenges among MSM in general, we aimed to design a targeted, culturally appropriate intervention to promote men’s care engagement and ART adherence, and to describe the safety, feasibility, and acceptability of this intervention based upon a small pilot study.

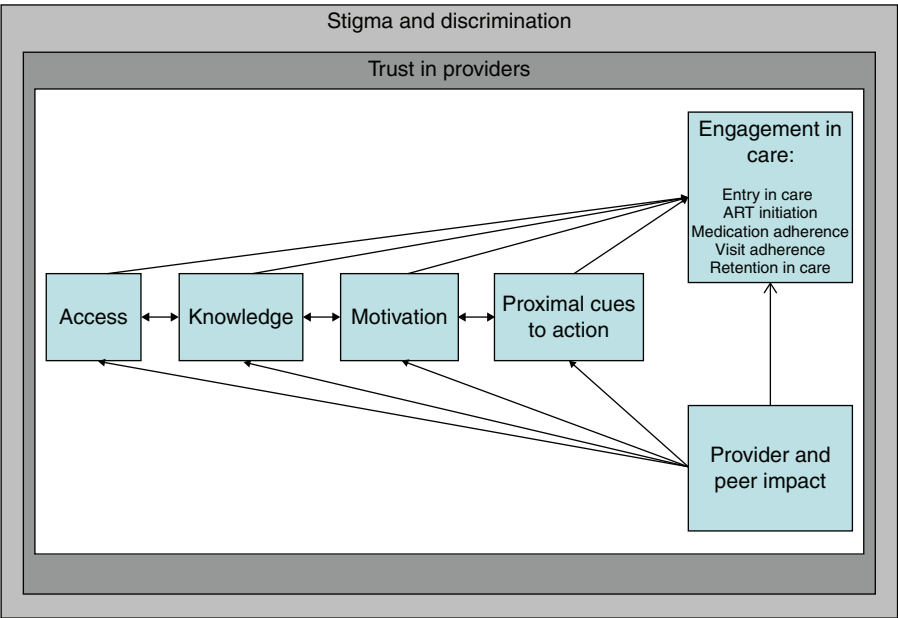
Methods

Overview

Our intervention development process consisted of three steps: conceptualizing the intervention based on theory and empirical qualitative research; developing and standardizing the intervention; and pilot testing the intervention for safety, feasibility, and acceptability before conducting a planned clinical trial. We named our intervention *Shikamana* after a Kiswahili word meaning “to form a bond or stick together.”

Conceptual model

Based on our prior cross-cultural work [15,16] and the adherence literature [17–19], we used the four-step conceptual model in Fig. 1 as the foundation for our qualitative work and intervention development process. This model identifies four steps we believed necessary for Kenyan MSM to engage in care and adhere to treatment: access, information, motivation, and proximal cues to action. The model emphasizes the context of stigma and discrimination, but we posited that the effects of stigma and discrimination would be moderated by trust in



**Fig. 1. Conceptual model.** The figure presents the four steps in our conceptual model that are needed in order to ensure engagement in HIV care, which starts with care entry and includes both adherence and retention in this model. In the *Shikamana* intervention, providers and peer navigators are trained to impact each of the four steps. By building trust in providers, the intervention aims to combat the background stigma and discrimination that MSM face.

**Table 1. Characteristics of men who have sex with men interviewed about intervention development.**

Characteristic	Median (range) or <i>N</i> (%)
ART status	
ART-naïve	10 (33.3%)
ART-experienced, currently taking ART	18 (60.0%)
ART-experienced, not taking ART	2 (6.7%)
Age, years	31 (19–51)
Education, years	8 (4–14)
Ethnicity	
Bajun	6 (20.0%)
Digo	1 (3.3%)
Girama	7 (23.3%)
Kalenjin	1 (3.3%)
Kamba	1 (3.3%)
Kauma	1 (3.3%)
Kikuyu	5 (16.7%)
Luhya	5 (16.7%)
Luo	2 (6.7%)
Swahili	1 (3.3%)
Religion	
Catholic	5 (16.7%)
Protestant	8 (26.7%)
Other Christian	3 (10.0%)
Muslim	13 (43.3%)
None	1 (3.3%)
Marital status	
Single	12 (40.0%)
Married, monogamous	2 (6.7%)
Married, polygamous	1 (3.3%)
Separated/divorced	9 (30.0%)
In relationship	6 (20.0%)
Employment	
Formal employment	3 (10.0%)
Casual laborer	5 (16.7%)
Self-employment	16 (53.3%)
Unemployed	6 (20.0%)
Ever been paid for sex	
Yes	25 (83.3%)
No	5 (16.7%)
Ever had sex with a woman	
Yes	20 (66.7%)
No	10 (33.3%)
Sexual identity	
Gay	15 (50.0%)
Homosexual	3 (10.0%)
Bisexual	2 (6.7%)
Straight	2 (6.7%)
None of the above <sup>a</sup>	4 (13.3%)
Other <sup>b</sup>	4 (13.3%)

ART, antiretroviral therapy.

<sup>a</sup>When asked for Swahili identity terms, these four men identified as 'Basha' (2), 'Shoga' (1), or 'Kuchu' (1).

<sup>b</sup>When asked for Swahili identity terms, these four men identified as 'Basha' (1), 'Shoga' (1), or 'Kuchu' (1), or 'None of the above.'

providers. Based on our experience with MSM in Kenya [5,13,20,21], we identified several intervention strategies that could address the steps in our model: patient-centered care [22], motivational interviewing [23], peer support, pill-taking or appointment reminders, discrete pill carriers, Internet-based approaches, and a telephone hotline.

## Qualitative work

To understand individual experiences, qualitative in-depth interviews were conducted with 20 ART-

experienced and 10 ART-naïve MSM recruited through peer outreach teams, local care providers, and local lesbian, gay, bisexual, and transgender (LGBT) organizations. Purposive sampling was used to recruit men with a range of ages, education levels, employment, and experience with HIV care. Interviews followed a semi-structured format with questions about barriers to and facilitators of ART adherence, followed by questions about potential intervention components. To gain an understanding of provider consensus, four focus group discussions (FGD) were conducted with 29 local providers serving MSM clients, identified through an established provider training network [24,25]. We asked providers to identify barriers and facilitators from their perspective and elicited their feedback on potential intervention components. Characteristics of interviewees and FGD participants are presented in Tables 1 and 2, respectively. Interviews and FGD were conducted in Kiswahili and recorded. Facilitator notes written in English were submitted for review after each session, and recruitment continued until saturation of emergent themes was reached. Digital recordings were transcribed and translated before coding using both a priori and emergent codes by two researchers using NVivo version 10 (QSR International, Burlington, Massachusetts, USA). A phenomenological approach was used for data analysis, with codes and qualitative results discussed by the team to achieve consensus. Results were shared with local LGBT groups for further input and member checking.

## Intervention development

Based on our qualitative research, our conceptual model, and review of the literature on evidence-based adherence

**Table 2. Characteristics of providers asked about intervention development.**

Characteristic	Median (range) or <i>N</i> (%)
Sex	
Male	14 (48.3%)
Female	15 (51.7%)
Age, years	36 (28–59)
Employer type	
Public facility	22 (75.9%)
Private facility	5 (17.2%)
Research institute	2 (6.9%)
Cadre	
Clinical officer	12 (41.4%)
Counselor	8 (27.6%)
Nurses	6 (20.7%)
Nurse-counselor	1 (3.4%)
Pharmacist	1 (3.4%)
Government AIDS programme coordinator	1 (3.4%)
Experience providing ART, years	3 (1–11)
Experience working with MSM patients, years	2 (1–11)
Prior MSM sensitivity training	
In-person	14 (48.3%)
On-line	13 (44.8%)
Both in-person and on-line	1 (3.4%)
None	1 (3.4%)

ART, antiretroviral therapy.

interventions, we developed an intervention integrating both provider- and peer-delivered components, supplemented by additional components (e.g., phone reminders, pill carriers) for patients who thought these would help. Following the general approach recommended by Bartholomew *et al.* [26], we identified deficits in access, knowledge, motivation, and skills, and moderators of these deficits. We then wrote desired performance outcomes for HIV-positive MSM, peer navigators, and HIV care providers (i.e., clinicians and counselors). Throughout the intervention development process, we actively solicited feedback from research staff, participants, and local LGBT organizations, care providers, and public health officials regarding the safety and feasibility of different intervention components (e.g., peer navigators). Based on this work, we created training manuals for providers and peers, adapting materials from evidence-based interventions when possible (see Supplemental Digital Content 1 and 2, <http://links.lww.com/QAD/A788>, <http://links.lww.com/QAD/A789>).

The *Shikamana* provider manual targets counselors primarily and clinicians secondarily, as clinicians also provide patient counseling. We identified Next-Step Counseling (NSC), developed by Amico *et al.* [27], as an appropriate model due to its patient-centered focus, use of motivational interviewing, and demonstrated acceptability to MSM at international sites. NSC material was adapted by streamlining procedures and simplifying counseling visit forms to enhance feasibility in the Kenyan context. The manual presents didactic material, as well as interactive exercises and sample cases. Staff training included role-playing and was carried out over four half-days.

For peer navigator training, we identified material from Project PAL [28,29], a peer support intervention, as a model that could be adapted for the Kenya MSM context. Based on Project PAL, we designed didactic material and interactive exercises on providing three types of support: information, empathy, and encouragement. Additional material was incorporated, based on our qualitative work and desired performance outcomes. The *Shikamana* peer manual also includes basic information on HIV, ART medications and adherence, positive living, and practical information on obtaining refills when travelling, transferring care if needed, and accessing ART when incarcerated. Maintaining confidentiality and referring patients to providers when indicated are both emphasized.

Peer navigators were called *Washikaji* (meaning “those who bond or stick together”) and were identified through local LGBT organizations, providers, and informal peer outreach. We required that *Washikaji* have at least 2 years’ experience taking ART, report one or more male partners within the past 2 years, and be able to communicate in English or Kiswahili. We suggested that

*Washikaji* should support other MSM taking ART, be nonjudgmental, be flexible and willing to problem-solve, have excellent interpersonal skills, be committed to maintaining confidentiality, be a responsible team worker, and be a role model (i.e., good adherence, positive living). *Washikaji* were reassured that they were not responsible for problems unrelated to ART adherence (e.g., relationships, housing), for which they should refer patients to their friends and family for assistance. *Washikaji* training was conducted over 2 days, with certificates provided to men who completed. Meals and a transport reimbursement were provided.

### Pilot testing

Ten pilot study participants were recruited from an ongoing HIV-1-seropositive cohort [13]. To be eligible, men had to be at least 18 years of age, Kenyan, sexually active with a male partner in the past 12 months, ART-naïve, eligible for ART per Kenyan guidelines at the time (i.e., CD4<sup>+</sup> cell count less than 500, WHO stage III or IV disease, hepatitis B coinfection, or seronegative partner), resident locally, able to communicate in Kiswahili or English, and willing to undergo study procedures. We judged that 10 participants would be enough to trial all intervention procedures and obtain feedback on safety, acceptability, and feasibility.

Participants attended visits at enrolment, ART initiation, week 2 postinitiation, then monthly through month 3. A peer was assigned to each patient at ART initiation, based on proximity of residences. At the initial meeting, preferences for peer support (e.g., contact frequency, meeting in person or by telephone) were discussed. Peers contacted their assigned patients in person or by telephone at least weekly during the first month of ART, then at least monthly for the remaining follow-up. Peers met the provider team every week to discuss progress and receive ongoing training and support. Peers received a small stipend (≈\$15 per month) and telephone credit (≈\$5 per month) for their work, as well as transportation (≈\$2) to attend clinic meetings.

NSC was delivered at months 1, 2, and 3; sessions were recorded if patients consented. Progress was monitored at regular staff meetings and during counseling supervision. Evaluation of intervention delivery was provided by KEMRI Clinical Trials Facility (KCTF) staff, who reviewed recorded NSC sessions and used a standardized rating form to provide feedback. Safety was monitored throughout by close supervision of peers and clinic staff, and by reporting of adverse events such as breach of confidentiality, mental distress, and physical harms using a detailed standard operating procedure. Feedback on feasibility (i.e., staff time and effort required, availability and performance of peer navigators) and acceptability (i.e., tolerability of procedures to staff, peers, and patients) was collected through staff and peer meeting notes and counseling notes. After pilot study completion at month

3, exit interviews were conducted with patients, peers, and staff, to elicit additional feedback on feasibility and acceptability, and identify any unreported harms of participation.

### Human study participants

Written informed consent was obtained from all study participants, including interview and FGD participants and pilot study providers, peers, and patient participants. The study was approved by ethical review boards at the Kenya Medical Research Institute and University of Washington.

## Results

### Development: MSM input

Supplemental Digital Content 3 (<http://links.lww.com/QAD/A790>) contains quotations from these participants. In terms of *provider approaches*, men were interested in *patient-centered care* and felt it would add flexibility, as “the patient is in a position to negotiate what he wants.” However, some felt that providers could not be trained to attend to the needs of MSM: “The challenge will come in when you get providers that will not understand, especially for us gay people.” Several men felt it would be preferable to have MSM as physicians. There was some concern that patients are not used to advocating for themselves or would not access care due to stigma or denial. Generally, participants also strongly supported the idea of *motivational interviewing*, although men had concerns about whether MSM patients would be open to receiving such support because “it is a challenge to open up.”

Most men enthusiastically supported the idea of *trained MSM peer navigators*, both to improve adherence and provide social support: “You feel that there is someone in the world who cares about you.” Men were already familiar with family or friends reminding them when to take ART, and felt that a peer could help connect men to MSM-friendly providers: “It’s a very nice approach, especially to individuals who are reluctant to access care services.” Generally, participants wanted a peer who was sincere, discrete, and of similar age. Men preferred that researchers identify qualified peers: “You are well aware of the individual qualities that you require.” However, they thought MSM should provide input to ensure that “someone who is active and one they can trust” was selected.

Regarding *pill-taking or appointment reminders*, men had mixed views. Some men felt that SMS messages or alarms could help MSM with disclosure concerns, as such reminders are anonymous. Others felt these might attract unwanted questions. Some said that men might not appreciate being reminded of their HIV status in this way:

“It’s like every time I remind you ‘do you know that you are positive?’” A few expressed anxiety about unexpected phone calls, whereas others expressed concerns about missing or switched-off phones or dead batteries.

Most respondents who were asked about *discreet pill containers* endorsed their use, provided they were truly inconspicuous. Men pointed out that even small objects like key chains designed to conceal medications could become conspicuous if widely distributed to HIV-positive patients only. Several MSM described their own methods to protect themselves from being noticed carrying or consuming ART.

We also asked participants their views on *Internet-based approaches* to promoting adherence. Assessing the utility of a website was difficult, because 14 of 30 respondents reported either no Internet literacy or no access to devices, and thus were unable to address the question. Several respondents were intrigued by Internet-based health promotion, pointing out the appeal of maintaining anonymity. However, because Internet access is uncommon, training and improved access would be needed to make this approach feasible.

Of respondents asked about feasibility of a *telephone hotline*, several favored the idea but voiced reservations about potential misuse. A few respondents thought that education about the hotline’s purpose and staff would be needed, in order to assure men of confidentiality. This was a particular concern because hotline staff and callers could potentially recognize one another by voice, given the small size of the MSM population in the area. A few men cautioned that some MSM might overuse the service, whereas others would have spotty access.

### Development: provider input

Supplemental Digital Content 4 (<http://links.lww.com/QAD/A790>) contains quotations from these participants. When asked about *patient-centered care*, providers had heard of this approach through the national AIDS programme but expressed concerns about feasibility in busy clinic settings. Most said that they provide longer refill periods when requested, although some said this service was abused and many were concerned that patients miss important clinical monitoring. Although the value of adapting to individual patients was recognized: “We need to treat them on a case by case basis, create rapport with them,” providers expressed frustration at not being able to meet patients’ social needs: “Some people require support that you can’t offer...”

The idea of *motivational interviewing* was also endorsed, but providers were concerned about the time this would take and unsure how effective it could be: “it might take a longer time...the progress is slower.” In addition, some felt that many patients want providers to tell them what to do and not to make them solve the problem: “They expect

you to give them something...” Despite this concern, it was recognized repeatedly that adherence was ultimately the responsibility of the patient: “It is important for them to find out what they can do for themselves.”

Regarding use of an *MSM peer navigator* to promote adherence, providers were positive and felt that such men could be accepted if discrete and properly trained: “It is good when they see someone who has gone through it, and he is doing well.” They thought MSM peers could help ART programmes by facilitating men’s entry and retention in care and by helping remind others, especially those without phones, of their appointments or pill-taking. Providers cautioned that peers should not simply claim refills for their assigned patients, and patients should not become dependent upon peers. Providers thought it important that a peer should be: “one who has organised himself, one who respects himself, who is a role model even in the wider community.”

Although alarm or SMS reminders were perceived to be potentially useful, providers felt that patients would be concerned about confidentiality: “Sometimes it can be a danger, for example if this person is their sexual partner.” Several thought that MSM had unreliable contacts: “They keep changing their telephone numbers.” Providers had mixed opinions about the use of *pill carriers* other than the container in which pills were dispensed, and were concerned men would lose or damage tablets. However, some thought “it is better than them touching the tablets and putting them in tissue.”

Regarding use of a *telephone hotline*, they wanted MSM peers to manage the line and refer patients to providers. But there may be problems “if we don’t clearly stipulate...how far we can help.” Regarding *Internet-based approaches*, they suggested that in addition to sites tailored to MSM patient needs, there should be sites to provide information and other services to men’s family and friends, “who need to be able to live with them and support them, and the first step is in understanding them.” Although there was some support for both these modalities, providers were quick to observe that not all MSM have phone or Internet access and that these interventions would only be helpful to those “who are willing, who are socio-economically able, or know how to access [the] Internet.”

### Pilot testing

Six counselors, three clinical officers, and four MSM peers were trained in intervention procedures. Ten ART-naïve participants were enrolled in the pilot test. These men represented eight ethnic groups, were 24–42 years of age, and had 4–14 years of education; half reported transactional sex in the past 3 months. One trained peer failed to demonstrate sufficient commitment and was not assigned a patient. The other three trained peers each participated, with one assigned four patients, another

assigned three patients and another assigned two patients. Eight patients initiated ART and completed all follow-up visits with no adverse events reported. One participant was lost to follow-up after 2 months. One patient failed to initiate ART despite ongoing counseling, and was not assigned a peer.

KCTF staff provided feedback on 19 taped counseling sessions. Although counselors were able to discuss barriers and facilitators without problem, they found helping patients identify a “next step” (a discrete step to work on for the next visit) more difficult, and sometimes forgot to review strategies and successes from previous visits. Staff received feedback in real time from KCTF staff and participated in refresher training to improve skills mid-way through; in addition, counselors translated materials into Kiswahili to serve as memory aids when counseling in that language. KCTF evaluations noted a marked improvement in counseling skills over time.

Seven of eight participants who completed the study underwent an exit interview, as did the participant who did not initiate ART. One participant failed to return for his scheduled interview. All men thought the counseling had helped them. One pointed out a specific “next step” that had helped him learn to take his ART discretely. Four participants used phone alarms in addition to peer reminders, and three found the discrete pill holders we offered very helpful. All described good relationships with their peers, who provided pill-taking reminders and advice on managing side-effects, nutrition, and safe disclosure. In most cases, contacts were by telephone with only occasional in-person meetings. Despite this, many participants felt close to their peers and all felt well supported. No participant reported any adverse effect or concern about peer support. The participant who did not initiate ART stated he was not ready to disclose and did not feel he needed ART yet. He was offered peer support to help address these issues, but declined due to fear about gossip; counseling is ongoing.

Staff feedback at the end of the pilot indicated that the intervention was feasible and acceptable. Staff appreciated the work of the peer navigators, although they were unsure they got the entire story in a few instances. In addition, counselors voiced concerns that some patients might want to choose their own peer navigator, which could compromise peers’ confidentiality; staff preferred to continue assigning peer navigators based on availability and proximity to a given patient. Training materials and procedures were refined based on pilot study results.

### Discussion

Our goal was to develop and pilot test an evidence-based adherence intervention tailored to the needs of MSM

patients in a highly stigmatized setting. We used interviews with MSM patients and their providers to develop our intervention, which combines motivational interviewing from providers with support from MSM peers experienced with taking ART. The intervention includes provider and peer support to encourage engagement in care, provide information on living with HIV, motivate patients, and address any skill deficits through NSC and advice from an experienced peer. In this pilot study, we found that the intervention was well-tolerated, feasible, and acceptable. We concluded that *Shikamana* is ready for testing in a small randomized clinical trial (RCT) that is currently ongoing.

The above preliminary stage of research was promising, but a larger controlled trial will ultimately be needed in order to evaluate intervention efficacy. In general, clinic staff liked the patient-centered approach, and became comfortable with working more collaboratively. Our experience with this approach is in accord with published work showing that patient-centered care may lead to a more accurate understanding of patient concerns and expectations [30,31], higher patient and provider satisfaction [30,32–35], and better quality of care [36]. In addition, motivational interviewing using the modified NSC approach we developed, although challenging to master, was generally thought by staff to build trust in providers and by patients to have been helpful.

Perhaps the most successful component according to feedback received was the peer support. Peer interventions have been successful in other contexts, but may be particularly useful for reaching and supporting marginalized populations, such as Kenyan MSM [37,38]. Participants found inspiration in the examples provided by peers, who were appreciated for their training and their willingness to provide a positive example. Peers called or texted patients frequently, and patients only occasionally used phone alarms or pill carriers to assist with adherence. We believe peers helped address all four steps in our conceptual model, although it remains to be seen whether peers can address access for men not in contact with a clinic. We have concluded that the personal connection formed was more important to patients than technological aids; indeed, many of the peer–patient pairs elected to continue occasional contacts after this study ended.

This study has several limitations. First, our pilot study was small and designed only to test *Shikamana* for safety, feasibility and acceptability; it was not powered to test any adherence or clinical outcomes. In exit interviews, men cited the importance of friendly staff who “treat people like human beings” and of the experience, training, and commitment of the *Washikaji*. However, at least one participant felt unready to disclose to a peer and benefit from this support. Second, the provider skills required for the *Shikamana* intervention are not limited to patient-

centered care and motivational interviewing; our counselors and clinicians have many years’ experience working with MSM patients and therefore had skills not always found in African clinical settings. Third, this pilot study took place in a research clinic with substantial resources and the local community included sensitized HIV care providers, active LGBT groups, and peers willing to volunteer for this project; as such, our results may not be generalizable to other settings. In addition, most MSM who have participated in our research, including this study, have been sex workers. Additional efforts to reach MSM not participating in sex work and determine their needs are clearly warranted.

In conclusion, we have developed an adherence intervention targeting HIV-positive MSM living in an African setting. It has guided our design of a small randomized controlled trial currently ongoing to evaluate safety, feasibility, and acceptability of a scaled-up intervention and to estimate effect sizes for a larger trial. Future work will involve a RCT fully powered to assess the efficacy of *Shikamana* to improve outcomes, including adherence biomarkers, and if warranted, work on optimal implementation and dissemination.

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Author contributions: S.M.G. and J.M.S. designed the study. M.M. conducted the interviews and focus group discussions, and E.vdE. assisted with the qualitative work. S.M.G., J.M.S., M.M., J.K., E.vdE., and P.M.M. assisted with intervention development and pilot study supervision. E.K. evaluated the NSC transcripts. F.A. and B.K. reviewed interview transcripts and helped S.M.G. draft

the manuscript. E.J.S. provided oversight of all fieldwork. All authors reviewed and approved of the manuscript.

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### Conflicts of interest

We declare that we have no conflicts of interest.

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