# The Effect of the Shikamana Peer-and-Provider Intervention on Depressive Symptoms, Alcohol Use, and Other Drug Use among Gay, Bisexual, and Other Men Who Have Sex with Men (GBMSM) in Kenya

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**Abstract**

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Kenyan gay, bisexual, and other men who have sex with men (GBMSM) face unique stigma and discrimination, which may contribute to adverse mental health symptoms, and could limit antiretroviral therapy (ART) adherence among GBMSM living with HIV. This secondary analysis of data from a randomized pilot study evaluated whether the *Shikamana* peer-and-provider intervention was associated with changes in psychosocial factors over time. Psychosocial measures were taken at three quarterly study visits by audio computer-assisted self-interview (ACASI). Generalized estimating equations (GEE) were used to evaluate whether rates of change in depressive symptom severity, alcohol use, or other drug use differed by allocation group. We used linear regression to further examine when these differences were observed and to identify other predictors of changes in depressive symptoms. At baseline, both groups were comparable, but the intervention group reported greater depressive symptomatology on average (p=0.09). The intervention was associated with a 1.6 point greater (95% CI: 0.2 – 3.1 points) reduction in depressive symptoms per visit over the 6-month period compared to the standard of care. There were no significant changes in scores for other psychosocial factors. In an exploratory analysis, baseline HIV stigma was associated with greater reductions in depressive symptoms. For each one-point increase in baseline HIV stigma in the intervention group, participants had a 0.12-point (95% CI: 0.02 – 0.23 points) monthly reduction in depressive symptoms. We found that the *Shikamana* intervention was associated with a reduction in depressive symptoms, and baseline HIV stigma may predict response to the intervention to some extent. Additional research is required to understand factors that influence this peer-and-provider intervention's effects and whether depressive symptoms, stigma, or other psychosocial factors could be affected in a larger trial.

## INTRODUCTION

Gay, bisexual, and other men who have sex with men (GBMSM) are marginalized populations in many settings globally, and are consistently found to be at high risk for HIV and AIDS, including in countries that have generalized epidemics (1). In Kenya, GBMSM face substantial discrimination and stigma, which affect access to healthcare and preventive services (2), contributing to health disparities between GBMSM and heterosexual populations. One cohort study of 449 GBMSM in coastal Kenya measured an HIV incidence rate of 8.6 (95% CI: 6.7 – 11.0) cases per 100 person-years (3), which is considerably higher than the 2016 UNAIDS HIV incidence estimate of 0.25 (95% CI: 0.18 – 0.33) cases per 100 person-years in the general Kenyan population (4). HIV prevalence among GBMSM in coastal Kenya has been estimated at approximately 25% (5).

A cross-sectional study of 112 GBMSM in coastal Kenya identified a substantial burden of depressive symptoms, alcohol abuse, and substance abuse, with approximately 31% reporting PHQ-9 scores consistent with a depressive disorder, 45% reporting hazardous alcohol use, and 60% reporting harmful use of other drugs (6). Common exposures in this population included childhood abuse (78%) and recent abuse, including forced or coerced sex, physical abuse, emotional abuse and threats or intimidation (67%) (6). A recent systematic review and meta-analysis of 111 studies estimated that among people living with HIV (PLHIV), adequate ART adherence (≥80% of doses taken) was 42% lower among those with depression (7). Among GBMSM, psychosocial issues, including depressive symptoms, alcohol abuse, and other substance abuse, tend to co-occur as synergistic epidemics, or “syndemics” (8). Studies have also demonstrated that, among HIV-positive GBMSM, higher syndemic burdens are associated with reduced engagement in HIV care (9), lower adherence to ART (10,11), and higher viral loads over time (11).

Kenyan GBMSM who are living with HIV also report difficulties accessing care and adhering to antiretroviral therapy (ART) (2), which could be due in part to stress and adverse mental health symptoms or alcohol or other drug use (12). GBMSM have been repeatedly found to have high prevalence of mental health conditions such as depressive symptoms in many settings (6,13–16). The minority stress model

theorizes that the high prevalence of psychosocial disorders among GBMSM is due, in part, to stigma and discrimination; however, resilience and social support are also posited as important protective factors (13). Stress can lead to a variety of mental health symptoms, including depressive symptoms and alcohol or other drug use, so factors associated with minority stress could help explain changes in psychosocial symptom severity over time among GBMSM: changes in HIV stigma, sexual stigma, social support, and resilience may therefore mediate changes in psychosocial health.

In order to improve HIV care and treatment outcomes among Kenyan GBMSM, novel approaches are necessary to support and retain GBMSM in care and to improve adherence to ART. The *Shikamana* intervention (from the Kiswahili word for "to form a bond" or "stick together") is a theory-based peer-and-provider intervention aiming to improve engagement in care and ART adherence for GBMSM living with HIV (17). Peer guides, termed *Washikaji* ("those who bond or stick together" in Kiswahili), were trained to provide support to intervention participants. In 2016, a two-arm randomized clinical trial (RCT) was conducted to evaluate the feasibility, acceptability, and safety of *Shikamana*. Although this trial was not powered to demonstrate an impact on adherence or clinical outcomes, *Shikamana* was associated with a somewhat higher but insignificant reduction in viral load at the end of 6 months (p=0.35), and intervention participants rated higher both how well they took their ART (mean 4.80/6 vs. 4.41/6, p=0.002) and how often they took their ART as prescribed (mean 5.25/6 vs. 4.83/6, p=0.001) (18).

Anecdotally, peers and providers reported that their counseling and support efforts often centered on depressive symptoms and substance use among the trial participants, which led to the hypotheses addressed in the present analysis. The primary aim of this analysis was to determine whether *Shikamana* was associated with changes in depressive symptoms, alcohol use, or other drug use. A secondary aim was to determine whether changes in HIV stigma, sexual stigma, social support, or resilience were predictive of changes in depressive symptoms, alcohol use, or other drug use in an exploratory mediation analysis. These variables were hypothesized to be mediators *a priori* as variables potentially affected by the peer-and-provider intervention, which could potentially cause changes in outcome measures.

## METHODS

*Study Design*. The present study is a secondary analysis of the RCT conducted to evaluate the *Shikamana* intervention as compared to the current standard of care. Participants were eligible if they were at least 18 years old, male, had engaged in any sex with a man in the past 12 months, lived in the study area, were of Kenyan nationality, and had been diagnosed with HIV infection. Sixty individuals were randomized with stratification by experience taking ART. The allocation sequence was concealed using sequentially numbered, opaque, sealed envelopes. Individual participants were allowed to select their own envelope, as the GBMSM community stated that they wanted to participate in the selection process. Due to the nature of the intervention, blinding after allocation was not possible for either participants or the study team.

*Intervention.* The *Shikamana* intervention consists of several elements. First, healthcare providers (clinicians and counselors) were trained in patient-centered care and took an online training in male sexual health (http://www.marps-africa.org), to improve access to tailored care and services. Second, these providers were trained in a modified version of Next-Step Counseling, a form of motivational interviewing that was successfully used in the iPrEx trial (19). *Washikaji*, who were all HIV-positive, Kenyan GBMSM who were experienced in taking ART, were trained to provide informational, empathetic and motivational support, to encourage regular ART adherence and help address barriers to adherence (20). Participants and *Washikaji* were introduced at baseline, then communicated via phone, text messaging, or in-person meetings every week for the first month and then at least monthly thereafter. At each study visit, participants were exposed to the provider intervention, and contact with *Washikaji* was ongoing throughout the study period.

*Standard care.* Participants in the standard care arm were provided counseling in accordance with Kenyan guidelines and offered participation in a support group for MSM living with HIV infection.

Counselors used a checklist for standard counseling that has been used in previous research in Kenya (21).

*Procedures for all participants.* The follow-up period was 6 months, with study visits at enrollment, ART initiation, week 2, and then monthly for 6 months. Data on psychosocial factors were collected via audio computer-assisted self-interview (ACASI) at baseline, month 3, and month 6. ART refills were provided monthly, with assessment of adherence by ACASI at these visits. Discrete key chain pill carriers and MEMS® cap-enabled pill storage containers were provided to participants. Research staff used text messaging and phone calls to remind participants of study visits.

*Study Setting.* The study was conducted at the KEMRI–Wellcome Trust research clinic in Mtwapa, Kenya (approximately 18 km north of Mombasa).

*Study Subjects.* Study participants were recruited from an ongoing cohort of HIV-positive Kenyan MSM, supplemented by community outreach through peer mobilizers and provider referrals.

*Data Collection*. All psychosocial and demographic variables were obtained by ACASI during baseline, 3-month, and 6-month study visits. Research staff were available to help participants if they did not understand a question or if they experienced technical difficulties. ACASI has been used successfully at this research clinic for a number of years (22).

*Measures.* Outcomes were measured as follows. Depressive symptoms were assessed with a 10-question version of PHQ-9 (23), which asks about common symptoms of depression over the past two weeks; each question is answered on a 4-point scale with responses ranging from “not at all” to “nearly all the days.” Alcohol use was measured using AUDIT (24), a 10-question survey tool assessing frequency of alcohol consumption and associated harms using 5-point scales. Other substance use was evaluated with the DAST-10 (25), a 10-question tool which asks about potential harms associated with substance

use. All psychosocial measures were analyzed as continuous scales, so no cut-points were used in this analysis. This approach was adopted to maximize power, given the small sample size.

Potential mediators of any impact of the *Shikamana* intervention on these three outcomes, which were hypothesized to be affected by the intervention and thought to potentially exacerbate or mitigate the primary outcomes, include HIV stigma, sexual stigma, social support, and resilience. The HIV Stigma Scale (26) was adapted for this study, involving 7 questions regarding disclosure of HIV status and 5 questions about negative self-image as a result of HIV status. Sexual stigma was measured with an 11-question tool adapted from The China MSM Stigma Scale (27) asking about negative experiences participants may have had because they are GBMSM. Social support was assessed with the Medical Outcomes Study (MOS) Social Support Scale, a 19-question tool (28) addressing four types of social support: emotional/informational, tangible, and affectionate support, as well as positive social interactions. Resilience was ascertained with a 14-question tool, which is geared specifically toward GBMSM (14).These scales do not have validated cut-points, so they were also analyzed as continuous measures.

For each of the scales described above, total scores were calculated by summing each participant's responses to the tool's component questions, following reverse scoring or other specific rules pertaining to each scale.

*Data Analysis.* A directed acyclic graph (DAG) was designed to guide planning of this analysis (Figure 1).

*Missing Data and Data Quality.* Retention was balanced across arms, at 85% in each, and visit attendance did not differ (median 7 clinic visits and 3 ACASI visits in both arms), so a complete cases approach was adopted for loss to follow-up. Differences in sociodemographic and psychosocial factors between participants lost to follow-up were compared to those who were retained. Additionally, the timing of data collection with respect to planned window periods was assessed. Nine participants (15%) had at least one ACASI visit day that did not occur at the baseline, month 3, or month 6 visits. These

irregularities were balanced across arms (5 irregular visits in each arm). Two participants (one from each arm) had month 3 ACASI visits that occurred more than one month later than 90 days since enrollment.

*Main analysis.* Because the intervention was randomly assigned at baseline, confounding is not expected in the total effect of *Shikamana* on the outcomes, so the main analysis did not involve adjustment for any covariates. Seven response variables were of interest: PHQ-9, AUDIT, and DAST as outcomes, and HIV stigma, sexual stigma, social support and resilience as potential mediators. Initially, several graphs were plotted to examine changes in outcome measures among individual participants (Figure 2).

To account for intra-subject correlation due to repeated measures over time, longitudinal associations between the intervention and outcomes at months 3 and 6 were evaluated with generalized estimating equations (GEE). Each model was fit using an exchangeable correlation structure, and robust standard errors were calculated to ensure misspecification of the correlation structure would not impact inference. A series of three GEE models were fit for each of the seven variables of interest. An unadjusted marginal model using data from all ACASI visits addressed the primary question of whether the intervention was associated with larger differences in mean outcome scores compared to standard care, on average, over time. A conditional (post-intervention) model using data from month 3 and month 6 visits with adjustment for baseline values was used to evaluate whether baseline outcome scores confounded this association, which would be the case if the effect estimate was different. Additionally, a model describing the individuals' change in outcome values from baseline, using data from all ACASI visits, was used to evaluate whether there were differences in mean outcome score trajectories between allocation groups. Statistically significant coefficients for the group-by-time interaction term indicated an effect of the intervention on that variable's mean change over the study period.

To identify mechanisms of any effect of the intervention on psychosocial outcomes, an exploratory mediation analysis was also planned to be performed if the intervention was associated with at least one outcome and at least one potential mediator. Because of the nature of the intervention, HIV stigma, sexual stigma, social support, and resilience were thought to be affected by the *Shikamana* intervention *a*

*priori*. These factors were also thought to be causally associated with changes in depressive symptoms, alcohol use, and other drug use (Figure 1).

*Sensitivity analysis.* To evaluate change in depressive symptoms over time and explore the short- and long-term intervention impact across visits while incorporating actual visit dates, a series of segmented linear regressions were performed modeling each participant's PHQ-9 trajectory over three time segments: overall (baseline and month 6 visit data only), first quarter (Q1: baseline and month 3 visit data only), and second quarter (Q2: month 3 and month 6 visit data only). These regressions were performed at the individual level to calculate each participant's mean change in PHQ-9, with time since enrollment (expressed in 30-day increments, roughly "months") as a continuous predictor. These individual slope values were analyzed as outcomes by linear regression of individual slope values on allocation group, to determine when the intervention group had a significantly different rate of change in PHQ-9 score compared to the control group. For each time segment, the group-level slope coefficients from regressions of individual-level slopes on allocation group represent a difference in differences, providing inference on whether the intervention group's mean difference in response variable level between time 1 and time 2 was different from the mean difference in the same response variable level between the same timepoints in the control group. Differences in rates of change by group were identified by a group-level beta coefficient statistically significantly different from 0 (i.e., 95% confidence interval excludes 0).

*Exploratory analysis.* A post-hoc, exploratory analysis was performed to identify predictors of the intervention's overall effect on depressive symptoms among the intervention participants only, using Figure 1 to select potential predictors. Baseline variables, including HIV stigma, sexual stigma, social support, and resilience were assessed bivariately as predictors of rates of change in PHQ-9 score in the overall segment, choosing predictors with a p-value less than 0.1 for inclusion in a multivariate model. CD4 count, ART experience, age, and MSME status (i.e., men who have sex with men exclusively [MSME] vs. men who have sex with men and women [MSMW]) were assessed as potential confounders

of these associations and were included in the adjusted model if adjusting for that variable changed the magnitude of the effect estimate by at least 10%.

## RESULTS

*Demographics and baseline characteristics.* Sixty participants were enrolled. Because participants selected their own envelopes and were randomized with stratification by ART experience, 27 participants were allocated to the intervention group and 33 to standard care. Demographic and psychosocial covariates were balanced across groups, including age, marital status, MSME status, education, alcohol use, history of sex work, socioeconomic status, ART experience, CD4 counts, time since HIV diagnosis, experience of anti-GBMSM violence in the past year, as well as outcome and potential mediator variables (Table 1). The intervention group had a higher, but statistically insignificant, prevalence of childhood abuse (90% vs. 69%, p=0.22). Notably, mean baseline PHQ-9 score was higher in the intervention group (10.9 compared to 8.2), but this difference was not significant (p = 0.09).

*Follow-up Visits and Retention.* Nine participants were lost to follow-up: seven participants were lost to follow-up between baseline and month 3, and two more were lost between month 3 and month 6, with no differences in timing of loss to follow-up by arm. There were no differences in demographic or psychosocial characteristics between retained and lost participants, except that participants lost to follow up were more likely to be MSME than retained participants (6 of 9 lost to follow-up, 67% vs. 9 of 51 retained, 18%, p=0.007). This difference was similar across allocation groups, with 3 MSME lost to follow-up in each arm.

*Main analysis.* Group-by-time interaction terms were not significant for AUDIT or DAST (Table 2). However, the decrease in PHQ-9 score was 1.6 points per visit greater (95% CI: 0.2 – 3.1 points) in the intervention group compared to the control group (Table 2). The effect size was unchanged in the post-intervention model, indicating that baseline PHQ-9 score was not a confounder (Table 2). The change-

from-baseline model showed a significant effect, with the intervention group's PHQ-9 scores decreasing by 2 more points (95% CI: 0.5 – 3.5 points) from baseline per visit than the control group (Table 2)**.**

The intervention was not associated with changes in HIV stigma, sexual stigma, social support, or resilience (Table 2). These variables were considered potential mediators because they were hypothesized to be affected by the intervention and to be further associated with changes in depressive symptoms, alcohol use, and other drug use. The planned mediation analysis was not performed because this analysis showed that the mediators were not associated with the intervention and therefore could not mediate changes in outcomes.

*Sensitivity analysis.* Results of the sensitivity analysis are shown in Table 3. In the overall model, the intervention group's mean PHQ-9 scores decreased by 0.7 points more (95% CI: 0.2 – 1.3 points) per month than the control group. No statistically significant difference was observed between groups in PHQ-9 during Q1 and Q2, but the point estimates are all of similar magnitude, and individual-level slopes describing rates of change in PHQ-9 were more negative in the intervention group during each time segment. Figure 3 provides a full graphical representation of these segmented, individual-level linear regressions for the main outcomes.

*Exploratory analysis.* Baseline HIV stigma was associated with changes in individual-level rates of change in PHQ-9 in the overall segment. In a bivariate model, each one-point higher difference in baseline HIV stigma was associated with a 0.11-point (95% CI: 0.01 – 0.21 points) per month greater decrease in PHQ-9 score (Table 4). Other baseline predictors, including sexual stigma, social support, and resilience were not associated with differences in rate of change in PHQ-9. Only MSME status was included as a confounder in an adjusted model, which estimated the association between baseline HIV stigma score and change in PHQ-9 score to be a 0.12 point (95% CI: 0.02 – 0.23) per month greater improvement in PHQ-9 score (Table 4).

## DISCUSSION

In this secondary analysis of data from a small pilot randomized trial, we found in the main analysis that the *Shikamana* peer-and-provider intervention was associated with a 1.6 point-per-visit (95% CI: 0.2 – 3.1 points per visit) greater improvement in depressive symptom severity measured by PHQ-9, compared to standard care among Kenyan GBMSM living with HIV. Although the *Shikamana* intervention was associated with a reduction in depressive symptoms, it was not associated with changes in alcohol use, other drug use, HIV stigma, sexual stigma, social support, or resilience in any of the analyses. Because the intervention was not associated with any of the hypothesized mediators, we did not identify any mechanism by which depressive symptoms were reduced.

PHQ-9 scores are used clinically to monitor depressive symptoms within the following categories: 0–4, minimal depression; 5–9, mild depression; 10–14, moderate depression; 15–19, moderately severe depression; and ≥20, severe depression (23). The mean PHQ-9 value at baseline among standard care participants was 8.2 (range: 0 – 24) with 12% reporting moderately severe to severe depressive symptoms, whereas the intervention group's mean was 10.9 (range: 3 – 25) with 22% reporting at least moderately severe depressive symptoms. This is in line with other studies among Kenyan GBMSM, which have found substantial burdens of depressive symptoms, with prevalence of moderately severe to severe depression estimated at 13% and 23% (6,15).

Evidence about the effectiveness of peer-delivered interventions for depressive symptoms is mixed, with one systematic review, which primarily focused on serious mental illness, finding no effect of peer-delivered interventions on depression (29), whereas a meta-analysis and another review, both focusing on depression, found beneficial effects of peer support interventions (30,31). The present study adds to the evidence base suggesting peer support interventions may contribute to improving depressive symptoms. Over the whole study period, we estimate that the intervention group's mean PHQ-9 score decreased by approximately 3.4 points (95% CI: 0.4 – 6.2 points) more than the control group's

depressive symptoms decreased. For comparison, one study of pharmacological treatment among adults with diagnosed depression estimated the minimal clinically important difference for change in PHQ-9 scores in response to treatment to be 5 points (32). Participants in our study were not selected for depressive symptoms or diagnoses of depression, so many participants therefore had less severe symptoms than that population. The observed effect of the intervention is smaller but may still contribute to enhancing quality of life in a population of individuals not diagnosed with depression, who may not all be in need of pharmacological treatment.

In the sensitivity analysis using segmented linear regressions, we found that *Shikamana* was associated with a 0.7-point (95% CI: 0.2 – 1.3 points) greater monthly reduction in PHQ-9 score than was standard care. This finding was significant when analyzed over a six-month period, but the reduction in depressive symptom severity did not reach significance during either of the two three-month periods constituting that six-month period, suggesting that this improvement was gradual over the study period, and not achieved quickly in the first 3 months. In Q1 and Q2, the effect estimates were similar to the overall model in direction and magnitude for PHQ-9.

Other studies among Kenyan GBMSM have not found an association between HIV status and depressive symptoms (6,15). All participants in this study were HIV-positive, and, in an exploratory analysis, we identified baseline HIV stigma as a potential predictor of improvement of depressive symptoms in response to *Shikamana*. Among intervention group participants, on average, each one-point increase in baseline HIV stigma was associated with a 0.12-point (95% CI: 0.02 – 0.23 points) per month reduction in depressive symptoms, after adjusting for MSME status. A key role of the trained *Washikaji*—who are also GBMSM living with HIV—was to provide information, encouragement, and empathy, so it may be possible for peer guides like *Washikaji* to change participants' self-perceptions and reduce internalized HIV stigma. In fact, participants in a qualitative study, among mostly women, in Tanzania reported that untrained, HIV-positive treatment partners helped to reduce perceived HIV-related stigma (33). Future research should evaluate the role of peer support in reducing HIV stigma, and identify mechanisms linking HIV stigma to depressive symptoms.

There are several limitations to this study. The present study is a secondary analysis of a small pilot study designed to evaluate the feasibility, acceptability, and safety of the *Shikamana* intervention, so only 60 participants were enrolled, which limited statistical power. Several participants were lost to follow-up, and these participants were more likely to be MSME, suggesting that loss to follow-up may not have occurred at random. PHQ-9 has been validated in Kenya among PLHIV (34), but not among GBMSM, so the reliability and validity of this scale are unknown in this population. Strengths of the present study include its longitudinal design, which allowed for measurement of change over time among individuals, and random assignment of the intervention, which removed the potential for confounding in the main analysis. The baseline difference in depressive symptom severity between allocation groups, although not statistically significant, suggests that some of the reduction in depressive symptoms in the intervention group could be due to regression to the mean. However, it is also possible that persons with greater depressive symptom severity may benefit more from an intervention like *Shikamana*. The present study is among the first to examine the effect of an intervention on psychosocial conditions among GBMSM in Kenya. More research is needed to understand how to optimize peer support interventions to improve both HIV treatment outcomes and mental health outcomes in this vulnerable population.

**CONCLUSION**

Kenyan GBMSM are a vulnerable population, and novel approaches are necessary to improve engagement in care and adherence to ART after HIV infection. Psychosocial conditions can act as barriers to adherence, so interventions which reduce adverse psychosocial symptom severity could be especially promising approaches for improving ART adherence. In this analysis, we found that the *Shikamana* peer-and-provider intervention was associated with a 1.6 point per visit greater (95% CI: 0.2 – 3.1 points), reduction in depressive symptom severity compared to standard care over the six-month study period. Sensitivity analysis revealed that these changes did not occur quickly, but only were statistically significant over the whole six-month period. We also identified baseline HIV stigma as a potential predictor of response to the *Shikamana* intervention. Few studies, if any, have examined the impact of interventions on psychosocial factors among Kenyan GBMSM, but additional research into

psychosocial conditions in this population could be beneficial to improving HIV treatment outcomes and limiting onward transmission.

**TABLES AND FIGURES:**

Table 1. Baseline sociodemographic, HIV-related, and psychosocial factors in each arm.

| | Intervention (n = 27) | | Control (n = 33) | |
|---|---|---|---|---|
| | **Mean or n** | **SD or %** | **Mean or n** | **SD or %** |
| Age | 29.8 | 7.0 | 29.4 | 6.1 |
| Marital Status | | | | |
| Single | 25 | 93% | 28 | 85% |
| Married | 1 | 4% | 2 | 6% |
| Divorced, widowed | 1 | 4% | 3 | 9% |
| Education | | | | |
| Primary | 9 | 33% | 16 | 48% |
| Secondary | 15 | 56% | 14 | 42% |
| Tertiary or higher | 3 | 11% | 3 | 9% |
| Religion | | | | |
| Christian | 14 | 52% | 17 | 52% |
| Muslim | 7 | 26% | 10 | 30% |
| Other/none | 6 | 22% | 6 | 18% |
| Employment | | | | |
| None | 9 | 33% | 9 | 27% |
| Self-employed | 12 | 44% | 17 | 52% |
| Formally employed | 6 | 22% | 7 | 21% |
| Drinks any alcohol | 19 | 73% | 19 | 59% |
| Uses khat | 22 | 81% | 24 | 72% |
| Condom use (past week) | | | | |
| No sexual activity | 21 | 78% | 22 | 67% |
| All protected | 5 | 19% | 8 | 24% |
| Any condomless sex | 1 | 4% | 3 | 9% |
| Has sex with men exclusively | 8 | 30% | 7 | 21% |
| Sex work (ever) | 20 | 74% | 29 | 88% |
| Disclosed HIV status | 16 | 59% | 16 | 50% |
| Asset score | 3.0 | 1.5 | 2.9 | 1.5 |
| SES score | 2.9 | 1.3 | 2.7 | 1.4 |
| ART Experienced | 16 | 59% | 17 | 51% |
| CD4 count | 437 | 171 | 475 | 195 |
| Days since diagnosis (enrollment) | 995 | 1089 | 1481 | 1420 |
| Experienced any childhood abuse[1] | 19 | 90%[2] | 18 | 69%[2] |
| Victim of anti-MSM violence, past year | 20 | 74% | 20 | 65% |
| PHQ-9 | 10.9 | 5.8 | 8.2 | 6.2 |
| AUDIT | 5.0 | 5.1 | 5.6 | 8.2 |
| DAST | 3.3 | 2.7 | 3.3 | 2.5 |
| HIV Stigma | 28.9 | 4.5 | 28.3 | 5.8 |
| Sexual Stigma | 13.3 | 6.7 | 11.6 | 8.2 |

| | | | | |
|---|---|---|---|---|
| Social support | 63.1 | 27.7 | 65.5 | 22.7 |
| Resilience | 32.5 | 8.6 | 32 | 8.5 |

1. Data were missing from 12 participants: 6 intervention (22%), 6 control (18%)
2. Percentages of non-missing data

Table 2. GEE Summary, group-by-time interaction terms for each model: coefficient point estimate (95% CI).

| | Marginal | Post-intervention | Change from Baseline |
|---|---|---|---|
| Outcomes | | | |
| PHQ-9 | **-1.6 (-3.1 – -0.2)** | -1.7 (-4.7 – 1.4) | **-2.0 (-3.5 – -0.5)** |
| AUDIT | 0.4 (-1.0 – 1.8) | -0.1 (-2.7 – 2.4) | 0.4 (-1.1 – 1.9) |
| DAST | -0.2 (-0.7 – 0.3) | -0.4 ( -1.4 – 0.5) | -0.2 (-0.8 – 0.3) |
| Mediators | | | |
| HIV Stigma | 0.0 (-1.8 – 1.8) | -0.2 ( -2.7 – 2.3) | -0.1 (-2.0 – 1.7) |
| MSM Stigma | -0.1 (-1.8 – 1.5) | -0.6 (-2.8 – 1.7) | -0.1 (-1.7 – 1.6) |
| Social Support | -2.1 (-6.9 – 2.6) | -4.9 (-13.7 – 4.0) | -2.7 (-7.6 – 2.3) |
| Resilience | 0.0 (-1.8 – 1.7) | 1.1 (-1.6 – 3.7) | 0.2 (-1.6 – 2.0) |

Table 3. Segmented linear regression showing group-level results of the impact of allocation group on change PHQ-9 over time for each time segment: beta coefficient (95% CI)

| | Overall | Q1 | Q2 |
|---|---|---|---|
| PHQ-9 Slope | **-0.71 (-1.25 – -0.17)** | -0.82 (-1.90 – 0.26) | -0.69 (-1.84 – 0.47) |

Table 4. Exploratory analysis of the effect of baseline HIV stigma on monthly rates of change in PHQ-9 score among intervention participants only.

| | Change in PHQ-9 rate of change[1] | 95% CI |
|---|---|---|
| Unadjusted model | -0.11 | -0.21 – -0.01 |
| Adjusted model[2] | -0.12 | -0.23 – -0.02 |

1. For each one-unit difference in baseline HIV stigma
2. Adjusted for MSME status

Figure 1. Directed acyclic graph (DAG) depicting hypothesized associations with the *Shikamana* intervention, including outcomes (blue), potential mediators (green), and mediator-outcome confounders (gray).

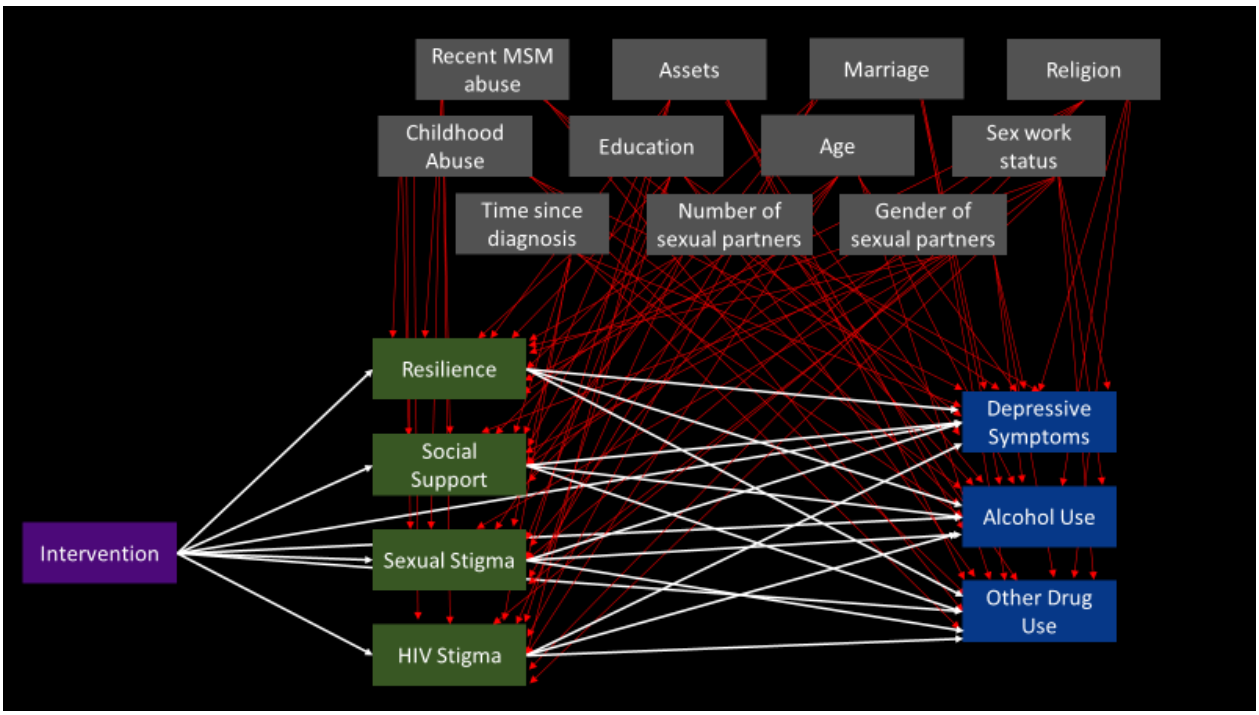


Figure 2. Individual participant trajectories in outcome measures with group mean lines derived from GEE overlaid. A. PHQ-9; B. AUDIT; C. DAST

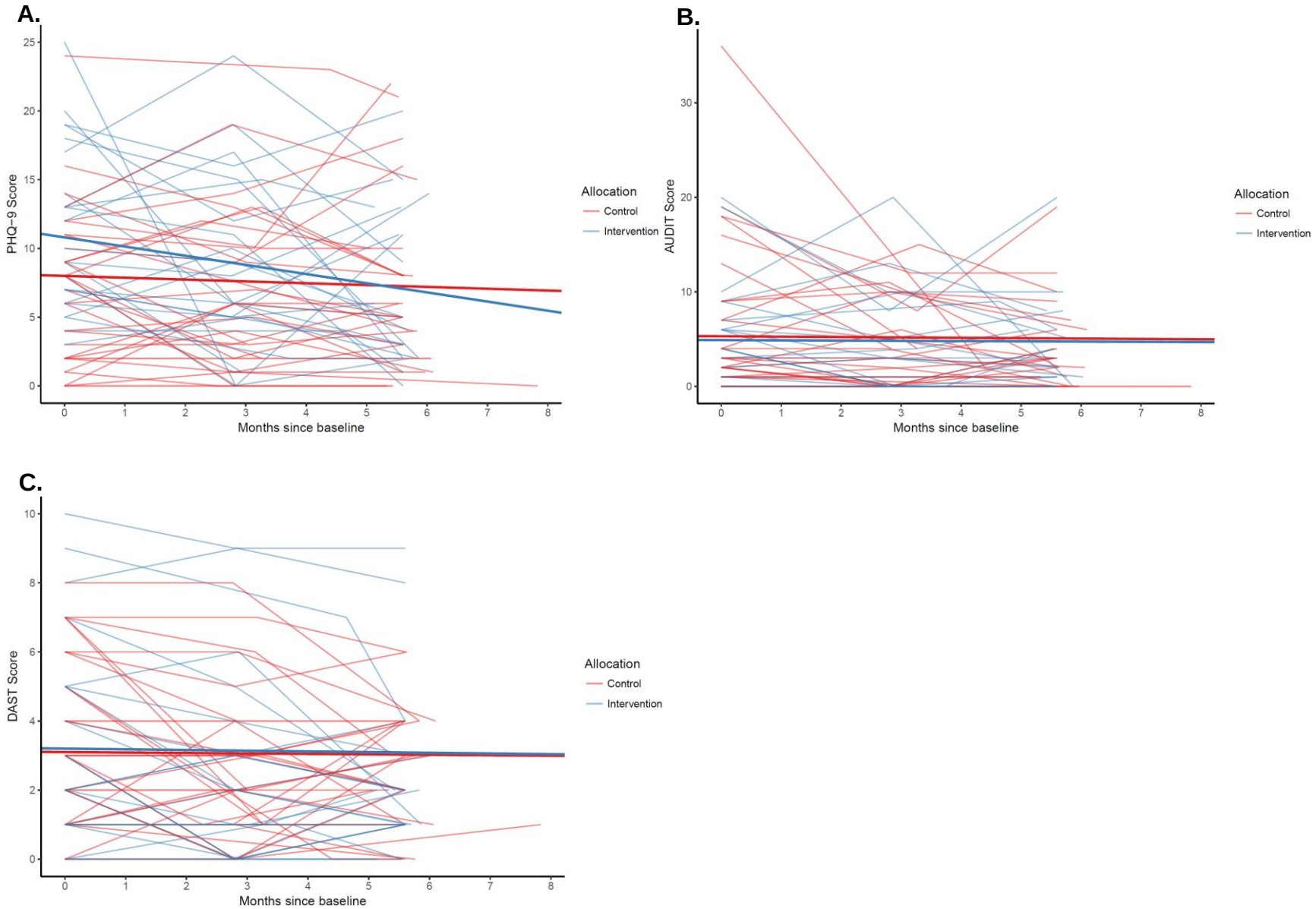
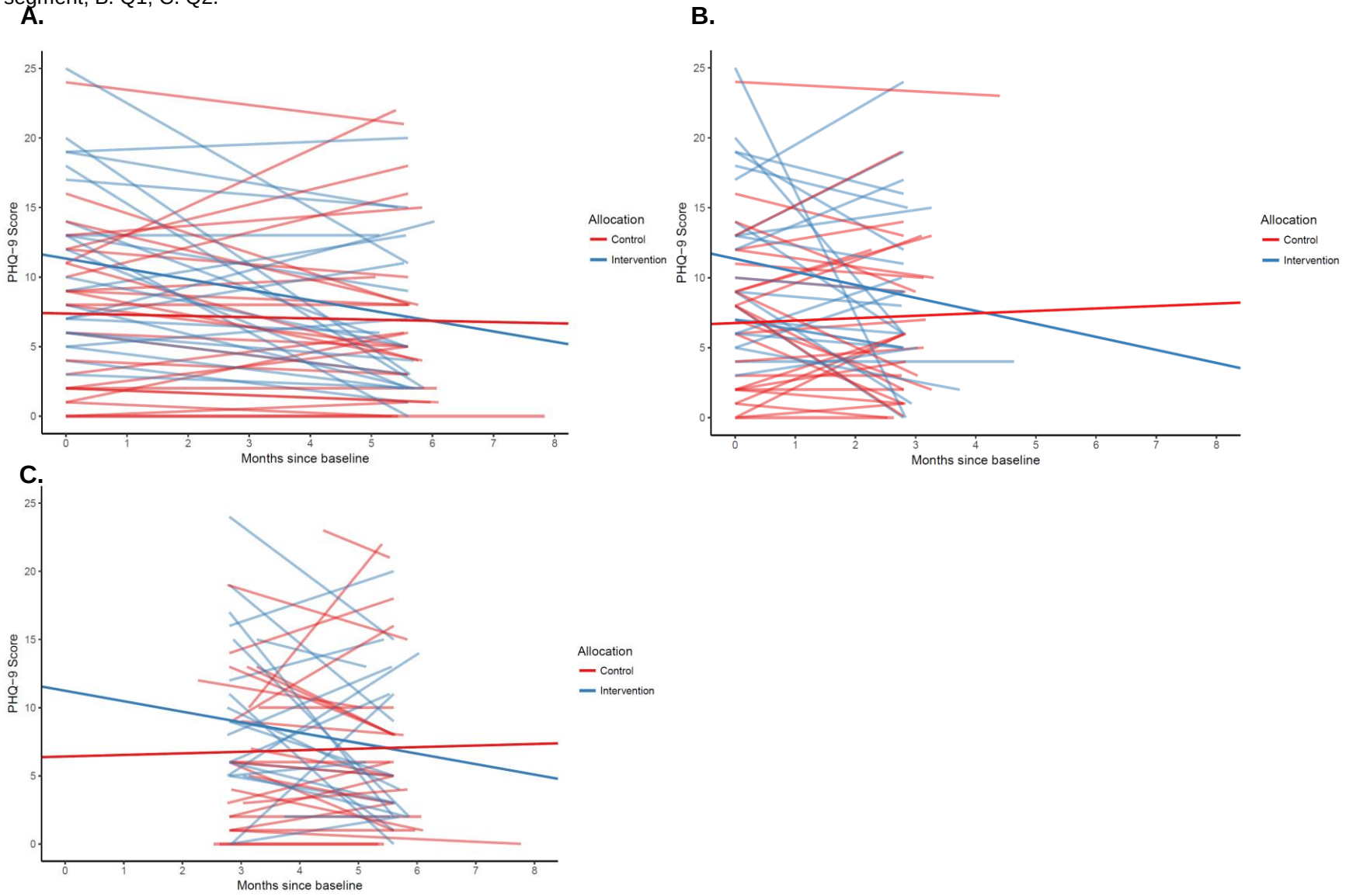


Figure 3. Individual-level linear regressions showing changes in PHQ-9 over each time segment, with group mean lines overlaid. A. Overall segment; B. Q1; C. Q2.



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