The Shikamana Intervention to Support ART Adherence and Care Engagement for Kenyan MSM

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Background

• **Shikamana** (Kiswahili for “to form a bond or stick together”) was developed to enlist HIV care providers and HIV-positive peers to support Kenyan MSM living with HIV
• A conceptual model to inform intervention development was based on qualitative interviews with HIV-positive MSM
• Focus group discussions with providers helped identify provider training needs and assess acceptability and feasibility of the approach
Conceptual Model

Figure 1. Situated IMB Model Used in the Shikamana Intervention

Sociocultural/Policy
- Stigma, criminalization, human rights, funding

Institutional/Community
- Service provision factors, MSM-friendly services, tailored information, community MSM stigma

Inter-personal
- Trust in providers, support from peers, friends, family, connection to MSM and other community groups

Intra-personal
- Personal knowledge, motivation, skills and cues, resilience, patient financial constraints, patient behavioral issues

Access
- Service provision factors, trust in providers, MSM-friendly services, tailored information, patient financial constraints, patient behavioral issues, community MSM stigma

Knowledge
- HIV knowledge, ART/adherence knowledge, cotrimoxazole knowledge, positive living

Skills and Cues
- Disclosure of HIV status, pill-taking skills, planning skills, problem-solving skills

Motivation
- Maintaining or recovering health, physical appearance, acceptance of HIV status, belief in ART, psychosocial support, mental health, substance abuse, self-efficacy to adhere, belief in alternative medicine, fear of gossip, side effects

Resilience
- Self-worth, social identity, connection to non-sexual minority group, disclosure of MSM status, connection to sexual minority group, homophobia management, external monitoring, goal-setting, altruism

Care Engagement
- Entry in Care
- ART Initiation
- ART Adherence
- Visit Adherence
- Retention in Care

Smith AIDS Patient Care STDs 2012, Graham Adherence 2014
Intervention Components

1. *Sensitivity training.* All *Shikamana* clinicians and counselors took a free on-line training course (www.marps-africa.org) on GBMSM sexual health.

2. *Patient-centered care.* This approach focuses on developing goals of care with the patient, to enhance patient motivation.

3. *Motivational Interviewing.* Next Step Counseling, used to promote PrEP adherence in iPrEx, was adapted to the Kenyan context.

4. *Peer support.* *Shikamana* peers, called “Washikaji,” were HIV-positive men with ART experience who were trained to provide support.

5. *Mental health screening and support.* Counselors and peers trained to recognize mental health problems and refer as needed.
Washikaji Training and Procedures

- Washikaji training based on the PAL intervention developed by Jane Simoni et al.
- Peers to provide information (education), encouragement (coaching), and empathy (basic counseling).
- ART-experienced men nominated by staff or local LGBT groups based on maturity and interpersonal skills.
- Washikaji and patients met at ART initiation and interacted by phone, SMS, WhatsApp or in person.
- Washikaji also met regularly (at least monthly) with care team to exchange information and reinforce training.
Modified Next Step Counseling

- Six steps for patient-centered adherence counseling, based on work by K. Rivet Amico et al
  1. INTRODUCE the counseling session
  2. REVIEW the patient’s experience and progress
  3. EXPLORE the patient’s context (facilitators and barriers) and motivation
  4. IDENTIFY the next step (WHAT)
  5. STRATEGIZE (HOW) and AGREE ON a plan
  6. RECORD the session

Graham AIDS 2015
Shikamana RCT

• Pilot work conducted with 10 participants to field-test and refine intervention delivery
• Randomized controlled trial enrolled 60 men assigned to the *Shikamana* intervention vs. standard care (informational counseling with no assigned peer) for 6 months of follow-up
  – To assess feasibility, acceptability, and safety, compared to standard care
  – To estimate effect size and determine sample size required for a larger trial of intervention efficacy
Trial Procedures

- Block randomization by ART status (experienced vs. naïve), with men selecting own envelope from relevant stack
- Monthly ART refills with adherence data collection by self-report measures and MEMS caps
- Quarterly blood draw for CD4 count and viral load testing
- Quarterly ACASI measures of IMB constructs, self-efficacy, trust in providers, social support, stigma, mental health
- Staff and peers (*Washikaji*) provided formal feedback at exit interviews
- Trial monitoring by KEMRI Trials Group, with audits of recorded counseling sessions to ensure fidelity of delivery
# RCT Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control (n=33) Median (IQR) or N (%)</th>
<th>Intervention (n=27) Median (IQR) or N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>29 (25-32)</td>
<td>27 (25-34)</td>
</tr>
<tr>
<td>Education (years)</td>
<td>10 (7-12)</td>
<td>12 (8-12)</td>
</tr>
<tr>
<td>Single</td>
<td>28 (84.8)</td>
<td>25 (92.6)</td>
</tr>
<tr>
<td>Self- or unemployed</td>
<td>26 (78.8)</td>
<td>21 (77.7)</td>
</tr>
<tr>
<td>Transactional sex</td>
<td>16 (48.5)</td>
<td>12 (44.4)</td>
</tr>
<tr>
<td>Male partners only</td>
<td>7 (21.2)</td>
<td>8 (29.6)</td>
</tr>
<tr>
<td>ART-experienced</td>
<td>17 (51.5)</td>
<td>16 (59.3)</td>
</tr>
<tr>
<td>Disclosure of HIV status</td>
<td>16 (48.5)</td>
<td>16 (59.3)</td>
</tr>
<tr>
<td>TDF/3TC/EFZ*</td>
<td>32 (97.0)</td>
<td>26 (96.3)</td>
</tr>
</tbody>
</table>

* Two participants were on ZDV/3TC/NVP
Feasibility, Acceptability, and Safety

- **Next Step Counseling**
  - Counselors came to prefer NSC over standard didactic counseling
  - Several ART-experienced participants noted a difference from standard counseling and a few participants mentioning specific “next steps” they had worked on

- **Washikaji Component**
  - Three intervention participants withdrew from the *Washikaji* component with no reported problems for participants or peers
  - For the 24 successful *Mshikaji*-peer pairings (89%), acceptability was high and feedback positive
  - Some *Washikaji* have continued to provide support after the study ended

- No related adverse events reported by participants or *Washikaji*
Initial Efficacy Results

- Retention (85% in both arms) and visit attendance (median 7 visits in both arms) did not differ
- Self-reported adherence by GEE across monthly refill visits, adjusting for intra-individual correlation

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<tr>
<th>Question</th>
<th>Beta (95% CI)</th>
<th>P value</th>
</tr>
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<tbody>
<tr>
<td>Since your last visit, how well did you take your ART? (0-6 scale)</td>
<td>0.39 (0.14 to 0.64)</td>
<td>0.002</td>
</tr>
<tr>
<td>Since your last visit, how often did you take your ART as prescribed? (0-6 scale)</td>
<td>0.42 (0.18 to 0.67)</td>
<td>0.001</td>
</tr>
<tr>
<td>Visual analog scale (0-100 scale)</td>
<td>2.20 (-2.88 to 7.28)</td>
<td>0.395</td>
</tr>
</tbody>
</table>
MEMS

- MEMS data on 59/60 participants (98.3%)
- Of 375 refill visits, MEMS collected on 290 (77.3%)
  - MEMS bottle forgotten, lost, misplaced
- Pills remaining at visit: median 3, range 0-31
- Rough estimate MEMS coverage:
  - Median 78.3 control vs. 73.2 intervention, p=0.244
- Times opened but did not take: median 0, range 0-15
- Times took out >1 pill: median 0, range 0-15
  - Removed 1-25 tablets typically, with up to 45 pills removed
- At least 6 men received refills from outside the study
In GEE analysis with adjustment for baseline suppression (<40 copies/mL), men in the intervention group had an increased odds of virologic suppression at months 3 and 6 (aOR, 5.7, 95% CI 1.1-30.7, p=0.04), as did men with virologic suppression at baseline (aOR 23.0, 95% CI 2.7-196.7, p=0.004).
Conclusions

• The *Shikamana* intervention appears to be safe, acceptable, and feasible
• MEMS data capture was complicated in this population
• Results suggest that *Shikamana* may increase ART adherence among Kenyan GBMSM
• A larger trial to evaluate efficacy is needed
• A combined provider and peer support approach may also improve PrEP adherence in this population
Acknowledgments

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