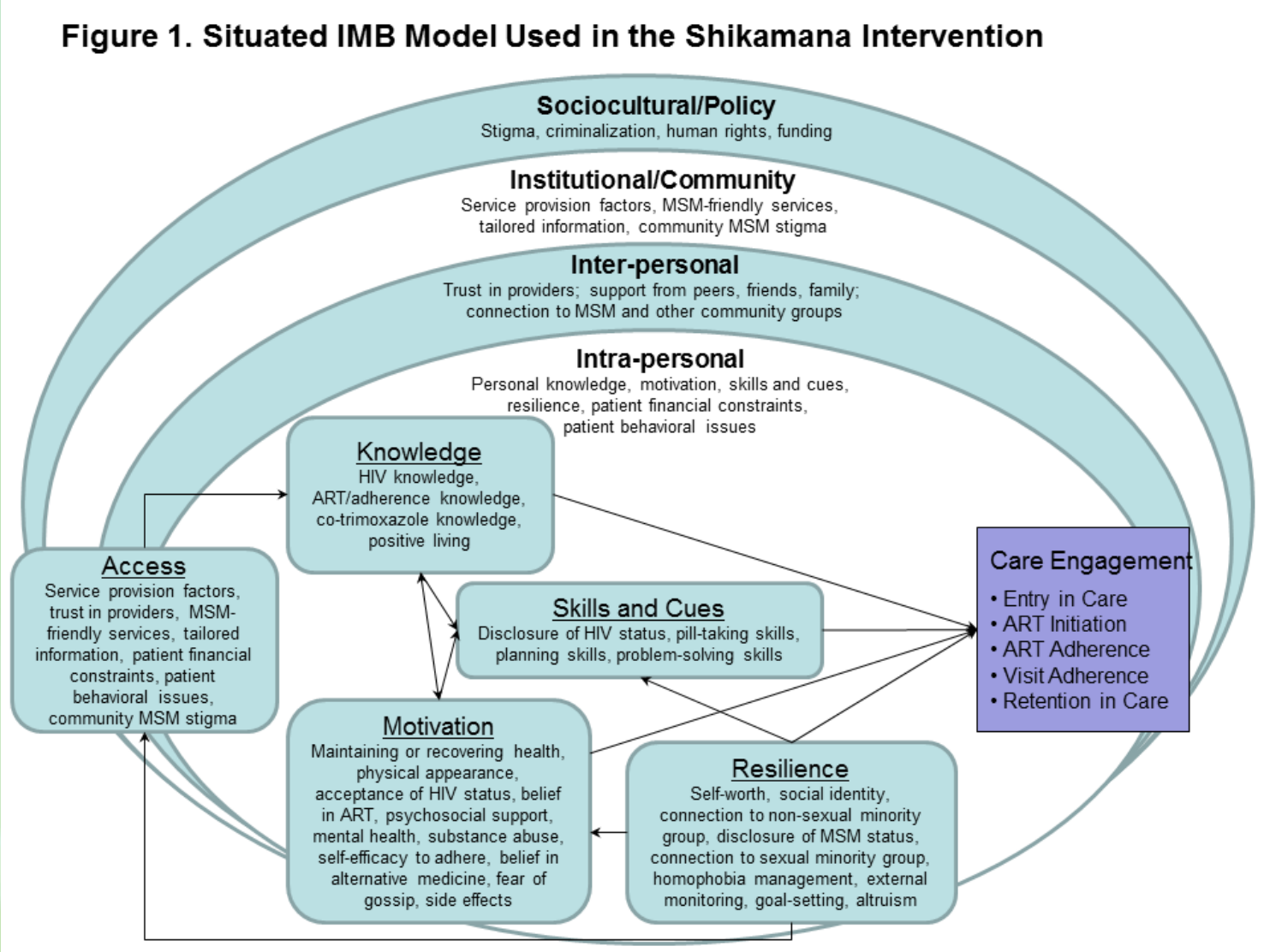
The *Shikamana* Intervention to Support ART Adherence and Care Engagement for Kenyan MSM

Susan M. Graham, MD MPH PhD
University of Washington

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



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.

Graham *AIDS* 2015

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.

Graham *AIDS* 2015

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

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

* 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

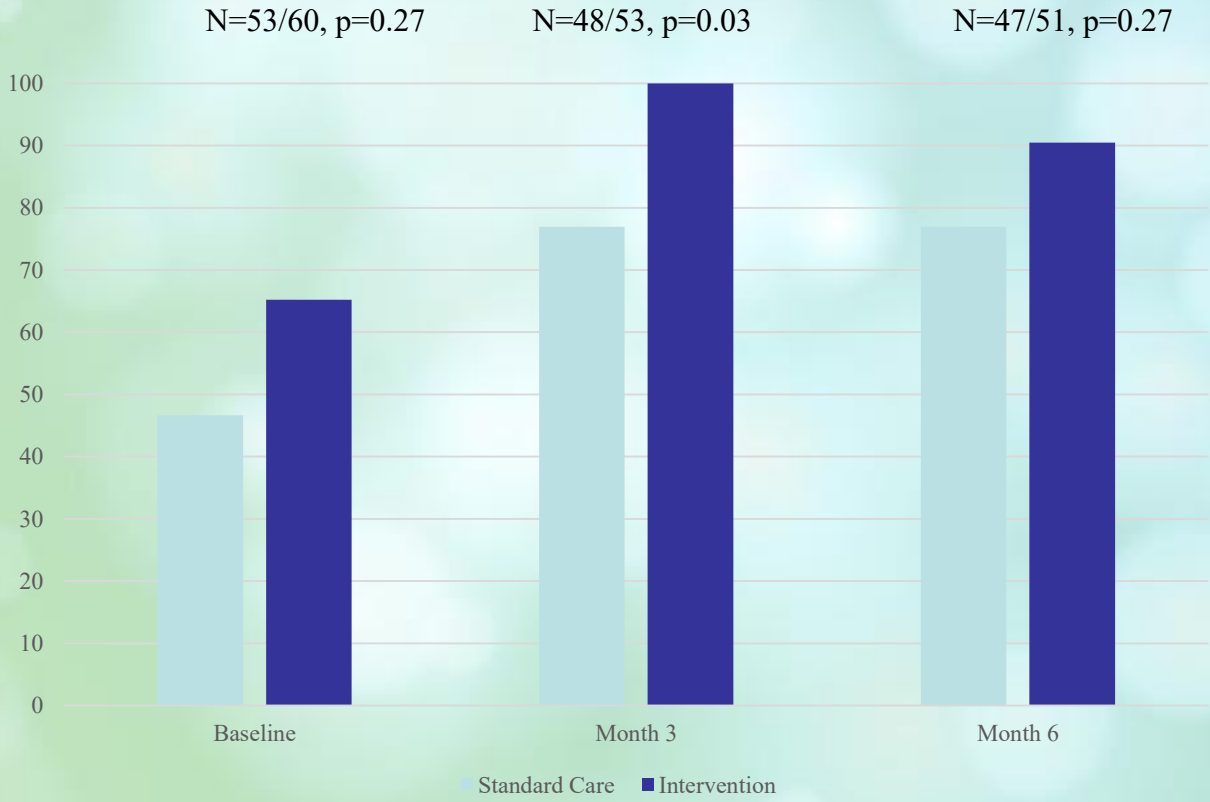
- Retention (85% in both arms) and visit attendance (median 7 visits in both arms) did not differ
- Self-reported adherence by GEE across monthly refill visits, adjusting for intra-individual correlation

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

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

Virologic Suppression by Study Arm



- 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

#ADHERENCE2017

Acknowledgments

- Participants in the qualitative work, pilot study, and RCT
- Our seven dedicated and hard-working *Washikaji*

- The National Institutes of Mental Health and Michael Stirratt for funding (R34MH099946)
- Collaborators: Jane Simoni, Rivet Amico, Ed Sanders, Don Operario, Elise van der Elst, Murugi Micheni, Andrew Secor, Peter Mugo, Jennifer Kanungi, Bernadette Kombo, Norbert Peshu, Anisa Omar, and all clinicians and counselors who participated