A Stepped Care, Peer-Delivered Intervention to Improve ART Adherence and SUD in Primary Care

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• 1/3 of people with HIV in SA have unhealthy alcohol or substance use
• Unhealthy use is associated with worse HIV treatment adherence
• Treatment of substance use is large provided outside of HIV care
Goal of Project Khanya

*Improve the health and HIV outcomes among people with HIV and substance use*

- Increase access to evidence-based interventions for HIV medication adherence and substance use
- Understand how to integrate substance use interventions into HIV care
Patient Focused

Phase 1: Formative Work
Key findings: Preference for a Peer, Stigma a Barrier

- First step was to get feedback from patients, providers, other stakeholders (N=30)
  - Three main findings:
    - Overwhelming preference for a peer interventionist
    - Role of community health workers (CHWs) in detecting substance use
    - Lack of awareness of co-located SU treatment program
Patient Focused

Phase 2: Adaptation
Adapted evidence-based intervention components based on formative work: “Khanya”

Formative work

Adaptation of “Khanya”

Khanya Pilot

Khanya R01
Phase 3: Khanya Pilot Trial
Feasible, acceptable, and effective for improving HIV medication adherence and alcohol use among patients who use drugs

Project Khanya: results from a pilot randomized type 1 hybrid effectiveness-implementation trial of a peer-delivered behavioural intervention for ART adherence and substance use in HIV care in South Africa

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ClinicalTrials.gov identifier: NCT03529409, Trial registered on May 18, 2018.
**Khanya Pilot trial**

*Feasible, acceptable, and effective for improving HIV medication adherence and alcohol use among patients who use drugs*

**Key findings**

- Khanya was **highly feasible, acceptable, and delivered with >90% fidelity by peer**
- Significant increases in ART adherence in Khanya vs. ETAU
- Significant reductions in alcohol use in sample who used other drugs vs. ETAU (n=21)
- Significant increases in employment in Khanya vs. ETAU at 6-months (**61% vs. 34%**)

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"Now, I have a picture of a house that is tumbling down or it has been demolished. That's how my life was. And then when I came to Khanya it's like ... this house [has] been built from foundation up. And that is my experience from the therapy."

– 36 year old, male
A stepped care, peer-delivered intervention to improve ART adherence and SUD in primary care

- Aim 1: Effectiveness outcomes over 12 months
- Aim 2: Implementation outcomes
- Aim 3: Cost of implementation and sustainability

Recruit from 4 clinics in Khayelitsha → co-located SUD treatment program

Eligibility: ≥18 years; HIV positive and on ART; at least moderate SUD; risk of virological failure (re-engaging in care after ≥ 1 month of being out of care; ≥ 1 episode of VL >400 copies/mL; on 2nd or 3rd line ART

- n=80 – Project Khanya (Referral to Matrix + Life-steps)
  ‘Stepped-up’ to full Khanya intervention when showing continues adherence difficulties

- n=160
- n=80 – Enhanced Standard of care (ESOC) (Referral to Matrix)
Step 1: Life-Steps
- Strategies for taking ART while using substances
- Minimize harms from SU that interfere with HIV care
- Based on CBT and more specific principles of problem solving therapy

Step 2 Full Khanya Intervention
- Second dose of Life-Steps
- 5 additional sessions based on: behavioural activation; problem solving; mindfulness; relapse prevention
- 6 Optional booster sessions

Stepped-care approach
Continues adherence challenges – missing ≥3 doses of ART in continuous 2 weeks

Khanya Intervention

Reduced Substance Use
Increased ART Adherence
Viral suppression
R01: Project Khanya

Session 1: Life Steps for Adherence
Goals for adherence; Barriers to adherence; Plan for overcoming barriers

Session 2: Behavioural Activation for Substance Use
Setting healthy goals for alcohol/drug use; Overview of behavioural activation; Behavioural monitoring

Session 3: Behavioural Activation for Substance Use
Review behavioural activation, Life areas and Values Exercise; Activity scheduling (positive events)

Session 4: Mindfulness-based relapse prevention
Introduction to mindfulness; Mindfulness in daily life; Recognising urges/cravings

Session 5: Relapse prevention
Identifying high-risk situations; Identifying skills to respond to high-risk situations

Session 6: Relapse prevention
Maintaining gains/relapse prevention; Review skills from intervention; Plan for continued practise
Timeline

Enrolment → Baseline → Khanya Step 1 → Randomise (2w post-baseline) → 1MFU → Khanya Step 2 → 3MFU → Optional booster sessions → 6MFU → 12MFU
Outcomes

HIV Medication Adherence

**Wisepill** - Real-time, wireless, electronic adherence monitoring device used to assess ART adherence

**Dried Blood Spots (DBS)** – Confirm that at least some recent ART is present in the system

Substance use

**Biological measure** of substance use - (Urinalysis & PEth test)

**WHO-ASSIST** – Screens for Alcohol, Smoking, and Substance involvement

Reach and Uptake

**Attendance and retention of participants** – Session attendance and drop-out rates

**Semi-structured interviews** – 30 qualitative interviews to assess perceptions, barriers and facilitators to uptake

Implementation Fidelity

**Rating checklist** – to assess peer interventionist adherence to treatment components

Cost effectiveness

**Drug abuse Treatment Cost Analysis Program (DATCAP)** – tool to capture intervention resources in multiple settings for the purpose of estimating costs
THANK YOU!