STREAM (SIMPLIFYING HIV TREATMENT AND MONITORING)

Evidence-Based Structural Intervention Evidence-Based for Engagement in HIV Care Evidence-Based for Viral Suppression

INTERVENTION DESCRIPTION

Goals of Intervention

- Improve engagement in HIV care
- Improve viral suppression

Intended Population

• Adults with HIV on antiretroviral therapy (ART)

Brief Description

The STREAM (Simplifying HIV TREAtment and Monitoring) intervention focuses on point-of-care HIV viral load testing with same-day counseling and same-day delivery of test results, and task shifting to improve engagement in HIV care and viral suppression. Adults with HIV receive their point-of-care HIV viral load test at the beginning of their clinic visit and receive their test results on the same day. Participants who are virally suppressed and have no comorbidities are seen by an enrolled nurse (equivalent to a registered nurse in the U.S.) instead of a professional nurse (equivalent to a nurse practitioner in the U.S.). The enrolled nurse is trained to conduct all HIV-related tasks (e.g., taking vital signs and assessing adherence) that were previously conducted by a professional nurse. If the enrolled nurse detects clinical symptoms or abnormal vital signs, the participant is referred to a professional nurse for additional comprehensive care.

Theoretical Basis

None reported

Intervention Duration

• 12 months

Intervention Setting(s)

- Clinical research site
- Public health clinic within the community

Deliverers

- Trained enrolled nurse (equivalent to a registered nurse in the U.S.)
- Trained professional nurse (equivalent to a nurse practitioner in the U.S.), as needed

Delivery Methods

- Enhanced adherence counseling
- · Point-of-care viral load testing
- Task shifting
- Training of nurses

Structural Components

- Access HIV Health Care
 - Provided point-of-care viral load testing with same-day counseling and same-day delivery of test results
- Capacity building Provider/Supervisor training
 - Trained enrolled nurses to conduct additional HIV care-related tasks (e.g., vital signs, adherence assessment), using the standard South African Nurse Initiated and Managed ART training
- Policy/Procedure Institutional Policy /Procedure
 - o Implemented point-of-care viral load testing with same-day counseling and same-day results, and shifted HIV care-related tasks to trained enrolled nurses

INTERVENTION PACKAGE INFORMATION

An intervention package is not available at this time. Please contact **Paul K. Drain**, Department of Global Health, University of Washington, 3980 15th Ave., NE, Seattle, WA 98195.

Email: pkdrain@uw.edu for details on intervention materials.

EVALUATION STUDY AND RESULTS

Study Location Information

The original evaluation study was conducted in Durban, South Africa between 2017 and 2018.

Key Intervention Effects

- Increased viral suppression
- Increased engagement in HIV care

Recruitment Settings

Public health clinic within the community

Eligibility Criteria

Adults with HIV were eligible if they were 18 years or older and presenting for the first routine HIV viral load test 6 months after ART initiation. Adults with HIV were excluded if they were pregnant or had active tuberculosis at baseline, or if they required acute medical care by a physician.

Study Sample

The baseline study sample of 390 adults with HIV is characterized by the following:

Intervention (n = 195)

- 61% female, 39% male
- 99% Black, 1% other
- Median age of 31 years, interquartile range (IQR): 27-38
- Highest level of education: 5% none or primary school, 46% Did not pass secondary school, 33% passed secondary school, 16% tertiary education

• 92% viral load <200 copies per mL at enrollment

Standard of care (n = 195)

- 60% female, 40% male
- 99% Black, 1% other
- Median age of 32 years, interquartile range (IQR): 27-38
- Highest level of education: 9% none or primary school, 39% did not pass secondary school, 35% passed secondary school, 17% tertiary education
- 94% viral load <200 copies per mL at enrollment

Assignment Method

Adults with HIV (N = 390) were randomized to 1 of 2 study arms: STREAM intervention (n = 195) or a standard of care comparison (n = 195).

Comparison

The standard of care comparison participants were seen by a professional nurse, who also received the standard South African Nurse Initiated and Managed ART training and received laboratory-based viral load test that was sent to the National Health Laboratory Service for processing. Participants received their viral load results at their next clinical visit, which was scheduled at the clinician's discretion, approximately after 4 weeks (28 days) or 8 weeks (56 days).

Relevant Outcomes Measured

- The following outcomes were measured together as a composite outcome and as individual outcomes:
 - Engagement in HIV care (operationalized in the manuscript as retention in care) was defined as collecting ART at the study clinic or at a public health clinic within the community at 12 months postenrollment (e.g., between 44 weeks and 56 weeks post-enrollment).
 - o Viral load was measured 12 months post-enrollment as <50 copies per mL, <200 copies per mL, and <100 copies per mL, with viral suppression defined as <200 copies per mL.

Participant Retention

Because participant retention is not a criterion for the Structural Interventions chapter, the Prevention Research Synthesis project does not evaluate that information.

Significant Findings on Relevant Outcomes

- At 12 months post-enrollment, a significantly greater percentage of STREAM intervention participants than standard of care participants were:
 - $_{\odot}$ Engaged in HIV care at the study clinic and virally suppressed (90% vs. 76%; Absolute risk difference (ARD) = 13.9%; 95% CI: 6.4 21.2; p = 0.0004).
 - Virally suppressed (93% vs. 83%; ARD = 10.3%; 95% CI: 3.9 16.8; p = 0.0025).
 - Engaged in HIV care at the study clinic (92% vs. 85%; ARD = 7.7%; 95% CI: 1.3 14.2; p = 0.026).
 - o Engaged in HIV care at a public health clinic within the community and virally suppressed (91% vs. 79%; Absolute risk difference = 12.3%; 95% Confidence Interval: 5.2 19.4; p = 0.0011).

Considerations

Additional significant positive findings on non-relevant outcomes

• At 12 months post-enrollment, a significantly greater percentage of STREAM intervention participants than standard of care participants were:

- \circ Engaged in HIV care at the study clinic and had a viral load < 1000 copies per mL (90% vs. 78%; ARD=12.3%; 95% CI: 5.1 19.5; p = 0.0013).
- \circ Engaged in HIV care at the study clinic and had a viral load < 50 copies per mL (86% vs. 71%%; ARD = 14.4%; 95% CI: 6.2 22.3; p = 0.0080).
- At 12 months post-enrollment, a significantly greater percentage of STREAM intervention participants than standard of care participants had a viral load < 1000 copies per mL (94% vs. 85%; ARD = 9.2%; 95% CI: 3.2 15.4; p = 0.0041).
 - \circ There was also a significant intervention effect on viral load of < 50 copies per mL (88% vs. 78%; ARD = 10.3%; 95% CI: 2.8 17.6; p = 0.0099).

Non-significant findings on relevant outcomes

- There were no significant intervention effects at 12 months post-enrollment for engagement in HIV care at either the study clinic or a public health clinic within the community (93% vs. 87%; ARD = 6.2%; 95% CI: 0.2 12.2; p = 0.059)
- There were no significant intervention effects for viral suppression at 12 months post enrollment (96% vs. 91%; ARD = 5.3%; 95% CI: 0.2 10.7; p = 0.051)

Negative findings

· None reported

Other related findings

- This intervention is also determined to be evidence-based for the Linkage to, Retention in, and Re-Engagement in HIV Care (LRC) Chapter.
- There are significant intervention effects for communication of the viral load result to the participant for all viral load results (overall viral load results, and at enrollment and 6 months post-enrollment). There are also significant intervention effects for the following:
 - o Referral into a community-based ART delivery program,
 - o Time to entry of viral load results into the health information system (overall blood draws, and at enrollment and 6 months post-enrollment),
 - Time to communication of viral load result to the participant (overall blood draws, and at enrollment and 6 months post-enrollment),
 - o Appropriate switch to second-line ART after viral failure, and
 - o Time from enrollment to referral into a community-based ART delivery program.

Implementation research-related findings

None reported

Process/study execution findings

• Acceptability – In focus groups and interviews, both participants and health care workers reported that the point-of-care testing and task shifting was acceptable.

Adverse events

• There were no adverse events related to point-of-care viral load testing and task shifting, as reported by the authors

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REFERENCES AND CONTACT INFORMATION

Drain, P. K., Dorward, J., Violette, L. R., Quame-Amaglo, J., Thomas, K. K., Samsunder, N., Ngobese, H., Mlisana, K., Moodley, P., Donnell, D., Barnabas, R. V., Naidoo, K., Abdool Karim, S. S., Celum, C., & Garrett, N. (2020). <u>Point-of-care HIV viral load testing combined with task shifting to improve treatment outcomes (STREAM):</u>
Findings from an open-label, non-inferiority, randomised controlled trial. *Lancet HIV*, 7(4), e229–e237.

Dorward, J., Garrett, N., Quame-Amaglo, J., Samsunder, N., Ngobese, H., Ngomane, N., Moodley, P., Mlisana, K., Schaafsma, T., Donnell, D., Barnabas, R., Naidoo, K., Abdool Karim, S., Celum, C., & Drain, P. K. (2017).

Protocol for a randomised controlled implementation trial of point-of-care viral load testing and task shifting:
The Simplifying HIV TREAtment and Monitoring (STREAM) study. *BMJ Open*, 7(9), 1-8.

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