Study Title: Peer-led HIV care and the UNAIDS 90-90-90 treatment targets in Sidama Ethiopia: A cluster randomized trial and economic evaluation of Teach-Test- Link-Trace model (TTLT) trial

Short title: TTLT

Phase of the trial: Procedure

CTA Number: ET-CT-0045

Protocol No.:

Version No.:

National Principal Investigator (NPI): Dr. Hailay Abrahm Gesesaw

Trial Site: Sidama region, Ethiopia

Sponsor: Torrens University Australia

Ethics Approval date: January 2, 2025

Submission Date to EFDA: July 3, 2024

EFDA Status of trial (Approval or Rejection): Approved **Date:** February 7, 2025

Study Rationale

This study aims to test a new and comprehensive intervention program, never been implemented in Ethiopia before, called the teach-test-link-trace (TTLT) model. The TTLT model involves HIV positive volunteer patients (peer educators) who do HIV counselling (teach), perform HIV testing (test) through HIV self-testing (HIVST) and house-to-house HIV testing (H2H), link HIV positive patients to HIV care (link) and trace lost patients house-to-house (trace).

General objective / Study aims

Primary endpoint.

- Acceptability of trial
- Proportion of individuals who will know their HIV status (UNAIDS first 90)
- Proportion of individuals who will be linked to HIV care (UNAIDS second 90)
- Proportion of individuals who will know their HIV status (UNAIDS third 90)
- Proportion of individuals who will achieve virological suppression (UNAIDS third 90)
- Suitability of the trial
- Feasibility of trial

Primary objectives

Objective

(i) To determine the proportion of individuals who will know their HIV status (UNAIDS 1st 90.

(ii) To determine the proportion of individuals who will be linked to HIV care (UNAIDS 2nd 90.

(iii) To determine the proportion of individuals who will achieve virological suppression (UNAIDS 3rd 90).

Outcome measures

(i) Proportion of individuals who will know their HIV status (UNAIDS 1st 90)- this will be measured using community based cross-sectional survey at enrollment of the trial through HIVST and H2H.

(ii) Proportion of individuals who will be linked to HIV care (UNAIDS 2nd 90)- this will be measured at 0 month (enrollment at ART) through extracting their linkage of care from clinical registry (prospective cohort).

(iii) Proportion of individuals who will achieve virological suppression (UNAIDS 3rd 90)- this will be measured at 6 months through extracting viral counts from clinical registry (prospective cohort).

Secondary Objectives and Outcome Measures

Objective
(i) To measure Health related quality of life (HRQoL)
(ii) To measure HIV related stigma
. (iii) To measure Adherence to ART

Outcome measures

(i) Health related quality of life (HRQoL)- this will be measured through facility based cross-sectional survey using the 31 items WHO-QoL-BREF Tigrigna version17 at 3 and 6 months after ART initiation.

(ii) HIV related stigma- this will be measured through facility based cross-sectional survey using 12 items HIV related stigma scale18 translated to Tigrigna at 3 and 6 months after ART initiation and qualitative interviews.

(iii) Adherence to ART- this will be measured through facility based cross-sectional survey using 8 items Morisky scale19 translated to Tigrigna at 3 and 6 months after ART initiation.

Study Design

The TTLT model trial uses a 4-arm parallel cluster-randomized controlled design (CRT) including three intervention groups and a control group.

Study Population

Individuals age 18 years and above irrespective of their HIV status.

Eligibility Criteria

Inclusion Criteria:

Individuals age 18 years and above irrespective of their HIV status.

Exclusion criteria:

(i) Who do not want to disclose their HIV status during the HIV counseling and testing process, (ii) who are not fit to conduct home-to-home visit, (iii) who are not willing to participate in the trial.

Study Duration

5 year

Investigational Medicinal Product

NA

Intervention (s)

Formulation : NA Dose :NA Route of administration : NA Other interventions: NA

Sample size

In total, 40 villages (clusters) will be recruited using simple random sampling, of which 10 clusters each will be randomly assigned to one of the four study groups. The total sample size would be 6909 households. The expected sample size for outcomes second UNAIDS 90 (linkage), third UNAIDS 90 (Virological suppression), QoL and HIV-related stigma is 166.

Evaluator's Risk/Benefit Assessment:

Given that Ethiopia remains distant from achieving UNAIDS' 90-90-90 targets, this trial is critically important. It will generate evidence to inform and drive innovative service delivery models, ultimately accelerating progress toward these public health goals.