ISRCTN31351715 https://doi.org/10.1186/ISRCTN31351715

# Acceptability of treatment as prevention messages in Malawi

**Submission date**
27/07/2022

**Recruitment status**
No longer recruiting

**Registration date**
15/03/2024

**Overall study status**
Completed

**Last Edited**
08/11/2024

**Condition category**
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

## Plain English summary of protocol

Background and study aims
The “U=U” (Undetectable=Untransmittable) concept is a message that a person living with HIV who is undetectable and on anti retroviral therapy (ART) cannot transmit the virus through sexual contact. The message is globally endorsed. However, most people living with HIV are not aware of the ‘U=U’ message and are receiving outdated information on transmission risk. There is a gap in evidence on the availability of “U=U” communication materials in Malawi and information on how HIV serodiscordant (one person is HIV-positive and the other is HIV-negative) couples who are expecting a baby can manage their HIV status to minimise the probability of transmitting HIV virus to the partner or the infant. This gap needs to be filled to enable policy makers and implementers in Malawi to make informed choices on how “U=U” communication material can be integrated within the ANC care and HIV programme in Malawi. The broad aim is to develop contextually relevant TasP messaging materials that emphasise “U=U” information targeting HIV discordant couples. The specific objectives are to:
1. To explore the understanding of TasP and “U=U” among HIV-discordant couples and recipients of ART care.
2. To develop culturally relevant communication materials that optimise user comprehension of “U=U” concepts targeting HIV sero-discordant heterosexual couples.
3. To test the acceptability of the developed “U=U” messages targeting HIV discordant couples.

Who can participate?
Females aged 18 years or above, attending antenatal care services, who are HIV positive, and their male partners.

What does the study involve?
This research will employ a mixed-methods approach combining qualitative and quantitative approaches to develop and pilot “Undetectable = Untransmittable” in short “U=U” communication materials that could be delivered through ANC clinics in Blantyre, Malawi.

What are the possible benefits and risks of participating?
The study will develop 'U=U' materials and test these on their acceptability and outcomes. The study will therefore provide participants the opportunity to express how they feel about “U=U” communication messages. Their views will enable policy makers and implementers in Malawi to

make informed choices on how “U=U” communication material can be integrated within the ANC care and HIV programme in Malawi.

Where is the study run from?
College of Medicine Helse Nord Tuberculosis Initiative (Malawi)

When is the study starting and how long is it expected to run for?
March 2021 to July 2024

Who is funding the study?
European and Developing Countries Clinical Trials Partnership

Who is the main contact?
Dr Moses Kumwenda, kumwenda@gmail.com

# Contact information

### Type(s)
Principal investigator

### Contact name
Dr Moses Kumwenda

### ORCID ID
https://orcid.org/0000-0003-3091-7330

### Contact details
Helse Nord TB Initiative
Kamuzu University of Health Sciences
Mahatma Gandhi Road
Blantyre
Malawi
-
+265 999981677
mkumwenda@kuhes.ac.mw

# Additional identifiers

### Protocol serial number
P.04/21/3300

# Study information

### Scientific Title
Developing “U=U” communication messages targeting HIV discordant couples in Malawi: Establishing evidence on feasibility and acceptability

### Acronym
ACCEPTU2U

## Study objectives
Undetectable=Untransmittable messages can be made understandable in low education settings where people do not understand pathogen 'germ theory'

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 20/07/2022, College of Medicine Research Ethics Committee (Kamuzu University of Health Sciences, Private Bag 360, Chichiri, Blantyre, -, Malawi; +265 1871911 ext. 334; comrec@medcol.mw), ref: P.04/21/3300

## Study design
Qualitative and quantitative mixed-methods study

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Prevention of HIV transmission in HIV-mixed status relationships through the provision of undetectable = untransmittable information

## Interventions
As well as the care provided in the control arm, those in the intervention arm (n=25) will receive the "U=U" information via SMS and other pictorial, video, audio and written materials about the role of ART in preventing HIV transmission. They will also be invited with their male partner to attend 2 sessions spaced 3 months apart on "U=U", men's engagement in HIV care delivered and provision of treatment adherence support to couples for the initial 6-month period to attain viral suppression. Considering the commitments that men usually have to provide for their families, the proposed 2 sessions will be acceptable to most men. These sessions and couples support will be facilitated and provided by a trained and supervised HIV Diagnostic Assistant. The intervention will be delivered by an HIV Diagnostic Assistant specifically trained in the intervention, not providing routine care during the pilot to minimise contamination.

Quantitative study participants will be randomised to intervention and control arms using randomly generated numbers.

The qualitative study will purposively recruit the participants to participate in the optimisation process of the developed materials to ensure co-production of the materials with study participants.

## Intervention Type
Behavioural

## Primary outcome(s)

1. Proportion of male partners of HIV-Positive ANC attendees who test for HIV within 28 days measured using self-report
2. Proportion of male partners testing for HIV within 28 days of receipt of “U=U” communication materials by the woman measured using self-report

### Key secondary outcome(s))
1. Proportion of male partners who accept to participate in U=U sessions measured through attendance to sessions at 28 days - project records
2. Proportion of male partners reporting HIV prevention approaches measured at 28 days using project records
3. Number of HIV-related intimate partner violence or gender-based violence measured using self-report at 28 days

### Completion date
04/07/2024

## Eligibility

### Key inclusion criteria
1. Antenatal care attendees in the second trimester
2. PLHIV (known or newly diagnosed)
3. 18 years or older
4. Primary male partner of unknown HIV status (last negative test >3 months/not known to be on ART) intending to remain in Blantyre for 6 months

### Participant type(s)
Mixed

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
All

### Total final enrolment
106

### Key exclusion criteria
1. Unwilling or unable to provide informed consent;
2. Requires urgent medical attention or has severe mental health problems e.g. actively suicidal

### Date of first enrolment
14/05/2024

**Date of final enrolment**
06/06/2024

# Locations

**Countries of recruitment**
Malawi

**Study participating centre**
**Bangwe, Mpemba, Limbe and Madziabango Health Centres**
Blantyre
Malawi
-

# Sponsor information

**Organisation**
Kamuzu University of Health Sciences

# Funder(s)

**Funder type**
Government

**Funder Name**
European and Developing Countries Clinical Trials Partnership

**Alternative Name(s)**
The European & Developing Countries Clinical Trials Partnership, The European & Developing Countries Clinical Trials Partnership (EDCTP), European and Developing Countries Clinical Trials, Le partenariat Europe-Pays en développement pour les essais cliniques, A Parceria entre a Europa e os Países em Desenvolvimento para a Realização de Ensaios Clínicos, EDCTP

**Funding Body Type**
Private sector organisation

**Funding Body Subtype**
International organizations

**Location**
Netherlands

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the subsequent results publication

### IPD sharing plan summary
Published as a supplement to the results publication