

Acceptability of treatment as prevention messages in Malawi

Submission date 27/07/2022	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 15/03/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 08/11/2024	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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 However, most people living with HIV are not aware of the ‘U=U’ message and are receiving outdated information on transmission risk.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

<http://orcid.org/0000-0003-3091-7330>

Contact details

Helse Nord TB Initiative

Kamuzu University of Health Sciences

Mahatma Gandhi Road

Blantyre

Malawi

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+265 999981677

mkumwenda@kuhes.ac.mw

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Hospital

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

250

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

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Sponsor information

Organisation

Kamuzu University of Health Sciences

Sponsor details

Private Bag 360, Chichiri Blantyre 3

Blantyre

Malawi

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+265 1810 911

vc@kuhes.ac.mw

Sponsor type

University/education

Website

<https://www.medcol.mw/about-com/>

Funder(s)

Funder type

Government

Funder Name

European and Developing Countries Clinical Trials Partnership

Alternative Name(s)

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

Funding Body Type

Private sector organisation

Funding Body Subtype

International organizations

Location

Netherlands

Results and Publications

Publication and dissemination plan

Expected results from this study include well developed and contextualised “U=U” messages, and outcomes following a pilot test of the application of “U=U” messages within primary health care context in Malawi. The results of this research will be used to guide the formation of national and international policies. Findings will be circulated to the College of Medicine Research and Ethics Committee, the Health Sciences Research Committee and the University Research and Publication Committee. Results will also be distributed to global health policy makers, nationally to the Malawian government, including HTS technical working group. Research findings will be published in journals and presented at conferences.

Intention to publish date**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