# Evaluating the integration of health services for chronic diseases in Africa

Submission date 04/04/2020	<b>Recruitment status</b> No longer recruiting	[X] Prospectively registered		
		[X] Protocol		
Registration date 21/04/2020	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 09/09/2025	Condition category Infections and Infestations	Individual participant data		

# Plain English summary of protocol

Background and study aims

In Africa, chronic diseases such as high blood pressure (hypertension) and high blood sugar (diabetes) are now common and require treatment for life. HIV-infection is also common and also requires life-long treatment.

At the moment, in most African countries, health services for hypertension, diabetes and HIV infection are provided in separate clinics or on separate days. Given the growing need for these services, the researchers don't know if this is the best way or whether services for these conditions should be provided together (i.e. all provided in one clinic). The researchers call bringing these services under one roof, integrated care. Integrating these services under one roof could be easier for patients and for health services but it might put pressure on the health worker seeing people with different conditions.

The goal is to compare a model of integrated care for people living with HIV-infection, diabetes or hypertension against the current standard model of separate clinics for each of these conditions.

The researchers will compare these models in terms of various health indicators measured among people with these conditions and the costs that both patients and the health services incur.

The researchers are working closely in partnership with health policy makers in Tanzania and Uganda. They will be the principal users of the research. They will use the information from the study to decide how future health care should be organised for chronic conditions.

# Who can participate?

Adults aged over 18 years with confirmed HIV infection, diabetes, hypertension or any combination of these

#### What does the study involve?

The researchers want to generate clear evidence that can feed into consideration of future policy. In this trial, some health facilities will be asked to provide integrated care, and some will continue with the current stand-alone care. Health facilities will be randomly assigned (i.e. by chance) to deliver one of the two options of care. This is called a cluster-randomised trial. Within each health facility, patients will be selected systematically for the study. They will be invited to join if they meet the criteria (for example that they live within reasonable distance).

They will receive care from the regular health workers who will receive refresher training on how to manage HIV-infection, hypertension and diabetes. Participants will be followed up over 12 months to work out how well their disease has been managed, the financial costs that they incurred to come to the health facility, costs incurred by the health services to provide the care, and other indicators.

The researchers plan to enrol 32 health facilities in the two countries and a total of about 220 participants at each facility with one of the target diseases (HIV-infection, high blood pressure or high blood sugar). These participants will be included in the main overall evaluation of the two models of care.

What are the possible benefits and risks of participating?

There are no direct or immediate benefits to participants but the information from this study will help the Ministry of Health to decide on how to provide service for people who need chronic care.

Where is the study run from?

- 1. Medical Research Council/Uganda Viral Research Institute/London School of Hygiene & Tropical Medicine Uganda Research Unit (Uganda)
- 2. The AIDS Support Organisation (Uganda)
- 3. National Institute for Medical Research (Tanzania)

When is the study starting and how long is it expected to run for? March 2020 to May 2022

Who is funding the study? European Union

Who is the main contact? Prof. Shabbar Jaffar s.jaffar@ucl.ac.uk

# **Contact information**

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# Additional identifiers

# Clinical Trials Information System (CTIS)

Nil known

# ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

19-100

# Study information

#### Scientific Title

Integrating HIV, diabetes and hypertension services in Africa: a cluster-randomised trial in Tanzania and Uganda

# Acronym

**INTE-AFRICA** 

#### Study objectives

Integration of chronic care services will lead to improved outcomes for people living with diabetes or hypertension and will not compromise outcomes among people living with HIV infection.

# Ethics approval required

Old ethics approval format

# Ethics approval(s)

1. Approved 16/01/2020, Liverpool School of Tropical Medicine (LSTM) Governance and Ethics Committee (Pembroke Place, L3 5QA, Liverpool, UK; +44 (0)151 705 3762; lstmrec@lstmed.ac.

uk), ref: 19-100

- 2. Approved 23/03/2020, National Health Research Ethics Sub-Committee (3 Barack Obama Drive, P.O.Box 9653, 11101, Dar es Salaam, Tanzania; +255 222 121 400; nimrethics@gmail.com), ref: NIMR/HQ/8.a/Vol. IX/3394
- 3. Approved 03/02/2020, The AIDS Support Organisation ethics committee (Mulago Hospital Complex, P.O.Box 10443, Kampala, Uganda; +256 414320385/6, mijumbia@tasouganda.org), ref: TASOREC/090/19-UG-REC-009

# Study design

Multi-centre open-label parallel two-arm cluster-randomized controlled trial

# Primary study design

Interventional

# Study type(s)

Other

# Health condition(s) or problem(s) studied

HIV-infection, diabetes, or hypertension or combinations of these conditions

#### **Interventions**

Experimental arm: Integrated health service provision at health facilities providing primary care for HIV infection, diabetes and hypertension.

Control arm: standard care – separate stand-alone services for HIV infection, diabetes or hypertension.

# Integration will involve

- A single one-stop clinic where patients with either HIV infection, diabetes or hypertension will be managed. Patients can have one or more of these conditions.
- They will be seen and managed by the same clinicians, nurses, counsellors and other staff
- There will be one pharmacy where dispensing is integrated
- Patient records will be the same a similar card will be used for all patients
- Laboratory tests will be done by the same laboratory service

Participants will be followed up from enrolment into the study for a period of 12 months.

Randomisation of the health facilities will be stratified in each country by location, type of health facility (as defined by the clinical infrastructure available at the health facility) and by patient load at the health facility (i.e. the numbers of patients attending the facility on a monthly basis). Within each stratum, the researchers will randomise in a 1:1 ratio to either the experimental integration arm or the standard care arm using a computer-generated randomisation list.

# Intervention Type

Mixed

# Primary outcome(s)

- 1. Retention in care for patients on diabetes and hypertension management measured using patient records at 12 months
- 2. Plasma viral load suppression among persons HIV-infected measured using lab test (suppression will be defined as plasma viral load <1000 copies per ml.) at 12 months

# Key secondary outcome(s))

- 1. Cost-effectiveness measured using a decision analytical model at 12 months
- 2. Biomedical indicators measured at baseline and 12 months
- 2.1. Fasting blood glucose
- 2.2. HbA1c
- 2.3. Blood pressure (mmHg)
- 3. Clinic usage (aggregated data on day-to-day patient numbers, time spent at clinic by patients, and basic indicators of quality of service such as consultation times) measured over 12 months

# Completion date

16/05/2022

# Eligibility

# Key inclusion criteria

- 1. Adults aged 18 years and above
- 2. Confirmed HIV infection, diabetes, hypertension or any combination of these
- 3. Living within the catchment population of the health facility
- 4. Likely to remain in the catchment population for 6 months
- 5. Willing to provide written informed consent

# Participant type(s)

Patient

# Healthy volunteers allowed

No

# Age group

Adult

# Lower age limit

18 years

#### Sex

All

# Total final enrolment

7030

#### Key exclusion criteria

Sick patients requiring immediate hospital care at time of assessment

#### Date of first enrolment

02/07/2020

#### Date of final enrolment

01/04/2021

# Locations

#### Countries of recruitment

Tanzania

Uganda

# Study participating centre

Medical Research Council/Uganda Viral Research Institute/London School of Hygiene & Tropical Medicine Uganda Research Unit

Plot 51-59 Nakiwogo Road Entebbe Uganda P.O. Box 49

# Study participating centre The AIDS Support Organisation

Mulago Hospital Complex Kampala Uganda P.O. Box 10443

# Study participating centre National Institute for Medical Research

Muhimbili Medical Research Centre Dar es Salaam Tanzania P.O. Box 9653

# Sponsor information

## Organisation

Liverpool School of Tropical Medicine

#### **ROR**

https://ror.org/03svjbs84

# Funder(s)

# Funder type

Government

#### **Funder Name**

European Union

# **Results and Publications**

# Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository. The LSTM subscribes to the FAIR Guiding Principles for scientific data management and stewardship. All datasets from research are committed to the Electronic Data Repository with associated study documentation as well as metadata. Currently, this repository is only accessible to staff. Interested parties can request for metadata of projects in certain disease areas or keywords by contacting the Data controller via email.

# IPD sharing plan summary

Stored in non-publicly available repository

# **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Results article		07/10 /2023	04/04 /2024	Yes	No
<u>Protocol article</u>	Protocol of qualitative process evaluation	07/10 /2020	14/10 /2020	Yes	No
Protocol article	Protocol of RCT	13/10 /2021	15/10 /2021	Yes	No
Other publications	Process evaluation	02/06 /2023	05/06 /2023	Yes	No
Other publications	Qualitative study in women living with HIV	02/12 /2022	04/04 /2024	Yes	No
Other publications	Qualitative-observational study understanding stigma	09/01 /2023	04/04 /2024	Yes	No
Other publications	Cost-minimisation analysis	09/09 /2025	09/09 /2025	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Study website	Study website	11/11 /2025	11/11 /2025	No	Yes