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Controlling chronic diseases in Africa: Development and evaluation of integrated community-based management for HIV, diabetes and hypertension in Tanzania and Uganda

Submission date 24/05/2022	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 07/06/2022	**Overall study status** Completed	
Last Edited 30/06/2025	**Condition category** Other	

Plain English summary of protocol

Background and study aims

In Africa, diseases such as high blood pressure (hypertension) and high blood sugar (diabetes) are now common and require treatment for life. HIV is also common and also requires treatment for life. Some health facilities in Tanzania and Uganda have combined the care for these three chronic conditions into the same clinic, this is known as integrated care. Within this study, our aim is to understand whether running integrated care clinics at the health facility is the best way to manage patients with chronic conditions that are well-controlled or whether they could be better managed by receiving integrated care in their local communities.

Who can participate?

Male and female patients aged 18 years or older with a diagnosis of hypertension, diabetes or HIV, but whose condition has been stable for the last 6 months.

What does the study involve?

Study participants will receive integrated care either at their health facility or a community location. If they are assigned to receive facility-based care, then they will be asked to attend as normal and be seen by their usual doctors and nurses. If they are assigned to receive care in the community, they will be asked to come to a place in the community (such as health outpost or maybe a school or church) at their usual frequency (e.g. every month). Here, they will receive their care at the community point and be seen by a nurse and a trained lay-worker. The participants medicines will be brought to the community point by the nurse for collection. The health care workers will check blood pressure and blood sugar in the usual way as they do now, either at the facility or in the community, depending on which type of care is assigned. If the participant has HIV, they should also attend the facility to have their viral load test done when this is due. These routine tests will be used by the health care staff to guide treatment, but the research team will also use these data in their evaluations. Thus, they will access clinical notes.

Participants will receive the same quality of care no matter which study arm they are allocated to.

What are the possible benefits and risks of participating?
The research team will be supporting the health service in monitoring patients. Patients will fund their medication in the usual way. We will not pay for your medicines but will help the health services to have a small stock of emergency supplies of medicines so as to reduce the number of stock-outs of medicines. So there might be small improvements in the health care received. The information from this study will help policy-makers in each country to decide on how to provide service for long-term conditions. Regarding potential risks, the participant may spend more time at the clinic or the community meeting point on the days we will be asking questions. We will try to keep this time to a minimum and ensure that they do not lose their place in the queue to see the health service provider.

Where is the study run from?
The study will take place in Uganda and Tanzania but is being run through a partnership between the Medical Research Council/Uganda Virus Research Institute/London School of Hygiene & Tropical Medicine, the National Institute for Medical Research Tanzania and University College London in the UK.

When is the study starting and how long is it expected to run for?
October 2020 to October 2024

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Professor Shabbar Jaffar
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Study website
https://www.lstmed.ac.uk/research/departments/international-public-health/respond-africa/inte-comm

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Development and evaluation of integrated community-based management for HIV, diabetes and hypertension in Tanzania and Uganda

Acronym
INTE-COMM

Study objectives
Community-based integrated management of HIV, diabetes and hypertension is more, or equally as, effective at improving patient outcomes when compared to health facility-based integrated management of these conditions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 25/10/2022, University College London Research Ethics Committee (Graduate School, North Cloisters, Wilkins Building UCL, Gower Street, London, WC1E 6BT, United Kingdom; +44 020 3108 4312; ethics@ucl.ac.uk), ref: 23821/001
2. Approval pending, LSTM Research Ethics Committee (Pembroke Place, L3 5QA, UK; +44(0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 21-091
3. Approval pending, Uganda Virus Research Institute Research Ethics Committee, Plot 51-59 Nakiwogo Road, P.O.Box 49, Entebbe, Uganda; no telephone number provided; directoruvri@uvri.go.ug), ref: GC/127/872
4. Approval pending, National Institute for Medical Research (3 Barack Obama Drive, PO Box 965, 11101 Dar es Salaam, Tanzania; +255 (0)22 2121400; nimrethics@gmail.com), ref: NIMR/HQ /R8aVOL III /157

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community, Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Development of integrated community care for patients with diabetes, hypertension and HIV

Interventions
Patients will be cluster randomised to either a model of community-based integrated care (intervention) or health facility-based integrated care (control) using a computer generated random number.

Community-based integrated care arm (intervention):
After an initial baseline visit at the health facility, participants will attend 10 monthly meetings in the community with a nurse and trained lay-worker. Medication adherence, diet and lifestyle advice will be provided each time. A nurse will monitor participants with similar frequency as monitoring conducted in the control arm (e.g. monthly blood pressure, 3-monthly glycaemia). Medicines will be dispensed at the facility, taken and handed to participants at the community point. Participants will end the study at a 12-month health facility visit

Health-facility integrated care arm (control):
As per standard care, participants will visit health facilities monthly for medicines and basic adherence, diet and lifestyle over the course of 12-months. They will have BP checked monthly and glycaemia 3-monthly and medicines dispensed monthly.

Intervention Type
Mixed

Primary outcome measure
1. Blood pressure measured using electronic blood pressure monitor every month for 12-months
2. Blood glucose measured using fasting blood glucose test every three months for 12-months
3. HIV disease activity measured using viral load test at baseline (if not already available in medical records) and 12-month follow-up

Secondary outcome measures
1. General health information (i.e., Family history, comorbidities, smoking & alcohol status) measured via patient completed survey at study baseline clinic
2. Height and weight measured by health facility scales and tape measure at study baseline clinic
3. Retention in care measured as the proportion of people alive and in care at 12 months of

follow-up
4. Medication use will be measured via patient completed survey each month for the 12-months of the study
5. Health-related quality of life measured using SF-12 at baseline and 12-month follow up clinics
6. Health economics measured using the EuroQoL-5D at baseline and 12-month follow-up clinics

Overall study start date
01/10/2020

Completion date
30/10/2024

Eligibility

Key inclusion criteria
1. Either diagnosed with HIV or diagnosed with diabetes type 2 or hypertension (or with combinations of these conditions.
2. In regular care at the health facility for 6 months or more (i.e. attending routine appointments)
3. considered by the clinical team not to have any complications/co-infections or that these are well managed. Also has remained on the same treatment regimen for at least 3-6 months (both the type of medication and dose) and does not require a change in management.
4. considered adherent to treatment by clinical team over the last 6 months.
5. Adult, age 18 years or older.
6. Living within the catchment population of the health facility.
7. Planning to remain in the area for at least 6 months.
8. Willing to attend for health services in the community.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1736

Total final enrolment
1864

Key exclusion criteria
1. Blood pressure >160/100 mmHg at the current visit (average of 2 readings).
2. Blood pressure recorded on more than one occasion as over 180/110 mmHg any time in the last 6 months.
3. Fasting glycaemia recorded on more than one occasion as over >13 mmol/L any time in the

last 6 months.
4. Complications of diabetes or hypertension that are unmanaged/uncontrolled.
5. Any clinical condition that requires health facility management.
6. Pregnant women as these require specialist care. However, we will refer patients who become pregnant in the course of the study to the health facility for antenatal care and further management. These patients will be welcome to attend community meetings after delivery.

Date of first enrolment
02/12/2022

Date of final enrolment
06/10/2023

Locations

Countries of recruitment
Tanzania

Uganda

Study participating centre
Medical Research Council/Uganda Virus Research Institute and London School of Hygiene & Tropical Medicine Uganda Research Unit
Plot 51-59 Nakiwogo Road
Entebbe
Uganda
PO Box 49

Study participating centre
National Institute for Medical Research
3 Barack Obama Drive
P.O.Box 9653
Dar-es-Salaam
Tanzania
11101

Study participating centre
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA

Study participating centre
Institute for Global Health University College London
30 Guilford Street
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Sponsor information

Organisation
University College London

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Institute for Global Health, 30 Guilford Street
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Sponsor type
University/education

Website
https://www.ucl.ac.uk/about/

ROR
https://ror.org/02jx3x895

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2025

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 1.1	02/03/2022	07/06/2022	No	No
Protocol article		20/03/2024	30/06/2025	Yes	No