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Evaluating the integration of health services for chronic diseases in Africa

Submission date
04/04/2020

Recruitment status
No longer recruiting

Registration date
21/04/2020

Overall study status
Completed

Last Edited
04/04/2024

Condition category
Infections and Infestations

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 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

Study website
https://inteafrica.org/

Contact information

Type(s)
Scientific

Contact name
Prof Shabbar Jaffar

ORCID ID
http://orcid.org/0000-0002-9615-1588

Contact details
Institute for Global Health, University College London, 30 Guildford Street
London
United Kingdom

WC1N 1EH
None provided
s.jaffar@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Joseph Okebe

ORCID ID
http://orcid.org/0000-0001-5466-1611

Contact details
Department of International Public Health
Liverpool School of Tropical Medicine
Pembroke Place
Liverpool
United Kingdom
L3 5QA
+44 151 702 9361
Joseph.Okebe@lstmed.ac.uk

Type(s)
Scientific

Contact name
Dr Anupam Garrib

ORCID ID
http://orcid.org/0000-0003-2305-3749

Contact details
Institute for Global Health, University College London, 30 Guildford Street
London
United Kingdom
WC1N 1EH
None provided
a.garrib@ucl.ac.uk

Type(s)
Scientific

Contact name
Dr Kaushik Ramaiya

ORCID ID
http://orcid.org/0000-0003-3309-5395

Contact details

Shree Hindu Mandal Hospital
Dar es Salaam
Tanzania
-
+255 753333332
ceo@hc.shm.or.tz

Type(s)
Scientific

Contact name
Prof Sayoki Mfinanga

ORCID ID
http://orcid.org/0000-0001-9067-2684

Contact details
National Institute for Medical Research (NIMR)
Muhimbili Centre
Dar es Salaam
Tanzania
-
+255 784755632
gsmfinanga@yahoo.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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 Trial

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 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 2-arm cluster-randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Hospital

Study type(s)
Other

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

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 measure
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

Secondary outcome measures
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

Overall study start date
15/02/2020

Completion date
16/05/2022

Eligibility

Key inclusion criteria
1. Adults, 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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
7,040

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

Sponsor details
Pembroke Place
Liverpool
England
United Kingdom
L3 5QA
+44 (0)151 705 3100
lstmgov@lstmed.ac.uk

Sponsor type
University/education

Website
http://www.lstmed.ac.uk/

ROR
https://ror.org/03svjbs84

Funder(s)

Funder type
Government

Funder Name
European Union

Results and Publications

Publication and dissemination plan
INTE-AFRICA is designed to generate the evidence to inform scale up of integrated chronic care services. The research programme will work closely with policy makers and senior programme managers in both countries. We will provide them with the findings and support them in the decision that they take.

If the trial demonstrates the effectiveness of integrated care, we will support the health facilities to scale this up. We will share protocols on integration and monitor the scale up to record the lessons learnt to facilitate other health facilities to follow.
The findings will also be published in at least one peer-reviewed journal and data will be made accessible to other bodies for further dissemination.

Intention to publish date
30/10/2022

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 repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	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 unpublished results	qualitative study in women living with HIV	02/12/2022	04/04/2024	No	No
Other unpublished results	qualitative-observational study undertanding stigma	09/01/2023	04/04/2024	No	No
Results article		07/10/2023	04/04/2024	Yes	No