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Integrated care for HIV and non-communicable diseases in Africa: a pilot study to inform a large-scale trial (MOCCA and MOCCA Extension Study)

Submission date
31/08/2021

Recruitment status
No longer recruiting

Registration date
28/09/2021

Overall study status
Completed

Last Edited
12/12/2022

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Between 2018 and 2019 the Management of Chronic Conditions in Africa (MOCCA) study delivered care in an integrated approach whereby patients with either HIV infection, diabetes or hypertension (high blood pressure) were managed in a single clinic (i.e. with shared waiting and consultation rooms, shared pharmacy, and similar adherence counselling support, medical records, and tracing of patients lost from care). The study was done in 10 health facilities (five in Tanzania and five in Uganda) with varying clinical infrastructure, ranging from health centres to district hospitals offering primary care. In the MOCCA extension study, the researchers are re-establishing the integrated care clinics and inviting the participants of the original MOCCA study to attend the clinics again. The aim is to determine if the integrated care clinic remains acceptable to patients and to determine the clinical impact of participating in integrated care.

Who can participate?
Participants of the original MOCCA trial who were alive and in care at the end of the MOCCA follow-up

What does the study involve?
The integrated care clinic will be re-established (as was previously ran during the original MOCCA study) where patients who have either HIV, diabetes, hypertension or any combination of these conditions can receive care. Patients who have more than one condition will receive care in a single consultation. Patients will attend the clinic as directed by the health facility staff, following standard of care visit schedules. All aspects of clinical care, including blood testing, clinical monitoring and drug prescriptions will be according to the national guidelines and as prescribed by the health facility staff. In addition, cross-testing for diabetes, hypertension and HIV will be offered to recruited participants, for example, patients who have diabetes will be offered testing for hypertension and HIV. A blood lipid test for all patients will be done at

enrolment. Biomedical measurements including blood glucose, blood pressure and plasma viral loads will be recorded according to the conditions that patients are being treated for at enrolment, the end of study follow up and if they are taken during any follow-up appointments.

What are the possible benefits and risks of participating?
Participants may have to change from the facility or clinic they were attending in order to re-attend at the integrated care clinic. As there will be cross-testing of conditions, participants will have the opportunity to be screened for diabetes, hypertension or HIV (as appropriate). Early diagnosis of any of these conditions is very important in order to prevent the development of poor health and complications. There will also be a test of blood cholesterol. If participants are found to have high cholesterol, they can make changes to their diet and lifestyle to prevent the development of heart disease.

Where is the study run from?
This study is run by a partnership of institutions including the Liverpool School of Tropical Medicine (UK), the National Institute of Medical Research (Tanzania), and the MRC/LSHTM/UVRI Uganda research institute.

When is the study starting and how long is it expected to run for?
February 2018 to December 2021

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

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Protocol version 4.2

Study information

Scientific Title
Management of chronic conditions in Africa extension study

Acronym
MOCCA Extension

Study objectives
Does the provision of integrated care (as delivered during the original MOCCA study) remain acceptable to patients and what is the impact on clinical outcomes?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 07/08/2018, amendment approved 04/12/2019, LSTM Research Ethics Committee (Pembroke Place, L3 5QA, UK; +44(0)151 705 3100; lstmrec@lstmed.ac.uk), ref: 18-044
2. Approved 21/05/2018, amendment approved 07/12/2020, The AIDS Support Organisation (TASO, TASO Headquarters, Mulago Hospital Complex, PO Box 10443, Kampala, Uganda; +256 (0) 414 532 580/1; mail@tasouganda.org), ref: TASOREC/015/18-UG-REC-009
3. Approved 23/05/2018, amendment approved 07/12/2020, 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/R.8a/Vol. IX/2793

Study design
Single-arm intervention study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Integration of care for patients with diabetes, hypertension or HIV

Interventions
Implementation of an integrated care clinic (as previously ran during the original MOCCA Study) where patients who have either HIV, diabetes, hypertension or any combination of these conditions can receive care. Patients who have more than one condition will receive care in a single consultation.

Patients will attend the clinic as directed by the health facility staff. The MOCCA visit schedule will follow the standard of care visit schedules.

All aspects of clinical care, including blood testing, clinical monitoring and drug prescriptions will be according to the national guidelines and as prescribed by the health facility staff.

In addition, cross-testing for diabetes, hypertension and HIV will be offered to recruited participants, for example, patients who have diabetes will be offered testing for hypertension and HIV. A blood lipid test for all patients will be done at enrolment. Biomedical measurements including blood glucose, blood pressure and plasma viral loads will be recorded according to the conditions that patients are being treated for, at enrolment, end of study follow up and if they are taken during any follow-up appointments.

Intervention Type
Other

Primary outcome(s)
Retention in care (defined as being alive and in care in a MOCCA clinic) at 12 and 24 months from enrolment into MOCCA.

Key secondary outcome(s))
Biomedical measurements at 12 and 24 months including:
1. Fasting blood glucose in diabetic patients measured using a point of care blood glucose monitor
2. Blood pressure in patients with hypertension measured using a digital blood pressure monitor
3. Plasma viral load measured in the HIV treatment programme in each country and recorded in patient clinical notes

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. All participants who were alive and in care in the integrated care clinics in the original MOCCA study
2. Adult >18 years old
3. Living within the catchment population of the health facility
4. Planning to remain in the area for at least 6 months

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Pregnant women
2. Very sick, requiring immediate hospital

Date of first enrolment
05/01/2021

Date of final enrolment
31/08/2021

Locations

Countries of recruitment
Tanzania

Uganda

Study participating centre
Amana Hospital
Uhuru Street
Dar es Salaam
Tanzania
-

Study participating centre
Hindu Mandal Hospital
Chusi Street
Dar es Salaam
Tanzania
-

Study participating centre
Mkuranga District Hospital
Mkuranga District
Dar es Salaam
Tanzania
-

Study participating centre
St Vincent Health Centre
Mkuranga District
Dar es Salaam
Tanzania
-

Study participating centre
Bunju Health Dispensary
Kinondoni
Dar es Salaam
Tanzania
-

Study participating centre
TASO Mulago
Old Mulago Complex
PO Box 10443
Kampala
Uganda
-

Study participating centre
Wakiso Health Centre IV
Wakiso Town Council
Namirembe Rd
Wakiso
Kampala
Uganda
-

Study participating centre
Ndejje Health Cente IV
Kampala

Uganda
-

Study participating centre
Kisugu Health Centre III
1a Nzirebera Cl
Kampala
Uganda
-

Study participating centre
Kiswa Health Centre
Opposite shell Bugolobi Kataza Cl
Kampala
Uganda
-

Sponsor information

Organisation
Liverpool School of Tropical Medicine

ROR
https://ror.org/03svjbs84

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

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?
Results article	health economics	10/09/2021	12/12/2022	Yes	No
Results article	retention in care and clinical indicators	02/11/2021	12/12/2022	Yes	No