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A randomized controlled evaluation of an intervention package to improve health services for chronic diseases in Uganda and Tanzania

Submission date
16/04/2016

Recruitment status
No longer recruiting

Registration date
09/08/2016

Overall study status
Completed

Last Edited
06/03/2019

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Countries in Africa and other low and middle income countries across the world are seeing a rise in non-communicable diseases (diseases that do not spread from person to person) such as hypertension (high blood pressure) and diabetes (a disease where a person has difficulty controlling their blood sugar levels). Health systems in these countries are often not prepared to cope with treating these diseases, as they are already dealing with widespread by infectious diseases such as malaria, tuberculosis and HIV. The team of researchers from the London School of Hygiene and Tropical Medicine, the Mwanza Intervention Trials Unit at the National Institute for Medical Research (MITU/NIMR) in Mwanza, Tanzania, and the MRC Uganda Research Unit at the Uganda Virus Research Institute (MRC/UVRI) in Entebbe, Uganda found in a recent study that hypertension and diabetes are very common in SW Uganda and NW Tanzania. It was also observed that a large proportion of the general population already carries life style related risk factors for HT and DM, even among young adults and in rural areas, and that local health facilities are unable to cope with the increase of these diseases due to lack of training, supplies and guidelines. Two years ago, 40 health facilities in these areas took part in a programme to help them better deal with the burden of non-communicable diseases. This involves training of health workers and district based supervisors, providing equiptment and medications, and providing treatment guidelines for diabetes and hypertension. This study comprises of six small studies which are looking at the effects of this programme, by comparing the 40 health facilities that did take part to 40 who did not. The overall aim of this study is to evaluate the readiness and quality of care in Uganda and Tanzania for the diagnosis and treatment of hypertension and diabetes.

Who can participate?
1. Health facilities located in participating areas in South West Uganda and North West Tanzania
2. Health workers in charge of outpatient services who provide care for patients with high blood pressure or diabetes
3. Adult patients with high blood pressure or diabetes who are seen at participating health

facilities
4. Adult patients with high blood pressure or diabetes who live in the catchment areas of participating health facilities
4. Adults who live in the communities neighboring participating health facilities

What does the study involve?
This study is made up of six studies which each look at different aspects of care.
Sub-study 1: 40 health facilities who took part in the programme and 40 that did not undergo an inspection and complete a questionnaire in order to judge the care that they are able to provide for patients with hypertension and diabetes.
Sub-study 2: Four randomly selected patients from each of the facilities in the first study are interviewed about their medical history and what treatment they received. Their medical records are then reviewed for completeness, and they undergo a brief physical examination to check for risk factors for developing hypertension or diabetes.
Sub-study 3: Patients who have been diagnosed with hypertension or diabetes who live in the catchment areas of the facilities in study one are interviewed about their health and treatment seeking behaviour.
Sub-study 4: Costs pent on non-communicable disease services at all study centres are calculated to find out how cost effective the care offered by facilities who took part in the programme is.
Sub-study 5: Health facilities are compared to find out if the facilities that took part in the programme have used the skills taught in the programme and applied them to other clinics offered by the facilities (such as family planning). This is done using staff interviews.
Sub-study 6: Focus groups and in-depth discussions are carried out with members of the community in order to find out whether people feel the programme has changed the way they access health care.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
The study is run from the Mwanza Intervention Trials Unit (Tanzania) and the MRC/UVRI Uganda Research Unit on AIDS (Uganda) and takes place in 80 health facilities in South West Uganda and North West Tanzania.

When is the study starting and how long is it expected to run for?
September 2009 to April 2017

Who is funding the study?
Medical Research Council, Efficacy and Mechanism Evaluation Programme (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomized controlled evaluation of an intervention package to improve health services for chronic diseases in Uganda and Tanzania

Study objectives
The overall aim is to evaluate the readiness and quality of primary care services in Uganda and Tanzania for the diagnosis and treatment of non-communicable diseases (NCDs) provided at 40 facilities in each country, with a focus on hypertension and diabetes care. The study comprises six observational cross-sectional sub-studies, each evaluating a different aspect of service provision.

Individual sub-study aims:
Sub-study 1: To assess the service readiness of primary care facilities with respect to NCD prevention and care
Sub-study 2: To assess the quality of NCD case management currently received by individual patients registered at these primary care facilities
Sub-study 3: To assess the health status and treatment seeking behaviour of NCD patients residing in the catchment areas of participating facilities
Sub-study 4: To document the costs and estimate the cost-effectiveness of improved NCD care services
Sub-study 5: To investigate potential secondary effects of improved NCD care on other services at participating facilities
Sub-study 6: To document community perceptions on NCDs in the general population residing in the catchment of participating facilities

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Committee of the Uganda Virus Research Institute, 04/02/2016, ref: nu GC/127 /16/02/539

2. National Health Research Ethics Review Committee, National Institute for Medical Research Tanzania, 09/05/2016, ref: NIMR/HQ/R.8a/Vol. IX/2190
3. Ethics Committee of the London School of Hygiene and Tropical Medicine, 07/07/2016, ref: 11344

Study design
Six cross-sectional observational studies

Primary study design
Observational

Study type(s)
Other

Health condition(s) or problem(s) studied
1. Hypertension
2. Diabetes mellitus (type II)

Interventions
Sub-study 1:
In each country (Uganda and Tanzania), 40 primary health care facilities will be assessed, stratified by kind of facility ('health centres' and 'dispensaries 'in Tanzania; 'health centres III' and 'health centres II' in Uganda). The head of the facility and the health worker in charge of the outpatient department (OPD) will be interviewed. OPDs, pharmacies and laboratories will be physically inspected, the presence and functionality of essential equipment investigated, availability and validity of essential drugs documented, and NCD related records checked for availability and completeness of entries. The findings will be documented using standardised data collection tools, and scores allocated to reflect the degree of service readiness found. All consenting health workers who routinely or occasionally provide outpatient care will be requested to complete a standardised validated multi-choice based knowledge test about selected chronic diseases; the results will feed into a facility specific summary score, again to reflect the degree of service readiness of the facility.

Sub-study 2:
At each primary health care facility participating in sub-study 1, four consenting randomly selected patients currently registered for diabetes and/or hypertension care will be invited for an interview on their NCD related medical history, risk factors and the treatment obtained. Their medical records will be evaluated for completeness and consistency. A brief physical examination will be conducted including three separate blood pressure measurements, assessment of NCD risk factors including measurement of body weight, height and BMI. Blood will be collected to determine fasting levels of blood glucose and haemoglobin A1c. The findings will be documented using standardised data collection tools, and scores will be allocated to reflect the degree of service quality received. The status of individuals whose condition is not adequately controlled will be discussed with the health worker in charge; and if necessary referred to hospital. In total the study is expected to collect data from up to 160 patients in each country.

Sub-study 3:
A cross-sectional survey will be conducted among patients known to have a diagnosis of diabetes and/or hypertension and to reside in the catchment of the health facilities participating in sub-study 1. Consenting patients will be visited at home and invited for an interview about

their health and treatment seeking behaviour. They will be offered a medical check up using the methodology described for sub-study 2. Individuals whose condition is not adequately controlled will be referred to their health facility; and immediate accompanied referral arranged for any seriously affected patients. Observations will be documented using standardised data collection tools, and scores allocated to reflect the degree of service quality received. In total the study is expected to collect data from up to 240 patients in each country.

Sub-study 4:
The costs spent on NCD care services will be documented from the provider perspective. Costs of equipment and consumables related to NCD care will be recorded from source documents at government and project offices. Costs for space utilisation, utilities and health worker time allocated to NCD care will be collected during visits of health facilities involved in sub-study 1. Cadre-specific salary costs of health workers working on NCD care will be obtained from district health offices. Costs of district staff time spent to train or supervise NCD services will be estimated. The number of NCD patients treated at health facilities will be documented for the last 6 months. Data will be documented using Excel spreadsheets. Research related costs will excluded from the analysis. Cost-effectiveness will be estimated by relating costs spent on NCD care to the numbers of NCD cases managed according to guidelines, and comparing these data across participating health facilities. The work will be conducted by a total of 3 health economists from Uganda, Tanzania and the UK.

Sub-study 5:
Potential secondary effects of improved NCD care on other services at participating primary care facilities will be assessed using qualitative research methods, applied by social science teams from the research units in Uganda and Tanzania. Facilities participating in sub-study 1 will be visited and consenting health workers invited to participate in in-depth interviews that will be conducted using a-priory agreed interview guides. Aspects to be explored include potential changes in health workers' work assignments that may have occurred due to an increasing NCD case load, in particular with regards to possible negative effects on other services (such as antenatal clinics, under-5 care, or family planning services), possible positive effects (such as NCD case finding occurring at ANC clinics) and effects on job satisfaction. Aiming for information saturation, up to 20 IDIs will be conducted in each country. Field research staff will collect data taking written notes, and if permitted using electronic recorders. Data will be transcribed and translated into English and analysed using qualitative data analysis software.

Sub-study 6:
Community perceptions and health seeking beliefs for the prevention and care of NCDs will be assessed through qualitative research methods, applied by by social science teams based at the research units in Uganda and Tanzania. In each country, up to 8 focus-group discussions and 40 in-depth interviews will be conducted with consenting members from the general adult population residing in the catchment of participating health facilities, using a-priory agreed interview guides, until information saturation has been reached. Data will be collected by taking written notes, and if permitted by means of electronic recorders. Data will be transcribed and translated into English and analysed using qualitative data analysis software.

Intervention Type
Mixed

Primary outcome(s)

Quality of services provided for selected NCDs (hypertension and diabetes mellitus) at 40 public health facilities each in Uganda and Tanzania, measured through a composite evaluation score. The primary outcome is measured in sub-studies 1, 2 and 3.

Sub-study 1: Service readiness at primary care facilities for the diagnosis and case management of hypertension and diabetes will be assessed using physical inspection of essential equipment and consumables; health workers' knowledge on selected chronic diseases will be assessed using a validated knowledge test;

Sub-study 2: Quality of NCD case management currently received by individual patients will be assessed through patient interviews, evaluation of medical records, physical examination, blood pressure measurement and blood tests for diabetes.

Sub-study 3: Health status and treatment seeking behaviour of NCD patients residing in the catchment areas of participating health facilities will be assessed as in sub-study 2, i.e. through patient interviews, evaluation of medical records, physical examination, blood pressure measurement and blood tests for diabetes.

Key secondary outcome(s))
1. Costs and cost-effectiveness of NCD care services will be documented from the provider perspective by collating costs for equipment, consumables, utilities and health worker time. Cost-effectiveness will be estimated by relating costs to the numbers of NCD cases managed according to guidelines, and comparing these data between participating health facilities (sub-study 4 only).
2. Potential secondary effects of NCD services on other services provided at the same facilities(e. g. mother-and child care), will be assessed through in-depth interviews of health workers working at the participating health facilities (sub-study 5 only)
3. Community perceptions and health seeking beliefs for the prevention and care of NCDs will be assessed through focus-group discussions and in-depth interviews conducted with members from the general adult population residing in the catchment of participating health facilities (sub-study 6 only)

Completion date
30/04/2017

Eligibility

Key inclusion criteria
Health facilities:
1. Located in one municipality and two rural districts each in SW Uganda and NW Tanzania

Health workers
1. Those in charge of outpatient services
2. All HWs who provide care for patients with hypertension (HT) and/or diabetes mellitus (DM)
3. Working at the above intervention and comparison HFs

Patients at HFs:
1. Aged 18 or over
2. Diagnosis of hypertension or diabetes mellitus
3. Access services at intervention or comparison health facilities

Patients, community based:
1. Aged 18 or over
2. Diagnosis of hypertension or diabetes mellitus
3. Reside in the catchment areas of intervention or comparison health facilities
4. Diagnosed during a previous cross-sectional survey conducted prior to the intervention project

Community members:
1. Aged 18 or over
2. Reside in communities adjacent to intervention and comparison facilities

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
Health workers:
Thosenot involved in providing OPD care for HT/DM

Patients:
1. Aged <18 years
2. Not affected by HT/DM

General population
1. Aged <18 years
2. Not a resident in a community adjacent to an intervention or comparison health facility

Date of first enrolment
01/05/2016

Date of final enrolment
31/10/2016

Locations

Countries of recruitment
Tanzania

Uganda

Study participating centre
Mwanza Intervention Trials Unit (MITU)
National Institute for Medical Reserach
Mwanza
Tanzania
-

Study participating centre
MRC/UVRI Uganda Research Unit on AIDS
Uganda Virus Research Institute
Entebbe
Uganda
-

Sponsor information

Organisation
London School of Hygiene and Tropical Medicine

ROR
https://ror.org/00a0jsq62

Funder(s)

Funder type
Research council

Funder Name
Medical Research Council

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

United Kingdom

Funder Name
Department for International Development

Alternative Name(s)
Department for International Development, UK, DFID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

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