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Scaling-up packages of interventions for cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa: an implementation research (SPICES Project)

Submission date
03/01/2019

Recruitment status
No longer recruiting

Registration date
23/01/2019

Overall study status
Completed

Last Edited
04/07/2023

Condition category
Circulatory System

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

Plain English summary of protocol
Background and study aims
Cardiovascular diseases (CVD) which involve the heart and blood vessels are on the rise in sub-Saharan Africa. Uganda is experiencing a shift in major causes of death with cases of stroke, heart attack, heart failure, hypertensive (high blood pressure) heart disease and diabetes reportedly on the rise. In a study in central region focusing on Mukono and Buikwe districts, more than one in four adults were reportedly hypertensive. Moreover, very few (36.5%) reported to have ever had a blood pressure measurement. The rising burden of CVD is compounded by a lack of integrated primary health care for early detection and treatment of people with increased risk. Many people have less access to effective and equitable health care services which respond to their needs. Capacity gaps in human resources, equipment, drug supply, and laboratory capabilities are evident. Prevention of risk factors for CVD and provision of effective and affordable treatment to those who require it can prevent disability and death and improve quality of life. The aim of this study is to improve health profiles for people with intermediate and high risk factors for CVD at the community and health facility levels.

Who can participate?
Adults aged 18 years in the districts of Mukono and Buikwe

What does the study involve?
Every 6 months (at 0, 6, 12 and 18 months), a new set of five health facilities are randomly allocated to receive the intervention until all have received it. The intervention involves health promotion and education, screening for CVD risk factors at the community and health facility levels, and improved care and management and follow-up at the primary healthcare level.

What are the possible benefits and risks of participating?
All participants including patients will benefit from planned community interventions which include screening for CVD risk factors and primordial prevention guidance and referral to health facilities. It is hoped that the community intervention will increase the knowledge of members

on CVD, understand their CVD risk profiles and support them to adopt healthy lifestyles to improve CVD prevention and control. Moreover, those identified with high risk profiles are referred to benefit from strengthened services at primary healthcare facilities. At the health facility, practices benefit from improved availability of supplies to support management of CVD risk factors and staff receive training which boosts their confidence and competence in the management of CVD risks.

Where is the study run from?
The study is conducted by Makerere University School of Public Health and takes place in 20 HCIIIs, 1 HCIV, 1 hospital and 20 parishes in Mukono and Buikwe districts (Uganda)

When is the study starting and how long is it expected to run for?
October 2018 to December 2022

Who is funding the study?
The study is part of the bigger grant funded by the European Commission (Horizon 2020)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

SPICES_Uganda

Study information

Scientific Title
An Implementation science study to enhance cardiovascular disease prevention in Mukono and Buikwe districts in Uganda: a stepped-wedge design

Acronym
SPICES

Study objectives
The general objective of the current study is to implement and evaluate the implementation process and determine the effectiveness of an enhanced CVD prevention program on improving profiles for people with intermediate and high risk factors for CVD at the community and health facility levels. The research questions are:
1. How effective is an enhanced community approach in improving population knowledge and screening for CVD risk factors, referral and enhancing lifestyle change in a real world setting versus usual care? What is the uptake and what factors influence implementation?
2. How effective is an enhanced primary healthcare approach in improving CVD risk profiles of patients attending healthcare facilities? What is the uptake in routine practice and what factors influence implementation?
3. What is the utility of an e-health screening tool in profiling for CVD risk factors at the community and at primary healthcare level? What is the uptake and what factors influence implementation uptake?
4. What is the impact of an enhanced comprehensive CVD prevention program on patient outcomes versus usual care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Makerere University School of Public Health Higher Degrees Research and Ethics Committee, PO Box 7072, Kampala, Tel: +256 (0)414532207/543872, Email: wtusiime@musph.ac.ug, ref: 624
2. Uganda National Council for Science and Technology, ref: HS HS 2477

Study design
Type 2-hybrid stepped-wedge (SW) design

Primary study design
Interventional

Secondary study design
Stepped wedge cluster randomised

Study setting(s)
Community

Study type(s)
Prevention

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
Cardiovascular disease risk factors

Interventions
Packages of interventions along the cascade (community and health facility levels) classified under four work packages: health promotion/education; CVD risk profiling; care and management; and self-management & follow-up.

The trialists propose to draw lessons from the HIV response in combination with the Innovative Care for Chronic Conditions (ICCC) framework to implement contextually appropriate interventions that address prevention of CVD in Mukono and Buikwe districts in Uganda. Specifically, they advance CVD prevention along the cascade through health promotion and education and screening for risk factors at the community (community plan) and strengthen health services at the primary healthcare level (primary healthcare strengthening).

Primary health facility plan:
Following the stepped wedge design, five health center IIIs are initially randomized at time zero (T0) to the intervention arm and will be strengthened with certain elements that are required to improve their response to CVD prevention, care & management and follow-up. The elements include: supplies and equipment such as blood pressure (BP) monitoring devices, glucometers and buffer stock for first line anti-hypertensive medicines; guidelines and standardized treatment protocols; and improving data capture by provision of computer/digital devices; and training personnel in prevention and management of CVD risk factors and patient provider relationships. Health workers in these facilities will be trained. Current materials developed by the Ministry of health will be utilized with appropriate modifications to train the health workers. Trained health workers will deliver the enhanced package at the primary healthcare level using a simplified algorithm (adopted with modification from the hearts protocol and the Uganda Clinical guidelines) to all adults attending the outpatient units in order to improve detection, care and management of risk factors for CVD. The in-charge at the selected health facilities with support from the investigation team, the district health team and the Uganda Ministry of Health closely supervise the enhanced CVD program including trained providers. Additionally, the project will identify and train peers and equip them with skills to conduct peer education, counselling (brief advice) and follow-up of those enrolled for follow-up. The health facility/unit in charge closely supervises the activities of the peers. Every 6 months, at time 6, 12 and 18, a new set of five health facilities are crossed over to intervention until all are exposed.

Community plan:
The community plan revolves around working with community health workers (VHTs), existing networks and community structures to promote knowledge, improved lifestyles, risk assessment and cardiovascular health. CHWs are trained to conduct health education, promote lifestyle change through motivational interviewing and goal setting techniques, screen for risk factors at the community using non laboratory tools, and conduct home to home visits. Existing community networks and community structures are identified and supported to promote improved lifestyle behaviours, screening for risk factors and cardiovascular health education and promotion. Electronic and print media (messages) are circulated to enhance health promotion and improved lifestyle behaviours.

Series cross sectional surveys are proposed every 6 months at T0, T1, T2, T3 and T4 at the community and health facility levels entailing household members, health facilities, health workers, and patients. The evaluations use both qualitative assessments to evaluate the process, barriers and opportunities, and quantitative measurements to assess effects and process outcomes. During the interventions formative processes (process evaluations) and detailed documentation of process, costs and activities are undertaken.

Intervention Type
Mixed

Primary outcome measure
1. Reach: proportion of the health care/community providers/target population approached; uptake of intervention packages; and proportion of adherent. Measured by analysis of routine data generated by CHW, peers & health facilities and individual/patient quantitative assessments using household/patient questionnaires at 0, 6, 12, 18 and 24 months
2. Appropriateness:
2.1. The extent to which proposed interventions can be delivered at health facilities/community, measured using individual interviews, focus group discussion and key informant interviews at 0, 6, 12, 18 and 24 months
2.2. Organizational readiness: availability and functionality of infrastructure including personnel, equipment, supplies etc. measured using the health facility readiness and capacity assessment questionnaire at 0, 6, 12, 18 and 24 months
2.3. Linkage to healthcare: self-report using h/h questionnaire, data extraction checklist at 12 and 24 months
2.4. Referrals for task sharing/shifting: data extraction checklist at 12 and 24 months
3. Acceptability: user and provider feedback, focus group discussion guides, key informants (formative process ongoing); individual/patient satisfaction (needs) assessed using Patient Satisfaction Questionnaire at 12 and 24 months
4. Self-efficacy: personal beliefs about own competencies to achieve implementation goals, assessed using provider questionnaire,
pre/post training assessment tools at 12 and 24 months
5. Adoption: implementation of the project and challenges to implementation (barriers and opportunities and coping mechanisms), assessed using focus group discussions, individual interviews and key informant interviews at 0, 6, 12, 18 and 24 months (formative process ongoing)
6. Cost: Costs associated with implementing the packages, assessed using checklists for cost data (health facility cost data related to the project; community program cost data) at 12 and 24 months
7. Feasibility: exposure to and retention of the enhanced interventions e.g. CVD education, counseling etc. Data extraction checklist (daily activities conducted related to the enhanced interventions e.g. counselling, no. of people profiled, followed up etc) at 12 and 24 months
8. Fidelity: the extent to which providers are delivering packages as per the protocol/guidelines, assessed using observer rating forms (formative process ongoing)
9. Sustainability: the extent to which the program is being implemented as a standard of practice, assessed using key informant interviews with providers at 12 and 24 months

Secondary outcome measures
Risk factors/clinical profiles e.g. blood pressure, BMI, alcohol history, smoking status, assessed using household questionnaire adapted with modification to suit local context from several

standardised questionnaires – WHO steps survey, international physical activity questionnaire (IPAC), EuroQual EQ 5D 5L, and the Uganda Demographic survey questionnaire. Assessed at 0, 6, 12, 18 and 24 months

Overall study start date
02/10/2018

Completion date
30/12/2022

Eligibility

Key inclusion criteria
1. Both male and female
2. Aged 18 years and above
3. Consent to participate in the study

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Interventions target all community members in the selected 20 parishes (clusters). Series cross sectional surveys target approximately 4000 participants per evaluation cycle

Total final enrolment
4372

Key exclusion criteria
1. The mentally ill will not be included in the evaluations
2. Non consenting adults

Date of first enrolment
10/12/2018

Date of final enrolment
30/06/2022

Locations

Countries of recruitment
Uganda

Study participating centre
Makerere University College of Health Sciences School of Public Health
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Sponsor information

Organisation
Makerere University School of Public Health

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Sponsor type
University/education

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ROR
https://ror.org/03dmz0111

Funder(s)

Funder type
Government

Funder Name
Horizon 2020

Alternative Name(s)
EU Framework Programme for Research and Innovation, Horizon 2020 - Research and Innovation Framework Programme, European Union Framework Programme for Research and Innovation

Funding Body Type

Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
The project will utilize both the Green Open Access and Gold Open Access model to disseminate and publish research data. Dissemination workshops and meetings will be organized at the local, national and international platforms.

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a repository. Access can be requested from the PI a year after completion of the study.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	25/04/2019	29/04/2019	Yes	No
Other publications	Results informed by data from the baseline assessment of SPICES	22/07/2020	27/07/2020	Yes	No
Interim results article	Focus group discussion results during the first cycle (6 months) of intervention implementation	09/12/2022	04/07/2023	Yes	No
Interim results article	risk factor mapping and analysis is drawn from the baseline survey conducted in December 2018 and January 2019	10/06/2022	04/07/2023	Yes	No
Other publications	descriptive qualitative study conducted among purposively selected adults who had engaged in SPICES	17/02/2022	04/07/2023	Yes	No