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Heart health without a doctor: an implementation study of CVD prevention and behaviour change interventions in community settings

Submission date 29/05/2019	**Recruitment status** Suspended	[ ] Prospectively registered [X] Protocol
Registration date 09/08/2019	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 16/01/2023	**Condition category** Circulatory System	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
SPICES is an EU Horizon 2020 project working simultaneously in six settings across five countries (Limpopo, South Africa; Kampala, Uganda; Brest, France; Antwerp, Belgium; Brighton and Nottingham, United Kingdom). This two-year study is exploring the effectiveness of community-based heart disease prevention interventions against Primary Care based risk profiling, advice and support.

Who can participate?
All adults (over 18 years old)

What does the study involve?
Participants are randomly allocated to receive either:
1. In-person, community-based, Behaviour Change Support (individual and group work) delivered by trained volunteers using techniques of risk profiling, national guidelines on healthy behaviours, goal setting, action planning, problem solving, and motivational interviewing. Interventions are repeated up to 11 times over 24 months starting weekly and then less frequently.
2. Risk profiling and national guidelines on healthy behaviours.

What are the possible benefits and risks of participating?
Benefits are expected to include greater awareness of behavioural risks and remedies for a healthy heart; better informed decision making within participating families around diet, exercise and smoking; and intensive and academically informed support for participants in the intervention group through a series of intervention workshops sustained over 2 years. Risks include potential emotional distress and anxiety on being made aware of a high risk category score.

Where is the study run from?
1. Nottingham Trent University (UK)
2. Brighton and Sussex Medical School (UK)

When is the study starting and how long is it expected to run for?
March 2019 to March 2021

Who is funding the study?
Horizon 2020

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
SPICESUK1

Study information

Scientific Title
Scaling up Packages of Interventions for the prevention of Cardiovascular disease in selected European and sub-Saharan countries (an implementation research project)

Acronym
SPICES

Study objectives
Engaging with target populations outside of formal healthcare facilities will be more effective in increasing knowledge of CVD risk factors, scaling up CVD risk-profiling, and supporting personal and community behaviour change than Primary Care situated interventions.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/03/2019, Research Office, Nottingham Trent University (Arkwright B113, 50 Shakespeare Street, Nottingham, NG1 4FQ; Tel: +44 (0)115 848 8117; Email: anton.muszansky@ntu.ac.uk), ref: 2018/286

Primary study design
Interventional

Study design
Mixed methods incorporating stepped wedge, cluster-randomised, controlled intervention trial with qualitative investigation of barriers and facilitators to individual and organisational change

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
Participants are randomised according to postcode and partner community organisations from which participants have been recruited:
1. In-person, community-based, Behaviour Change Support (individual and group work) delivered by trained volunteers using techniques of Risk Profiling, National Guidelines on Healthy Behaviours, Goal Setting, Action Planning, Problem Solving, and Motivational Interviewing. Interventions will be repeated up to 11 times over 24 months starting weekly and then less frequently.
2. Control group provided only with Risk Profiling and National Guidelines on Healthy Behaviours.

Intervention Type
Behavioural

Primary outcome(s)
1. Predicted cardiovascular risk profile score measured using survey incorporating the non-clinical INTERHEART risk profiling instrument at baseline, 6, 12, 18 and 24 months
2. Perception of CVD risk score measured using survey (ABCD questionnaire) incorporated into baseline survey at baseline, 6, 12, 18 and 24 months
3. Adherence to Dietary Approaches to Stop Hypertension (DASH) dietary advice measured through administration of adapted ‘DASH-Q’ survey instrument with Intervention Group 9 times during 18-24 month period
4. Adherence to national (UK) guidelines on recommended levels of Physical Activity measured through administration of International Physical Activity Questionnaire (IPAQ) with Intervention Group 9 times during 18-24 month period

Key secondary outcome(s)

1. Qualitative data on barriers and facilitators to healthy behaviour change collected through individual interviews with Intervention Group 9 times during 18-24 month period
2. Qualitative data on impact of social determinants on behaviour change intentions gathered through focus groups and individual case studies with selected Intervention Group participants

Completion date
30/09/2021

Eligibility

Key inclusion criteria
All eligible adults (over 18 years old)

Participant type(s)
All

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Under 18 (non-adult)
2. Pregnant
3. Previously diagnosed with heart condition

Date of first enrolment
01/04/2019

Date of final enrolment
30/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Nottingham Trent University
50 Shakespeare Street
Nottingham
United Kingdom
NG1 4FQ

Study participating centre
Brighton and Sussex Medical School
Bsms Teaching Building
University Of Sussex
Brighton
United Kingdom
BN1 9PX

Sponsor information

Organisation
EU Horizon 2020

ROR
https://ror.org/00k4n6c32

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

Individual participant data (IPD) sharing plan

All survey data (baseline survey and intervention survey) are uploaded to the secure research data server at the University of Antwerp using the 'RedCap' application. RedCap has extensive security measures (see https://projectredcap.org/about/faq/). If you require assistance or have any questions about REDCap, please contactREDCap Administrator (swabra.nakato@uantwerpen.be/+3232658862). Participant data will only be available to third parties in aggregate and anonymised form as and when results are published in due course.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	Protocol for UK study	12/03/2020	16/01/2023	Yes	No
Interim results article	Validation of ABCD Risk Questionnaire with additional smoking behaviur questions		16/01/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes