

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	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/08/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 16/01/2023	Condition category Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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?

Prof. Harm Van Marwijk

H.VanMarwijk@bsms.ac.uk

Study website

<https://www.uantwerpen.be/en/projects/spices/>

Contact information

Type(s)

Scientific

Contact name

Prof Harm Van Marwijk

Contact details

Bsms Teaching Building

University Of Sussex

Brighton

United Kingdom

BN19PX

+44 (0)1273644774

H.VanMarwijk@bsms.ac.uk

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Study design

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

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Community

Study type(s)

Prevention

Participant information sheet

<http://j.mp/2XcRvEB>

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 measure

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

Secondary outcome measures

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

Overall study start date

01/03/2019

Completion date

30/09/2021

Eligibility

Key inclusion criteria

All eligible adults (over 18 years old)

Participant type(s)

All

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

800

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

England

United Kingdom

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

Sponsor details

EU HQ

Rue de la Loi 175

Brussels

Belgium

1000
+32 (0)2 281 59 20
erc-uk@bbsrc.ac.uk

Sponsor type

Other

Website

<https://ec.europa.eu/programmes/horizon2020/en>

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

Publication and dissemination plan

1. A joint protocol for publication by Nottingham Trent University and Brighton and Sussex Medical School is being drafted. A copy can be provided as soon as this has been approved by partners.
2. Implementation Science paper
3. Public Health & Community Engagement paper

Intention to publish date

01/10/2021

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 contact REDCap 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?
Interim results article	Validation of ABCD Risk Questionnaire with additional smoking behaviour questions		16/01/2023	Yes	No
Protocol article	Protocol for UK study	12/03/2020	16/01/2023	Yes	No