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Interventions for cardiovascular disease prevention in sites in Europe

Submission date
23/04/2019

Recruitment status
No longer recruiting

Registration date
10/05/2019

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Cardiovascular diseases are the main cause of morbidity and mortality with an increasing economic burden in healthcare. One in three deaths is attributed to a cardiovascular disease. 90% of morbidity and mortality in cardiovascular disease is associated with preventable lifestyle-related risk factors, including poor diet, smoking and lack of exercise Adults are less at risk of cardiovascular disease if they follow a healthy diet and increase their daily exercise. This confirms the importance of primary prevention measures. In practice, there is therefore a need for structured optimization of behavioral change to a healthy lifestyle. Moreover, the current evidence supports a link between inequalities in socio-economic status (SES) and CVD, CVD risk factors and unhealthy lifestyle, making people with a low SES more vulnerable to developing a CVD. To support the overburdened primary health care in systematically taking preventive tasks in the context of cardiovascular disease, care models such as interprofessional working in general practice with a nurse practitioner and engaging social workers in a community in working on health, can be solutions to meet current care needs in primary care. The context of Belgian primary health care is currently evolving from fragmented care to an integrated approach led by policymakers. This offers a solid input for the sustainability of this project. Current developments with regard to the integration of nursing competencies in general practice can be an important opportunity to optimize cardiovascular prevention in primary care. In addition, we have learned from our stakeholder meetings that welfare organizations are open to enable CVD profiling with existing community initiatives, in addition to reaching the part of our target population that is not yet registered with a general practice (proportional universalism perspective). It will be interesting to investigate these opportunities as a possible solution for improving the accessibility of preventive care for cardiovascular diseases.

Purpose of the study:
The primary goal of this study is to investigate how a CVD primary prevention program, consisting of a profiling and multi-component behavioral change intervention, can be implemented in primary health care and welfare organizations in vulnerable (high proportion of people with low socio-economic status) Antwerp city districts in Belgium, to support people to be aware of their cardiovascular risk and change their risk behavior for the primary prevention of CVD.
The secondary objectives of this study are (1) monitoring the impact of the SPICES program on

individual behavioral outcomes (self-reported health behavior) in persons with moderately increased CVD risk and (2) monitoring the impact of the presence of a SPICES program in the target regions for “awareness” of CVD risk and the importance of a healthy lifestyle at a broader population level.

Who can participate?
Adults aged between 40-65 years in Deurne, Borgerhout or Wommelgem (Antwerp, Belgium) who give consent to participate and are at moderately increased risk of developing CVD based on the Interheart profiling tool score.

What does the study involve?
All participants will receive the same evidence-based intervention as stated below. Follow-up measures include pre-post evaluation with self-reported health behavior outcomes (questionnaires every 6 months).
1. Profiling
The first step in behavioral change is to be aware of the individual risk for heart disease. With the help of the non-laboratory Interheart Risk Scoring tool, members of the population will be invited to participate through general practice or welfare organization. When participating, they are divided into 3 categories based on a number of questions: low, moderate, high risk of cardiovascular disease. Based on the score, the electronic interheart will automatically generate advice, which the profiler will transfer to the person using motivational interviewing techniques. The group with moderately increased risk is our target population within SPICES and will be referred to 2 behavioral change counseling interventions.
2. Behavioral change counseling
Here too, work is being carried out on 2 levels. General practices wishing to participate in this study will be supported in their preventive consultation. The community level will also look at which initiatives regarding healthy lifestyle are already present in the neighborhood and the providers / organizers will also be supported in their program here. In this way, this project wants to link primary care and community to each other and familiarize all stakeholders with the range of available initiatives.

What are the possible benefits and risks of participating?
All participants including patients will benefit from the planned interventions which include profiling for CVD risk factors and primordial prevention guidance and referral to health facilities. It is hoped that the 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?
University of Antwerp - Faculty of Medicine and Health Sciences Department of Primary and Interdisciplinary care

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

Who is funding the study?
Horizon 2020, European commission

Who is the main contact?
Miss Naomi Aerts (scientific contact), naomi.aerts@uantwerpen.be

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
SPICES_Belgium

Study information

Scientific Title
Scaling-up packages of interventions for cardiovascular disease prevention in selected sites in Europe and sub-Saharan Africa: an implementation research

Acronym
SPICES

Study objectives

General objectives
1. To implement, and evaluate the impact, of a comprehensive CVD prevention program in a population in a Belgian urban setting with a high number of 'vulnerable' inhabitants with low socio-economic status.
2. To identify the contextual barriers and facilitators that influence the scale-up of the comprehensive CVD prevention interventions and compare them across SPICES study sites.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/04/2019, Ethics committee of Antwerp University Hospital (Ethics committee UZA, UZA Wilrijkstraat 10, 2650 Edegem, Antwerp, Belgium; + 32 3 821 35 44; ethisch.comite@uza.be) ref: B300201940009. Study tracking number: 19/13/171.

Study design
Hybrid type III convergent parallel mixed method design

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Primary prevention of cardiovascular diseases (addressing CVD risk factors)

Interventions
1. CVD profiling & risk communication
The identification of people who might be at risk for CVD (profiling), will be obtained by using the InterHeart tool; this choice is supported by a scoping literature review and consensus with consortium partners. This first intervention will be carried out on two levels, being GP practices and in the community.
GP practices: CVD risk profiling, amongst other preventive tasks, falls under the responsibility of general practitioners. However, in current practice we see that this does not happen in a systematic way, which makes this an opportunity for improvement through task shifting to the community?
Community: Lay people who are active in welfare organizations (depending on organization, e.g. social workers, volunteers) and who are familiar with interacting with our target vulnerable population, have an entry-point given their pre-existing trust-based relationship. Moreover, people who don't have a regular GP yet will be given the guidance towards primary health care when needed.
Based on the InterHeart score, people will be stratified based on their CVD risk in three categories: green (low risk), amber (medium risk), red (high risk). Regardless of risk category or setting, all profiled individuals will receive very brief advice and if necessary a referral appropriate to their risk, preferences and needs.
-Very brief advice: A very brief advice follows the communication of CVD risk, and together they are carried out in order to initiate patient activation and health seeking behavior for the amber and red scoring individuals. This knowledge transfer may be supported by educational materials (e.g. eHealth visualization of risk, leaflet). The green scoring individuals will receive a 'supportive

communication': congratulation on successfully maintaining a healthy lifestyle, brief information on CVD risk factors, motivational message in sustaining healthy lifestyle in the future.
-Referral: Profiles people get an individualized referral appropriate to their health needs derived from their risk score.
1. Green category: will be made aware of pre-existing, community based, bottom-up initiatives in the neighborhood (or within the organization that supports the profiling) that support the target lifestyle behavior(s).
2. Amber category: will be made aware of pre-existing, community based, bottom-up initiatives in the neighborhood (or within the organization that supports the profiling) that support the target lifestyle behavior(s). In addition, for this amber population we will focus on the group offer on lifestyle behavior that is already available and which is "SPICES-approved" (screen that offer for if it to the evidence and if the people who offer it are competent-if not the organizers get the support they need e.g. training). The amber people that are registered with a GP practice with a practice nurse that collaborates with SPICES, be referred to make an appointment with the practice nurse for follow-up of their CVD risk and behavior change.
3. Red category: will be referred to usual care

2. Brief behavior change counseling
Behavioral counseling with the purpose of helping people change their unhealthy lifestyle, will be implemented in general practices, guided by the components as described in the 'Change4Health document'. During these counselling sessions, primary health care providers will be applying evidence-based behavioral change strategies, such as motivational interviewing, goal-setting, action-planning and problem-solving. These strategies imply a higher level of patient engagement, thanks to the focus on the patient's perspective. Based on the recommendations found in international guidelines, follow-up of the behavior change will be pursued for at least one year.

Intervention Type
Behavioural

Primary outcome(s)
Current primary outcome measure as of 27/01/2020:
The primary outcomes of this study are implementation outcomes. In order to achieve the aims of our process evaluation we use the RE-AIM framework for evaluating our mixed method implementation study and use it as a preliminary guide and adapt it to our study setting to formulate the key areas to evaluate. RE-AIM is the acronym for five evaluation components: reach, effectiveness, adoption, implementation, and maintenance.
1. Reach
The reachability of the intervention package will be assessed in terms of the absolute number, the proportion, and representativeness of sites who are willing to participate in the SPICES intervention. The number, the proportion, and representativeness of the individuals (staff, patients, community,…) from each site who take part in the SPICES intervention.
2. Effectiveness/efficacy
The positive or negative effects which the implementation of a SPICES program will be evaluated through mixed methods
a. The population survey will be used to evaluate the effectiveness of the intervention in improving participant knowledge, perception and change in risk behavior.
b. Behavior change outcomes (pre-post)
c. Notes from records kept from engagement meetings with staff.
d. Recorded contacts made from contacts with sites and all relevant stakeholders
3. Adoption

The absolute number, the proportion, and representativeness of sites and the stakeholders who are willing to initiate the SPICES program 3.1 Notes from records kept from engagement meetings with staff.
a. Recorded contacts made from contacts with sites and all relevant stakeholders
4. Implementation
SPICES program agents' fidelity to the various elements of the SPICES protocol—includes consistency of delivery and time and cost of intervention.
a. Records of costs of training, material, etc. of each component of the SPICES program
b. Notes from records kept from engagement meetings with staff.
c. Recorded contacts made from contacts with sites and all relevant stakeholders
d. Fidelity checklists for all components of the SPICES program
5. Maintenance
The extent to which the SPICES program (and the action plans that emerge from this) become institutionalized or part of routine organizational practices.

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1. Reach
The absolute number, the proportion, and representativeness of sites who are willing to participate in the SPICES intervention. The number, the proportion, and representativeness of the individuals (staff, patients, community,…) from each site who take part in the SPICES intervention.
2. Effectiveness/efficacy
The positive or negative effects which the implementation of a SPICES program
2.1 Population survey
2.2 Behavior change outcomes (pre-post)
2.3 Notes from records kept from engagement meetings with staff.
2.4 Recorded contacts made from contacts with sites and all relevant stakeholders
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The extent to which the SPICES program (and the action plans that emerge from this) become institutionalized or part of routine organizational practices.

Key secondary outcome(s))

Current secondary outcome measures as of 27/01/2020:
Pre-post (Intermediate Risk cohort)

1. InterHeart risk score (translated to Dutch).
2. CVD risk awareness: ABCD questionnaire (validated in English, translated to Dutch)
3. Quality of life: WHOQOL bref (validated in Dutch)
4. Smoking level (Reduction of smokers/ reduction of number of cigarettes per smoker)
5. Improvement of diet (fruits/ vegetables consumption): Dash-Q (translated to Dutch and adapted to Belgian context), Feel4Diabetes diet questionnaire (validated in Dutch).
6. Activity level using the shortened version of the International Physical Activity questionnaire: short IPAQ (validated in Dutch)
7. Alcohol consumption (weekly declarative dose of alcohol)
8. The change in CVD knowledge, risk perception, intention to change, and physical activity behavior will be assessed using a population survey at baseline and 12 months.

Previous secondary outcome measures:
Pre – post (Intermediate Risk cohort)
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Completion date
31/12/2021

Eligibility

Key inclusion criteria
Current participant inclusion criteria as of 27/01/2020:
To be included to the cohort;
1. Both male and female
2. Aged 40-65 years
3. Consent to participate in the study
4. At moderate risk for CVD based on Interheart profiling score
For population survey:
1. Age ≥18 years
2. Consent to participate in the study

Previous participant inclusion criteria:
1. Both male and female
2. Aged 40-65 years
3. Consent to participate in the study
4. At moderate risk for CVD based on Interheart profiling score

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Mentally ill
2. Non-consenting adults
3. At low or high risk for CVD based on Interheart profiling score

Date of first enrolment
01/12/2018

Date of final enrolment
30/08/2021

Locations

Countries of recruitment
Belgium

Study participating centre
University of Antwerp - Faculty of Medicine and Health Sciences Department of Primary and Interdisciplinary care
Campus Drie Eiken
Gouverneur Kinsbergencentrum
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Sponsor information

Organisation
University of Antwerp

ROR
https://ror.org/008x57b05

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
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?
Other publications	Qualitative process evaluation study	08/03/2023	14/06/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes