After the Health Check in vulnerable groups: an individually tailored self regulation intervention led by Community Health Workers.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Interventional

Summary

ID

NL-OMON39897

Source
ToetsingOnline

Brief title
ATHC; After The Health Check.

Condition

- Cardiac disorders, signs and symptoms NEC
- Glucose metabolism disorders (incl diabetes mellitus)
- Lifestyle issues

Synonym
Cardiovascular disease, Diabetes

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: LekkerLangLeven (fondsen: Hartstichting;Diabetesfonds en Nierstichting).

Intervention

Keyword: Community Health Workers, Lifestyle change, Self regulation, Vulnerable groups

Outcome measures

Primary outcome

The primary outcome measures are cardiometabolic risk factors: blood pressure,

glucose, total and HDL cholesterol, body mass index, waist

and hip circumference.

Secondary outcome

The secondary outcome measures are nutrition, physical activity and smoking.

Furthermore information will be collected on psychosocial determinants of

health behaviors. The questionnaire is based on the questionnaire developed in

the study mentioned earlier (ABR nr. 37141) and self-regulation questionnaires.

Study description

Background summary

With the vast rise of individuals with chronic conditions, the focus of our health care system will shift from cure to prevention by identifying people at high risk for cardiovascular disease (CVD), Diabetes Mellitus type II (DM II), and kidney disease. Especially non-Western immigrant groups are at (very) high risk for these chronic diseases. It is well established however, that identifying high risk individuals by health checks in primary care only to a limited extent reach those high risk groups from deprived neighborhoods. In above-mentioned study (ABR nr. 37141) our research group will develop tools to increase participation in health checks in individuals from non-Western immigrant populations. However, increasing participation with health checks is

only a first step towards illness prevention for migrant populations. Effective follow-up interventions are necessary to ensure that they will really benefit from the health check information by changing unhealthy lifestyle behaviors. The current study focuses on how high risk individuals with a non-Western background are motivated to start and maintain a healthy lifestyle.

Changing behavioral patterns that have become habitual is complex. Evidence shows that simple health education interventions like just providing lifestyle advice by general practitioners yield little or no effects, especially when behavior maintenance is considered. Previous reports have criticized self-management interventions for applying a *one-size-fits-all approach* without relating them to individuals* needs and personal goals.

Community Health Workers (CHWs) who have expertise in motivational interviewing techniques may improve uptake, maintenance, adherence, and self-control in our patients. CHWs facilitate social support, community education, access and adherence to preventive / rehabilitation care
and monitoring of risk, adherence to treatment recommendations, promotion of self-care skills, and other follow-up care.

In the Netherlands, there are no CHWs yet. Health professionals matching the CHW most closely are (migrant) lifestyle coaches of existing lifestyle programs like *Exercise on prescription*. Also, the general practitioners* practice nurse often has received specific training for the role we propose for the CHW. For this study, these different professionals will receive specific (additional) training to be able to perform the role of CHW.

Key elements in a strategy to reach sustainable behavioral changes are among others: personal, longstanding guidance, feasible goals, tailored and repeated advices, tuning at the patients* own beliefs and possibilities. Based on our knowledge of the literature, an approach with CHWs helping high risk individuals to restructure their environment and to set and keep attainable health goals seems promising.

Study objective

The overall objective of this study is to increase the uptake and maintenance of healthy behaviors among adults from non-Western immigrant populations who are identified as having a high risk of cardiometabolic disease after completing a health check. This will be achieved by developing and testing an individually tailored self-regulation intervention provided by a trained CHW.

The study has a stepped approach in which (1) we will carefully develop a self-regulation intervention for the follow-up care for high risk individuals of non-Western immigrant populations by applying an intervention mapping protocol to build a sound foundation and by locating relevant existing interventions that can be integrated in the program; (2) the effectiveness of

the intervention will be evaluated by conducting a randomized controlled trial (RCT); (3) the evaluation of phase 1 and 2 will result in a set of recommendations for successful implementation of a strategy to support high risk individuals of the target population in starting and maintaining a healthy lifestyle.

Research questions are the following:
1. Which factors play a key role in the uptake and maintenance of behavioral changes in high risk groups for cardiometabolic disease according to (high risk) individuals from non-Western immigrant populations and health professionals? (Earlier approved under P11.030)
2. Which tailored theory-based interventions for self-management of cardiometabolic disease exist (in the Netherlands and in foreign countries)?
3. Is a tailored CHW-led self-regulation intervention for the target group superior as compared to usual care?
4. Which recommendations can be given for implementing strategies for an adequate follow-up after a high risk identification by a health check assessment to change risky lifestyle behaviors on the short and long term?

Study design

Stratified randomized controlled trial and process evaluation.

Intervention

The self-regulation intervention will consist of a self-regulation protocol for guidance of high risk individuals from non-Western immigrant populations. This self-regulation intervention will be pretested. Individuals from the study population with a
high risk of cardiometabolic problems will be referred to a CHW. The CHW will analyze the personal circumstances and behavioral factors of the patients, develop a personalized self-regulation program, and follow-up maintenance of behavior change. The focus of this pretest is on testing procedures and gaining feedback on the process by the patient, CHW, and other health professionals. The self-regulation intervention will be pretested in two general practices, in the setting of the Foundation Prevention and Care (Stichting Preventie en Curatie) in The Hague . Two CHWs will be trained. These trained CHWs will both manage three patients. The training will be evaluated, activities will be registered and CHW, general practitioner, practice nurse, and patients will be interviewed. One contact of each CHW will be observed. After the pretest the self-regulation intervention or the guiding protocol will be adapted if necessary.

For the intervention, patients from the study population will be randomly assigned to the intervention (n=150) or control group (n=150). The intervention group will receive a prevention consultation at the general practitioner

followed by a self-regulation intervention guided by a trained CHW. The control group will only receive the prevention consult at the general practitioner and be advised according to *usual care* standards. Stratification will be effectuated to include individuals of all three vulnerable groups (Turkish, Moroccan, and Surinamese immigrant groups).

For the outline of the interventionprogram, see p.8 of the protocol.

Study burden and risks

Outcome criteria will be measured 3 times in both the intervention and the control group: at the start of the prevention consultation at the general practitioner, directly after the intervention period and 3 months after the intervention period.

The baseline measurement consists of the completed health risk assessment prior to the prevention consultation at the general practitioner. During the prevention consultation blood pressure, weight and length, hip and waist circumference are measured, blood samples are obtained for glucose, total and HDL cholesterol, and patients fill out the questionnaire on psychosocial determinants of health behaviors. The questionnaire is estimated to take approximately 30 minutes.

Directly after the intervention period and 3 months after the intervention period the participants will complete the health risk assessment and the questionnaire on psychosocial determinants of health behaviors.

Three months after the intervention period, blood pressure and blood samples will be obtained during a visit at the general practitioner / assistant nurse.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Turkish, Moroccan or Creole Surinamese origin, 45 - 70 years old, and increased risk of cardiometabolic disease according to the health check (ABR 37141).
Hindustani Surinamese origin, 35 - 70 years old, and increased risk of cardiometabolic disease according to the health check (ABR 37141).

Exclusion criteria

- Patients with known cardiometabolic disease.
- Patients who are not able, physically or mentally, to participate in the intervention. This will be judged by their GP; e.g. people with serious psychiatric problems or cognitive limitations.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-12-2013
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	24-04-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL41620.058.13