Unravelling the effectiveness of a behaviour change intervention to enhance physical activity in nurse-led cardiovascular risk management: study protocol of a clustered-randomized controlled trial in primary care

Published: 21-10-2015
Last updated: 20-04-2024

The main objective of this study is to evaluate the effectiveness of the Activate intervention in adult patients at risk for cardiovascular disease (CVD) in primary care. Secondary aims are to identify which patient-related characteristics modify…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON45037

Source
ToetsingOnline

Brief title
Activate study

Condition

- Other condition

Synonym
at risk for heart and vessel disease, cardiovascular risk

Health condition

cardiovasculair risico

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Behaviour change techniques, Physical activity, Primary care nursing, Self-management support

Outcome measures

Primary outcome

Primary outcome is level of physical activity measured with the Personal

Activity Monitor.

Secondary outcome

Secondary outcomes are sedentary behaviour, self-efficacy for physical

activity, patient activation and health status (EQ-5D). Potential

patient-related effect modifiers are age, body mass index, level of education,

social support, anxiety and depressive symptoms, patient-provider relationship

and baseline amount of minutes of physical activity. Furthermore a process

evaluation will be conducted to evaluate the fidelity, dose and reach of the

Activate intervention, identify barriers and facilitators for implementation,

and to assess the satisfaction of participants. Data will be collected at

baseline, at 3 months of follow up and at 6 months of follow up.

Study description

Background summary

Self-management interventions are considered effective in chronic disease patients, but trials have shown inconsistent results and it is unknown which patients benefit most. To unravel this variance in effect size focus is needed on specific homogeneous components of self-management and its success across heterogeneous subgroups of chronic disease patients who can benefit from behaviour change. A systematically designed behaviour change intervention using the Behaviour Change Wheel is developed to increase the level of physical activity in patients at risk for cardiovascular disease in primary care - the Activate intervention. The Activate intervention consists of four consultations integrating effective behaviour change techniques and high-standard training of health care providers.

Study objective

The main objective of this study is to evaluate the effectiveness of the Activate intervention in adult patients at risk for cardiovascular disease (CVD) in primary care. Secondary aims are to identify which patient-related characteristics modify change in physical activity levels in patients at risk for CVD in primary care and to perform a process evaluation.

Study design

a clustered randomized controlled trial will be conducted to compare support in physical activity in the Activate intervention with care as usual. Clustering is at the level of the general practice.

Intervention

Participants in the intervention group will visit their practice nurse 4 times in a 3-month period for structured and comprehensive support in achieving an improved level of physical activity. Patients in the control group will receive care as usual.

Study burden and risks

Since the Activate intervention concerns additional support in primary care, which is familair to the patient, in their neighbourhood, and supplementary to their routine care, we assume participation will be of minimal burden to the patient. The risk of participation is negliglible since participation entails extra (low burden) consultations, use of accelerometer and low burden

questionnaires, and measurements.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Eligible patients have at least one of the following risk factors of cardiovascular risk management according to the Dutch guideline for Cardiovascular risk management: ;Aged 40-75;AND
* 1 of the following criteria ;1. have a high blood pressure (* 140 mmHg) or are already treated for high blood pressure
2. have a high total cholesterol (* 6.5 mmol/l) or already treated for high cholesterol
3. have diabetes mellitus type 2 (DM2)
4. have a positive family history of CVD;AND;Not adhere to the Dutch Norm for Healthy Exercise according to a self-reported questionnaire

Exclusion criteria

- Have participated in a program to increase their level of physical activity in the past 2 years.
- Are unable to give informed consent (eg. due to cognitive impairment)
- Are unable to speak, write and read Dutch
- Have contra-indications to increase their physical activity level (eg. unstable angina pectoris, unstable heart failure, acute illness)
- Have a terminal illness
- Have severe psychiatric illness or chronic disorder(s) that seriously influence the ability to improve their psychical activity level

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-03-2016
Enrollment:	277
Type:	Actual

Ethics review

Approved WMO

Date:	21-10-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	24-02-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	19-04-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	03-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-06-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	06-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	27-07-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	26-08-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	

Date:	27-10-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-02-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL54286.041.15