Internet-based vascular Riskfactor Intervention and Selfmanagement study

Published: 30-09-2008
Last updated: 07-05-2024

The objective of the proposed study is to evaluate the efficacy on risk factor management and toevaluate cost-effectiveness of an internet-based risk factor management program for patients at highcardiovascular risk.The research questions are...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Interventional

Summary

ID

NL-OMON32176

Source
ToetsingOnline

Brief title
IRIS

Condition

- Coronary artery disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
atherosclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: ZonMw;projectnummer 17088.2705

Intervention

Keyword: internet, nurse practitioners, self-management, vascular risk-factors

Outcome measures

Primary outcome

After 1 year all patients (usual care and internet-based care) are asked to return to the clinic for an evaluation visit to obtain the same information on vascular risk factors and risk indicators as was done as at baseline: Total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, glucose, body mass index, waist circumference, blood pressure and smoking. A questionnaire will be used to gather data about health-care use, labour, self-care, exercise, food-choices, self-efficacy, social support, and quality of life.
At the beginning of the study and at the end of the intervention period, the 10-year absolute cardiovascular risk will be carculated using the Framingham risk-score. The difference in 10-year risk between end-of-study (after 1 year) and baseline will serve as primairy summary risk outcome. The primairy outcome is the relative difference in absolute risk between the intervention group and copntrol group.

Secondary outcome

The absolute change in each risk factor (the level at 1 year minus the level at baseline) and the percentage of patients reaching the treatment goal for each risk factor will be calculated and serve as secondary outcome.

Change in self-management related parameters and actual health behavior between

the intervention group and the control group will be related to achieved

treatment goals.

Study description

Background summary

Vascular diseases are among the most prevalent medical disorders in the Netherlands, leading to premature death, (severe) disability and reduced quality of life. The health care costs for patients and society are increasing. In the last 10 years very effective treatment strategies for reducing cardiovascular risk have been evaluated in numerous large randomized clinical trials. It has become very clear that blood pressure lowering, LDL-cholesterol lowering, smoking cessation, weight control and exercise are the principle targets for risk reduction in patients at high risk for developing new vascular events. Across trials in different high-risk populations, the average reduction in relative risk for cholesterol-lowering is 30%, blood pressure lowering 30%, stop smoking 20-40% and weight reduction 30-40%. In the recently issued CardioVascular Risk Management (CVRM 2006) guideline in the Netherlands, these interventions are considered to be crucial in risk reduction (9,10). Nevertheless, poor management of vascular risk factors leaves many patients unnecessarily at increased risk. New healthcare strategies need to be developed to deal with this health problem in an increasing number of patients.(11-15) Given the fact that more patients survive an acute cardiovascular event, the number of high risk patients will further increase. Therefore new healthcare strategies not only need to be more effective but must also be very efficient. It is expected that using current internet technology and aiming at improving self management capacity of patients by providing treatment and medical support in their own home, away from the high-cost hospital environment, this strategy could be very effective as well very efficient in

terms of costs.

Study objective

The objective of the proposed study is to evaluate the efficacy on risk factor management and to
evaluate cost-effectiveness of an internet-based risk factor management program for patients at high
cardiovascular risk.
The research questions are defined as follows:
- Is an internet-based vascular risk factor management program on top of usual care more effective than
usual care alone in reducing vascular risk factors in patients with a recent clinical manifestation of a
vascular disease?
- Is an internet-based vascular risk factor management program for reducing vascular risk factors in
patients with a recent clinical manifestation of a vascular disease cost-effective?

Study design

Randomized, non-blinded trial

Intervention

Patients randomised to the internet-program will receive an internet-based risk factor
management program on top of usual care for 12 months. Patients will be invited for a visit to the nurse
practitioner in the hospital. During this visit patients receive information on the treatment advices and
corresponding risk factors, receive instructions on the internet program and receive a username and
password for their personalized website. The following contacts between patient and nurse practitioner
will be by the internet. Depending on presence of risk factors that need (additional) treatment, a tailored
internet file is made for each individual patient. The opening page gives an overview of all the status of
all risk factors (green=good, yellow=close to goal, red=needs attention), medication use and (new)
messages from the nurse. Within the program, each risk factor is displayed on a separate internet page
containing a history of risk factor measurements (e.g. blood pressure or LDL-cholesterol, etc), current

treatment, treatment goal, advices from the nurse, correspondence between nurse and patient, news
items of that particular risk factor. Patients are encouraged to log-in frequently and to fill in new
measurements (blood pressure, weight, smoking status, cholesterol) and to read and send messages.
The internet program is linked to the www.vaatcentrum.nl website of the UMCU for general information
on risk factors and vascular diseases. The nurse practitioner is able to view all files and pages from all
patients and has access to pages with a total overview of the current status of risk factors, last log-in
attempts of each patient and new messages send by patients. In general the nurse practitioner will log-in
every day and this overview enables her to very efficiently reply to messages send by patients and to
send messages to patients not using the program regularly. If necessary telephone contact can be
made. Change in medication regimen can be made by sending a pharmacy-recipe. Patients are
encouraged to self-measure blood pressures at home. If applicable, the patients has the option to log-in
at the office of the general practitioner for direct viewing and addition of information about vascular risk
factors. In this way the general practitioner can be actively involved in risk factor management and has
access to all patient information regarding risk factor management. It is up to the patient and general
practitioner whether this opportunity provided by the program is taken and whether the general
practitioner will be granted with full access to his/her medical information on vascular risk factors. For
measuring plasma lipids and/or glucose patients receive laboratory forms from the nurse by mail for
drawing blood in their own city or at the UMCU or Rijnstate Hospital, whatever is convenient for the
patient. The nurse practitioner works according the guidelines described in the latest version of
*handboek voor verpleegkundig specialisten' (6) based on the national CVRM 2006 guideline for the
diagnosis and treatment of vascular risk factors.
The care delivered by the nurse practitioner with the internet program is on top of usual care and can not
replace the care given by the treating physician in the hospital and the general practitioner. The
internet-based care should be seen as on-top-of usual care. A possible draw back of the web-based risk

factor management program is that the nurse practitioner is likely to be focussed on the protocol
('handboek') and on vascular risk factors and by using internet there are limited face-to-face contacts
with the patients. Therefore co-morbidity may not become evident. At the start and during the program
the nurse practitioner will encourage patients to contact their own doctor(s) for medical issues, whether
or not related to vascular diseases and/or vascular risk factors. At the end of the study (after 12 months)
patients randomized to the internet program are asked to report visits to doctors, diagnoses made during
the 12 months and medication use, in order to evaluate whether additional diagnoses were made that
may have been missed by the nurse practitioner unless the fact that the nurse practitioner is vigorously
supervised by an internist.

Study burden and risks

n.a.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with an recent clinical manifestation of atherosclerosis in the coronary, cerebral or peripheral arteries undergoing a standardized risk factor screening program revealing 2 or more treatable risk factors. Patients are between 18 and 80 years of age, capable to read and write Dutch, independent in daily activities and have access to internet at home.

Exclusion criteria

No access to internet.
Malignant disease, dependancy in daily activities

Study design

Design

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

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2008
Enrollment:	380
Type:	Actual

Ethics review

Approved WMO Date:	30-09-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-11-2008
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	NL22261.041.08