Effectiveness of two intensive counselling methods for smoking cessation and relapse prevention in persons with coronary heart disease

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

Summary

ID

NL-OMON32953

Source
ToetsingOnline

Brief title
Smoking Cessation among Patients with Coronary Heart Disease - SCPCH

Condition

- Coronary artery disorders

Synonym
'heart disease' and 'coronary heart disease'

Research involving
Human

Sponsors and support

Primary sponsor: Open Universiteit Nederland

Source(s) of monetary or material Support: Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie (ZonMw)

Intervention

Keyword: coronary heart disease, patients, smoking cessation

Outcome measures

Primary outcome

Primary outcome will be point prevalence abstinence from smoking (PPA) after 6 and 12 months. PPA is considered to be the most sensitive and valid measure of smoking cessation.

Secondary outcome

Secondary outcomes will be continued abstinence, quit attempts, lapses and relapse into smoking. Health outcomes that will be measured are new coronary events, hospital readmissions for coronary events, TC/HDL cholesterol ratio, blood pressure, prescribed medication, number of visits to the cardiologist since discharge.

In telephone interview after 6 and 12 months will assess: visits to general practitioner in past months, cardiology outpatient visits in past months, hospitalisations in past months and death related to cardiovascular disease, contacts with caregivers, absence from work due to illness, and resource use specifically for the interventions. Patients who die during the study will directly be excluded from the study to avoid any further contact with family.

OTHER MEASUREMENTS

The baseline measurement (questionnaire) and the 6 and 12 months post-test

(telephone interview) will also include factors that are related to smoking

cessation and/ or relapse among this patient population. These include:

- demographics;

- smoking related factors (smoking history, addiction);

- disease related factors (severity of disease, diagnosis);

- BMI;

- psychological state (depression, anxiety, type D behaviour); smoking

cessation related cognitions (for example attitude, selfefficacy, smoking

behaviour of important others) only measured baseline

Study description

Background summary

Cardiovascular disease is the leading cause of death, and coronary heart diseases have an important share in this. Smoking cessation after development of coronary heart disease improves prognosis more than any other treatment and prevents future cardiovascular diseases. Yet, 57% of those who smoked prior to a cardiac event persist in smoking or relapse. Usual smoking cessation care in Dutch cardiology wards is often very minimal and not structured. Moreover nurses experience difficulties in providing this care. Hence, there is need for improved intensive and feasible smoking cessation interventions for Dutch cardiac inpatients. Previous studies and reviews provide strong indications that intensive counselling interventions including relapse prevention strategies and pharmacotherapy are effective, also among patients with coronary heart disease. They are expected to be feasible in practice if carried out by smoking cessation professionals instead of ward nurses and can be provided by telephone of face-to-face. However, such interventions have not yet been tested in cardiac inpatients nor cost-effectiveness is clear.

Study objective

This study finally aims to provide hospitalized coronary heart disease patients who smoke with proven (cost)effective smoking cessation interventions. Point prevalence abstinence is estimated in the experimental groups at 60% at 6 months, against 43% in the control group. After 12 months, 55% abstinence in experimental groups and 35% in the control group are estimated.
The following studies are proposed:
STUDY 1:
- To assess effects of TC and FC on smoking cessation and health outcomes in cardiac inpatients compared to usual care.
- To assess patients* appreciation of and experiences with the interventions.
STUDY 2:
- To assess incremental cost-effectiveness and budgetary impact of the interventions comparing them to each other and to usual care.
- To compare health outcomes and smoking cessation outcomes with costs of the interventions, including usual care.
STUDY 3:
- To assess feasibility of the interventions, experiences of counsellors, nurses and
cardiologists in working with them, and detecting relevant conditions for large-scale dissemination.

Study design

A crossover experiment with a baseline measurement and post-tests at 6 and 12 months after baseline
will be conducted. We have chosen to use a crossover experimental design with seven comparable hospitals providing the interventions after each other. Therefore the study has three phases: A) usual care; B) FC or TC; C) TC or FC.

Outline of the study design
Ward 1 O1 X FC TC O2 O3 Ward 4 O1 X FC FC O2 O3
Ward 2 O1 X FC TC O2 O3 Ward 5 O1 X TC FC O2 O3
Ward 3 O1 X FC TC O2 O3 Ward 6 O1 X TC FC O2 O3
Ward 7 O1 X TC FC O2 O3

O1: baseline measurements by means of questionnaire; X: usual care; FC: face-to-face counselling; TC: telephone counselling; O2: 6 months after first measurement by means of telephone interview; O3: 12 months after first measurement by means of telephone interview + personal contact (for measuring health outcomes).

Intervention

The interventions consist of intensive counselling by smoking cessation professionals, either by telephone in one intervention and by face-to-face counselling in the other. These comparable interventions differ in delivery

mode and
duration. In both interventions, ward nurses start assessing patients* smoking behaviour followed by providing stop-smoking advice and referral to smoking cessation counselling. In one intervention, we deliver counselling by telephone (TC), in the other face-to-face (FC). During the TC, the patient is called seven times x fifteen minutes. During the FC, the patient has six consultations x 45 minutes with the personal coach and a telephone follow-up call five weeks after the last consultation (fifteen minutes). Both interventions include nicotine replacement therapy.

Study burden and risks

Patients who succesfully quit smoking reduce their risk of myocardial reinfarction by 50%. Their mortality risk, hospitalisation rate and chance to experience new revascularization procedures will also be lowered in case they quit smoking.

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients who are admitted with coronary heart disease at cardiac wards and smoked at least five cigarettes a week prior to hospital admission will be recruted. Inclusion criteria are:
- stable cardiac situation
- one of the following diagnoses: angina pectoris, myocardial infarction, post-PCI, post-CABG or a combination
- 18 years or older
- sufficiently fluent in Dutch and able to read Dutch.

Exclusion criteria

Exlusion criteria are:
- unstable cardiac situation
- terminal stage of the disease
- smoking less than 5 cigarettes per week
- smoking cessation more than one month prior to hospital admission
- insufficiently fluent in Dutch.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	02-11-2009
Enrollment:	798
Type:	Actual

Ethics review

Approved WMO Date:	02-09-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	24-03-2010
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL27637.029.09