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A comparison of Nicotine Replacement Therapy and Nicotine Replacement Therapy combined with the Minimal Intervention Strategy for smoking cessation in cardiovascular outpatients.

Submission date
29/08/2005

Recruitment status
No longer recruiting

Registration date
13/09/2005

Overall study status
Completed

Last Edited
08/11/2022

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
NHF 2000/B216

Study information

Scientific Title

A comparison of Nicotine Replacement Therapy and Nicotine Replacement Therapy combined with the Minimal Intervention Strategy for smoking cessation in cardiovascular outpatients.

Study objectives
In the literature evidence exists that Nicotine Replacement Therapy (NRT) approximately doubles smoking cessation rates, regardless of the setting. The Minimal Intervention Strategy (MIS) is propagated by several health institutions, but its incremental effect to NRT in cardiovascular patients if performed by a nurse in an outpatient setting is not known. In this study it is hypothesised that the combination of C-MIS and NRT significantly decreases the number of smokers if compared with NRT alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Cardiovascular disease

Interventions
In the experimental arm: Nicotine Replacement Therapy (patches) and The Minimal Intervention Strategy (short behavioural counselling)

In the control arm: only Nicotine Replacement Therapy (patches)

Intervention Type
Mixed

Primary outcome(s)
The primary endpoint of the study is smoking cessation at 12 months follow-up, as indicated by patient self-report and objectivated by urine cotinine levels.

Key secondary outcome(s)
Secondary endpoints are:
1. Changes in cognitions and smoking behaviour
2. Change in quality of life (generic and disease specific quality of life)
3. Adherence to NRT
4. Evaluation of the intervention

Completion date
01/05/2004

Eligibility

Key inclusion criteria
Consecutive patients who attend the cardiological or vascular surgical outpatients clinic, have a diagnosis of atherosclerotic cardiac or arterial disease and who smoked until the cardiac event more than 5 cigarettes per day, will be included.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Total final enrolment
385

Key exclusion criteria
1. Acute myocardial infarction in the month prior to randomisation
2. Unstable angina
3. Serious arrhythmia
4. Recent stroke
5. Skin allergy complicating the use of nicotine patches

Date of first enrolment
01/09/2001

Date of final enrolment
01/05/2004

Locations

Countries of recruitment
Netherlands

Study participating centre
PO Box 22700
Amsterdam
Netherlands
1100 DE

Sponsor information

Organisation
The Netherlands Heart Foundation (The Netherlands)

ROR
https://ror.org/05nxhgm70

Funder(s)

Funder type
Charity

Funder Name
The Netherlands Heart Foundation (The Netherlands) (ref: NHF2000/B216)

Results and Publications

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/12/2006	08/11/2022	Yes	No
Other publications	Literature review	01/11/2003		Yes	No
Other publications	Cognitive changes related to smoking behaviour	01/06/2005		Yes	No
Other publications	Effect of patient preferences	01/08/2005		Yes	No