

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

<b>Submission date</b> 29/08/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 13/09/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2022	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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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

### **Study design**

Randomised controlled trial

### **Primary study design**

Interventional

### **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?
<a href="#">Results article</a>		01/12/2006	08/11/2022	Yes	No
<a href="#">Other publications</a>	Literature review	01/11/2003		Yes	No
<a href="#">Other publications</a>	Cognitive changes related to smoking behaviour	01/06/2005		Yes	No
<a href="#">Other publications</a>	Effect of patient preferences	01/08/2005		Yes	No