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# Randomised EXhaustion Intervention Trial

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|---|---|---|
| **Submission date**<br>19/12/2005 | **Recruitment status**<br>No longer recruiting | [ ] Prospectively registered<br>[ ] Protocol |
| **Registration date**<br>19/12/2005 | **Overall study status**<br>Completed | [ ] Statistical analysis plan<br>[ ] Results |
| **Last Edited**<br>03/11/2008 | **Condition category**<br>Signs and Symptoms | [ ] Individual participant data<br>[ ] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

**Study website**
http://www.cpsych.org.uk/VE/therapy.htm

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
N/A

# Study information

### Scientific Title
Effects of treating exhaustion in angioplasty patients on new coronary events: results of the randomised exhaustion intervention trial

### Acronym
EXIT

### Study objectives
Behavioural intervention in exhausted patients post-percutaneous coronary intervention (PCI) is hypothesised to reduce exhaustion and depression, improve quality of life, and improve prognosis.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Received from the local medical ethics committee

### Study design
Multicentre, randomised, placebo controlled, parallel group trial

### Primary study design
Interventional

### Secondary study design
Randomised controlled trial

### Study setting(s)
Hospital

### Study type(s)
Treatment

### Participant information sheet

### Health condition(s) or problem(s) studied
Percutaneous coronary intervention (PCI), exhaustion

### Interventions
1. Behavioural intervention including relaxation therapy
2. Usual care

Secondary sponsor details:
The Netherlands Organisation for Health Research and Development (ZonMw) (The Netherlands)
P.O. Box 93245
Den Haag
2509 AE
Netherlands

Email: info@zonmw.nl
Sponsor website: http://www.zonmw.nl

### Intervention Type
Other

### Phase
Not Specified

### Primary outcome measure
1. Exhaustion
2. New coronary event
3. 'De novo' lesions

All at 18 months follow-up.

### Secondary outcome measures
1. New coronary events (less than 6 months)
2. Late coronary events (greater than 6 months)

### Overall study start date
01/07/1996

### Completion date
30/04/2001

## Eligibility

### Key inclusion criteria
Exhausted patients being treated successfully with PCI (reduction in stenosis of greater than 50%).

### Participant type(s)
Patient

### Age group
Adult

### Sex
Both

### Target number of participants
710

### Key exclusion criteria
1. Severe somatic or mental comorbidity
2. Somtisation disorder, fibromyalgia or chronic fatigue
3. Participation in a behavioural, rehabilitation program other than EXIT
4. Unsuccessful treatment for a recent depression or panic disorder
5. Inability to speak Dutch

**Date of first enrolment**
01/07/1996

**Date of final enrolment**
30/04/2001

## Locations

**Countries of recruitment**
Netherlands

**Study participating centre**
**Tilburg University**
Tilburg
Netherlands
5000 LE

## Sponsor information

**Organisation**
Netherlands Heart Foundation (Nederlandse Hartstichting) (The Netherlands)

**Sponsor details**
P.O. Box 300
The Hague
Netherlands
2501 CH
+31 (0)70 315 5555
info@hartstichting.nl

**Sponsor type**
Research organisation

**Website**
http://www.hartstichting.nl

**ROR**
https://ror.org/05nxhgm70

## Funder(s)

**Funder type**
Not defined

**Funder Name**
Not provided at time of registration

# Results and Publications

**Publication and dissemination plan**
Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration