

Randomised EXhaustion Intervention Trial

Submission date 19/12/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 19/12/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 03/11/2008	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

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

Study type(s)

Treatment

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(s)

1. Exhaustion
2. New coronary event
3. 'De novo' lesions

All at 18 months follow-up.

Key secondary outcome(s)

1. New coronary events (less than 6 months)
2. Late coronary events (greater than 6 months)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Severe somatic or mental comorbidity
2. Somatisation 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)

ROR

<https://ror.org/05nxhgm70>

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes