ISRCTN98393380 https://doi.org/10.1186/ISRCTN98393380

Randomised EXhaustion Intervention Trial

Submission date 19/12/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 19/12/2005	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 03/11/2008	**Condition category** Signs and Symptoms	[ ] Individual participant data [ ] 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

Protocol serial number
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

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. 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)

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