

Exercise therapy for Stress-related Mental Disorder

Submission date 16/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/11/2011	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
4200.0004

Study information

Scientific Title

Exercise therapy for Stress-related Mental Disorder: A randomised controlled parallel group trial

Acronym

ODIN

Study objectives

Exercise therapy will enhance recovery from stress-related mental disorder

Stress-related Mental Disorder (SMD) is a common problem in general practice. In DSM-IV SMD is partly but not exclusively covered by adjustment disorder, in ICD by adjustment disorder (F43.2), neurasthenia (F48.0), to some extent Burn-out (Z73.0), and work-related disorders (Z56.1-7). In a more general way it is also known as nervous breakdown, "overstressed", or "overburdened".

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of University Medical Centre of Utrecht approved on the 27th of October 2003 (protocol number: 03/109)

Study design

Randomised controlled parallel group open label clinical trial multicentre in general practice

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Stress-related Mental Disorder

Interventions

Patients in the intervention group are referred to a physical therapist for structured exercise at 70% (50-85%) of maximum intensity, for at least 30 minutes, 5 days per week, over 12 weeks. The control group will receive care as usual from the GP.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

General health, assessed by questionnaire (SF-36) at 6 weeks after start of the intervention

Secondary outcome measures

1. General health, assessed by questionnaire (SF-36) at 12 and 24 weeks
2. Social health, assessed by questionnaire (SF-36) at 6,12 and 24 weeks
3. Mental health, assessed by questionnaire (SF-36) at 6,12 and 24 weeks
4. Level of distress, assessed by four-dimensional health questionnaire (4DSQ) at 6,12 and 24 weeks
5. Mean abstinence from work at 6 and 12 weeks

Overall study start date

01/11/2003

Completion date

01/05/2005

Eligibility

Key inclusion criteria

Patients of 18 years old or more, presenting to their general practitioner with signs and symptoms of stress-related mental disorder

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

100

Key exclusion criteria

Patients with florid depression, anxiety disorder, addiction or otherwise pathological state of mind

Date of first enrolment

01/11/2003

Date of final enrolment

01/05/2005

Locations

Countries of recruitment

Netherlands

Study participating centre

Dorpsstraat 12-14

de Bilt

Netherlands

3732 HJ

Sponsor information

Organisation

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

Sponsor details

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Sponsor type

Government

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Government

Funder Name

Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands) - small ailments fund (file nr 42000004)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	26/07/2011		Yes	No