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Exercise therapy for Stress-related Mental Disorder

Submission date	Recruitment status	[ ] Prospectively registered
16/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
22/11/2011	Mental and Behavioural Disorders	

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
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)

Primary study design
Interventional

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

Study type(s)
Quality of life

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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

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)

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

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