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Treatment of functional symptoms due to work-related stress

Submission date	Recruitment status	[X] Prospectively registered
06/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
15/04/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/04/2010	Mental and Behavioural Disorders	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
02

Study information

Scientific Title
A randomised controlled trial of a immediate versus delayed stress management program versus traditional psychological therapy in adults suffering from work-related stress symptoms

Acronym
COPESTRESS

Study objectives
This study will evaluate the effectiveness of a stress management program, designed to treat work-related stress symptoms, help the participant back to work and prevent relapse.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Danish Central Scientific-Ethical Committee pending as of 08/03/2010

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Stress, adjustment disorders

Interventions
This study will analyse the effect of a stress management program. The program is composed of:
1. Stress management therapy
2. Mindfulness therapy
3. Dialogue with the participants workplace/employer
4. Physical exercise plan

210 participants are randomly assigned to three treatment groups (70 participants in each group):

Group 1: Start in the stress management program immediately
Group 2: Start in the stress management program after a latency of 4 months. This is a control group, to see the effect of the stress management program compared to no treatment, measured after 4 months, and the effect of the waiting time measured after 8 months.
Group 3: 12 sessions of psychological therapy, starting the therapy immediately. This is a control group, to compare the stress management program with traditional psychological therapy.

Total duration of treatment for all arms is 4 months and follw up will be one year after baseline.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Return to work rate, measured at 4 months and one year.

Secondary outcome measures
1. Symptom Checklist 92, measured at 4 months
2. World Health Organization (WHO) Major Depression Inventory, measured at 4 months
3. Absenteeism, measured at 4 months
4. Copenhagen Psychosocial Questionnaire (COPSOQ), measured at 4 months
5. Objective measures:
5.1. Salivary cortisol, measured at 4 months
5.2. High density lipoprotein (HDL) cholesterol, total cholesterol, blood pressure, measured at 4 months
5.3. C-reactive protein (CRP) and interleukin-6 (IL-6) (immunological status), measured at 4 months
5.4. HbA1C and dehydroepiandrosterone sulfate (DHEA-S) (metabolic condition), measured at 4 months
5.5. Heart rate variability (HRV), measured at 4 months
5.6. Neo Pi-r Personality Inventory (personality testing), measured at baseline

Overall study start date
01/05/2010

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Adults aged 18 - 64 years, either sex
2. Employed
3. On sick leave
4. Moderate to high stress symptom score

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
64 Years

Sex
Both

Target number of participants
210

Key exclusion criteria
1. If alcohol or substance abuse has contributed substantially to the load condition
2. Unemployment
3. Major illnesses for example cancer and heart diseases, which has contributed substantially to the load condition
4. Physically impaired abilities, which prevent physical activity as a fast walk
5. Major mental disorder

Date of first enrolment
01/05/2010

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
Denmark

Study participating centre
Department of Occupational and Environmental Medicine
Copenhagen
Denmark
2400

Sponsor information

Organisation
Trygfonden (Denmark)

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Sponsor type
Research organisation

Website
http://www.trygfonden.dk/

ROR
https://ror.org/02rcazp29

Funder(s)

Funder type
Research organisation

Funder Name
Trygfonden (Denmark)

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