

# Treatment of functional symptoms due to work-related stress

<b>Submission date</b> 06/03/2010	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/04/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/04/2010	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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 follow up will be one year after baseline.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Upper age limit**

64 years

### **Sex**

All

### **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)

**ROR**

<https://ror.org/02rcazp29>

## **Funder(s)**

**Funder type**

Research organisation

**Funder Name**

Trygfonden (Denmark)

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration