

# Treatment for work-related stress complaints

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<b>Registration date</b> 08/09/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 25/09/2017	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Work-related stress is one of the major reasons for people taking sick leave from work. Research suggests that cognitive behavioural therapy (CBT) treatment works better than other treatments for reducing symptoms of stress, but only a few studies have included patients with clinical levels of stress; such studies have had mixed results. Stress can cause sufferers to develop sleep problems and cognitive functioning problems (for example, problems with memory and concentration). This study is looking at whether a CBT based treatment together with a brief workplace programme (or intervention) for patients on sick leave due to clinical levels of work-related stress is effective.

### Who can participate?

Adults diagnosed with clinical levels of work-related stress.

### What does the study involve?

All participants attend an interview to see whether they are suitable for the study. Eligible participants are then randomly allocated to one of two groups. Those in group 1 are placed in the treatment group. They are offered six sessions of CBT over the course of 4 months. They are also offered a brief work-place intervention which involves one or two meetings at the workplace with the patient, the psychologist treating them and their employer to discuss the causes of the stress and possible ways to alleviate it. Participants in group 2 are not offered either the CBT or workplace intervention, but are free to seek help elsewhere. All participants on both groups are asked to fill in questionnaires prior to taking part in the study and then again 4 months and 10 months after being included.

### What are the possible benefits and risks of participating?

Patients might benefit through improved coping with regards to work stressors as well as symptom improved. There are no serious risk by participation.

### Where is the study run from?

Department of Occupational Medicine, Regional Hospital West Jutland (Denmark)

### When is the study starting and how long is it expected to run for?

January 2008 to November 2011

Who is funding the study?  
Danish Working Environment Research Fund

Who is the main contact?  
Dr David Glasscock  
david.john.glasscock@vest.rm.dk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr David Glasscock

**Contact details**  
Gl. Landevej 61  
Herning  
Denmark  
7400  
045 78433431  
david.john.glasscock@vest.rm.dk

## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
34-2007-03

## Study information

**Scientific Title**  
Stress management intervention for patients on sick leave due to work-related stress complaints

**Study objectives**  
It was hypothesized that patients in the intervention group would experience a faster recovery, including a reduced self-perceived stress and a greater reduction in symptoms of poor mental health and with regards to specific stress symptoms like sleep problems and cognitive difficulties compared with a control group. We also hypothesized that the intervention group would return to work at a faster rate than the control group.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

Danish Data Protection Agency. The study has been classified as a survey and therefore needed not be reported to the Health Research Ethics Committee

## **Study design**

Randomized 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 to request a patient information sheet

## **Health condition(s) or problem(s) studied**

Work-related stress disorders and adjustment disorder

## **Interventions**

Participants were randomly allocated to either a intervention group or a control group.

The intervention was manualized (in Danish) and comprises six sessions of individual cognitive behavioural therapy over the course of 4 months as well s a small work place intervention in the form of the offer of a meeting at the work place attended by the treating psychologist, the employer of the patient. The purpose of this meeting would be to discuss and if necessary advice the work place on how to assist the return to process in a suitable way for patient.

Both the intervention group and the control group received a clinical assessment at the department before being randomized to either group. However, the control group did not receive further help at the department but were free to seek help elsewhere.

Randomization was carried out by the project secretary. Each patient was assigned the next 4-digit number on a list of true random numbers. If the number of these digits was even, the patient would be allocated to the treatment group and if the number was odd, the patient would be allocated to the control group.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Self-reported levels of stress, measured using the The perceived Stress scale
2. Mental health status, measured using the General health questionnaire (scale for mental health)

Measured at baseline, 4 months and 10 months.

Group differences on primary outcomes were compared with multivariate repeated measurements analysis.

### **Secondary outcome measures**

1. Sleep problems, assessed using the Basic Nordic Sleep Questionnaire
2. Cognitive functioning, measured using the Cognitive Failures Questionnaire
3. Return to work rate, measured using register data and questionnaires

Measured at baseline, 4 months and 10 months.

### **Overall study start date**

01/01/2008

### **Completion date**

02/11/2011

## **Eligibility**

### **Key inclusion criteria**

1. Had a diagnosis of adjustment disorder or reactions to stress (ICD 10-diagnose code: F43.2 – F43.9 not PTSD) or mild depression (F32.0) (47)
2. The patient had to be on sick leave due to the above
3. The condition had to be evaluated by the psychologist as primarily work-related
4. Patients had to plan on returning to their work place

### **Participant type(s)**

Patient

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

120

### **Key exclusion criteria**

1. Co-morbidity of another psychiatric illness (e.g. moderate to severe depression)
2. Co-morbidity of a recently emerged chronic somatic disease
3. Pregnancy
4. Substance abuse
5. Sick leave for more than 4 months
6. Any degree of disability pension
7. Fired or no wish to return to the work place

### **Date of first enrolment**

01/09/2008

**Date of final enrolment**

01/01/2011

## Locations

**Countries of recruitment**

Denmark

**Study participating centre**

Department of Occupational Medicine, Regional Hospital West Justland

Gl. Landevej 61

Herning

Denmark

7400

## Sponsor information

**Organisation**

Department of Occupational Medicine, Regional West Jutland

**Sponsor details**

Arbejdstilsynet

Postboks 1228

Arbejdstilsynet | Postboks 1228

Denmark

0900 København C

7012 1288

at@at.dk

**Sponsor type**

Government

**ROR**

<https://ror.org/04p0nk708>

## Funder(s)

**Funder type**

Government

**Funder Name**

Danish Working Environment Research Fund (project number 34-2007-03)

# Results and Publications

## Publication and dissemination plan

Expect to publish paper on the efficacy of the intervention with regards to Perceived stress and General Health and return to work.

## Intention to publish date

02/09/2017

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Stored in repository

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/11/2014		Yes	No