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Treatment for work-related stress complaints

Submission date	Recruitment status	[ ] Prospectively registered
19/08/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
08/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
25/09/2017	Mental and Behavioural Disorders	

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 throught 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 Justland (Denmark)

When is the study starting and how long is it expected to run for?
Janaury 2008 to November 2011

Who is funding the study?
Danish Working Environment Research Fund

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s))
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.

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 – F 43.9 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Department of Occupationa Medicine, Regional West Jutland

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

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?
Results article	results	01/11/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes