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An intervention for work-related stress disorders

Submission date	Recruitment status	[ ] Prospectively registered
08/05/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
03/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
24/08/2017	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
The aim of this study is to find out whether a work-focussed cognitive intervention can lead to faster symptom reduction and return to work for patients on sick leave due to work-related stress.

Who can participate?
Patients who are referred to a department of occupational medicine by their family doctor, because it is suspected their symptoms are related to work stress.

What does the study involve?
Participants are randomly allocated to either an intervention group or a control group. The intervention group is treated with the work-focussed cognitive intervention, which involves two elements: individual cognitive therapy, which focuses on improving patients' ability to cope with work-related stress, and changing conditions at the workplace to make it less stressful. Changing workplace conditions is achieved either indirectly via counselling of the patient, or directly via contact to the place of work, when patients agree to this. The control group do not receive any treatment at the department of occupational medicine but are free to seek treatment elsewhere. In general the hospital system in Denmark has no standardised offer of treatment to this group of patients, so those in the control group are in effect receiving 'treatment as usual', seeking counselling from family doctors and psychologists in private practice.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Herning Hospital (Denmark)

When is the study starting and how long is it expected to run for?
May 2009 to April 2013

Who is funding the study?
Danish Working Environment Authority (Denmark)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Danish data protection agency (journal number: 2008-41-1966)

Study information

Scientific Title
A work-focused cognitive intervention for people on sick leave due to work-related stress reactions: a randomized controlled trial

Study objectives
The objective of the study is to promote symptom reduction and return to work in patients, who are on sick leave due to work related stress disorders. Patients are referred to a clinic of occupational medicine from three different municipalities.

The main hypothesis is that patients receiving the intervention will experience a significantly greater stress reduction at follow-up and shorter periods of sick leave.

Specific hypotheses are that a combined intervention involving individual cognitive therapy and advice about work place changes/return to work is more effective than usual care in terms of

1. Improving mental health
2. Reducing perceived stress, sleep disturbance and cognitive deficits
3. Promoting return to work

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Central Denmark Region Commmittees on Biomedical Research Ethics did not find it necessary to review the study since it was based on cognitive therapy and since data was collected by questionnaire.

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

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

Interventions
Referred patients receive a thorough psychological interview by a trained psychologist and a medical examination by a medical doctor. Patients who fulfill inclusion criteria and agree to participate are randomly assigned to a control group or an intervention group.

Control group: Treatment as usual

The intervention comprises an individual cognitive intervention and the offer of a small work place intervention.

1. The individual cognitive intervention comprises six sessions with a psychologist. The program has been developed together with specialists in cognitive therapy and is aimed specifically at patients who are on sick leave due to work related stress reactions. The aim of the intervention is to reduce the level of psychological and physical stress symptoms, to strengthen the ability to cope with stressors at work and to reduce the length of sickness leave.

The intervention is based on cognitive methods and involves the following:
1. Indentifying work related stressors or challenges.
2. Restructuring of cognitive and behavioral strategies that may be contributing to the development of stress symptoms
3. Psychoeducation about work related stress, stressors, symptoms a.s.o.
4. Homework assignments are assigned following each session.

The patient will receive six session over 12 weeks. The cognitive treatment has been thoroughly described in the project manual. The manual also contains an overview of what may be the content of each the six sessions. However, the psychologist has some flexibility to choose which types of exercises/homework are most relevant for the patient. The choice of exercise is recorded on a separate sheet. The cognitive methods being used in the intervention are thoroughly described in the manual. All sessions are conducted by clinical psychologists with experience in the usage of cognitive therapy

2. The offer of a small work place intervention:
A 7th session is available to prepare the work place intervention, if the patient is interested in this possibility. The work place intervention consists of one or two meetings at the work place with the participation of the patient, the psychologist, a leder or other representatives from the work place. The aim of the work place intervention is to facilitate the proces of returning to work. This might involve reductions of stressors at work, and/or increasing support from the work place.

The role of the psychologist is to explain the psychological condition of the patient and to help the work place reach an understanding of how they may contribute to an improvement in the condition of the patient. If necessary, the psychologist may also focus on improving communication and understanding between relevant parties at the work place. The work place intervention is also described in the manual mentioned above.

Before randomization, baseline data is collected by questionnaire and by the psychological and medical examination. Patients receive follow-up questionnaires at 4 and 10 months. Statistical analyses are performed according to the intention-to-treat principle.

Intervention Type
Behavioural

Primary outcome measure
1. Perceived stress as measured by the Perceived Stress Scale (10 items)
2. Psychological well-being as measured by the General Health Questionnaire (30 items)

Measured at 4 and 10 months

Secondary outcome measures
1. Quality of sleep as measured by an adapted version of the Nordic Sleep Questionnaire
2. Cognitive function, measured by and adapted version of the Cognitive Failure Questionnaire
3. Duration of sick-leave (self reported and register based)

Measured at 4 and 10 months

Overall study start date
01/05/2009

Completion date
01/04/2013

Eligibility

Key inclusion criteria
1. Age > 18
2. Employed
3. Sick listed (full time or part time) due to stress reactions and/or adjustment disorders [but not PTSD (F43,2 F43,9), and mild depressive episodes (F32,0). The condition is judged via a clinical interview to be work related.
4. Ability to complete questionnaires in Danish
5. Ability to carry a conversation in Danish without an interpreter
6. Employed at current work place for at least 6 months

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Comorbidity of another psychiatric disorder, chronic somatic disorder or alcohol abuse
2. Pregnancy
3. No intention to return to work place
4. Fired/or quit job
5. Sickness absence longer than 4 months
6. Unable to speak the danish language

Date of first enrolment
01/05/2009

Date of final enrolment
01/04/2013

Locations

Countries of recruitment
Denmark

Study participating centre
Herning Hospital
Herning
Denmark
7400

Sponsor information

Organisation
The Danish Working Environment Authority (Denmark)

Sponsor details
Arbejdstilsynet
Postboks 1228
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Denmark
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Sponsor type
Government

Website
http://arbejdstilsynet.dk/en/engelsk.aspx

ROR
https://ror.org/05fm0gf36

Funder(s)

Funder type
Government

Funder Name
The Danish Working Environment Authority (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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/08/2017		Yes	No