ISRCTN33165676 https://doi.org/10.1186/ISRCTN33165676

Work related respiratory disease due to indoor air and work ability

Submission date
10/07/2012

Recruitment status
No longer recruiting

Registration date
30/08/2012

Overall study status
Completed

Last Edited
05/05/2016

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Indoor air problems in non industrial work environments are associated with respiratory health problems. Symptoms are usually temporary, but long-lasting symptoms and work limitation are common in some individuals despite building repairs or moving an alternative work environment. Our goal is to see if better symptom management will result in better work ability and less sickness absences. We want to develop strategies for occupational health professionals to support work ability.

Who can participate?
The study recruits patients referred to the Finnish Institute of Occupational Health due to suspected respiratory disease related to workplace dampness and other indoor air problems. We recruit patients who experience reduced work ability and who have had sick leaves due to indoor air symptoms.

What does the study involve?
Two groups of 30 patients each will be created. 30 patients will be allocated to the better symptom management group, where they will receive objective information (given by a physician) about indoor air symptoms and their mechanisms. They will also get psychological training about symptom management. The other 30 patients will undergo only customary examinations, which are needed to assess the possibility of an occupational disease. At the beginning of the study and after six months, we will compare the work ability, the amount of sick leave days, the quality of life and illness worries between the groups by a questionnaire.

What are the possible benefits and risks of participating?
Those who are taking part will learn to improve symptom management. Participating causes no harm to the patient.

Where is the study run from?
The Finnish Institute of Occupational Health

When is the study starting and how long is it expected to runs for?
The pilot phase started in January 2012. The study will start in August 2012 and will run for 5

months or until the required number of 30 intervention and 30 control patients has been recruited.

Who is funding the study?
The Finnish Ministry of Social Affairs and Health, and the Finnish Institute of Occupational Health.

Who is the main contact?
Dr Kirsi Karvala
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Work related respiratory disease due to indoor air and work ability: a randomized controlled trial

Study objectives
Effective patient information on indoor air symptoms and asthma management, combined to a psychological intervention using methods of cognitive and motivational psychology, will lead to less disability days, better self-assessed work ability and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Coordinating Ethics Committee of Hospital District of Helsinki and Uusimaa, 27/04/2010, ref: 61/13/03/00/2010, amendment approved 11/11/2011

Study design
Single-center randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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
Respiratory disorders

Interventions
Intervention: Effective patient information on indoor air symptoms and asthma management, combined to a psychological intervention using methods of cognitive and motivational psychology.

Control: Only usual examinations to assess if the patient has an occupational disease without an intervention

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Self-assessed work ability (on a scale 0-10)
2. Total number of sick leave days during the past six months

Secondary outcome measures
1. Quality of life (RAND-36)
2. Illness worries (Ilness Worry Scale IWS)

Overall study start date
01/08/2012

Completion date
31/12/2012

Eligibility

Key inclusion criteria
1. Patients who are referred to the Finnish Institute of Occupational Health because of a suspicion of an occupational respiratory disease related to workplace indoor air (non-industrial workplaces)
2. Minimum of 14 days on sick leave due to indoor air symptoms during the preceding year
3. Self-assessed work ability not more than 7 (on a scale 0-10, compared to lifetime best)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Patient refusal
2. Not actively participating working life (retired or unemployed)

Date of first enrolment
01/08/2012

Date of final enrolment
31/12/2012

Locations

Countries of recruitment
Finland

Study participating centre
Finnish Institute of Occupational Health
Helsinki
Finland
FI-00250

Sponsor information

Organisation
Finnish Institute of Occupational Health (Finland)

Sponsor details
Topeliuksenkatu 41 a A
Helsinki
Finland
FI-00250

Sponsor type
Government

Website
http://www.ttl.fi/en/

ROR
https://ror.org/030wyr187

Funder(s)

Funder type
Government

Funder Name
Finnish Institute of Occupational Health (Finland)

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	01/07/2015		Yes	No