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Can a participatory intervention with actions plans across multiple organizational levels lead to changes in stress and the psychosocial working environment within two different organizations?

Submission date
12/04/2019

Recruitment status
No longer recruiting

Registration date
23/04/2019

Overall study status
Completed

Last Edited
31/01/2025

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Stress at work is the second most common threat posed by the working environment. In 2005 stress was experienced by 22% of EU workers. In 2016, 15.5% of the Danish population reported that they felt stressed "all the time" or "often" during the last two weeks, and 43.3% pointed to work as the main cause of stress. Work-related stress may be defined as “a condition which arises when demands of the work environment exceed the workers’ ability to cope with (or control) them”. Research has indicated that stress at work is associated with cardiovascular diseases, musculoskeletal diseases, immunological problems, and problems with mental health (anxiety and depression disorders). Moreover, stress increases absenteeism, presenteeism and staff turnover, and decreases productivity. Thus, stress poses significant challenges at the individual, group, organizational and societal level.
Studies have shown positive effects of individual strategies to reduce stress, although the effects may be temporary. A few studies have focused on organizational aspects, such as workload. Researchers agree that organizational prevention has the potential to prevent stress rather than primarily alleviate symptoms. Overall, prevention studies have mostly intervened at one level of the organization rather than conducting interventions at several levels simultaneously. In contrast, this study aims to address and integrate interventions across the individual, group, leader/manager and organizational levels (IGLO). Furthermore, this study will draw upon participation and combine bottom-up and top-down intervention strategies and as such stimulate cooperation across organizational levels.

What does the study involve?
This study aims to test and adjust a method, which was constructed by and implemented in Novo Nordisk. Their results showed a reduction from 15 % to 10 % in employee stress levels. The method is characterized by the use of participatory risk assessment and action planning at the team level, after which identified risks, which cannot be addressed at the team level are

reported to the management for further action planning. The method has a particular focus on the organizational level, as this level has the potential for broader actions and more enduring stress prevention. The invention activities include:
1. Train the Trainer: All HR Partners will be trained to use dialogue based mapping tools.
HR Partners subsequently train leaders in use of mapping tools
2. Team dialogues: All leaders use a dialogue tool in their team. As part of the team dialogue process, participants note future actions in the IGLO action plans
3. Escalation: Action plans, which only can be resolved at the O-level are escalated to the next management level.
4. Collection: All IGLO action plans are sent to a HR mailbox after the team sessions. Issues are placed at relevant level. General trends are identified.
5. Consolidation: All organizational levels work with IGLO plans
To evaluate the intervention's success, the study conducts a thorough effect and process evaluation. Data is collected using questionnaires before and after the intervention, and further by interviews during the implementation phase. Finally, all action plans are collected in order to asses to which degree actions are actually implemented.

Who can participate?
Workplaces with a minimum of three organizational levels and with some heterogeneity among staff, such as professions and educational level. We have a total of 2 organizational settings with no less than 500 employees.

What are the possible benefits and risks of participating?
The benefits are a potential improvement of work conditions and a reduction of stress levels among employees. There are no risks of participating.

Where is the study run from?
The study is a collaboration between Aarhus University, Department of Occupational Medicine, Regional Hospital Herning, and the National Research Centre for the Working Environment.

When is the study starting and how long is it expected to run for?
The study is starting in spring 2019 beginning with baseline measures and ending in spring 2020, so the approximate duration of the study is one year.

Who is funding the study?
The Danish Working Environment Research Fund (Denmark)

Who is the main contact?
Tanja Kirkegaard, tanjak@psy.au.dk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2016-051-000001

Study information

Scientific Title
Organizational stress prevention – a participatory intervention with actions plans across multiple organizational levels.

Acronym
TvIS project

Study objectives
Main hypothesis:
Stress levels and the psychosocial working environment (PSWE) will improve significantly post-intervention compared to baseline.

Secondary hypotheses:
If the main hypothesis is confirmed, then:
1. Changes in stress will be mediated by changes in PSWE at follow-up
2. Workplaces with low baseline scores of stress and more positive perceptions of PSWE will experience smaller improvements post-intervention (i.e., a ceiling effect)
3. The psychosocial safety climate and employees' satisfaction with the psychosocial working environment will improve significantly post-intervention compared to baseline.
4. Employee participation will improve significantly post-intervention compared to baseline.

Ethics approval required
Old ethics approval format

Ethics approval(s)
As no biological data is collected ethics approval is not necessary according to the Danish regulations.

Study design
Prospective cohort design

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Quality of life

Interventions
The intervention consists of four phases:
1. Mapping: questionnaires sent to all employees at the workplace
2. Intervention: training HR, HR training managers, team dialogues and sending actions plans to HR for further categorization.
3. Consolidation: escalating action plans to the relevant level, all levels working with action plans
4. Evaluation: questionnaires sent to all employees at the workplace

The specific components of the intervention include education on work environment and work stress, training in general communicative practices and use of a specific dialogue tool. Further, the intervention involves specific materials such as actions plans targeting both individual, group, leader/manager and organizational levels (i.e., the IGLO principle), and a systematic strategy for collecting and analyzing action plans.

We will collect data by use of questionnaires, interviews, action plans, implementation documentation and background documents (for example organizational structure) from the participating workplaces.

A prospective cohort design examining changes in stress and the psychosocial working environment within two different organizations after the implementation of a participatory intervention with actions plans across multiple organizational levels.

Intervention Type
Other

Primary outcome measure
1. Perceived stress measured by perceived stress scale (PSS-10) and a single-item measure of stress symptoms (Ero A-L & A. Leppänen 2003) at baseline in May 2019, June 2019 and follow-up in April 2020 and June 2020
2. Measures of the psychosocial working environment measured with the Danish Psychosocial Questionnaire domain (Clausen et al. 2017): influence, possibilities for performing work tasks,

predictability, quantitative demands, justice, justice in the workplace, recognition, social support from colleagues, trust between colleagues, social support from management , work-life balance; at baseline in May 2019, June 2019 and follow-up in April 2020 and June 2020.

Secondary outcome measures
1. Psychosocial safety climate assessment (Dollard et al. 2010)
2. Satisfaction with the psychosocial work environment questionnaire (Clausen et al. 2017)
3. Voice behavior questionnaire (Detert & Burris 2007)
4. Distributed leadership questionnaire (Jønsson 2019)
5. Empowering leadership questionnaire (Arnold et al. 2000)
6. Psychological safety questionnaire (Edmondson 1999)
Secondary outcomes are measured at the same time points as the primary outcomes.

Overall study start date
01/04/2017

Completion date
15/06/2020

Eligibility

Key inclusion criteria
1. Staff at workplaces with a minimum of three organizational levels
2. Staff at workplaces with some heterogeneity among staff, such as professions and educational level.

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Individuals not employed at the participating companies

Date of first enrolment
05/05/2019

Date of final enrolment
15/06/2020

Locations

Countries of recruitment

Denmark

Study participating centre
Aarhus University
Bartholins Alle 9
Aarhus C
Denmark
8000

Study participating centre
Department of Occupational Medicine, Region Hospital of Herning
Gl. Landevej 61
Herning
Denmark
7400

Study participating centre
The National Research Center of Working Environment
Lersø Park Alle 105
København
Denmark
2100

Sponsor information

Organisation
Department of Occupational Medicine, Regional Hospital of Herning

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/02ckh3s34

Funder(s)

Funder type
Government

Funder Name
The Danish Working Environment Research Fund (Arbejdsmiljø) Denmark

Results and Publications

Publication and dissemination plan
We expect to publish the trial results in up to three scientific research papers submitted to peer-reviewed journals. At least one paper will report the main analyses focusing on the primary and secondary outcomes. In addition, we expect one or two of the papers to involve analyses of process evaluation data which can elucidate important preconditions and mechanisms influencing the trial outcomes.

Intention to publish date
01/06/2021

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		30/01/2025	31/01/2025	Yes	No