ISRCTN14333710 https://doi.org/10.1186/ISRCTN14333710

Effects of a work-related stress model based mental health promotion program on job stress, stress reactions and coping profiles of women workers

Submission date
26/09/2020

Recruitment status
No longer recruiting

Registration date
03/10/2020

Overall study status
Completed

Last Edited
26/01/2021

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Background and study aims
Work-related stress and its detrimental effects on human health have rapidly increased during the past several years. It causes many different stress reactions, related diseases and unhealthy behavior among workers, but especially women workers. Thus, the aim of this study is to examine the effects of the Workplace Mental Health Promotion Programme on job stress, social support, reactions, saliva immunoglobulin A and cortisol levels, work absenteeism, job performance and coping profiles of women workers.

Who can participate?
Women workers aged over 18 with a higher level of work-related stress

What does the study involve?
The programme was carried once to the intervention group (35 women workers) in factory A at 9 am by the first researcher. A visual presentation and video training are provided, and a digital camera is used to video record workers while they were practising the programme, which consists of stress management techniques, effective coping skills, and relaxation exercises. The programme also provides definitions for and explanations of stress and work-related stress, stress physiology, stress reactions, stress-related diseases, stress-related factors and effective coping and stress management skills, relaxation exercises, and deep breathing techniques. In the context of coping with stress, these exercises are taught, along with correct abdominal deep breathing skills, to the intervention group. During this interactive training, the work-related stress factors are defined and discussed interactively and in detail with the workers, who offer examples from their work experiences. During the training, the exercises are practised as a group and video recorded. The training lesson lasts 45 minutes and takes place in a meeting room at the workplace. After the training, a brochure explaining the content and process of the programme and a video describing the exercises are given to the workers. The exercise times (10: 00 am, 1:00 pm, and 4:00 pm) are organized in cooperation with the workers, supervisors, and administrators while considering the employees' work schedules. This is followed by direct

observation, a weekly self-reported checklist, and recording with a factory-fixed camera for 12 weeks. The mobile phone application WhatsApp is used to send reminder messages and videos to the participants to reinforce the training during the follow-up stage. The effects of the programme are assessed in the first and third months in both groups, but saliva immunoglobulin A and cortisol levels are assessed only in the intervention group before and just after the intervention.

What are the possible benefits and risks of participating?
The possible benefits of participating are improved coping skills, stress management, and mental health.

Where is the study run from?
Akademi Tekstil Factory (Turkey)

When is the study starting and how long is it expected to run for?
February 2014 to May 2016

Who is funding the study?
Istanbul University (Turkey)

Who is the main contact?
Ozlem Koseoglu Ornek
ozlem.koseoglu@med.uni-muenchen.de

Contact information

Type(s)
Scientific

Contact name
Dr Ozlem Koseoglu Ornek

ORCID ID
http://orcid.org/0000-0002-9101-6256

Contact details
Occupational and Environmental Epidemiology & NetTeaching Unit
Institute and Clinic for Occupational, Social and Environmental Medicine
University Hospital, LMU
Ziemssenstr. 1
Munich
Germany
80336
+49 (0)89 440052483
ozlem.koseoglu@med.uni-muenchen.de

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
50902

Study information

Scientific Title
Effects of a work-related stress model based mental health promotion program on job stress, stress reactions and coping profiles of women workers: a control groups study

Study objectives
Compared to those who do not participate in the Work-ProMentH intervention, workers who do participate in the program will have decreased job stress, less severe physical and mental stress reactions, lower S-cortisol levels, less job absenteeism, increased S-IgA levels, more social support, better job performance, and improved coping profiles.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 28/11/2014, Ethical Committee of Istanbul Medipol University (Kavacık mah, Ekinciler cad, No:19, 34810 Beykoz/Istanbul; +90 (0)2166815137; ilknurfil@medipol.edu.tr), ref: 10840098-299

Study design
Pre-test–post-test non-equivalent control group design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Mental health problems

Interventions

The aim of this study, which features a pre-test–post-test non-equivalent control group design, is to examine the effects of the WRS model-based Work-ProMentH on women workers' job stress, physical and mental reactions, social support, coping profiles, work absenteeism, job performance, and salivary IgA (S-IgA) and cortisol (S-cortisol) levels. The research is carried out in two textile factories (A and B) since the intervention is considered to affect workers in the same factory. Factory B is defined as a subcomponent and partner of factory A. The factories mainly manufacture knitwear and export it abroad. Both factories have demonstrated adherence to the laws and regulations on occupational health and common international inspections. The factories also have the same occupational health physician and nurse. Additionally, the first researcher voluntarily worked two hours per week for more than a year before the study began to observe the work process, working conditions, and work environments

The study examined five measurements that were selected and developed by researchers based on the components (Risks for work-related stress, Stress reactions, Stress long-term consequences, Individuals characteristics) of the causes and consequences in the WRS model to evaluate stress, stress reactions, long-term stress responses, and coping profiles. The risks for the work-related stress component of the model were measured by the brief job stress questionnaire and the assessment form; stress reactions were measured by the brief job stress questionnaire and salivary-specific ELISA kits; individual characteristics were measured by the Brief Stress Coping Profile scale and the assessment form; and stress long-term consequences were measured by the performance questionnaire, formal, digital factory input and output card and checklist.
1. The Descriptive Workers Assessment Form
2. The Brief Job Stress Questionnaire (BJSQ)
3. The Brief Stress Coping Profile (BSCP)
4. Salivary-specific ELISA kits that are lucent and have a cover were used to evaluate cortisol and IgA levels in every participant's saliva. When saliva is collected with the kit, it should be covered carefully and saved in a portable freeze at +4°, and it has to be transferred to a laboratory with an International Accreditation. The analyses were conducted at baseline (at 08:45 am, February) and just after the IG intervention (at 10:15 am, February) in the morning. The eligibility criteria for collecting saliva-cortisol and saliva-IgA are as follows: there should not be any blood contamination from the mouth, there should not be any medication that affects cortisol used in the last week, and there should not be anything eaten 30 minutes before saliva collection.
5. The work absenteeism of all participants was checked through formal digital factory timecards and self-reported checklists. The absenteeism duration was calculated based on hours.

Workplace Mental Health Promotion Program Intervention
The Work-ProMentH is a health-promotion programme based on the WRS model. Before the Work-ProMentH intervention, the approval and follow-up procedures of the factories' administration were explained to the IG and verified. The programme was applied once to the IG (35 women workers) at baseline in factory A at 9 am by the first researcher. A visual presentation and video training were provided, and a digital camera was used to video record workers while they were practising the programme, which consisted of stress management techniques, effective coping skills, and relaxation exercises. The programme also provided definitions for and explanations of stress and WRS, stress physiology, stress reactions, stress-related diseases, stress-related factors and effective coping and stress management skills, relaxation exercises, and deep breathing techniques. In the context of coping with stress, these exercises were taught, along with correct abdominal deep breathing skills, to the IG. During this interactive training, the WRS factors were defined and discussed interactively and in detail with the workers, who offered examples from their work experiences. During the training, the exercises were practised as a group and video recorded. The training lesson lasted 45 minutes and took place in a meeting room at the workplace. After the training, a brochure explaining the content

and process of the programme and a video describing the exercises were given to the workers. The exercise times (10:00 a.m., 1:00 p.m., and 4:00 p.m.) were organized in cooperation with the workers, supervisors, and administrators while considering the employees' work schedules. This was followed by direct observation, a weekly self-reported checklist, and recording via a factory-fixed camera for 12 weeks. The mobile phone application WhatsApp was used to send reminder messages and videos to the participants to reinforce the training during the follow-up stage. The effects of the programme were assessed in the first and third months in both groups, but S-IgA and S-cortisol levels were assessed only in the IG before and just after the intervention

Intervention Type
Behavioural

Primary outcome measure
1. Perceived job performance measured using the Descriptive Workers Assessment Form concerns at baseline, 1 month and 3 months
2. Job stress, stress reactions (physical and mental), and social support measured using the Brief Job Stress Questionnaire (BJSQ) at baseline, 1 month and 3 months
3. Coping profiles measured using the Brief Stress Coping Profile (BSCP) at baseline, 1 month and 3 months
4. Cortisol and IgA levels measured using Salivary-specific ELISA kits at baseline, and just after the intervention.
5. The work absenteeism measured using formal digital factory timecards and self-reported checklists at baseline, 1 month and 3 months

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
18/02/2014

Completion date
02/05/2016

Eligibility

Key inclusion criteria
1. A job-stress subscale score above the median (med: 45), indicating a higher level of WRS
2. No use of any medication that has effects on cortisol and IgA

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
70

Total final enrolment
70

Key exclusion criteria
1. Use of any medication that affects salivary cortisol and/or IgA levels
2. Age under 18 years
3. Diagnosed psychiatric health problems
4. Illiteracy

Date of first enrolment
01/02/2016

Date of final enrolment
30/03/2016

Locations

Countries of recruitment
Türkiye

Study participating centre
A+B factories
Başakşehir
Istanbul
Türkiye
34400

Sponsor information

Organisation
Istanbul University

Sponsor details
Merkez Kampüsü Rektörlük Binası
Beyazıt/Fatih
Istanbul
Türkiye
34452
+90 (0)212 440 00 17
bilimap@istanbul.edu.tr

Sponsor type
University/education

Website

http://www.istanbul.edu.tr/

ROR
https://ror.org/03a5qrr21

Funder(s)

Funder type
University/education

Funder Name
Istanbul Üniversitesi (Project No: 50902)

Alternative Name(s)
Istanbul University

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Türkiye

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
25/10/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Ozlem Koseoglu Ornek (Ozlem.koseoglu62@gmail.com).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/11/2020	26/01/2021	Yes	No