Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Employee Assistance Programme for Stress: An Intervention study of psychological symptoms and sickness absence in public university

Protocol summary

Summary

Main Objective To determine the effectiveness of EAP for occupational stress in reduction of psychological symptoms and sickness absence in public university. Inclusion Criteria: 1. Staff aged between 35 to 65 years old. 2. Working in University of Malaya and has join University of Malaya Wellness Programme. Exclusion criteria: 1. Staff with underlying psychological illnesses. Sample size Sample size was calculated using PS power and sample size software. With power of 80% and alpha of 0.05, sample size needed for this study is 150 subjects (75 subjects per arm). Interventions For intervention group: 1. Group half day workshop on Stress Management inclusive of practical session on stress relaxation therapy (breathing therapy and progressive muscle relaxation therapy) 2. Two sessions of one hour individual counselling on health and work psychological problems. 3. Self application of breathing therapy and progressive muscle relaxationn at workplace on as needed basis. For comparison group: 1. Self-help phamplet on stress management will be given to them. Primary outcome measure 1. Self-perceived depression, anxiety and stress measured via DASS-21 questionairre. 2. Work psychological risk factors measured via JCQ questionairre. 3. Serum cortisol, Fasting blood sugar and Fasting serum lipid through blood biochemical examination. 4. Body mass index, waist hip ratio and blood pressure via clinical examination. 5. Sickness absence data obtained from Human resource department.

General information

Acronym

Employee assistance programme, Wellness Programme, Stress, Job Stress, Sickness absence

IRCT registration information

IRCT registration number: **IRCT201102275923N1**
Registration date: **2011-03-16, 1389/12/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-16, 1389/12/25

Registrant information

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Recruitment status

Recruitment complete

Funding source

Postgraduate Research Grant University of Malaya, Kuala Lumpur

Expected recruitment start date

2010-04-01, 1389/01/12

Expected recruitment end date

2010-04-10, 1389/01/21

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Employee Assistance Programme for Stress: An Intervention study of psychological symptoms and sickness absence in public university

Public title
Employee Assistance Programme (EAP) for Stress: An Intervention study of psychological symptoms and sickness absence in public university
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion Criteria: 1. Staff aged between 35 to 65 years old. 2. Working in University of Malaya and has join University of Malaya Wellness Programme. Exclusion criteria: 1. Staff with underlying psychological illnesses.
Age
From **35 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
University Malaya Medical Centre Medical Ethics Committee
Street address
University Malaya Medical Centre, Lembah Pantai,
City
Kuala Lumpur
Postal code
59100
Approval date
2009-08-20, 1388/05/29
Ethics committee reference number
714.16

Health conditions studied

1

Description of health condition studied
Self Perceived depression
ICD-10 code
F41.9
ICD-10 code description
The patient is currently depressed, as in a depressive episode of either mild or moderate severity

2

Description of health condition studied
Self-perceived anxiety
ICD-10 code
F43.0
ICD-10 code description
Anxiety NOS

3

Description of health condition studied
Self-perceived stress
ICD-10 code
F31.3
ICD-10 code description
A transient disorder that develops in an individual without any other apparent mental disorder in response to exceptional physical and mental stress and that usually subsides within hours or days. Individual vulnerability and coping capacity play a role i

4

Description of health condition studied
Blood pressure
ICD-10 code
I10
ICD-10 code description
High blood pressure

5

Description of health condition studied
Fasting serum lipid
ICD-10 code
E78.0
ICD-10 code description
Familial hypercholesterolaemia

6

Description of health condition studied
Fasting Blood Sugar
ICD-10 code
E10, E11
ICD-10 code description
Insulin-dependent diabetes mellitus, Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Self-perceived depression, anxiety and stress.

Timepoint
After 6 months
Method of measurement
DASS questionnaire

2

Description
Work psychological risk factors
Timepoint
6 months
Method of measurement
JCQ questionnaire

3

Description
Sickness absence
Timepoint
6 months
Method of measurement
Secondary data of sickness leaves from human resource department

Secondary outcomes

1

Description
Fasting blood sugar
Timepoint
After 6 months
Method of measurement
Blood biochemical measurement

2

Description
Blood pressure
Timepoint
After 6 months
Method of measurement
Clinical measurement with manual sphigmanometer

3

Description
Fasting serum lipid
Timepoint
After 6 months
Method of measurement
Blood biochemical measurement

4

Description
Body mass index
Timepoint
After 6 months
Method of measurement
Clinical measurement of height and weight

5

Description
Waist-hip ratio
Timepoint
After 6 months
Method of measurement
Clinical measurement of waist and hip circumference

Intervention groups

1

Description
InterventionEmployee Assistance Program will include:•Three days of training program for participants. •EAP Individual counseling •Stress Relaxation Therapy6.6.1Three days of training program for participants. This workshop will be done by EAP specialist from Turning Point Integrated Wellness Sdn Bhd and investigator himself. The objectives of this 3 days workshop are to ensure participants will be able to: •Understand what EAP is •Understand what stress is •Recognize symptoms of stress •Identify sources of stress •Acquire some skills on how to cope with stress Workshop Methodology The workshop will start with the theoretical discussions on “What is Stress? (Definition)”; “How does Stress happen and how to make it work for you”; “Various elements and sources of Stress” “Job Burnout” and coupled with a simple stress evaluation test that measure stress levels and symptoms of stress for all participants, to help identify and focus on areas that cause stress to that person. Three major stress coping techniques will be taught and experienced during the session itself with Role Play/exercises. In this workshop, we will do one coping skill as in relation with oneself, another coping skill on interpersonal relationship (others) and third skills is coping with change and transition (environment). First coping skill, a creative-based method in managing stress will be applied here combining with Relaxation Techniques using specific breathing, imagery and visualizing methods. The exercise will be further enhanced with cognitive restructuring method in order to complete the full set coping skill. For second coping skill, we will be working with stress by enhancing our communication skills for interpersonal relationship. There are two important components in effective communication - listening and conveying the messages. Participants will practice communication skills through a series of exercises during the session itself. For third coping skills, we will be focusing on how to handle change and transition. Every person goes through an internal transition process when external situations or events change. Going through transitions, takes energy and causes both physical and emotional stresses. We will be focusing on understanding “How to recognize the different stages of transition?” and “how to identify problems occurring from incomplete transitions at the different stages of transition and the various strategies in managing transition?” through lectures and exercises during the session itself.The final session will be discuss about healthy lifestyle which consist of healthy eating, physical activity and stop

smoking.6.6.2 EAP Individual counseling EAP individual counseling will be given three monthly and as needed by referral from supervisor for the whole one year program. In every session, participants will be allocated 30 minutes to one hour for them to discuss problems especially the psychological aspects. EAP counselor will listen and give the proper advice to participants. Compliance to stress relaxation therapy will also be emphasized here. Participants also can discuss about their medical condition and blood pressure will be measured in each session. This counseling session will be done by investigator; who is the Occupational Health Doctor with training in EAP counseling. Investigator had undergone 3 phase EAP counseling training which consist of:Phase 1: Counseling Skills for In-house Counselors – 3 daysPhase 2: Understanding Clients – 3 daysPhase 3: Simulation Exercises – 3 days6.6.3Stress Relaxation TherapyStress Relaxation Therapy will be taught to the participants by theory and practical session for one day period. The therapy includes deep breathing therapy, progressive muscular relaxation, imagery, musical and. To ensure compliance to the therapy, self-help material, phone follow-up and 3 monthly one-to-one counseling will be emphasized on this therapy. The best relaxation is achieved by using physical and mental techniques together. These useful physical relaxation techniques can help them to reduce muscle tension and manage the effects of the fight-or-flight response on your body. This is particularly important if they need to think clearly and perform precisely when they are under pressure. There are four types of Stress Relaxation Therapy:i)Deep Breathing TherapyDeep breathing is a simple, but very effective, method of relaxation. It is a core component of everything from the

Category

Lifestyle

2

Description

Control Group Participants in control group will be given self-help pamphlet on stress management

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

University of Malaya Wellness Programme

Full name of responsible person

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Kuala Lumpur

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Institutes of Research Management and Monitoring, University of Malaya

Full name of responsible person

Prof.Dr.Shaliza Ibrahim

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Grant name

Grant code / Reference number

PS175/2009B

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Institutes of Research Management and Monitoring, University of Malaya

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

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Name of organization / entity

University of Malaya

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty