

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effects of Progressive Muscle Relaxation as part of a Worksite Health Promotion Program to Alleviate Stress in the Automotive Assembly Line: A Quasi Experimental Study.

Protocol summary

Summary

The aim of this study was to evaluate the effectiveness of individual-focused Progressive Muscle Relaxation as part of a Worksite Health Promotion Program on self-perceived occupational stress among male automotive assembly-line workers. A quasi-experimental study was conducted in two automotive assembly plants in Malaysia over 9 months. One of the assembly plant received Progressive Muscle Relaxation training while other acted as a control by receiving pamphlets on stress and its ill-effects. Intention-to-treat analysis was conducted to test the effectiveness of the relaxation therapy. The level of stress was measured using Stress subscale of Depression Anxiety Stress Scales-21.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014021516578N1**

Registration date: **2014-02-28, 1392/12/09**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-28, 1392/12/09

Registrant information

Name

Bala Sundram

Name of organization / entity

University Malaya

Country

Malaysia

Phone

+60 (3) 7967 4756

Email address

balamurali@siswa.um.edu.my

Recruitment status

Recruitment complete

Funding source

Self-funded

Expected recruitment start date

2012-01-20, 1390/10/30

Expected recruitment end date

2012-09-30, 1391/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Progressive Muscle Relaxation as part of a Worksite Health Promotion Program to Alleviate Stress in the Automotive Assembly Line: A Quasi Experimental Study.

Public title

Effects of Progressive Muscle Relaxation as part of a Worksite Health Promotion Program to Alleviate Stress in the Automotive Assembly Line.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were all male workers directly attached to the production line and who had been working at the site for more than 1 year. Respondents with psychiatric illnesses with or without medication, having prior training or current use of relaxation therapy, working less than 1 year and respondents without consent were excluded.

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget sample size: **176****Randomization (investigator's opinion)**

Not randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids****1****Registry name**

WHO Universal Trial Number(UTN)

Secondary trial Id

U1111-1153-4963

Registration date

2014-02-18, 1392/11/29

Ethics committees**1****Ethics committee****Name of ethics committee**

Medical Ethics Committee, University Malaya Medical Centre

Street address

Lembah Pantai,

City

Kuala Lumpur

Postal code

59100

Approval date

2012-01-18, 1390/10/28

Ethics committee reference number

895.11

Health conditions studied**1****Description of health condition studied**

occupational stress

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Stress

Timepoint

2 monthly interval for 9 months from baseline

Method of measurement

Depression, Anxiety, Stress Scale (DASS-21)

Secondary outcomes

empty

Intervention groups**1****Description**

Plant B as the pamphlet group acting as control.

Category

Treatment - Other

2**Description**

The study was conducted in the state of Selangor, Malaysia at a place called Rawang, from the district of Hulu Selangor. Plant A was selected as the intervention group for the combined Progressive Muscle Relaxation (PMR) therapy. The study in both groups commenced in January 2012 and assessed with the shortened and self-administered Depression, Anxiety and Stress Scale (DASS-21) questionnaire. The reinforcement sessions were done from baseline at 2 monthly intervals till 9th month in the PMR group. The control group received pamphlet distribution on stress, at baseline and end of 9th month. The sample for the study were voluntary individuals willing to participate, taken from the study population whom were screened by the short, self-administered and validated Malay version of Depression, Anxiety and Stress Scale (DASS-21) questionnaire.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Perusahaan Otomobil Kedua Sdn Bhd Sungai Choh,
Locked Bag 226, 48009 Rawang, Selangor Darul
Ehsan, M

Full name of responsible person**Street address****City**

Rawang

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bala Murali Sundram

Full name of responsible person

Bala Murali Sundram

Street address

Department of Social and Preventive Medicine,
Faculty of Medicine Building, University of Malaya

City

Kuala Lumpur

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Bala Murali Sundram

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

Contact

Name of organization / entity

University of Malaya

Full name of responsible person

Bala Murali Sundram

Position

Doctorate student/MBBS, MPH

Other areas of specialty/work

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Person responsible for scientific

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Contact

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Full name of responsible person

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Associate Professor/ MBBS, MPH

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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