

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Comparison of the effectiveness of theory-based health promotion in the workplace to control stress in health care workers

Protocol summary

Study aim

Determining the Impact of Theoretical Intervention on Health Promotion in the Workplace in Stress Control

Design

A clinical trial with control and intervention group, parallel groups, Without blinding, simple accident.

Settings and conduct

The study population is health workers working in health centers in Qazvin province. The results are collected before and after and three months later and 6 months after training and organizational changes with the help of a questionnaire.

Participants/Inclusion and exclusion criteria

1. Official, contractual and corporate employees working as health care providers 2. Have at least 6 months of work experience as a health care provider 3. Do not use certain sedatives 4. Lack of specific diseases

Intervention groups

For the intervention group, 3 workshops will be held for two hours a week for 3 weeks. Group discussion sessions and daily practice reports will be held on virtual social networks during the intervention. Organizational changes are also applied to support. In the control group, no intervention is performed except for routine programs. The study questionnaire is completed in before, immediately after the intervention, 3 months later and six months later by the participants to measure the amount of stress.

Main outcome variables

Stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045322N1**

Registration date: **2020-04-06, 1399/01/18**

Registration timing: **prospective**

Last update: **2020-04-06, 1399/01/18**

Update count: **0**

Registration date

2020-04-06, 1399/01/18

Registrant information

Name

Masoumeh Zeinolabedini

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8822 0129

Email address

m.zeinolabedini@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-21, 1399/03/01

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of theory-based health promotion in the workplace to control stress in health care workers

Public title

Investigating the effect of theoretical intervention on health promotion in the workplace in controlling employee stress

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Official, contractual and corporate employees working as health care providers in comprehensive health care centers Have at least 6 months of work experience as a health care worker

Exclusion criteria:
Existence of any factors that make it difficult for employees to participate.

Age
To 45 months old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 100

Randomization (investigator's opinion)
Randomized

Randomization description
A simple coincidence, in this method, from the list of 6 cities of Qazvin province, each of which is covered by a health network, 2 cities are randomly selected, then the eligible people are registered and Finally, by lottery, one of the two cities will enter the control group and the other will enter the intervention group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tarbiat Modares University

Street address

Nasr, Jalal Al-Ahmad, Tehran

City

Tehran

Province

Tehran

Postal code

141173116

Approval date

2018-06-27, 1397/04/06

Ethics committee reference number

IR.MODARES.REC.1397.032

Health conditions studied

1

Description of health condition studied

Stress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of stress in employees

Timepoint

The study questionnaire is completed by the participants 3 months in advance and six months immediately after the intervention.

Method of measurement

Using a researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Educational and organizational intervention

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Qazvin Health Department

Full name of responsible person

Masoumeh Zeinolabedini

Street address

Next to Mofteh Street. Azadegan Boulevard. Qazvin

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Fax

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Email

health@qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Faculty of Medical Sciences, Tarbiat Modares Modares University

Full name of responsible person

Dr. Yaqub Fathollahi

Street address

Nasr Bridge, Jalal AleAhmad Highway,Tehran

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hidarnia@modares.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Faculty of Medical Sciences, Tarbiat Modares Modares University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Faculty of Medical Sciences, Tarbiat Modares University

Full name of responsible person

Alireza Heidarnia

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic information is confidential, but information

about research outcomes can be shared.

When the data will become available and for how long

One week after receiving the email request to the principal in charge of the study

To whom data/document is available

Researchers at scientific and academic institutions, Ministry of Health

Under which criteria data/document could be used

Health Departments of Medical Sciences Universities

From where data/document is obtainable

Dr. Heidarnia, Chief Research Officer

Email:hidarnia@modares.ac.ir

What processes are involved for a request to access data/document

One week after receiving the email request to the principal in charge of the study

Comments