Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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
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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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Qazvin

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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 scientific inquiries

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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