

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effectiveness of education based on the theory of planned behavior on the correct lifestyle for disease prevention and health promotion of hospital staff

Protocol summary

Study aim

Determining the effect of educational intervention based on the theory of planned behavior on the lifestyle of administrative staff of Isfahan regional hospitals in 2020-2021

Design

A clinical trial with a control group, with parallel, randomized groups, on 70 administrative staff of Isfahan Regional Hospital. For randomization, first a call will be made to participate in the study and the required sample size will be randomly selected from among the qualified people. After preparing the list of participants, the first number will be assigned to the intervention group and the next number to the control group.

Settings and conduct

Study place: The study place was the administrative department of a regional hospital in Isfahan. Study population: By random sampling method, 35 administrative staff members will be selected as the control group and 35 administrative staff members will be selected as the intervention group. Blinding: In this study, blinding has not been done.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study; Formal or contract employment in Isfahan regional Hospitals Non-inclusion criteria: Cardiovascular disease, hypertension and diabetes

Intervention groups

Intervention group: For the intervention group, an educational program will be designed based on the main components of promoting a healthy lifestyle. It is planned to implement a training program in at least four one-hour face-to-face training sessions. Meetings will be subject to change. In addition, sending letters of encouragement and encouragement to staff to improve their lifestyles and encouraging hospital officials to encourage staff to improve their lifestyles, etc. will be

part of the intervention program. Control group:None of these actions will be performed for the control group.

Main outcome variables

Lifestyle score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211015052776N1**

Registration date: **2021-12-14, 1400/09/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-14, 1400/09/23**

Update count: **0**

Registration date

2021-12-14, 1400/09/23

Registrant information

Name

Ali Jahangiri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3320 2789

Email address

hassanpoor37@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-11, 1400/09/20

Expected recruitment end date

2022-03-11, 1400/12/20

Actual recruitment start date

2021-12-11, 1400/09/20
Actual recruitment end date
2022-03-11, 1400/12/20
Trial completion date
2022-03-11, 1400/12/20

Scientific title
Comparison of the effectiveness of education based on the theory of planned behavior on the correct lifestyle for disease prevention and health promotion of hospital staff

Public title
The effect of an educational intervention based on the theory of planned behavior on the lifestyle of administrative staff

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Formal or contract employment in Isfahan regional Hospitals

Exclusion criteria:
Reluctance to cooperate Cardiovascular disease, hypertension and diabetes

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization

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 Baqiyatallah University of Medical Sciences

Street address
Baqiyatallah Hospital; Sheikh Baha'i street

City
Tehran
Province
Tehran
Postal code
1435916274

Approval date
2021-05-08, 1400/02/18
Ethics committee reference number
IR.BMSU.BAQ.REC.1400.008

Health conditions studied

1

Description of health condition studied
lifestyle

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Lifestyle score in the questionnaire

Timepoint
Before the intervention and three months later

Method of measurement
Health Promoting Lifestyle Questionnaire, the standard Persian version of which is available, as well as a theory-based questionnaire by the researcher and based on a study conducted by Banerji et al. In 2019.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:Necessary explanations about the plan and the purpose of doing it will be given to the participants (both control and intervention groups) and they will be asked to fill in the form of informed consent to participate in the study to enter the study, then complete the questionnaire. (The method of collecting information in this research will be through a researcher-made questionnaire, which is a two-step form of completing the questionnaires) and employees are asked to answer the questionnaires separately and accurately without consultation, then the questionnaires After analyzing the participants' information, an educational intervention tailored to the educational needs of learners, which will be determined in the pre-test, is designed and considered for the intervention group based on the main components of promoting a healthy lifestyle. In at least four one-hour face-to-face training sessions, the training program should be implemented, which according to the analysis of the information of the

first stage, the number of sessions can be changed. Three months after the intervention, the variables will be re-examined, ie at the end of the third month after completing the first questionnaire, the second stage will be performed to determine the effect of the educational intervention and the questionnaire will be completed as a self-report in the presence of the researcher.

Category

Lifestyle

2**Description**

Control group: No training program will be designed for the control group, only at the end of the study, educational materials will be provided to the administrative staff of the control group.

Category

Lifestyle

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

Isfahan Regional Hospital

Full name of responsible person

Ali Jahangiri

Street address

Behdari Lashkar Street; Artesh Square; Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174620314

Phone

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Email

alijahan1318@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

mohsan saffari

Street address

South Sheikh Baha'i St.Mulla Sadra St.,Vanak Square.,
Tehran

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Province

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Postal code

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alijahan1318@gmail .com

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

Yes

Title of funding source

Bagheiat-allah University of Medical Sciences

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**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohsen Saffari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

South Sheikh Baha'i St.Mulla Sadra St.,Vanak Square.,
Tehran

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

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Person responsible for updating data**Contact****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Mohsen Saffari

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available