

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Effect of health preservation principles (hefzossehhe) education based on Iranian Medicine on quality of life and number of visits of the insured of Iranian health insurance organization

Protocol summary

Study aim

determine of effect of health preservation principles (hefzossehhe) education on quality of life and number of visits of the insured of Iranian health insurance organization

Design

clinical trial with control group, with a parallel group, randomized

Settings and conduct

persons who are insured by Iranian Health Insurance Organization in the State Staff Fund and in accordance with health insurance software have been in upper pillars of Number of visits to outpatient department during the past year will be selected randomly. Individuals are randomly divided into two groups of case and control. the case group will undergo health preservation principles education based on the Health Belief Model.

Participants/Inclusion and exclusion criteria

1- persons who are insured by Iranian Health Insurance Organization in the State Staff Fund 2- 15 to 50 years old age 3- being in 50 to 70 percentile of number of visit during 6 month past 4- Satisfaction of participating in the study

Intervention groups

The intervention group received health preservation principles education based on the Health Belief Model. Educations have been face to face (4 hours), educational pamphlets and training through cyberspace for 6 months. The control group did not receive any education.

Main outcome variables

health preservation principles (hefzossehhe) education, quality of life, number of visits

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171125037625N1**

Registration date: **2019-06-03, 1398/03/13**

Registration timing: **retrospective**

Last update: **2019-06-03, 1398/03/13**

Update count: **0**

Registration date

2019-06-03, 1398/03/13

Registrant information

Name

Mostafa Abedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3300 5028

Email address

m.abedi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2017-10-23, 1396/08/01

Trial completion date

2017-10-23, 1396/08/01

Scientific title

Effect of health preservation principles (hefzossehhe) education based on Iranian Medicine on quality of life

and number of visits of the insured of Iranian health insurance organization

Public title

Effect of health preservation principles (hefzossehe) education based on Iranian Medicine on quality of life and number of visits of the insured of Iranian health insurance organization

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

persons who are insured by Iranian Health Insurance Organization in the State Staff Fund 15 to 50 years old being to 50-70 percentile number of visits in six months before the study, according to the statistics of the health insurance organization Satisfaction with participation in the study

Exclusion criteria:

Individuals from the control group who have been effective hygiene education in the course of the study in any way

Age

From **15 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahed University of Medical Sciences

Street address

Shahed Univercity, Persian Gulf Freeway

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-01-08, 1396/10/18

Ethics committee reference number

IR.Shahed.REC.1396.83

Health conditions studied

1

Description of health condition studied

being in upper pillars of Number of visits to outpatient department

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

number of visits

Timepoint

The first six months of the 1396

Method of measurement

health insurance organization software

2

Description

quality of life

Timepoint

The first six months of the 1396

Method of measurement

sf12 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: persons who are insured by Iranian Health Insurance Organization in the State Staff Fund and in accordance with health insurance software have been in upper pillars of Number of visits to outpatient department and receive health preservation principles education

Category

Lifestyle

2

Description

Control group: persons who are insured by Iranian Health Insurance Organization in the State Staff Fund and in

accordance with health insurance software have been in upper pillars of Number of visits to outpatient department and do not receive health preservation principles education

Category

Lifestyle

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

Health Center of Traditional Medicine, Shahed University

Full name of responsible person

Farhad Jafari

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No 17, Third Dashtestan Alley, Pasdaran Ave

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

Shahed University

Full name of responsible person

Dr.Davati

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

Yes

Title of funding source

Shahed 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**

Shahed University

Full name of responsible person

Mostafa Abedi

Position

MD-PHD Student

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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