

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 2026

Effectiveness of an educational program based on Health Measures Instruction (hefz alsehhe) of lifestyle and Treatment costs

Protocol summary

Study aim

The Effect of Education on the Quality of Life and the Cost of Treatment of Insured Persons in the Health Insurance Organization

Design

In order to achieve the goals, a theory-based education was developed based on a health education model and conducted through clinical intervention.

Settings and conduct

The place of study is Tehran and through the intervention of two groups

Participants/Inclusion and exclusion criteria

Entry requirements -A member of the health insurance organization in the State Staff Fund -Sen between 15 and 50 years -Africans who were at high percentiles (50 to 70 percentiles) spending six months before the study - Attitude of the people being studied Conditions of Exit Study - No consent of the subjects to continue to participate in the study - Any group from the control group who has had any training in the field of sanitation in the course of the study. - Patients with severe illness (cancer) Special patients (MS, hemophilia, dialysis, and kidney transplantation)

Intervention groups

For intervention, the two groups were considered The intervention group and the control group (control group) In the intervention group, an intervention was conducted using hygiene education (lifestyle based on traditional Iranian medicine), which included face training, instruction leaflets, and six months of monitoring through cyberspace There was no intervention in the control group

Main outcome variables

Cost of treatment : Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190109042302N1**

Registration date: **2019-01-16, 1397/10/26**

Registration timing: **retrospective**

Last update: **2019-01-16, 1397/10/26**

Update count: **0**

Registration date

2019-01-16, 1397/10/26

Registrant information

Name

Mohammadbagher Hadavand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 4055

Email address

dr_hadavand@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-03-20, 1396/12/29

Trial completion date

2018-03-20, 1396/12/29

Scientific title

Effectiveness of an educational program based on Health Measures Instruction (hefz alsehhe) of lifestyle and Treatment costs

Public title

Effectiveness of an educational program based on Health Measures Instruction (hefz alsehhe) of lifestyle and Treatment costs .

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Insured Persons Health Insurance Organization Age between 15 and 50 years People who are at high percentile costs in the six months of the year before study Satisfaction of the subjects studied

Exclusion criteria:

Dissatisfaction of the subjects studied Individuals from the control group who during the study had an effective education in accordance with sanitation training in any way. Patients with severe and late-onset illness Specific Patients (ms, hemophilia, kidney transplantation)

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

The method of assigning people to the intervention and control groups is simple simple distribution method Among the health insurance policies of Iran Health Insurance Organization in Tehran, which was placed at a cost of 50 to 70 percentile cost of treatment, 100 patients were randomly selected and ranged from 1 to 100, and then 50 random numbers were selected and classified as intervention group And 50 other numbers were considered as control groups. SPSS 21 was used for 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**

Shahed University Medical Ethics Committee

Street address

Shahed University-Beginning of the Free Way of Tehran Qom -tehran

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2017-07-04, 1396/04/13

Ethics committee reference number

IR.Shahed.REC.1396.28

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

All health insurers who are registered with health insurance software are covered by the plan and are not selected based on the disease.

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

Cost of treatment

Timepoint

The first 6 months of 1396 and the six months before the study

Method of measurement

Health Insurance Company Software

2**Description**

Quality of Life

Timepoint

At the beginning of the study and six months after the end of the study

Method of measurement

Questionnaire sf 12

Secondary outcomes**1****Description**

Treatment costs

Timepoint

The first six months of 1396 and the six months of the same year

Method of measurement

Health Insurance Company Software

2**Description**

Quality of Life
Timepoint
At the beginning of the study and six months later at the end of the study
Method of measurement
Questionnaire sf 12

Intervention groups

1

Description
Intervention group: The intervention group was trained in hygiene education (lifestyle based on traditional Iranian medicine) and they were trained in two sessions and then for 6 months, through cyberspace and pamphlet, continuing education for the control group continued.

Category
Lifestyle

2

Description
Control group: Control group: No intervention was performed in the control group and only the cost of treatment was received from the health organization before and after the study, and the quality of life questionnaire was received at the beginning and the end of the course (end of intervention).

Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Iran Health Insurance Organization
Full name of responsible person
Hamid Matinirad
Street address
Iran Health Insurance Organization ,. Ghods(gharb)
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1467863433
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hmatinibroumand@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University

Full name of responsible person
Seyed Abbas Hasheminejad
Street address
University of Shahed University-Persian Gulf Highway
(Tehran - Qom)- tehran
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Province
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3319118651
Phone
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Email
timshahed@yahoo.com
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
Hadavand Mohamad Bagher
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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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

Yes - There is 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

Title and more details about the data/document

Together with the article will be published

When the data will become available and for how long

Always

To whom data/document is available

All

Under which criteria data/document could be used

For use in similar research projects

From where data/document is obtainable

executor of plan

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

Request via email

Comments