

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

The effect of education on influenza vaccination In selected patients with chronic diseases (diabetes ,pulmonary diseases ,Hemodialysis ,heart disease)in the shahrood in 2018

Protocol summary

Study aim

Effect of training on influenza vaccination in pulmonary, cardiovascular diseases, hemodialysis and diabetic patients in the Shahrood in 2018.

Design

This study is a randomized, not blinded clinical trial. The study is parallel group design with 1:1 allocation ratio. The study population is selected from patients with pulmonary, cardiovascular diseases, hemodialysis and diabetic patients. The sample size is 80 people. Patients are divided into two intervention and control groups through randomized blocks. 80 patients would enroll between November 2018 and October 2018, and will follow for six months.

Settings and conduct

The study will conduct on referral patients to a specialized clinic in Imam Hossein Hospital at Shahrood. Assignment of patients to intervention and control groups will be done. In this study, not blind.

Participants/Inclusion and exclusion criteria

The inclusion criteria: history of pulmonary, cardiovascular diseases, hemodialysis and diabetes. Referring to specialized clinic, At least 18 years old, Minimum elementary education, Interest in participating in the study. The exclusion criteria: History of participation in influenza vaccine training classes, Inability to have regular attendance at training sessions and The presence of any influenza vaccine sensitivity

Intervention groups

Educational intervention is performed based on the theory of planned behavior. 3 sessions are arranged once a week. Summary of training sessions: Definition of the disease. Determine the mental norms. Determine the control of perceived behavior. For the control group, the same sessions will be completed after the end of the study.

Main outcome variables

Influenza vaccine injection rate in selected patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180526039841N1**

Registration date: **2018-06-14, 1397/03/24**

Registration timing: **prospective**

Last update: **2018-06-14, 1397/03/24**

Update count: **0**

Registration date

2018-06-14, 1397/03/24

Registrant information

Name

mina kahnoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3577 5300

Email address

kahnoseini@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2018-11-21, 1397/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of education on influenza vaccination In selected patients with chronic diseases (diabetes ,pulmonary diseases ,Hemodialysis ,heart disease)in the shahrood in 2018

Public title

The effect of education on influenza vaccination

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

any patients with pulmonary, cardiovascular and Hemodialysis disease, and diabetes volunteered for study Lack history of participation vaccination training classes People over 18 years old a minimum level of elementary education acceptance for participate in the research

Exclusion criteria:

Unwilling to participate in the study No regular attendance at training sessions The presence of any influenza vaccine susceptibility

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study we used random blocking method for randomization. Randomization unit was individual. Stratified random sampling was done before we use random block method, because we need to recruit 10 patients from selected diseases (DM, Hemodialysis, Cardiovascular & pulmonary). Randomization tool was random numbers table.

Blinding (investigator's opinion)

Not blinded

Blinding description

This study is a not blinded clinical trial. Since training to patients is done by someone other than the principal investigator, then study is not blinded.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shahrood University of Medical Sciences

Street address

Emam Hossein Square, Emam Hossein Hospital

City

Shahrood

Province

Semnan

Postal code

36147-73947

Approval date

2017-10-27, 1396/08/05

Ethics committee reference number

SHMU.REC.1395.61

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

pulmonary and heart and hemodylsis and diabetes

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

Influenza vaccination rate in selected patients

Timepoint

Beginning of study and 1 weak and 2 weak after education

Method of measurement

Researcher made questionnaire

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

The effect of education on influenza vaccination

Timepoint

At the beginning of the study, and then one week after the end of the training classes

Method of measurement

Researcher made questionnaire

Intervention groups**1****Description**

Intervention group: Pulmonary and diabetic and hemodialysis and cardiovascular patients.In the

intervention group, intervention was conducted based on Theory of Planning Behavior. For each group of patients in the intervention arm, 3 sessions are arranged once a week according to scheduled and pre-announced schedules in the clinic. Before the beginning of the sessions in the intervention group, a briefing is conducted for 30 minutes (referrals, group norms, statement of goals). It should be noted that a briefing session is organized for 4 groups of patients in intervention and control groups. The structure of the meetings is based on the table drawn up (appended). After completing the training program, in the 4 groups of patients, the intervention arm after completing the initial question during the final session; 2 by phone call with intervals of 1 week by the researcher. Intervention as well as in the control group.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Specialized Clinic of Imam Hossein Shahroud Hospital
Full name of responsible person
Mina khahhoseini
Street address
Imam hosein Hospital ,Imam hosein Squire
City
Shahrood
Province
Semnan
Postal code
36147-73947
Phone
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2

Recruitment center

Name of recruitment center
Specialized Clinic of Imam Hossein Shahroud Hospital
Full name of responsible person
Mina khahhoseini
Street address
Emam Hosein Hospital,Emam Hosein Squire
City
Shahrood
Province
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Mina khahhoseini
Street address
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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

Shahroud 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
Shahroud University of Medical Sciences
Full name of responsible person
mina khahhoseini
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
Street address
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Mina kanhoseini

Position

student

Latest degree

Medical doctor

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Person responsible for updating data

Contact

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

mina kanhoseini

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

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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

Yes - There is 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

Title and more details about the data/document

The main message is shared

When the data will become available and for how long

A few months after printing results

To whom data/document is available

Available to scientific institutions

Under which criteria data/document could be used

Educational

From where data/document is obtainable

email

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

Demand is provided after the necessary check

Comments