

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of educational intervention based on the theory of planned behavior on the increase of preventive behaviors of knee osteoarthritis in the elderly.

Protocol summary

Study aim

Determining the application of the theory of planned behavior in the preventive behaviors of knee arthritis (weight control, diet improvement, blood sugar control, exercise and smoking cessation) in the rural elderly of Bushehr province in 2022

Design

This clinical trial was designed as a single-group screening of 100 elderly people with osteoarthritis of the knee who were selected by random cluster sampling. They will be examined after three months of educational intervention.

Settings and conduct

This trial was conducted among the elderly over 60 years of age covered by the health services of the rural health centers of Bushehr province through random cluster sampling of 100 people. By referring to their homes, they first completed the questionnaire, then completed the training course designed for the intervention, and then again after three months. The questionnaire is completed for them. This intervention is a single group.

Participants/Inclusion and exclusion criteria

The inclusion criteria include age over 60 years, absence of cognitive (dementia and Alzheimer's) and mental disorders, willingness to participate in the study, and we will also examine patients with arthritis who have knee arthritis; For them, it has been diagnosed by a rheumatology specialist. The elderly who did not want to participate in the study and had cognitive and mental disorders were excluded from the study.

Intervention groups

A number of 100 elderly people over 60 years old with knee osteoarthritis based on the theory of planned behavior were subjected to educational intervention to increase the preventive behaviors of the subsequent complications of the disease.

Main outcome variables

attitude score; abstract norms; perceived behavior control; behavioral intention; preventive behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221206056722N1**

Registration date: **2022-12-12, 1401/09/21**

Registration timing: **prospective**

Last update: **2022-12-12, 1401/09/21**

Update count: **0**

Registration date

2022-12-12, 1401/09/21

Registrant information

Name

Sara Alamdarbushehri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 5410

Email address

saraalamdarbushehri@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-26, 1401/10/05

Expected recruitment end date

2023-03-25, 1402/01/05

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of educational intervention based on the theory of planned behavior on the increase of preventive behaviors of knee osteoarthritis in the elderly.

Public title
Investigating the effect of educational intervention based on the theory of planned behavior on increasing preventive behaviors of knee osteoarthritis complications in the elderly

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Age over 60 years Not having cognitive disorders (dementia and Alzheimer's) Definite diagnosis of osteoarthritis of the knee by a specialist Not having mental disorders

Exclusion criteria:

Reluctance to participate in the study

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University of Medical Sciences

Street address
Zand Ave. Shiraz University of Medical Sciences. Shiraz. Iran

City
Shiraz

Province
Fars
Postal code
7134814336

Approval date
2022-09-10, 1401/06/19

Ethics committee reference number
IR.SUMS.SCHEANUT.REC.1401.081

Health conditions studied

1

Description of health condition studied
KNEE OSTEOARTHRITIS

ICD-10 code
M17.0

ICD-10 code description
Bilateral primary osteoarthritis of knee

Primary outcomes

1

Description
Weight

Timepoint
The first day and three months after the educational intervention

Method of measurement
Theory of planned behavior questionnaire

2

Description
The rate of change in diet

Timepoint
The first day and three months after the educational intervention

Method of measurement
Theory of planned behavior questionnaire

Secondary outcomes

1

Description
Change in smoking

Timepoint
The first day and three months after the educational intervention

Method of measurement
Theory of planned behavior questionnaire

2

Description
Change in sports program

Timepoint
The first day and three months after the educational intervention

Method of measurement

Intervention groups

1

Description

Intervention group: This clinical trial has an intervention group, 100 elderly people with osteoarthritis of the knee who were selected by random cluster sampling method. In the first round, after collecting and analyzing the data, with the cooperation of education specialists Health, Rheumatology and Physiotherapy educational program (2 workshops for 12 hours) will be designed and implemented to improve behavior. Educational program using lectures and questions and answers (two sessions of 45 minutes), educational film (two sessions of 20 minutes), practical demonstration (40 minutes), group discussion (two sessions of 30 minutes) and educational aids including pamphlets in 2 sessions of the educational workshop. It will be provided by rheumatology and physiotherapy specialists, who will be evaluated after three months of educational intervention

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rural health care centers of Bushehr province

Full name of responsible person

Hamid Habibinia

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Valfajr Ave.Center Health Boushehr.Bushehr.Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Vahid Hossaini

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President_d@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Sara Alamdarbushehri

Position

Univercity Student

Latest degree

Bachelor

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

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