

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The Effectiveness of Multi Disciplinary Interventions Based on Health Belief Model on Musculoskeletal Pain in the Elderly Living in Nursing Homes

Protocol summary

Study aim

To determine the Effectiveness of Multi Disciplinary Interventions Based on Health Belief Model on Musculoskeletal Pain in the Elderly living in Nursing Homes

Design

A randomized controlled clinical trial. From each district of Tehran, two nursing homes, one for the control group and the other for the intervention group, are selected by lottery (60 people in the intervention group, 60 people in the control group).

Settings and conduct

The intervention is carried out on the elderly living in a nursing home in Tehran in the form of cluster sampling. Trainings are conducted by the training team on the intervention group. The researcher-made questionnaire is used for this study. Finally, after collecting the data, two intervention and control groups are compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: people aged 60 and older living in a nursing home ability to do physical activity, ability to answer questions. Exclusion criteria: elderly with Alzheimer's disease, elderly with mobility disabilities, and elderly who use medication to control pain.

Intervention groups

This six-month educational intervention includes three parts of physiotherapy, stress reduction and vitamin D intake, including: walking by the elderly and maintaining the correct body posture (correct exercises for standing, walking, etc which reduce the pressure on the muscles and thus reduce pain during daily activities), the benefits and The way to take vitamin D is by a doctor and to take 50,000 units of vitamin D tablets monthly and to control stress. According to the opinion of the physiotherapist and psychologist, 4 to 6 six sessions per month (one 45-minute session each week) are held. Control group: will not receive the educational

intervention, and the follow-up of this group will be to complete the questionnaire in specific time intervals.

Main outcome variables

Musculoskeletal pains

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220904055881N1**

Registration date: **2023-02-11, 1401/11/22**

Registration timing: **registered_while_recruiting**

Last update: **2023-02-11, 1401/11/22**

Update count: **0**

Registration date

2023-02-11, 1401/11/22

Registrant information

Name

Sogand Habibi

Name of organization / entity

دانشگاه تربیت مدرس

Country

Iran (Islamic Republic of)

Phone

+98 87 3362 7390

Email address

habibisogand252@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-11-21, 1401/08/30

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of Multi Disciplinary Interventions Based on Health Belief Model on Musculoskeletal Pain in the Elderly Living in Nursing Homes

Public title

Effectiveness of Multifaceted Interventions on Reducing Musculoskeletal Pain in the Elderly

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

People Aged 60 and over Living in a Nursing Home Ability to Perform Physical Activity Ability to Answer Questions

Exclusion criteria:

Elderly People with Alzheimer's Disease Elderly with Mobility Disabilities Elderly People Who Use Medicine to Control Pain

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is cluster sampling. Tehran is divided into four regions: north, south, west, and east. The lottery method is used to select nursing homes in each region. A number is considered for each nursing home. Then the numbers are written on the paper. The papers are placed in a container and stirred well. Then two cards are selected from among the papers. The first card is considered as the intervention group and the second card as the control. Then, from each center, the elderly who meet the entry criteria are identified and selected. The sample size in each group is 60 people (60 people in the intervention group and 60 people in the control group).

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The use of multifaceted interventions to reduce Musculoskeletal pain in the elderly is one of the innovative aspects of this plan.

Secondary Ids

empty

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

Ethics Committee of Tarbiat Modares University of Medical Sciences

Street address

Tehran Modares University., Nasar Bridge ., Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713116

Approval date

2022-08-27, 1401/06/05

Ethics committee reference number

IR.MODARES.REC.1401.111

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

Other osteoporosis without current pathological fracture

ICD-10 code

M81.8

ICD-10 code description

Other osteoporosis without current pathological fracture

2**Description of health condition studied**

Osteoarthritis, unspecified site

ICD-10 code

M19.9

ICD-10 code description

Osteoarthritis, unspecified site

3**Description of health condition studied**

Gout, unspecified

ICD-10 code

M10.9

ICD-10 code description

Gout, unspecified

Primary outcomes**1****Description**

Musculoskeletal pains

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire Made by the Researcher

Secondary outcomes

1

Description

knowledge

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

2

Description

Perceived Susceptibility

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

3

Description

Perceived Severity

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

4

Description

Perceived Barriers

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

5

Description

Perceived Benefits

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

6

Description

Cues to Action

Timepoint

Before the intervention, immediately, 3, and 6 months

after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

7

Description

Self-Efficacy

Timepoint

Before the intervention, immediately, 3, and 6 months after completing the educational intervention.

Method of measurement

Questionnaire made by the researcher

Intervention groups

1

Description

Intervention group: Physiotherapy includes training, maintaining correct body posture while standing, walking, and sitting by a physiotherapist for four to six 45-minute sessions and training walking for at least 30 minutes a day. Training reducing stress and anxiety including deep breathing, sleep regulation, etc. by a psychologist for four 45-minute sessions. Vitamin D intake includes training on how to consume vitamin D and its benefits by a doctor (every month one vitamin D tablet of 50,000 units is given to the elderly in the intervention group). the number of training sessions based on the Health belief model structures to change the beliefs of the elderly is determined based on confirmatory factor analysis. Intervention sessions will be held weekly (one session per week). The training sessions will last one to two months, but at least six months of vitamin D tablets are required to be effective, so the duration of the intervention will be six months.

Category

Prevention

2

Description

Control group: It includes elderly people living in Nursing Homes who will not receive any intervention during the research period. They will complete the questionnaire before the intervention, immediately, three and six months after the intervention. The results of this group will be compared and statistically analyzed with the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Kehrizak nursing home, Shahid Rajaei office

Full name of responsible person

Hassan Ahmadi

Street address

No289., Farhadi Kia Alley., Madaan square., Nazi Abad Street

City

Tehran

Province

Tehran

Postal code

1831993134

Phone

+98 21 5505 9556

Email

info@kahrizak.com

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

Tarbiat Modares University

Full name of responsible person

Amir Abdollah zadeh

Street address

Tehran Modares University., Nasar Bridge ., Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 21 8288 3502

Email

zadeh@modares.ac.ir

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

Yes

Title of funding source

Tarbiat Modares 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**

Tarbiat Modares University

Full name of responsible person

Sedigheh Sadat Tavafian

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Faculty of Medical sciences., Tehran Modares University., Nasar Bridge ., Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1417113116

Phone

+98 912 287 6439

Email

tavafian@modares.ac.ir

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

Tarbiat Modares University

Full name of responsible person

Sedigheh Sadat Tavafian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

Faculty of Medical sciences., Tehran Modares University., Nasar Bridge ., Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1417113116

Phone

+98 912 287 6439

Email

tavafian@modares.ac.ir

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

Tarbiat Modares University

Full name of responsible person

Sogand Habibi

Position

Student

Latest degree

Master

Other areas of specialty/work

Health Promotion

Street address

Tehran Modares University., Nasar Bridge ., Jalal Al Ahmad Highway

City

Tehran

Province

Tehran

Postal code

1411713116

Phone

+98 918 518 1076

Email

habibisogand252@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Information about the primary outcome can be shared.

When the data will become available and for how long

The access period will start six months after the results are published.

To whom data/document is available

Data for researchers, people working in universities and scientific institutions

Under which criteria data/document could be used

Evaluating the outcome of data analysis and verifying its correctness under the conditions of double-blindness

From where data/document is obtainable

Via email tavafian@modares.ac.ir

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

Via email tavafian@modares.ac.ir

Comments