# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Nov 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)

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**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-Efficcy

**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
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## Sponsors / Funding sources

### 1

**Sponsor**
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Tarbiat Modares University
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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**
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
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Sedigheh Sadat Tavafian
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professor
**Latest degree**
Ph.D.
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Health Promotion
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## Person responsible for updating data

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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**