

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of health promotion interventions based on a participatory ergonomic approach to improve the quality of life of housewives with musculoskeletal disorders

Protocol summary

Study aim

The effect of a health promotional intervention based on a participatory ergonomic approach to improving the quality of life of housewives with musculoskeletal disorders

Design

A clinical trial with control and interventions group.

Settings and conduct

Self-report Fars province Akbar Abad village

Participants/Inclusion and exclusion criteria

Inclusion criteria: The motivation and willingness to participate in the study. Being married and living with the family. Having no job other than housekeeping. Not taking medication to treat mental illness. Having an MSD pain intensity score of 4 and higher based on the visual analog scale (VAS). Having no child under 2 years of go. Exclusion criteria: Not be willing to participate in the study. The occurrence of an event or accident that does not allow the person to complete the whole study procedure. Becoming pregnant during the study.

Intervention groups

Four groups including: 1. Biomechanical Intervention Group 2. Psychosocial Intervention Group 3. Multidisciplinary Intervention Group (Biomechanical and Psychosocial) 4. Control Group.

Main outcome variables

Improving the quality of life in housewife with common skeletal disorders

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200602047640N1**

Registration date: **2020-09-07, 1399/06/17**

Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**

Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

samaneh norouzi

Name of organization / entity

The university of modares

Country

Iran (Islamic Republic of)

Phone

+98 61 4364 7401

Email address

norouzisamaneh@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2023-09-20, 1402/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of health promotion interventions based on a participatory ergonomic approach to improve the quality of life of housewives with musculoskeletal disorders

Public title

The effect of health promotion interventions on musculoskeletal disorders in housewives

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Being married and living with the family The motivation and willingness to participate in the study Having an MSD pain intensity score of 4 and higher based on the visual analog scale (VAS) Having no job other than housekeeping Having no child under 2 years of age Not taking medication to treat a mental illness

Exclusion criteria:

Not be willing to participate in the study Becoming pregnant during the study The occurrence of an event or accident that does not allow the person to complete the whole study procedure

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

The sample size in the quantitative phase will be calculated as 30 persons for each group according to the following formula, and considering the dropout rate of 30%, 40 persons will be selected as the participants in each group. A total of 160 persons will be selected as the participants in the four groups (the three intervention groups plus one control group). The sampling method at this phase is permuted block randomization. This randomization process gives each participant an equal chance of being placed in each group. Conducting successful randomization requires that the researchers and the participants not be able to predict the type of interventions that will be delivered.

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

Ethics Committee in Tarbiat Modares University

Street address

Tarbiat Modares University, Jalal Ahmad Highway

City

Tehran

Province

Tehran

Postal code

111-14115

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.MODARES.REC.1399.038

Health conditions studied

1

Description of health condition studied

Neck pain

ICD-10 code

ICD-10 code description

2

Description of health condition studied

Back pain

ICD-10 code

ICD-10 code description

3

Description of health condition studied

Shoulder pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The quality of life in the people of common musculoskeletal disorders

Timepoint

Before, three and six months after the intervention

Method of measurement

Using a questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group Based on the design of the randomized controlled trial intervention, the impact of the intervention program on musculoskeletal disorders, workability, and quality of life of the housewives will be evaluated. At this phase, women who meet the criteria to be included in the study will be randomly allocated to

four groups; (1) Biomechanical Intervention Group (2) Psychosocial Intervention Group (3) Multidisciplinary Intervention Group (Biomechanical and Psychosocial), and (4) Control Group. For psychosocial intervention groups, the required training content will be provided following the conceptual framework developed in the qualitative study and the resulting theory. Besides, for the biomechanical intervention group, the required training will be provided following the conceptual framework derived from the qualitative study and job safety analysis (JSA) method. Finally, mixed training provided for the previous two groups will be applied for the comprehensive intervention group. After providing the required training programs, the participants in the three intervention groups will be divided into 10 subgroups (4 subgroups for each group and 12 subgroups in total).

Category

Prevention

2

Description

Control group: After the final evaluation and comparisons of the three intervention groups, the participants in the control group also will receive the training interventions based on ethical principles.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

House of women

Full name of responsible person

Samaneh Norouzi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Tarbiat Modares University

Full name of responsible person

Yaghoob Fathollahi

Street address

Tarbiat Modarres University, Jalal Al-Ahmad Pol Nasr,

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fatollahi@modares.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Deputy of 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

Department of Health Education, Faculty of Medical Sciences, Tarbiat Modares University ,

Full name of responsible person

Sedigheh- Sadat Tavafian

Position

Professor of Health Education & Promotion

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

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Person responsible for scientific

inquiries

Contact

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Sedigheh- Sadat Tavafian

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Person responsible for updating data

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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

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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

I have no decision yet

When the data will become available and for how long

22. 9. 2023

To whom data/document is available

The person who evaluates the outcome Analytic person
Journal Reviewer Executor of plan

Under which criteria data/document could be used

To evaluate the outcome Data analysis and validation of data Under the conditions of the triple-blind

From where data/document is obtainable

Executor of plan

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

It is requested by e-mail to the project implementer with the address: tavafian@modares.ac.ir

Comments