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

Main outcome variables
Improving the quality of life in housewife with common skeletal disorders

General information

Reason for update
Recruiting

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
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Name of organization / entity
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Recruitment status
recruiting
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 Tarbit Modares University

Street address
Tarbit 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
Yaghoub Fathollahi
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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
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
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Other areas of specialty/work
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Person responsible for scientific
inquiries

Contact
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Full name of responsible person
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Person responsible for updating data
Contact
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Full name of responsible person
Samaneh Norouzi
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Ph.D student
Latest degree
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Other areas of specialty/work
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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