

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

The effect of physical activity training based on health belief model on quality of life during menopause in women 40 to 50 years

Protocol summary

Study aim

Determining the effect of physical activity training based on health belief model on quality of life during menopause in women 40 to 50 years old referring to comprehensive health service centers in Isfahan in 1399-1400

Design

Educational intervention with a control group, one blind,, on 80

Settings and conduct

in each health center, aquestionnaires are completed from ten eligible people, then randomly, four centers as the intervention group and the other four centers as the control group. in Intervention group, intervention is online training based on the health belief model through WhatsApp about the premenopausal period, the need to do physical activity in this period and the correct way to do physical activity. Two months after the training again Questionnaires are completed. The data analyzer does not know about assigning individuals to the intervention and control group and the study is a blind.

Participants/Inclusion and exclusion criteria

inclusion criteria: - Women 40 to 50 years old who have entered the menopausal period (who report signs of changes in menstrual cycles Exclusion criteria: - premature menopause

Intervention groups

The components of educational intervention are divided into two parts: teaching concepts based on model structures and teaching sports exercises. Concept training is sent to participants in the form of packages of videos, podcasts, posters and text messages every two weeks in the WhatsApp group. Then they have two weeks to think, discuss and provide feedback on the submitted content. Exercise training: Aerobics training, endurance and stretching exercises at home online by an exercise instructor, 3 sessions per week, each session for 40 minutes, for 2 months.The control group includes people who do not receive any educational intervention

Main outcome variables

The scores of health belief model constructs; physical activity score quality of life score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210602051478N1**

Registration date: **2022-05-17, 1401/02/27**

Registration timing: **retrospective**

Last update: **2022-05-17, 1401/02/27**

Update count: **0**

Registration date

2022-05-17, 1401/02/27

Registrant information

Name

Mahboobeh Amini. Neisiany

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-22, 1400/04/01

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of physical activity training based on health belief model on quality of life during menopause in women 40 to 50 years

Public title
The effect of physical activity training on quality of life in women aged 40 to 50 years

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Women in their 40s and 50s who have entered menopause (who report signs of changes in menstrual cycles) Housewives with active records in health centers At the doctor's discretion, they are not prohibited from doing aerobic exercise and endurance and stretching exercises Lack of regular regular physical activity in the last 3 months (150 minutes per week) No No Having a phone with the possibility of installing WhatsApp software and the ability to work with it
Exclusion criteria:
premature menopause use of estrogen in the last three months

Age
From **40 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, the person in charge of data analysis does not know which codes belong to the intervention group and which codes belong to the control group.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Esfahan University of Medical Sciences
Street address
Hezar Jerib St., Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice Chancellor for Research and Technology
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Esfahan
Province
Isfahan
Postal code
81746-73461
Approval date
2021-05-26, 1400/03/05
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.075

Health conditions studied

1

Description of health condition studied
perimenopause period
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Physical activity score
Timepoint
Before the intervention and two months after the intervention
Method of measurement
questionnaire IPAQ

2

Description
Quality of Life
Timepoint
Before the intervention and two months after the intervention
Method of measurement
questionnaire MENQOL

Secondary outcomes

1

Description
Perceived sensitivity score to the effects of sedentary lifestyle
Timepoint
Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

2

Description

Perceived severity score to sedentary effects

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

3

Description

Score the perceived benefits of physical activity

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

4

Description

Awareness score

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

5

Description

Score perceived barriers to physical activity

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

6

Description

Self-efficacy score

Timepoint

Before the intervention and two months after the intervention

Method of measurement

Health Belief Model of Physical Activity Questionnaire

Intervention groups

1

Description

Intervention group: Educational intervention is divided into two parts: teaching concepts based on model structures and teaching sport exercises. The concepts are sent to participants in the form of packages of videos, podcasts, posters and text messages every two

weeks in the WhatsApp group. They have two weeks to think and discuss and provide feedback on the submitted content. Individuals are asked to send their feedback in the form of an audio or text message to the group as desired. If people do not respond in the form of a message they are privately questioned. Exercise training: Aerobics training, endurance and stretching exercises at home online by the exercise instructor, 3 sessions per week, each session for 40 minutes, for 2 months. Video sessions will be provided to participants. In addition, the poster and the gif of exercises will be presented in the group. At the end, the educational content will be provided to the participants in the form of DVDs and booklets.

Category

Lifestyle

2

Description

Control group: no intervention is performed on them.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Health Deputy

Full name of responsible person

Dr. Kamal Heydari

Street address

Ibn Sina St., next to Amin Hospital, Isfahan Deputy Minister of Health

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mahboobeh Amini Neisiany
Position
student
Latest degree
Bachelor
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Person responsible for updating data

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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

Not applicable

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

