

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Theory-based Educational Interventions on Improvement of Physical Activities of Middle-aged Women Referring to Ahwaz Health Centers in 2017

Protocol summary

Study aim

Determine the effect of the theory-based educational intervention on the improvement of physical activities of middle-aged women referring to Ahwaz health centers

Design

The research units were randomly allocated into two intervention and control groups of 90 individuals

Settings and conduct

Ahwaz city was divided into 4 geographical regions with approximately equal populations of middle-aged women. Two centers (intervention and control groups) were selected in each region, and a total of 22 individuals were randomly in each center. The intervention program was conducted for a 2-month period for the intervention group. It consisted of 4 face-to-face consultation sessions, each for 90 minutes in a month, and 4 follow-up sessions (weeks 5- 8) after the consultation sessions for the intervention group.

Participants/Inclusion and exclusion criteria

women of 30-59 years of age, being able to read and write, not having chronic diseases such as cardiovascular or respiratory diseases or those that cause physical activities to be banned, not having mobility prohibition (able to move, participate in educational programs, and recommendations for physical activities), lack of pregnancy, lack of specific diseases, lack of a history of accidents resulted in a mental and physical problem during the past month, and willingness to participate in the research project. The exclusion criteria included the reluctance to participate in the study at any time and not attending various stages of the research (pre-education and post-education assessments, and educational sessions).

Intervention groups

The intervention program was conducted for a 2-month period for the intervention group. It consisted of 4 face-to-face consultation sessions, each for 90 minutes in a

month, and 4 follow-up sessions (weeks 5- 8) after the consultation sessions for the intervention group.

Main outcome variables

Physical Activities

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160418027449N2**

Registration date: **2019-01-31, 1397/11/11**

Registration timing: **retrospective**

Last update: **2019-01-31, 1397/11/11**

Update count: **0**

Registration date

2019-01-31, 1397/11/11

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 372510015

Email address

trakhshani@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2018-01-21, 1396/11/01

Actual recruitment end date

2018-04-30, 1397/02/10

Trial completion date

2018-04-30, 1397/02/10

Scientific title

Effect of Theory-based Educational Interventions on Improvement of Physical Activities of Middle-aged Women Referring to Ahwaz Health Centers in 2017

Public title

Effect of Theory-based Educational Interventions on Improvement of Physical Activities of Middle-aged Women

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

women of 30-59 years of age being able to read and write not having chronic diseases such as cardiovascular or respiratory diseases or those that cause physical activities to be banned, not having mobility prohibition (able to move, participate in educational programs, and recommendations for physical activities) lack of pregnancy lack of specific diseases lack of a history of accidents resulted in a mental and physical problem during the past month (traffic accident, death of a family member, etc.) willingness to participate in the research project

Exclusion criteria:

Dissatisfaction of participate in the project Absence in different stages of the project

AgeFrom **30 years** old to **59 years** old**Gender**

Female

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **180**Actual sample size reached: **180****Randomization (investigator's opinion)**

Randomized

Randomization description

We used the cluster sampling method. Firstly, Ahwaz city was divided into 4 geographical regions with approximately equal populations of middle-aged women. Two centers (intervention and control groups) were selected in each region, and a total of 22 individuals were randomly in each center.

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**

Vice chancellor for research affairs

Street address

Central building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

۷۳۳۶ - ۷۱۳۴۸

Approval date

2018-01-15, 1396/10/25

Ethics committee reference number

IR.SUMS.REC.1396.159

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

physical activity

ICD-10 code

Z50.1

ICD-10 code description

Other physical therapy

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

Physical Activities

Timepoint

Before and 8 weeks after the end of the intervention

Method of measurement

International Physical Activity Questionnaire

Secondary outcomes**1****Description**

knowledge

Timepoint

Two month post intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Control group: Routine care

Category

Behavior

2

Description

Intervention group: Train the physical activity.intervention: included 4 face-to-face counseling sessions, Each session for one and half hours in a month and Four follow-up sessions.The first consultation session included completing questionnaire form for every person,Determining the health status of the individual.The second session involves group discussion between Participants in the study and comment on each Whether or not physical activity is beneficial .The Third session,the researcher evaluated the level of thinking and readiness with the presentation of educational films.The fourth meeting was spent on the achievement of the goals of the previous three sessions.At weeks 5, 6.7 and 8,investigated in the amount of individual advance in physical activity,consideration the amount of activity and alteration phase and encourage her and also reasons of her failure recognition and sport and health pamphlets were introduced. At the end of the eighth week,the researcher filled the questionnaire of the amount of physical activity and alteration phases for experiment and witness group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahwaz health centers

Full name of responsible person

Taybeh Rakhshani

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trakhshani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Taybeh Rakhshani

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Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd.,

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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

Shiraz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Fatemeh Masrourpour

Position

student

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

Street address

International affairs office, of Ahvaz Jundishapour University of Medical Sciences Golestan St., Ahvaz, Iran

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Email

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Tayebeh Rakhshani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Fatemeh Masrourpour

Position

Health education expert

Latest degree

Bachelor

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

Any change or analysis in the data file requires coordination with the responsible layout

When the data will become available and for how long

One year after the publication of the article

To whom data/document is available

Researchers

Under which criteria data/document could be used

Only applicable to researchers

From where data/document is obtainable

Person in charge - Faculty of Health, Shiraz University of Medical Sciences

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

First, send an application by e-mail. In case of non-response, contact the respondent

Comments