

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of the theory-centered curriculum on the application of the health belief model and social support on physical activity in women aged 30-54 with overweight

Protocol summary

Summary

The purpose of the study was to determine the effect of the theory-centered curriculum using health belief model and social support on physical activity in women aged 30- 54 with high body mass referring to Shiraz, Iran. Mid-aged women (30 to 54 years old) with high body mass are covered by middle-aged care programs at health centers in Shiraz in 2017, where they have case records. Inclusion criteria: female sex; age range 30 to 54 years old; $30 \geq \text{BMI} \geq 25$ in overweight; fourth grade primary and higher. Non-inclusion criteria: pregnant women; any underlying disease with limited musculoskeletal, skeletal, normal and bodybuilding degree of obesity grade one, two and three; unwillingness to participate. Exit criteria: pregnancy occurrence in women with a history of previous abortions or early delivery; no attendance at training sessions; more than one session or tests; withdrawal from the study for any reason; including illness or withdrawal of the subject during the intervention. Sample size: Each group Intervention and comparison of 40 people and a total of 80 interventional subjects. After random allocation of subjects in two groups of intervention and comparison, the questionnaires were available to the subjects at the first session by the researcher and after completing them (pre-test) The data were analyzed and based on the results, the educational needs of the intervention group were determined and based on it the content of the training program and the number of meetings will be set. It is anticipated that educational intervention will be implemented in 4 weeks and the intervention group will be divided into four groups. It is estimated that the training program for each intervention group consists of 6 sessions of 60 minutes each with 2 times a weekly frequency and using direct methods such as interactive lectures, group discussions, role play and practical training and indirect methods with educational materials

such as pamphlets, poster and educational pamphlets will be delivered by a health education researcher and a physical education expert. Alternatively, the duration of the training sessions may be increased based on the capacity, the willingness, the conditions and the views of the participants in the classroom and other factors. During the intervention period, coordination centers were established so that the intervention group, other than the training, did not receive comparative training in the form of this study and the group. Intervention time: 4 weeks Initial Outcome: Physical Activity Behavior

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201706236261N17**

Registration date: **2017-07-19, 1396/04/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-19, 1396/04/28

Registrant information

Name

Mohammad Hussein Kaveh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 1725 1001

Email address

kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of the theory-centered curriculum on the application of the health belief model and social support on physical activity in women aged 30-54 with overweight

Public title

The effect of educational program on physical activity in women overweight 30 to 54 years old

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: female sex; age range 30 to 54 years old; $30 \geq \text{BMI} \geq 25$ in overweight; fourth grade primary and higher. Non-inclusion criteria: pregnant women; any underlying disease with limited musculoskeletal, skeletal, normal and bodybuilding degree of obesity grade one, two and three; unwillingness to participate. Exit criteria: pregnancy occurrence in women with a history of previous abortions or early delivery; no attendance at training sessions; more than one session or tests; withdrawal from the study for any reason; including illness or withdrawal of the subject during the intervention.

Age

From **30 years** old to **54 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

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 of Shiraz University of Medical Sciences

Street address

Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue

City

Shiraz

Postal code

Approval date

2017-01-08, 1395/10/19

Ethics committee reference number

IR.SUMS.REC.1395.165

Health conditions studied

1

Description of health condition studied

Physical activity

ICD-10 code

XXI

ICD-10 code description

Factors influencing health status and contact with health services

Primary outcomes

1

Description

Physical activity behavior

Timepoint

Before the intervention and one month after intervention

Method of measurement

International Physical Activity questionnaire

Secondary outcomes

1

Description

Knowledge

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

2

Description

perceived severity

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

3

Description

Perceived vulnerability

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

4

Description

perceived benefit

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

5

Description

perceived barriers

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

6

Description

Cues to Action

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

7

Description

Self-efficacy

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

8

Description

Perceived social support

Timepoint

Before the intervention and one month after intervention

Method of measurement

Researcher-made standardized questionnaire

Intervention groups

1

Description

Intervention group: In each intervention and comparison group, 40 patients and 80 subjects participated in the study: After the random allocation of the subjects in the intervention and comparison groups, the questionnaires

were distributed to the subjects at the first session by the researcher. After completing them (pre-test), the data were analyzed and based on the results, needs Educational intervention group and determine the content of the training program and the number of sessions will be set. It is anticipated that educational intervention will be implemented in 4 weeks and the intervention group will be divided into four groups. It is estimated that the training program for each intervention group consists of 6 sessions of 60 minutes each with 2 times a weekly frequency and using direct methods such as interactive lectures, group discussions, role play and practical training and indirect methods with educational materials such as pamphlets, Poster and educational pamphlets will be delivered by a health education researcher and a physical education expert. Alternatively, the duration of the training sessions may be increased based on the capacity, the willingness, the conditions and the views of the participants in the classroom and other factors. During the intervention period, coordination centers were established so that the intervention group, other than the training, did not receive comparative training in the form of this study and the group.

Category

Behavior

2

Description

Control group: In the control group, educational intervention does not take place. These group will participate in the pre-test and post-test.

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shohadaye Enghelab Center

Full name of responsible person

Masoomah Faghih

Street address**City**

Shiraz

2

Recruitment center**Name of recruitment center**

Shohadaye Valfajr Center

Full name of responsible person

Masoomah Faghih

Street address**City**

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Sayed Basir Hashemi

Street address

Vice chancellor for research, seventh floor, Shiraz University Center Building, Zand Avenue

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research of Shiraz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical sciences

Full name of responsible person

Masoomeh Faghih

Position

Master Student of Health Education

Other areas of specialty/work

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Person responsible for scientific inquiries

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Mohammad Hosein Kaveh

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Fax

Email

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty