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 ≥BMI≥ 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

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kaveh@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

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 ≥BMI≥ 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
Masoomeh Faghih
Street address
City
Shiraz

2

Recruitment center
Name of recruitment center
Shohadaye Valfajr Center
Full name of responsible person
Masoomeh 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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Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University of Medical Sciences
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Masoomeh Faghih
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Master Student of Health Education
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Health education and health promotion,School of Public Health , Shiraz University of Medical sciences
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Shiraz
Postal code
14336 71348
Phone
+98 71 3725 1001
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