

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### **Determining the Effect of Intervention on Health Education Based on the Planned Behavior Theory for Promoting Physical Activity in Women Health Volunteers of Health Centers in Shushtar**

#### **Protocol summary**

##### **Study aim**

The aim of this study was to evaluate the effect of an educational program based on the theory of planned behavior in physical activity in health volunteers of Shushtar city.

##### **Design**

A concealed, randomized, controlled clinical trial with a parallel group design of 110 female health volunteers (55 volunteers in the intervention group; 72 volunteers in the control group), enrolling from December 4 to 25, 2015, they entered the study, and following for 3 months after the end of the intervention.

##### **Settings and conduct**

Educational intervention was conducted through group education on female health volunteers in Shushtar. Also, they took a walking program for 3 months.

##### **Participants/Inclusion and exclusion criteria**

The inclusion criteria were: Holding health volunteer cards; At least one-year experience of cooperation with healthcare centers; No problems in terms of participation in educational classes; Consent to participate in the research study; Ability to read and write; Lack of any apparent mental and physical diseases influencing physical activity. The exclusion criteria comprised of unwillingness to continue cooperation, emergence of physical problems preventing physical activity, and migration to other cities.

##### **Intervention groups**

The intervention group received educational interventions related to physical activity in 3 sessions and a three-month walk program.

##### **Main outcome variables**

The mean score of physical activity, and the physiological cost index.

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20120910010804N12**

Registration date: **2018-07-01, 1397/04/10**

Registration timing: **retrospective**

Last update: **2018-07-01, 1397/04/10**

Update count: **0**

##### **Registration date**

2018-07-01, 1397/04/10

##### **Registrant information**

##### **Name**

Marzieh Araban

##### **Name of organization / entity**

Tarbiat Modares University

##### **Country**

Iran (Islamic Republic of)

##### **Phone**

تهران

##### **Email address**

m.araban@modares.ac.ir

##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2016-07-31, 1395/05/10

##### **Expected recruitment end date**

2016-08-26, 1395/06/05

##### **Actual recruitment start date**

2016-07-31, 1395/05/10

##### **Actual recruitment end date**

2016-09-03, 1395/06/13

##### **Trial completion date**

empty

### Scientific title

Determining the Effect of Intervention on Health Education Based on the Planned Behavior Theory for Promoting Physical Activity in Women Health Volunteers of Health Centers in Shushtar

### Public title

The effect of educational intervention on the promotion of physical activity

### Purpose

Education/Guidance

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Holding health volunteer cards; At least one-year experience of cooperation with healthcare centers; No problems in terms of participation in educational classes; Consent to participate in the research study; Ability to read and write; Lack of any apparent mental and physical diseases influencing physical activity.

#### Exclusion criteria:

Unwillingness to continue cooperation; Emergence of physical problems preventing physical activity; Migration to other cities.

### Age

No age limit

### Gender

Female

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **110**

Actual sample size reached: **110**

### Randomization (investigator's opinion)

Randomized

### Randomization description

At first, a list of health volunteers was prepared and then they were divided into two intervention and control groups (each group of 55) using the the random numbers table and by lottery method

### 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

Ahvaz Jundishapur University of Medical Sciences

#### Street address

Golestan Road

#### City

Ahvaz

#### Province

Khouzestan

#### Postal code

61357-15794

#### Approval date

2016-07-23, 1395/05/02

#### Ethics committee reference number

IR.AJUMS.REC.1395.274

## Health conditions studied

### 1

#### Description of health condition studied

physical activity

#### ICD-10 code

Y93.01

#### ICD-10 code description

Activity, walking, marching and hiking

## Primary outcomes

### 1

#### Description

Attitude toward physical activity

#### Timepoint

Before the intervention and 6 months after educational intervention

#### Method of measurement

Planned Behavior Theory constructs questionnaire

### 2

#### Description

Subjective norms about physical activity

#### Timepoint

Before the intervention and 6 months after educational intervention

#### Method of measurement

Planned Behavior Theory constructs questionnaire

### 3

#### Description

Perceived behavioral control about physical activity

#### Timepoint

Before the intervention and 6 months after educational intervention

#### Method of measurement

Planned Behavior Theory constructs questionnaire

### 4

#### Description

Behavioral intention to physical activity

#### Timepoint

Before the intervention and 6 months after educational intervention

**Method of measurement**

Physical Activity Readiness Questionnaire

**Secondary outcomes**

**1**

**Description**

Mean score of physical activity

**Timepoint**

Before the intervention and 6 months after educational intervention

**Method of measurement**

International Physical Activity Questionnaire

**2**

**Description**

Physiological cost index

**Timepoint**

Before the intervention and 6 months after educational intervention

**Method of measurement**

By Polar Heart Rate Monitor

**Intervention groups**

**1**

**Description**

Intervention group: educational interventions related to physical activity of 3 sessions and walking for three months

**Category**

Behavior

**2**

**Description**

Control group:no educational intervention

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Shushtar Health Centers

**Full name of responsible person**

Marzieh Araban

**Street address**

Taleghani Street, Shoushtar Health Center

**City**

Shushtar

**Province**

Khuzestan

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6451646441

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arabanm@ajums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Behzad Sharif Makhmalzadeh

**Street address**

Social Determinants of Health Research Center, Jondishapour University of Medical Sciences, Golestan Road, Ahvaz, Khuzestan, Iran

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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**

Ahvaz 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**

Marzieh Araban

**Position**

Faculty Members

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Health Promotion

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

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**Latest degree**

Ph.D.

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## Person responsible for updating data

**Contact****Name of organization / entity**

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**Full name of responsible person**

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**Position**

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**Latest degree**

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**Other areas of specialty/work**

Health Promotion

**Street address**

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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**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Data on primary and secondary outcome will be shared  
in the form of a spss file

**When the data will become available and for how long**

The access period will be September of 2018.

**To whom data/document is available**

Researchers of academic institutions

**Under which criteria data/document could be used**

The researcher will give the data to other researchers for  
scientific use only.

**From where data/document is obtainable**

Send an e-mail to arabanm@ajums.ac.ir

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

People who want the data, send your request by e-mail  
to the above address. The researcher, after consulting  
the research team, sends the data to them, if they agree.

**Comments**