

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of motivational intervention on promoting physical activity in middle-aged Iranian women

#### Protocol summary

##### Study aim

This study aimed to design, implement, and evaluate a conceptual model of physical activity (PA) promotion among Iranian middle-aged women (IMGW).

##### Design

Clinical trial with control group, including educational intervention in the intervention group and routine care in the control group, without blinding, available convenience sampling method, on 80 participants (40 people in each group)

##### Settings and conduct

In two different health centers in Tehran (intervention and control) The intervention was both face-to-face (once a month for 90 days and each time for an hour and a half) include aerobics video tutorial, two voice book and virtual (a social group called "Success" for three months). An algorithm including the following steps was designed in the intervention group: (i) inspire change and motivate excellence, (ii) decisive decision-making, (iii) write goals clearly, (iv) focus on the goal, and (v) plan to achieve the goal. Finally, the practical program to achieve the goal was implemented based on comprehensive studies of the health system and available resources. At the end of the third month, the level of PA and body mass index was assessed in both groups.

##### Participants/Inclusion and exclusion criteria

being into a middle-age group (30-59 years), having a middle-school literacy level or above, having an inactive lifestyle (less than 90 min of moderate-intensity PA per week according to IraPEN

##### Intervention groups

The intervention group consisted of participants who referred to health center number 1, during 2 months before study The control group consisted of participants who referred to health center number 2, during 2 months before study

##### Main outcome variables

physical activity before and after the intervention

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200717048124N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **retrospective**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

##### Registration date

2020-08-05, 1399/05/15

##### Registrant information

##### Name

Farnaz Khatami

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8896 2357

##### Email address

f-khatamik@tums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-09-22, 1397/06/31

##### Expected recruitment end date

2018-11-20, 1397/08/29

##### Actual recruitment start date

2018-09-22, 1397/06/31

##### Actual recruitment end date

2018-11-20, 1397/08/29

##### Trial completion date

2019-04-19, 1398/01/30

##### Scientific title

The effect of motivational intervention on promoting physical activity in middle-aged Iranian women

#### Public title

The effect of motivation on physical activity

#### Purpose

Education/Guidance

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

middle-age group (30-59 years) having a middle-school literacy level or above having an inactive lifestyle (less than 90 min of moderate-intensity PA (brisk walking, jogging) per week according to the instructions of the PA promotion program of Iran Package of Essential Non-communicable Disease completing the consent form to participate in the study

##### Exclusion criteria:

having some serious diseases such as CVDs, uncontrolled diabetes and hypertension, as well as chronic kidney disease

#### Age

From **30 years** old to **59 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

Actual sample size reached: **80**

#### Randomization (investigator's opinion)

Not randomized

#### Randomization description

#### Blinding (investigator's opinion)

Not blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Other

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

Community medicine department, medical school of ums, Kargar Ave., Tehran, Iran

##### City

Tehran

##### Province

Tehran

#### Postal code

1447935575

#### Approval date

2017-10-08, 1396/07/16

#### Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3662

## Health conditions studied

### 1

#### Description of health condition studied

physical inactivity

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

physical activity

#### Timepoint

before and 3 month after

#### Method of measurement

four-question form of PA vital sign according to the IraPEN instruction

## Secondary outcomes

### 1

#### Description

Body Mass Index

#### Timepoint

before and 3 month after intervention

#### Method of measurement

height with stadiometer , weight with SECA 768611 balance scale

## Intervention groups

### 1

#### Description

Intervention group: A number of behavioral change models, including trans-theoretical model (TTM), precede-proceed model (PPM), health belief model (HBM), beliefs, attitudes, subjective norms and enabling factors (BASNEF) model, and health promotion model (HPM), were considered to evaluate the best PA-promoting model after the literature review and unstructured face-to-face interview with the panel of experts. They included twenty specialists (sports medicine, community medicine, psychiatrists, health education, and genetics) with long-term executive backgrounds in the field of health system management and program directors. Before conducting the interview, the interview purpose and content as well as how to record and collect information were first examined. With open questions, the experts were then asked to

comment on the different PA behavior change models, the most important factors hindering PA in IMGW, and possible ways to improve their PA level. The interviewees were completely free to express their views. All the recorded and written data were consequently summarized without any individual judgment. Results of the experts' comments showed that the HBM was the best initial model to improve PA in IMGW. Accordingly, individuals in the intervention group completed the HBM-based questionnaire to find the most important solutions in promoting IMGW' PA. The intervention was both face-to-face and virtual. Face-to-face interventions were fulfilled once a month for 90 days and each time for an hour and a half. Aerobics video tutorial for women with useful knowledge for 80 min was provided to all members of the intervention group in the first face-to-face session. In this DVD, aerobic movements using stretch band, cardio fit ball, and 1-2 kg dumbbells from beginner to advanced were trained to strengthen muscles and keep the body in shape. A social group called "Success" was made by registering all individuals in the intervention group and followed by the virtual intervention for three months. In the first and second months of the intervention, the voice book of "goals! how to get everything you want faster than you ever thought possible" written by Brian Tracy, and the voice file of "unlimited power: the new science of personal achievement" from Anthony Robbins were respectively presented. After highlighting the key points of these books, an algorithm including the following steps was designed in the intervention group: (i) inspire change and motivate excellence, (ii) decisive decision-making, (iii) write goals clearly, (iv) focus on the goal, and (v) plan to achieve the goal. Finally, the practical program to achieve the goal was implemented based on comprehensive studies of the health system and available resources

#### Category

Lifestyle

## 2

#### Description

Control group: only some brochures and routine recommendations of healthcare centers on PA were presented to the control group.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahabadi and Abouzar health centers

##### Full name of responsible person

Farnaz Khatami

##### Street address

community medicine department, school of medicine of Tehran University of Medical Sciences, porsina Ave., Kargar Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1447935575

#### Phone

+98 21 8896 2357

#### Email

f-khatamik@tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr. Shahin Akhondzadeh (research dean)

##### Street address

Community medicine department, School of medicine of Tehran University of Medical Sciences, porsina Ave., Kargar Ave.

##### City

Tehran

##### Province

Tehran

##### Postal code

1447935575

##### Phone

+98 21 8896 2357

##### Email

f-khatamik@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Farnaz Khatami

##### Position

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**Kargar Ave., Poursina Ave., Tehran University of  
Medical Education**City**

Tehran

**Province**

Tehran

**Postal code**

1447935575

**Phone**

+98 21 8896 2357

**Fax****Email**

f-khatamik@tums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farnaz Khatami

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**Kargar Ave., Poursina Ave., Tehran University of  
Medical Education**City**

Tehran

**Province**

Tehran

**Postal code**

1447935575

**Phone**

+98 21 8896 2357

**Fax****Email**

f-khatamik@tums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farnaz Khatami

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**Kargar Ave., Poursina Ave., Tehran University of  
Medical Education**City**

Tehran

**Province**

Tehran

**Postal code**

1447935575

**Phone**

+98 21 8896 2357

**Fax****Email**

f-khatamik@tums.ac.ir

**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**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

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

data of primary and secondary outcome is available.

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

6 month after publication

**To whom data/document is available**

Academic researchers

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

Formal request for statistical analysis only

**From where data/document is obtainable**

corresponding author: f-khatamik@tums.ac.ir

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

Request from corresponding author, decision in the council of the research team - if agreed, the data will be send

**Comments**