Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 pablication
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