

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Implementation and evaluation of a program for improving physical activity among women: mixed method action research

Protocol summary

Study aim

improving physical activity among women with a mixed method action research approach

Design

before and after intervention or semi-experimental study

Settings and conduct

In Tehran, Khoramrudi neighborhood located in District 2 of Tehran Municipality was considered a suitable setting for research

Participants/Inclusion and exclusion criteria

- Women at the age 18-65 years have inadequate PA
- Entered the study based on at least one of the three strategies: assisting by the other athletes (sports assistants), improving their knowledge about the sports facilities available in the district, and participating in the cognitive behavioral therapy classes.

Intervention groups

The effectiveness of the programs was assessed through a quantitative study (pre- and post-semi-experimental study with the aim of determining and comparing PA before, one and three months after the intervention) and a qualitative study (with the aim of explaining the opinions, perceptions, feelings and experiences of participants of the process and outcome of promoting PA). Inclusion criteria were: women at the age 18-65 years have inadequate PA and entered the study based on at least one of the three strategies: assisting by the other athletes (sport assistants), improving their knowledge about the sports facilities available in the district, and participating in the cognitive behavioral therapy classes.

Main outcome variables

Amount of physical activity on the basis of minutes per week The severity of physical activity on the basis of energy expenditure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180427039436N5**

Registration date: **2019-07-31, 1398/05/09**

Registration timing: **retrospective**

Last update: **2019-07-31, 1398/05/09**

Update count: **0**

Registration date

2019-07-31, 1398/05/09

Registrant information

Name

Leila Amiri Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4365 1139

Email address

l.amirifarahani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2014-07-01, 1393/04/10

Expected recruitment end date

2015-01-30, 1393/11/10

Actual recruitment start date

2014-08-01, 1393/05/10

Actual recruitment end date

2015-03-02, 1393/12/11

Trial completion date

2015-03-02, 1393/12/11

Scientific title

Implementation and evaluation of a program for improving physical activity among women: mixed method action research

2013-08-16, 1392/05/25

Ethics committee reference number
92-02-28-23311

Public title

Program for improving physical activity among women

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

- Women at the age 18-65 years have inadequate PA Entered the study based on at least one of the three strategies: assisting by the other athletes (sport assistants), improving their knowledge about the sports facilities available in the district, and participating in the cognitive behavioral therapy classes.

Exclusion criteria:

Having a motion sickness requires no physical activity

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Actual sample size reached: **76**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Tohid Square

City

Tehran

Province

Tehran

Postal code

141973317

Approval date

Health conditions studied

1

Description of health condition studied

improving physical activity among healthy women

ICD-10 code

Z72.9

ICD-10 code description

Problem related to lifestyle, unspecified

Primary outcomes

1

Description

Amount of Physical activity on the basis of minute per week

Timepoint

Before the intervention, one month and three months after the intervention

Method of measurement

International physical activity questionnaire (IPAQ)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group received one of the three programs. Sport assistances program: The purpose of the program was to influence the role of sport assistances in encouraging women to increase their PA. Of the women who were attending the PA at the sports club, they were asked to work as sport assistance. A booklet entitled "Educational content for sports assistants" was compiled to increase their awareness of PA. This contained information on the importance of sport from the point of view of Islam, the Quran and hadiths, benefits of exercise, strategies for increasing PA, barriers to PA and the way to overcome them, the type, intensity and amount of PA. Sports assistants began to advertise participation in sports events in crowded places of the city, mosques, etc. Program of information plan: The goal was to increase people's information about sports facilities in the district. Text messages, banner, and trakets were used for informing women in women's gathering places such as Quran interpreting sessions and religious ceremonies, Husayniyah and Fatimah and the health center. The cognitive-behavioral therapy program. Behavior therapy was co-sponsored by a sports psychologist that used a ten-part protocol. It was consisted of sessions weekly for 90 minutes with 13 participants in the first course and 12 participants in the

second course at the health center. The protocol was endorsed by a psychologist and a psychiatrist and was consisted of: (1) Attracting members' trust and collaboration, as well as reducing stress; 2) Training to detect unpleasant emotions and detecting when these occur; 3) Teaching the relationship between thoughts, emotions, and behaviors, as well as familiarity with a variety of cognitive errors; 4) Learning to discover and challenge irrational thoughts; 5) Teaching the method of science to better understand and counteract irrational thoughts; 6) Teaching how to determine and prioritize goals; 7) Learning how to plan and how to increase the level of activity; 8) Reviewing the previous sessions and practice exercises, obtaining feedback and answering questions; 9) Training the group on relaxation techniques and application; 10) Providing feedback to members and emphasizing the continued use of what they have learned.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Khoramrudi neighborhood located in district 2 of Tehran municipality

Full name of responsible person

Leila Amiri Farahani

Street address

Tohid Square

City

Tehran

Province

Tehran

Postal code

1357868931

Phone

+98 21 4365 1139

Email

l.amirifarahani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ali Sahraeeyan

Street address

School of Nursing Midwifery ,Tehran University of Medical Sciences, Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

Province

Tehran

Postal code

141973317

Phone

+98 21 4365 1139

Email

l.amirifarahani@gmail.com

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

Leila Amiri Farahani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

• School of Nursing Midwifery ,Tehran University of Medical Sciences Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

Province

Tehran

Postal code

141973317

Phone

+98 21 4365 1139

Email

l.amirifarahani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

• School of Nursing Midwifery ,Tehran University of Medical Sciences • Nosrat st. Tohid sq. Tehran I.IRAN

City

Tehran

Province

Tehran

Postal code

141973317

Phone

+98 21 4365 1139

Email

l.amirifarahani@gmail.com

+98 21 4365 1139

Fax

+98 21 4365 1138

Email

l.amirifarahani@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not 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

it is not available

When the data will become available and for how long

it is not available

To whom data/document is available

it is not available

Under which criteria data/document could be used

it is not available

From where data/document is obtainable

it is not available

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

it is not available

Comments

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

Tehran University of Medical Sciences

Full name of responsible person

Leila Amiri Farahani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

Street address

Tohid square

City

Tehran

Province

Tehran

Postal code

141973317

Phone