

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The Effect of empowerment program based on Health Action Process Approach model on promoting physical activity among middle-aged women.

#### Protocol summary

##### Study aim

Determining the Impact of the Empowerment Program on the Health Process Behavioral Approach in Promoting the Physical Activity of Midwestern Women

##### Design

Sampling will be done in a simple multi-step and random manner. The sample size is 160 people including 80 in the intervention group and 80 in control group

##### Settings and conduct

Study will be done in Jouin Sabzevar city. The two groups first complete the completed questionnaires (pre-test). Then, the individuals in the intervention group will be assigned an empowerment training program designed to carry out physical activity. The first stage of intervention is for intention to be done immediately after the intervention and one month later, a post-test is performed to measure the intention to be formed. After a month from the intervention of the first stage, intervention of the second stage is performed. Immediately and 3 months later, post-test is measured to measure behavior and 6 months after the maintenance of the behavior is measured

##### Participants/Inclusion and exclusion criteria

1- The subjects must reside in Jouin County and have a middle age (59-30). 2- Have informed written consent for the voluntary participation in the study. 3. Not having enough physical activity (30 minutes a day for 5 days a week)

##### Intervention groups

All middle-aged women in the city

##### Main outcome variables

The educational package designed in this study, which is based on the structures of this pattern of behavior change, can be provided to the ministries of science and health, medical treatment and medical education for use in the planning of interventions to promote physical activity among women in the country. Be placed

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180626040243N1**

Registration date: **2018-07-12, 1397/04/21**

Registration timing: **prospective**

Last update: **2018-07-12, 1397/04/21**

Update count: **0**

##### Registration date

2018-07-12, 1397/04/21

##### Registrant information

##### Name

Zeinab Malaijerdi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 4522 2914

##### Email address

MalayjerdiZ94@medsab.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-01, 1397/05/10

##### Expected recruitment end date

2018-09-01, 1397/06/10

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

The Effect of empowerment program based on Health Action Process Approach model on promoting physical activity among middle-aged women.

## Public title

physical activity among middle-aged women

## Purpose

Education/Guidance

## Inclusion/Exclusion criteria

### Inclusion criteria:

In the age range of 30 to 59 (middle aged) Not having the recommended physical activity recommended by the World Health Organization

### Exclusion criteria:

Not in middle age Not having recommended daily physical activity

## 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: **160**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Multi-stage sampling will be done. In this way, two centers are randomly selected from among the five health centers covered by the city. At the next stage, between the bases and the home of the covered health centers, centers of two bases or health houses were selected randomly, then By contacting the Midwife Care Office, people will be randomly selected

## 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 Sabzevar University of Medical Sciences

##### Street address

Neghab , Imam Hossein Square , Qamar Bani Hashem Street

##### City

Sabzvar

## Province

Razavi Khorasan

## Postal code

9647165716

## Approval date

2017-12-01, 1396/09/10

## Ethics committee reference number

IR.MEDSAB.REC.1396.120

## Health conditions studied

### 1

#### Description of health condition studied

physical activity

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

physical activity

#### Timepoint

Measuring the amount of physical activity

#### Method of measurement

questionnaire

## Secondary outcomes

### 1

#### Description

Reduce noncommunicable diseases

#### Timepoint

Before the intervention, immediately, one month, three months, six months after the intervention

#### Method of measurement

Questionnaire

## Intervention groups

### 1

#### Description

Intervention group After collecting and analyzing the data of the first stage and identifying the factors associated with impulsivity, 160 women were randomly divided into intervention and control groups. Data collection in an interventional phase of the study is done using a self-made questionnaire based on the HAPA approach. This questionnaire is designed and validated by the researcher. The two groups first complete the completed questionnaires (pre-test). Then, the individuals in the intervention group will be assigned an empowerment training program designed to carry out physical activity. It should be noted that intervention is done in two stages. The first phase of the intervention is intended to form the intention, during which the educational

planning and preparation of the appropriate training package to increase outcome expectation, task self-efficacy, perception of the concepts of risk, and ultimately the intention to perform physical activity are carried out. The type, content, teaching method and the number and time of conducting the training classes will be performed according to the analysis of the results in the pre-test phase and the required teaching materials will be designed. The training method is likely to include lecture sessions, brain storming thoughts, modeling modeling, and distribution of educational package. Immediately after the intervention and one month later, a post-test is performed to measure the formation of the intent. After a month from the intervention of the first stage, intervention of the second stage is performed. In this stage, behavior planning, coping planning, coping self-efficacy, self-efficacy of returning to people is taught. It should be noted that the barriers and resources available for physical activity from the start of its activity or its sustainability are considered. Immediately and 3 months later, post-test is measured to measure behavior and 6 months after the maintenance of the behavior is measured. سابقه‌ذخیره شده‌ها:

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sabzevar University of Medical Sciences

##### Full name of responsible person

Masomeh Hashmian

##### Street address

Imam Hossein Square, Qamar Bani Hashem Street

##### City

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##### Phone

+98 51 4522 0688

##### Email

zmalaijerdi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Sabzevar University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Mojjadadi

##### Street address

Imam Hossein Square, Qamar Bani Hashem Street

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malayjerdiz94@medsab.ac.ir

#### Grant name

Research Grant Dr. Hashemian

#### Grant code / Reference number

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

Yes

#### Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

##### Full name of responsible person

Dr.Masomeh Hashemian

##### Position

Associate professor

##### 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

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##### Position

Associate professor

**Latest degree**

Ph.D.

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Health Promotion

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Sabzevar University of Medical Sciences

**Full name of responsible person**

Zeinab Malaijerdi

**Position**

1. Master

**Latest degree**

Master

**Other areas of specialty/work**

Health Promotion

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**Sharing plan**

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

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available