

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)

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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. سابقه‌خیزه شده‌ها:

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar University of Medical Sciences

Full name of responsible person

Masomeh Hashmian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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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1. Master

Latest degree

Master

Other areas of specialty/work

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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