

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of counseling on health promoting lifestyle in middle-aged women: a single-blind randomized controlled trial

Protocol summary

Summary

Objectives: To determine the effect of counseling on health promoting lifestyle in middle-aged women.

Design: A single-blind randomized controlled trial.

Conduct: This study will be conducted on middle-aged women referring to health centers of Tabriz. The researcher will be attended in health centers and a list of middle-aged women will be prepared through record or health volunteers. Researcher will call with them and if they comply with the inclusion criteria and have tendency to participate in study, they will be invited to be present at the health center. After attending health centers and obtaining written informed consent, pre-test questionnaires will be completed. Then, middle-aged women will be randomly assigned to two groups (one group receiving counseling and other groups without counseling) using block randomization with block sizes of 4 and 6 stratified by age (40 to 50 and 50 to 60 years). A person from research team not involved in the sampling will generate allocation sequence. Participants: 102 middle-aged women with 40-60 years old. Intervention: Group counseling will be provided to intervention group at three sessions of 45 minutes once a week about topics of spiritual growth, stress management, nutrition, physical activity, health responsibility and interpersonal relations. The main outcome variable is health-promoting lifestyle and secondary outcome is quality of life that will be assessed before, 4 and 8 weeks after the intervention by questionnaires.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122610324N27**

Registration date: **2016-02-04, 1394/11/15**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-02-04, 1394/11/15

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2016-02-20, 1394/12/01

Expected recruitment end date

2016-06-19, 1395/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling on health promoting lifestyle in middle-aged women: a single-blind randomized controlled trial

Public title

The effect of counseling on health promoting lifestyle in middle-aged women

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Women ages 40-60 years old; Being interested in participating in the study; Having a contact number for follow-up; Being literate of participants or a family member to read the booklet for the participant. Exclusion criteria: Having a history of physical illness according to the woman expression; Having a mental illness according to the woman expression; Recent tragic events; Use of cigarette, Alcohol, Drugs and other drugs affect the body and mind of a person; Sever economic poverty; Previous participation in counseling classes for promoting lifestyle.

Age

From **40 years** old to **59 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Research department, third floor, central construction number 2, Tabriz University of Medical Sciences, Golgasht Street, Azadi Avenue, Tabriz, East Azerbaijan

City

Tabriz

Postal code

Approval date

2016-01-10, 1394/10/20

Ethics committee reference number

1394.900.TBZMED.REC

Health conditions studied

1

Description of health condition studied

سبک زندگی

ICD-10 code

Y98

ICD-10 code description

Lifestyle-related condition

Primary outcomes

1

Description

Health promoting lifestyle

Timepoint

Before, 4 and 8 week after intervention

Method of measurement

Health promoting lifestyle questionnaire for middle-aged women

Secondary outcomes

1

Description

Quality of life

Timepoint

Before, 4 and 8 week after intervention

Method of measurement

Quality of life questionnaire (SF-36)

Intervention groups

1

Description

The intervention group will receive group counseling at three sessions of 45 minutes once a week about topics of spiritual growth, stress management, nutrition, physical activity, health responsibility and interpersonal relations.

Category

Lifestyle

2

Description

The control group will receive no intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers of Tabriz city

Full name of responsible person

Vahideh Karimlou
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Health centers, Tabriz
City
Tabriz

Fax
Email
vkarimlou@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
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Research department, third floor, central construction number 2, Tabriz medical science university, Golgasht Street, Azadi Avenue, Tabriz
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Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty
Informed Consent Form
empty
Clinical Study Report
empty

Analytic Code
empty
Data Dictionary
empty