

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of group counseling on health promotion behaviors in middle-aged women who referred to outskirts health centers of Urmia city in 2018

Protocol summary

Study aim

The effect of group counseling on health promotion behaviors in middle-aged women

Design

Randomized clinical trial with control group, without blinding

Settings and conduct

This study will be conducted on 90 middle-aged women referred to the outskirts health centers of Urmia city who randomly divided into the intervention and control groups. Intervention (group counseling) will be held for six weeks and each weekly session will be 90-60 minutes, and the number of people in each group will be 7-10 subjects. The control group will not receive any counseling and will receive routine care. There will not be blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 40-60 years, Having no recent stressful events in the past 6 months, Having no history of specific or acute disease (such as cancer or mental disorder). No-entrance criteria: Unwillingness to participate in the study

Intervention groups

Intervention group will receive group counseling. Intervention (group counseling) will be held for six weeks and each weekly session will be 90-60 minutes, and the number of people in each group will be 7-10 subjects. The control group will not receive any counseling and will receive routine care.

Main outcome variables

Mean scores of health promoting behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180926041148N1**

Registration date: **2018-10-14, 1397/07/22**

Registration timing: **prospective**

Last update: **2018-10-14, 1397/07/22**

Update count: **0**

Registration date

2018-10-14, 1397/07/22

Registrant information

Name

marziyeh Ebrahimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 9931

Email address

mebrahimi11@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-06, 1397/09/15

Expected recruitment end date

2019-06-05, 1398/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of group counseling on health promotion behaviors in middle-aged women who referred to outskirts health centers of Urmia city in 2018

Public title

The effect of group counseling on health promotion behaviors in middle-aged women

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 40-60 years Having no recent stressful events in the past 6 months Having no history of specific or acute disease (such as cancer or mental disorder)

Exclusion criteria:

Unwillingness to participate in the study

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Using random allocation software, the participants in the study were divided into the intervention and control groups.

Blinding (investigator's opinion)

Not 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 Urmia University of Medical Sciences

Street address

Urmia University of Medical Science Orjhans Street, Resalat Blvd Urmia, Iran

City

Urmia

Province

West Azarbaijan

Postal code

5714783734

Approval date

2018-02-07, 1396/11/18

Ethics committee reference number

IR.UMSU.REC.1396.398

Health conditions studied

1

Description of health condition studied

The effect of group counseling on health promotion behaviors in middle-aged women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean scores of health promoting behaviors

Timepoint

before intervention and one month after intervention

Method of measurement

Health-promoting lifestyle questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group will receive group counseling. Intervention (group counseling) will be held for six weeks and each weekly session will be 90-60 minutes, and the number of people in each group will be 7-10 subjects.

Category

Behavior

2

Description

Control group: The control group will not receive any counseling and will receive routine care. After completion of the study, a session will also be held for the control group and a training pamphlet will be presented to them.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Urmia University of Medical Sciences

Full name of responsible person

Javad Aghazadeh

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Urmia University of Medical Science Orjhans Street, Resalat Blvd Urmia, Iran

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info@urmia.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
Urmia University of Medical Science Orjhans Street,
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Email
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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Marziyeh Ebrahimi
Position
Instructor
Latest degree
Master
Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Urmia University of
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Fax

Email

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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

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

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

After completion of the study, final decision will be made.

When the data will become available and for how long

Six months after the completion of the study

To whom data/document is available

All collage researchers

Under which criteria data/document could be used

Just for scientific research

From where data/document is obtainable

Email

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

Just email

Comments