

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of group counseling with telephone counseling on Diet and Physical Activity among middle-aged women in Mehriz

Protocol summary

Study aim

The aim of this study is to compare the effect of group counseling with telephone counseling on the nutritional status and physical activity of middle-aged women.

Design

This study is a randomized clinical trial study

Settings and conduct

The research population will be all middle-aged women of mehriz City, which will be selected using purposeful sampling method of Hosseini and mosques of this city. The sample size is 75. The samples are randomly divided into three groups (two intervention groups and one control group). Three groups will be evaluated at the time of intervention (before) and immediately after the intervention and one month after the intervention with the health promotion lifestyle profile questionnaire of middle-aged women

Participants/Inclusion and exclusion criteria

Inclusion criteria: informed consent, ages 40-60 and access to the telephone and exclusion criteria: having hearing and speaking problems and the presence of severe or debilitating physical or mental illnesses that would prevent the person from attending the program

Intervention groups

The sample size is 75. The samples will be divided into three groups (two intervention groups and one control group) using the random numbers table. Persons in group counseling group will receive a group counseling (for 2 hours) for a period of 4 weeks. Persons in the telephone counseling group will receive a total of 8 telephone counseling calls twice a week for a period of four weeks, (30 minutes). The two groups will be free to call and visit. During this period no advice will be given to the control group.

Main outcome variables

Nutritional status and Physical activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180111038310N1**

Registration date: **2018-04-28, 1397/02/08**

Registration timing: **retrospective**

Last update: **2018-04-28, 1397/02/08**

Update count: **0**

Registration date

2018-04-28, 1397/02/08

Registrant information

Name

Behnaz Rahbarnia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3824 1751

Email address

behnaz@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-22, 1396/06/31

Expected recruitment end date

2017-12-20, 1396/09/29

Actual recruitment start date

2017-09-22, 1396/06/31

Actual recruitment end date

2017-11-18, 1396/08/27

Trial completion date

empty

Scientific title

Comparison of group counseling with telephone counseling on Diet and Physical Activity among middle-aged women in Mehriz		Approval date 2017-08-01, 1396/05/10 Ethics committee reference number IR.SSU.REC.1396.90
Public title Comparison of group counseling with telephone counseling on Diet and Physical Activity in middle-aged women in Mehriz	Health conditions studied <u>1</u> Description of health condition studied Nutrition status and physical activity ICD-10 code ICD-10 code description	
Purpose Prevention Inclusion/Exclusion criteria Inclusion criteria: Informed Consent Ages 40-60 Phone Access Exclusion criteria: The presence of severe or debilitating physical or mental illnesses that would prevent the person from attending the program Have a hearing and speaking problem	Primary outcomes <u>1</u> Description Nutrition status score Timepoint Before intervention, after intervention and 1 month after intervention Method of measurement Health promotion life style questionnaire for middle-aged women	
Age From 40 years old to 60 years old Gender Female Phase N/A Groups that have been masked <i>No information</i> Sample size Target sample size: 75 Actual sample size reached: 71 Randomization (investigator's opinion) Randomized Randomization description Sampling is done using random numbers table Blinding (investigator's opinion) Not blinded Blinding description Placebo Not used Assignment Parallel Other design features	<u>2</u> Description Physical activity score Timepoint Before intervention, after intervention and 1 month after intervention Method of measurement Health promotion life style questionnaire for middle-aged women	
Secondary Ids empty	Secondary outcomes empty	
Ethics committees <u>1</u> Ethics committee Name of ethics committee Ethics committee of Shahid Sadoughi University of Medical Sciences Yazd Street address Yazd, Bahonar Square, Central building of Shahid Sadoughi University of Medical Sciences, Yazd City Yazd Province Yazd Postal code 8916978477	Intervention groups <u>1</u> Description Intervention group: Group counseling 4 sessions with weekly intervals Category Lifestyle <u>2</u> Description Intervention group: Telephone counseling 8 phone calls, twice a week Category Lifestyle	

3

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hosseinieh and mosques

Full name of responsible person

Behnaz Rahbarnia

Street address

Mehriz

City

Yazd

Province

Yazd

Postal code

8981646589

Phone

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Email

bn.rahbarnia@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadoughi University of Medical Sciences, Yazd

Full name of responsible person

Dr. Amir Houshang Mehrparvar

Street address

Yazd, Bahonar Square, Headquarters of Yazd
University of Medical Sciences

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Province

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Email

ah.mehrparvar@gmail.com

Web page address

<http://www.ssu.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadoughi University of Medical Sciences, Yazd

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

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Rahbarnia

Position

Student of MSc in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Yazd, Safayee, Bou Ali Avenue, Nursing and Midwifery
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Enjezab

Position

Associate Professor in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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

Yazd University of Medical Sciences

Full name of responsible person

Behnaz Rahbarnia

Position

Student of MSc in Midwifery Counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Nursing and Midwifery University

City

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Province

Yazd

Postal code

8949147553

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

Not applicable

Data Dictionary

Not applicable