

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

The Effect Of Group Cognitive-Behavioral Therapy (CBT) On Health Promotion Life Style Of Post Menopausal Women

Protocol summary

Summary

The purpose of this study was to evaluate the effectiveness of Cognitive - Behavioral Group Study conducted on lifestyle of postmenopausal women in Ahwaz. In this clinical trial study, 33 postmenopausal women (17 participant in the intervention group and 16 participant in the control group.) were randomly assigned. Inclusion criteria included Age 45 - 60 years, Natural menopause (absence of menstruation for at least one year), Women who will achieve score of life style scale in medium or weak Level, Having Educational Level of Primary School and Exclusion criteria included Mental and Physical diseases, Having sad events during the last six months, Addictions to alcohol, drugs and other psychotropic drugs. Before intervention, a Health Promotion Life Style Questionnaire (HPLQ) will be completed by all women in both groups. Participants in both groups will complete the questionnaires immediately after the intervention and 6 weeks later. The intervention group, 8 sessions of cognitive - behavioral therapy in groups and the control group will receive usual care.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631030N2**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-02-15, 1395/11/27

Registrant information

Name

Shiva Yazdizadeh

Name of organization / entity

School Of Nursing And Midwifery

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 2620

Email address

shirinkhorramnia98@gmail.com

Recruitment status

Recruitment complete

Funding source

Jondi Shapour University Of Medical Sciences

Expected recruitment start date

2017-03-04, 1395/12/14

Expected recruitment end date

2017-04-05, 1396/01/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect Of Group Cognitive-Behavioral Therapy (CBT) On Health Promotion Life Style Of Post Menopausal Women

Public title

The Effect Of Group Cognitive-Behavioral Therapy (CBT) On Health Promotion Life Style Of Post Menopausal Women

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria : Natural menopause (Absence of Menstruation for at Least One Year); Women Who Will Achieve Score of Lifestyle Scale in Medium (104-155) or Weak (below 103) Level; Having Educational Level of Primary School; The Appropriateness of Participant for

CBT;Age 45 - 60 Years And Exclusion criteria :Mental and Physical Diseases Based on Self Report;Having Sad Events During The Last Six Months;History of Previous Use of Cognitive- Behavioral Therapy; Addictions to Alcohol, Drugs and Other Psycholic Drugs Based on Self Report;Use of Antipsychotic Drugs

Age

From **45 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **33**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Jondi Shapour University Of Medical Sciences

Street address

Jondi Shapour University Of Medical Sciences,
University Town, Golestan

City

Ahvaz

Postal code

6135715794

Approval date

2016-07-02, 1395/04/12

Ethics committee reference number

IR.AJUMS.REC.1395.481

Health conditions studied

1

Description of health condition studied

Life Style

ICD-10 code

Z72

ICD-10 code description

Problems related to lifestyle

Primary outcomes

1

Description

Spiritual Growth

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

2

Description

Responsibility For Health

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

3

Description

Interpersonal Relationships

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

4

Description

Stress Management

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

5

Description

Sport

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

6

Description

Nutrition

Timepoint

Befor And Immediatly After Intervention And Six Weeks
Later

Method of measurement

HPLQ(Health Promotion Life Style Questionnare)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Eight sessions of cognitive - behavioral therapy in groups will be held in weekly meetings . The duration of each session will be 90 minutes. In these meetings, the influence of the thoughts on emotional and behavioral and The impact of negative thoughts on Lifestyle-related behaviors will be explained. Promoting healthy lifestyle before and after the consultation and 6 weeks after the intervention will be evaluated.

Category

Lifestyle

2

Description

Control group: Did not receive any treatment and only received usual care health. For observe ethical principles, Two sessions on menopause, its symptoms, lifestyle and its effects on menopausal symptoms as well as cognitive-behavioral therapy model for Control group will be held. Health promoting lifestyle of this group will be evaluated In these times(before and after the consultation and 6 weeks after)

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Number 1, East Center

Full name of responsible person

Shiva Yazdizadeh

Street address

Number 1, East Center, Street Shahid Rastegary,
Haiway Behbehany Ayatollahh

City

Ahvaz

2

Recruitment center

Name of recruitment center

Number 2, West Center

Full name of responsible person

Shiva Yazdizadeh

Street address

South Sorrosh Street, Khashayar

City

Ahvaz

3

Recruitment center

Name of recruitment center

Number 14, East Center

Full name of responsible person

Shiva Yazdizadeh

Street address

Nuber 5, Shekofe Street, Ajajary Koy

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Jondi Shapour University Of Medical Sciences

Full name of responsible person

Doctor Behzad Sharif Makhmalzadeh

Street address

Jondi Shapour University Of Medical Sciences,
Research Center, Univehapour University Of Medical
Sciences, Research Center, University Town, Golestan

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Jondi Shapour 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

School Of Nursing And Midwifery Ahvaz

Full name of responsible person

Shiva Yazdizadeh

Position

Master In Midwifery

Other areas of specialty/work

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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