

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Evaluation of the effectiveness of cognitive-behavioral group counseling on premenopausal women's anxiety

Protocol summary

Study aim

Determine the effectiveness of group counseling, cognitive - behavioral anxiety premenopausal women

Design

In this study, 60 women from 40 to 60 years of age with pre-menopausal women who come to Imam Musa Kazem's health center are selected. the participants were randomly divided into two intervention and control groups and each person Blocks were assigned.

Settings and conduct

The location of the study is Imam Musa Kazem's health center. In this study, participants and information analyst are those who are blind. Participants were unaware of the nature of the control or intervention of Groups A and B. The information processor was also unaware of the subject matter of the codes.

Participants/Inclusion and exclusion criteria

Women aged 45-60 years The emergence of symptoms of menopause or complete menopause Having diploma degree Passing for at least 6 months from the onset of anxiety symptoms in them The presence of cognitive symptoms in addition to the physiological excitations

Intervention groups

In this study, there are two groups of intervention group 1 and intervention group 2 and one control group. The intervention group 1 consists of 15 people and the intervention group 2 consists of 12 people and the control group includes 15 people. In intervention group 1 and intervention group 2, educational and therapy interventions were performed based on the cognitive-behavioral therapy (CBT). These interventions were taught to women separately during 7 2-hour sessions in each intervention group. Educational interventions were developed step by step and in the short run with significant and practical changes. Educational methods in intervention groups are performed based on the first cognitive model and behavioral models, familiarity with treatment methods for intervention group, exposure and prevention of response, evaluation and confrontation

with avoidance, acceptance and commitment, educating the relief-making and diaphragmatic breathing, cognitive assessments, considering the worries and distinguishing between efficient worry and challenging worry, the challenge by inefficient self-thinking and acquaintance with distorted self-thinking, and self-perfection and skill-building, especially problem-solving skills. Also, a set of necessary tools, in addition to cognitive and behavioral techniques, are in the form of post-test and pre-test, evaluation worksheets, homework and self-help worksheets, and educational summary leaflet. The control group was consisted of 15 people. At first, they just filled out a pre-test in a single session, and after a two-month period, they again did the same test as post-test, and no intervention was conducted during the two sessions.

Main outcome variables

Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170826035896N2**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **retrospective**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

bahareh ameri

Name of organization / entity

Shahroud University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 32333275

Email address

ameri.b@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Government

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of cognitive-behavioral group counseling on premenopausal women's anxiety

Public title

The Effectiveness of Cognitive-Behavioral Group Counseling on Premenopausal Women's Anxiety

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Women aged 45-60 years The emergence of menopause symptoms or complete menopause Having diploma degree Passing at least 6 months from the onset of anxiety symptoms The presence of cognitive symptoms in addition to the physiological excitations

Exclusion criteria:

Women outside the age range Consuming psychiatric medications Not having enough education Occurrence of Psychoticsigns and symptoms Having hysterectomy surgery

Age

From 45 years old to 60 years old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Quadruple random blocks, consisted of replaced parts named A and B, have already been generated by R software and each of these blocks of size 4 is placed in a separate envelope. The envelopes are provided to one of the colleagues other than researcher. Then the co-

worker unlocks the design of one of the envelopes randomly, and according to the insertion, the four patients, who are referring sequentially, are allocated according to the sequence of the four blocks to each of the groups A or B, and then he selects a different envelope for the next reference

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the analyst and the participant are not aware of the type of intervention in each group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shahroud University of Medical Sciences

Street address

7 Tir Square, Shahroud

City

Shahroud

Province

Semnan

Postal code

۳۶۱۴۷-۷۳۹۴۷

Approval date

2017-07-19, 1396/04/28

Ethics committee reference number

IR.SHMU.REC.1396.61

Health conditions studied**1****Description of health condition studied**

Anxiety

ICD-10 code

F06.4

ICD-10 code description

Organic anxiety disorder

Primary outcomes**1****Description**

Anxiety

Timepoint

Before intervention, after the intervention, 2 months and 6 months after the intervention

Method of measurement

By Hamilton's Anxiety Inventory

Secondary outcomes

1

Description

Physical symptoms of menopause

Timepoint

Before and after intervention

Method of measurement

Copermanen Questionnaire

Intervention groups

1

Description

The intervention group 1 consists of 15 people .On intervention group 1 educational and therapy interventions were performed based on the cognitive-behavioral therapy (cbt). These interventions were taught to women separately during 7 sessions of 2 hours in each intervention group. Educational interventions were developed step by step and in the short run with significant and practical changes. Educational methods in intervention groups are performed based on the first cognitive model and behavioral models, familiarity with treatment methods for intervention group, exposure and prevention of response, evaluation and confrontation with avoidance, acceptance and commitment, educating the relief-making and diaphragmatic breathing, cognitive assessments, considering the worries and distinguishing between efficient worry and challenging worry, the challenge by inefficient self-thinking and acquaintance with distorted self-thinking, and self-perfection and skill-building, especially problem-solving skills. Also, a set of necessary tools, in addition to cognitive and behavioral techniques, are in the form of post-test and pre-test, evaluation worksheets, homework and self-help worksheets, and educational summary leaflet.

Category

Lifestyle

2

Description

the intervention group 2 consists of 12 people .On intervention group 2 educational and therapy interventions were performed based on the cognitive-behavioral therapy (cbt). These interventions were taught to women separately during 7 sessions of 2 hours in each intervention group. Educational interventions were developed step by step and in the short run with significant and practical changes. Educational methods in intervention groups are performed based on the first cognitive model and behavioral models, familiarity with treatment methods for intervention group, exposure and prevention of response, evaluation and confrontation with avoidance, acceptance and commitment, educating the relief-making and diaphragmatic breathing, cognitive

assessments, considering the worries and distinguishing between efficient worry and challenging worry, the challenge by inefficient self-thinking and acquaintance with distorted self-thinking, and self-perfection and skill-building, especially problem-solving skills. Also, a set of necessary tools, in addition to cognitive and behavioral techniques, are in the form of post-test and pre-test, evaluation worksheets, homework and self-help worksheets, and educational leaflet summaries.

Category

Lifestyle

3

Description

Control group: The control group is consisted of 15 people. At first, they just filled out a pre-test in a single session, and after a two-month period, they again did the same test as post-test, and no intervention was conducted during the two sessions.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Musa Kazem (AS) health center

Full name of responsible person

Bahareh Ameri

Street address

Imam Musa Kazem (AS) health center, Kargar Boulevard. Shahrood

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ameri.bahareh91@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrood University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hassan Emami

Street address

Shahrood University of Medical Sciences, Hafte-Tir Square

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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

Shahroud 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**

Shahroud University of Medical Sciences

Full name of responsible person

Bahareh Ameri

Position

Master of science student in Midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Full name of responsible person

Zahra Mottaghi

Position

PhD in reproductive health

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Health

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

Shahroud University of Medical Sciences

Full name of responsible person

Bahareh Ameri

Position

Master of science student in Midwifery counseling

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Fax**Email**

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Web page address**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