Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 envelopesrandomly, 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 performedbased 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 theworries and distinguishing between efficient worry and challenging worry, the challenge by inefficient self-thinkingand 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-testand 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 performedbased 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 theworries and distinguishing between efficient worry and challenging worry, the challenge by inefficient self-thinkingand 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-testand 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr. Mohammad Hassan Emami
Street address
Shahroud 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
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Person responsible for scientific inquiries

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Zahra Mottaghi
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PhD in reproductive health
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Ph.D.
Other areas of specialty/work
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Email
zhrmotaghi@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shahrood 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
Street address
Hafte-Tir Square, Shahroud
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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