

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Survey of the Effectiveness of Acceptance and Commitment Therapy (ACT) on Quality of Life in menopause Women

Protocol summary

commitment to quality of life in menopausal women

Study aim

The Effectiveness of Acceptance and Commitment (ACT) Therapy on the Quality of Life in menopausal Women

Design

This clinical trial has two groups of intervention and control in parallel and two-blind, blind and randomized groups. The intervention group receives counseling weekly for 6 sessions of 90 minutes. The control group will receive only the routine care of menopausal women. At the end of the treatment sessions, the post-test will be performed on both groups.

Settings and conduct

The place of research is the comprehensive health services centers of Sabzevar city. The beginning of the study was completed by filling in the demographic data and using Menopausal Quality of Life Questionnaire and WHO Quality of Life Questionnaire. The participants of each group do not aware about Existence of another group. Researcher dose not aware about randomized allocation because of closed packets. The analyzer dose not aware about the people in the group's neither.

Participants/Inclusion and exclusion criteria

Iranian nationality, reading and writing literacy, age range 45-60 years, physiological menopause, at least 12 months from the last menstruation, no alternative hormone therapy during the past 6 months, absence of specific diseases such as cancer, No drug addiction, lack of participation restrictions, willingness to participate in the study, and filling out a form of informed consent, not taking psychiatric drugs, no crisis during the last year. not attending more than two sessions, a person's unwillingness to continue to study, family crisis from the start of the study to the end of one month follow-up

Intervention groups

The control group receive routine cares, and the intervention group receive 6 sessions counseling of 90 minutes.

Main outcome variables

Effectiveness of treatment based on admission and

General information

Reason for update

Acronym

ACT

IRCT registration information

IRCT registration number: **IRCT20190401043150N1**

Registration date: **2019-05-30, 1398/03/09**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-30, 1398/03/09**

Update count: **0**

Registration date

2019-05-30, 1398/03/09

Registrant information

Name

Samaneh Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4465 9787

Email address

s.ghasemi3060@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Survey of the Effectiveness of Acceptance and Commitment Therapy (ACT) on Quality of Life in menopause Women

Public title

Effectiveness of Acceptance and Commitment Therapy (ACT) on Quality of Life in menopause Women

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Iranian nationality Literacy reading and writing Age range 45-60 years Physiologic menopause At least 12 months have passed since the last menstruation Hormone replacement therapy has not been consumed within the last 6 months Not having certain diseases like cancer Do not have drug addiction No restrictions on attending meetings The desire to participate in the study and fill out the informed consent form Non-use of psychiatric drugs The lack of a crisis in the last year, like the death of one of the loved ones, and so on

Exclusion criteria:

Do not attend more than two sessions Unwillingness to continue to study Crisis in the family from the beginning of the study to the end of a one-month follow-up

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomized sequences under the web and by person who out of the research team will be done. Randomized foursome block as a limited method will be used and the people in the order of arrival will stay on blocks. The researcher put each allocation in closed white packet and numbered it. Qualified people in the order of arrival will be register by researcher and receive a code and relevant questionnaire complete for theme. Then according to the codes one packet will be opened and the person will be allocated to one of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The Participants of each group do not aware about existence of another group. Researcher dose not aware about randomized allocation because of closed packets. After intervention questionnaires will complete by another person except researcher. The analyzer dose not

aware about the people in the groups nether.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Shahrood University of Medical Sciences

Street address

7th tir square, shahrood University of Medical Sciences

City

Shahrood

Province

Semnan

Postal code

3614773947

Approval date

2019-05-08, 1398/02/18

Ethics committee reference number

IR.SHMU.REC.1398.010

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

Quality of life in menopause

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Quality of life in menopausal women is measured using the WHO Quality of Life Questionnaire and Quality of Life questionnaire for menopausal women

Timepoint

Before the intervention, immediately after the intervention, during the follow-up one month later

Method of measurement

World Health Organization Quality of Life Questionnaire and Quality of Life Questionnaire for menopausal Women

Secondary outcomes

empty

Intervention groups

1

Description

Control group: dose not receive any intervention

Category

Behavior

2

Description

Intervention group: this group will receive the consultation Acceptance and Commitment Therapy (ACT). The women in the intervention group, in addition to routine menopausal care receive counseling weekly for 6 sessions of 90 minutes, with Acceptance and Commitment (ACT) Therapy and structured commitment in each session, with mind-awareness training, review of previous sessions, potential support exercises, and homework assignments. In this model, counseling and treatment will be provided. The content of the sessions is based on Acceptance and Commitment (ACT) Therapy to anxiety and depression, which is based on the six process (Acceptance, Defusion, Self as a context, Contact with present moment, recognition of values and committed action). The samples are gradually being enrolled in the study, samples are collected for 10 people who have received weekly sessions, and simultaneous sampling is ongoing for both groups. The length of the consultation period is expected to be two months for each 10-member group.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive Health Services Centers

Full name of responsible person

Dr Fatemeh Nowdeh

Street address

Taleghani St, Sabzevar Health Center

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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 Emamian

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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

Samaneh Ghasemi

Position

Midwife

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

Midwife

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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

publishable data include thesis interpreted results and papers and protocol if needed

When the data will become available and for how long

Access from 2019-2020

To whom data/document is available

Data are access for all researchers in scientific institutes

Under which criteria data/document could be used

In case of Author's permission

From where data/document is obtainable

To corresponding author or executive author

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

By contact with the department or send an email to authors

Comments