

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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

##### City

Sabzevar

##### Province

Razavi Khorasan

##### Postal code

9617684155

##### Phone

+98 51 4464 5200

##### Email

health@medsab.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Shahroud University of Medical Sciences

#### Full name of responsible person

Dr. Mohammad Hassan Emamian

#### Street address

7th tir square, Shahroud University of Medical Sciences

#### City

shahrood

#### Province

Semnan

#### Postal code

۳۶۱۴۷-۷۳۹۴۷

#### Phone

+98 23 3239 5054

#### Email

info@shmu.ac.ir

#### 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

##### Street address

No.1, Second Alley., Payam Ave

##### City

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##### Postal code

9618913111

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##### Email

s.ghasemi3060@gmail.com

## Person responsible for scientific 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**

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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 departmant or send an email to authors

**Comments**