

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

The effect of counseling based on acceptance and commitment therapy on middle-aged women`s quality of life

Protocol summary

Study aim

The effect of counseling based on acceptance and commitment therapy on middle-aged women`s quality of life

Design

A randomized clinical trial, with intervention and control group, parallel groups, on 62 women. Randomization using a quadruple block design.

Settings and conduct

This research will be a clinical trial study. The statistical population of this study will include middle-aged women referring to the health centers of Ahvaz city.

Participants/Inclusion and exclusion criteria

Conscious willingness to participate in research; Being literate in reading and writing; Age range between 40-60 years

Intervention groups

In the intervention phase, the test group will undergo group training during 8 counseling sessions with a counseling approach based on acceptance and commitment by the researcher. After coordinating with the people of the intervention group and contacting them to get their consent to attend the meetings regularly, once a week and on a certain day in a group for 1 to 1.5 hours in one of the classes of the center. Hygiene will be held. Thus, in each counseling session, a counseling program based on acceptance and commitment will be taught

Main outcome variables

Quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230418057954N1**

Registration date: **2023-05-09, 1402/02/19**

Registration timing: **registered_while_recruiting**

Last update: **2023-05-09, 1402/02/19**

Update count: **0**

Registration date

2023-05-09, 1402/02/19

Registrant information

Name

Saba Rajabi Pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3462 1525

Email address

rajabi.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-20, 1402/01/31

Expected recruitment end date

2023-06-21, 1402/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling based on acceptance and commitment therapy on middle-aged women`s quality of life

Public title

The effect of counseling based on acceptance and commitment therapy on middle-aged women`s quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

willingness to participate in research Being literate in reading and writing Age range between 40-60 years

Exclusion criteria:

having a history of known chronic and acute physical and mental illnesses and taking psychoactive drugs prescribed by a doctor or psychiatrist Participation in clinical trials similar to this plan

Age

From **40 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization method in the current study will be done in the form of simple randomization with a 4-block design according to the opinion of the respected professor of statistics. In this randomization method, 6 quadruple blocks are created as (aa,bb) (ab,ab) (ba.ba) (ab,ba) (ba,ab) (bb,aa) and written on separate sheets. Assuming that the letter a represents the intervention group and the letter b represents the control group. Then, in order to enter people into the study plan, one of the six sheets will be randomly removed, and in this way, 4 of the referring people will enter the intervention and control groups according to the lottery. In the same way, this process is repeated 16 times by lottery to complete the number of samples.

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

Ethics Committee of Jundishapur Ahvaz University

Street address

Isfahan, Kaveh St., Ishraq North St., Etihad alley, Ghadir blind alley, No. 7

City

Ahvaz

Province

Khouzestan

Postal code

8193633571

Approval date

2023-04-20, 1402/01/31

Ethics committee reference number

IR.AJUMS.REC.1402.016

Health conditions studied

1

Description of health condition studied

Quality of life of middle-aged women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

quality of life

Timepoint

before the start of the study and immediately after the end of the study and two months after the end of the study

Method of measurement

SF-36 questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The test group will undergo group training during 8 consultant sessions with a counseling approach based on acceptance and commitment by the researcher. After coordinating with the people of the intervention group and contacting them to get their consent to attend the meetings regularly, once a week and on a certain day in a group for 1 to 1.5 hours in one of the classes of the center. Hygiene will be held. Thus, in each counseling session, a counseling program based on acceptance and commitment will be taught.

Category

Lifestyle

2

Description

Control group: During the research period, no intervention will be done for the control group and they will do their daily activities and in order to appreciate them at the end of the intervention, they will be provided with a CD of exercises.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

مراکز بهداشت غرب اهواز

Full name of responsible person

خانم باقری

Street address

Abouzar hospital

City

Ahvaz

Province

Khuzestan

Postal code

0000000000

Phone

+98 61 3445 7420

Fax

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Email

name@domian.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra Abbas pour

Street address

Jundi Shapur University of Ahvaz, Faculty of Nursing and Midwifery

City

Ahvaz

Province

Khuzestan

Postal code

15794-61357

Phone

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Email

info@ajums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Saba Rajabi Pour

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Ahvaz, Jundishapur University, Ahvaz, Faculty of Obstetrics and Midwifery

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Esfahan

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Isfahan

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15794 - 61357

Phone

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Email

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Zahra abbas pour

Position

associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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159

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

saba rajabi pour

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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