Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effectiveness of Acceptance and Commitment Therapy and Schema Therapy on irrational beliefs, death anxiety, psychological coherence, and sleep quality in elderly women

Protocol summary

Study aim

The study aims to compare the effectiveness of Acceptance and Commitment Therapy and Schema Therapy on irrational beliefs, death anxiety, psychological coherence, and sleep quality in elderly women of Sabzevar.

Design

This study was a randomized, double-blind, parallel-group, controlled clinical trial in phase 2, conducted on 45 elderly women. The sample size was determined using effect size calculation and statistical power analysis. Participants were randomly assigned to three groups (two experimental groups and one control group) using the RAND function in Excel software. Interventions for the experimental groups were implemented in the form of group sessions, and data were collected from all three groups in three stages.

Settings and conduct

This study will be conducted in Sabzevar city in 2025, at the Social Security Pensioners Center and Elderly Health Centers. Interventions will include 8 weekly 90-minute sessions of Acceptance and Commitment Therapy and Schema Therapy in group therapy rooms. The control group will receive one support session after the 90-day follow-up. Data will be collected in three stages with standard questionnaires to measure irrational beliefs, death anxiety, psychological coherence, and sleep quality. The sessions will be conducted by trained psychologists in compliance with ethical and health protocols.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study included literacy in reading and writing, age above 60 years, willingness to cooperate, no smoking, and no receipt of psychological services in the past three months. The exclusion criteria included absence from more than one session in the experimental groups and lack of interest in cooperation.

Intervention groups

Group 1: 8 weekly sessions of Acceptance and Commitment Therapy Group 2: 8 weekly sessions of Schema Therapy

Main outcome variables

Irrational beliefs; Death anxiety; Psychological coherence; Sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250606066093N1**
Registration date: **2025-08-05, 1404/05/14**
Registration timing: **prospective**

Last update: **2025-08-05, 1404/05/14**
Update count: **0**

Registration date

2025-08-05, 1404/05/14

Registrant information

Name

Kobra Kazemian moghadam

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-23, 1404/06/01

Expected recruitment end date
2025-09-23, 1404/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of Acceptance and Commitment Therapy and Schema Therapy on irrational beliefs, death anxiety, psychological coherence, and sleep quality in elderly women

Public title
Comparison of two therapeutic methods in reducing concerns and improving sleep in elderly women
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Reading and writing Age above 60 years A tendency to cooperate Not smoking Failure to receive psychological services over the past 3 months
Exclusion criteria:
Age
From **60 years** old to **85 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization was performed using the RAND function in Excel software. Participants were randomly assigned to three groups (two experimental groups and one control group).
Blinding (investigator's opinion)
Double blinded
Blinding description
Double-blind randomization was achieved by concealing group assignments from both participants and evaluators. The psychologists conducting the interventions and the data analysts were also unaware of the group identities to minimize bias.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Islamic Azad University, Ahvaz Branch
Street address
Islamic Azad University, Farhang Shahr
City
Ahvaz
Province
Khouzestan
Postal code
6134937333
Approval date
2025-04-23, 1404/02/03
Ethics committee reference number
IR.IAU.AHVAZ.REC.1404.053

Health conditions studied

1

Description of health condition studied
Death anxiety
ICD-10 code
F41
ICD-10 code description
Other anxiety disorders

Primary outcomes

1

Description
Irrational beliefs
Timepoint
Irrational beliefs are measured at three time points: pretest (before the start of interventions), posttest (immediately after the completion of 8 therapy sessions), and follow-up (90 days after the posttest).
Method of measurement
Irrational beliefs are measured using the standardized Jones Irrational Beliefs Test (IBT) or similar validated tools. This questionnaire includes items that assess the intensity of irrational beliefs such as the need for approval, unrealistic expectations, and perfectionism on a Likert scale. Data are collected through self-reporting by participants, with higher scores indicating greater intensity of irrational beliefs. Data analysis is conducted using statistical methods such as analysis of variance.

2

Description
Death anxiety

Timepoint

Death anxiety is measured at three time points: pretest (before the start of interventions), posttest (immediately after the completion of 8 therapy sessions), and follow-up (90 days after the posttest).

Method of measurement

Death anxiety is measured using the standardized Templer Death Anxiety Scale (DAS) or similar validated tools. This questionnaire includes items that assess the intensity of fear and concerns related to death on a Likert scale. Data are collected through self-reporting by participants, with higher scores indicating greater levels of death anxiety. Data analysis is conducted using statistical methods such as analysis of variance.

3

Description

Psychological coherence

Timepoint

Psychological coherence is measured at three time points: pretest (before the start of interventions), posttest (immediately after the completion of 8 therapy sessions), and follow-up (90 days after the posttest).

Method of measurement

Psychological coherence is measured using the standardized Sense of Coherence Scale (SOC) by Antonovsky or similar validated tools. This questionnaire includes items that assess the three main components of psychological coherence (comprehensibility, manageability, and meaningfulness) on a Likert scale. Data are collected through self-reporting by participants, with higher scores indicating greater levels of psychological coherence. Data analysis is conducted using statistical methods such as analysis of variance.

4

Description

Sleep quality

Timepoint

Sleep quality is measured at three time points: pretest (before the start of interventions), posttest (immediately after the completion of 8 therapy sessions), and follow-up (90 days after the posttest).

Method of measurement

Sleep quality will be measured using the Pittsburgh Sleep Quality Index (PSQI). This instrument consists of 19 items that assess seven components of sleep quality over the past month. A higher total score indicates poorer sleep quality. The PSQI has demonstrated good reliability and validity in both domestic and international research.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Acceptance and Commitment Therapy (ACT) is structured as 8 sessions, each lasting 90 minutes, with each session focusing on one of the six core processes of this approach: acceptance, cognitive defusion, self-as-context, present-moment awareness, values, and committed action. The first session introduces ACT concepts, establishes the therapeutic relationship, and identifies personal values. The second session teaches psychological acceptance, helping individuals embrace negative emotions and thoughts without resistance. The third session focuses on cognitive defusion, enabling clients to view irrational thoughts as transient mental events rather than absolute truths. The fourth session emphasizes present-moment awareness and mindfulness practices. In the fifth session, clients identify and prioritize their personal values. The sixth session involves setting value-based goals and planning committed actions. The seventh session focuses on self-as-context, helping clients distinguish themselves from their thoughts and feelings. The eighth session reviews progress, consolidates skills, and plans for ongoing application. Each session includes practical exercises, group discussions, and homework assignments to reinforce skills in daily life.

Category

Behavior

2

Description

Intervention group 2: Schema Therapy is structured as 8 sessions, each lasting 90 minutes, focusing on identifying, understanding, and modifying maladaptive early schemas. The first session is dedicated to an initial assessment, introducing schema therapy concepts, and identifying the client's maladaptive schemas using questionnaires and interviews. The second session focuses on psychoeducation about schemas and their impact on behavior and emotions, with clients beginning to recognize recurring patterns in their lives. The third session introduces cognitive techniques, such as cognitive restructuring, to challenge maladaptive beliefs tied to schemas. The fourth session employs experiential techniques, like imagery rescripting and empty-chair dialogues, to help clients connect with emotions linked to their schemas. The fifth session focuses on modifying schemas through behavioral techniques, such as role-playing and changing maladaptive behavioral patterns. The sixth session emphasizes fostering healthy relationships and addressing unmet emotional needs from childhood. The seventh session concentrates on consolidating changes and developing coping strategies to manage schema triggers in daily life. The eighth session reviews progress, evaluates changes in schemas, and plans for maintaining gains and preventing relapse. Each session includes practical exercises, guided discussions, and homework assignments to deepen awareness and reinforce changes.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Social Security Retirees Association and Elderly Healthcare Centers in Sabzevar City

Full name of responsible person
Mitra Mazinani

Street address
Pasdaran Fifth Street, Pasdaran Boulevard,

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Sabzevar

Province
Razavi Khorasan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Pezhman Taghipour Birgani

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Email
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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Kobra Kazemian moghadam

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Psychology

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Individual participant data (IPD) will not be shared due to confidentiality concerns and the lack of prior participant consent for data sharing. Furthermore, there are no institutional guidelines or requirements mandating the availability of these data.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available