Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The Effectiveness of a Systemic Acceptance and Commitment Therapy (ACT) and Life Review therapy on Social Cognition, Emotional Adaptation, and Experiential Avoidance in Older Adults with Mild Cognitive Impairment

Protocol summary

Study aim

To evaluate the effectiveness of a systemic intervention based on Acceptance and Commitment Therapy (ACT) and life review provided by a family member on experiential avoidance, social cognition, and emotional adaptation in older adults with mild cognitive impairment at Yas Comprehensive Rehabilitation Center in Tehran.

Design

Design: Randomized controlled parallel-group clinical trial in older adults with mild cognitive impairment. Allocation: 1:1 randomization to ACT + family Life Review or usual care. Sample size: 30 participants (15 per group). Randomization: Random number table.

Settings and conduct

The study will be conducted at Yas Comprehensive Rehabilitation Center in Tehran. After baseline assessment and obtaining informed consent, participants will be randomly allocated to two groups. The intervention group will receive ACT (10 group sessions) and family-provided Life Review (6 sessions). The control group will receive usual care provided by the center.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The inclusion criteria include being male or female, aged 60 years or older; having cognitive impairment diagnosed by a specialist physician; having the ability to read and write; and obtaining a score higher than 24 on the Mini-Mental State Examination (MMSE). Exclusion criteria: The exclusion criteria include the presence of severe cognitive, sensory-motor, or psychological problems; absence from more than two sessions; and failure to complete the assigned tasks.

Intervention groups

Intervention group: Receiving ACT (10 group sessions) and family-provided Life Review (6 sessions); caregivers trained through 2 online sessions and supervised by the researcher. Control group: Receiving usual care from Yas Comprehensive Rehabilitation Center without ACT or Life Review.

Main outcome variables

Experiential avoidance; Social cognition; Emotional adaptation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260721070286N1**
Registration date: **2026-08-01, 1405/05/10**
Registration timing: **prospective**

Last update: **2026-08-01, 1405/05/10**
Update count: **0**

Registration date

2026-08-01, 1405/05/10

Registrant information

Name

Delara Soleimani

Name of organization / entity

IAU Tehran Medical Branch

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-08-03, 1405/05/12

Expected recruitment end date

2026-08-11, 1405/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effectiveness of a Systemic Acceptance and Commitment Therapy (ACT) and Life Review therapy on Social Cognition, Emotional Adaptation, and Experiential Avoidance in Older Adults with Mild Cognitive Impairment

Public title

The Effectiveness of a Systemic Acceptance and Commitment Therapy (ACT) and Life Review therapy on Social Cognition, Emotional Adaptation, and Experiential Avoidance in Older Adults

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

men and women aged ≥60 years A diagnosis of Mild Cognitive Impairment (MCI) confirmed by a specialist physician the ability to read and write a Mini-Mental State Examination (MMSE) score of 24 or above

Exclusion criteria:

severe cognitive problems, sensorimotor impairments, or psychological disorder absence from more than two intervention sessions failure to complete the assigned homework

Age

From **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization. Unit of randomization: Individual participant. Randomization tool: A random allocation sequence will be generated using a random numbers table. Generation of the random allocation sequence: A unique identification code will be assigned to each participant, and based on the generated random allocation sequence, participants will be allocated to the intervention and control groups in a 1:1 ratio. Allocation concealment: The allocation sequence will be maintained by an individual who is not involved in delivering the intervention or assessing the study outcomes. The allocation assignments will be placed in sequentially numbered, opaque, sealed envelopes. After completion of each participant's baseline assessment, the corresponding envelope will be opened in numerical order, and the participant's group allocation will be determined.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Participants in the intervention group will receive a combined intervention consisting of Acceptance and Commitment Therapy (ACT) and Life Review Therapy. The ACT sessions will be conducted by the therapist at Yas Comprehensive Rehabilitation Center in Tehran, in a group format, consisting of 10 sessions held twice weekly, with each session lasting one hour.The Life Review intervention will be conducted over 6 one-hour sessions. For participants who have a family caregiver, caregivers will initially receive two one-hour online training sessions on how to conduct the life review process. Subsequently, caregivers will implement the life review sessions at home with the older adults, and the implementation process will be monitored by the researcher.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Tehran Islamic Azad University Of Medical Sciences

Street address

Tehran Azad University of Medical Sciences, Headquarters Building, Corner of Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak Junction, Dr. Shariati Street, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1949635881

Approval date

2026-06-15, 1405/03/25

Ethics committee reference number

IR.IAU.TMU.REC.1405.094

Health conditions studied

1

Description of health condition studied

Mild Cognitive disorder

ICD-10 code

F06.7

ICD-10 code description
A disorder characterized by impairment of memory, learning difficulties, and reduced ability to concentrate on a task for more than brief periods. There is often a marked feeling of mental fatigue when mental tasks are attempted, and new learning is found

Primary outcomes

1

Description
Social cognition
Timepoint
At baseline (pre-intervention), immediately after completion of the intervention (post-intervention), and at follow-up (1 months after the intervention).
Method of measurement
1- Social cognition score measured by the Bar-On/Cohen Empathy Quotient (EQ). 2- Theory of Mind score measured by the Revised Reading the Mind in the Eyes Test (RMET).

2

Description
Emotional adaptation
Timepoint
At baseline (pre-intervention), immediately after completion of the intervention (post-intervention), and at follow-up (1 months after the intervention).
Method of measurement
Emotional adaptation score measured by the Rabiu et al. Emotional Adaptation Scale

3

Description
Experiential avoidance
Timepoint
At baseline (pre-intervention), immediately after completion of the intervention (post-intervention), and at follow-up (1 months after the intervention).
Method of measurement
Experiential avoidance score measured by the Acceptance and Action Questionnaire-II (AAQ-II)

Secondary outcomes

empty

Intervention groups

1

Description
Participants will receive a combined intervention consisting of Acceptance and Commitment Therapy (ACT) and Butler's Life Review protocol delivered by a family member. ACT will be delivered by a therapist in 10 group sessions (60 minutes each, twice weekly) at Yas Comprehensive Rehabilitation Center, Tehran. Butler's Life Review will consist of six 60-minute sessions. Family members will first receive two online training sessions on Butler's Life Review protocol and will then conduct the Life Review sessions at home with the older adult. Intervention implementation will be regularly monitored by the researcher.
Category
Rehabilitation

2

Description
Control group: Participants in the control group will receive usual care provided by Yas Comprehensive Rehabilitation Center, Tehran, and will not receive the study interventions (Acceptance and Commitment Therapy [ACT] or Butler's Life Review protocol) during the study period.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas Comprehensive Rehabilitation Center
Full name of responsible person
Marzieh Shirazikhah
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Second Street, Sattarkhan, Tehran, Iran
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Web page address
https://yasrehab.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Alireza khoshdel
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Tehran Azad University of Medical Sciences, Headquarters Building, Corner of Gol Yakh Street, Ayeneh Boulevard, Amir Pabarja Street, Qolhak Junction, Dr. Shariati Street, Tehran, Iran.
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Int.affairs@tms.iau.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
The Islamic Azad University, Tehran Medical Sciences Branch

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
Delara Soleimani

Position
Master's Student in Clinical Psychology

Latest degree
Bachelor

Other areas of specialty/work
Psychology

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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
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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

عنوان و جزئیات بیشتر: پروتکل نهایی مطالعه؛ نسخه فارسی English نهایی پروتکل پس از انتشار نتایج مطالعه، در صورت درخواست، قابل ارائه خواهد بود. Title and details: Final study protocol; the final version of the study protocol will be available upon reasonable request after publication of the study results.

When the data will become available and for how long

Availability period: From 6 months after publication of the study results for 5 years.

To whom data/document is available

Researchers and academic investigators affiliated with scientific or academic institutions

Under which criteria data/document could be used

For scientific research purposes only, upon submission of a reasonable request and approval by the principal investigator.

From where data/document is obtainable

By contacting the principal investigator via email

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

Requests should be submitted to the principal investigator. After review and approval, the study protocol will be shared with the requester

Comments

None