

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 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

Iran (Islamic Republic of)

##### Phone

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##### Email address

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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  $\geq 60$  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 Rabiou 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

##### Street address

Second Street, Sattarkhan, Tehran, Iran

##### City

Tehran

##### Province

Tehran

##### Postal code

02166500140

##### Phone

+98 21 6650 6012

##### Email

zendehbadazad@yahoo.com

##### 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

##### Street address

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

##### City

Tehran

##### Province

Tehran  
**Postal code**  
 1949635881  
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 +98 21 2200 6660  
**Email**  
 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  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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                                                                                                                                                                                                                                                                                                        | Researchers and academic investigators affiliated with scientific or academic institutions                                                  |
| <b>Data Dictionary</b>                                                                                                                                                                                                                                                                                                | <b>Under which criteria data/document could be used</b>                                                                                     |
| No - There is not a plan to make this available                                                                                                                                                                                                                                                                       | For scientific research purposes only, upon submission of a reasonable request and approval by the principal investigator.                  |
| <b>Title and more details about the data/document</b>                                                                                                                                                                                                                                                                 | <b>From where data/document is obtainable</b>                                                                                               |
| عنوان و جزئیات بیشتر: پروتکل نهایی مطالعه؛ نسخه فارسی English فارسی 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. | By contacting the principal investigator via email                                                                                          |
| <b>When the data will become available and for how long</b>                                                                                                                                                                                                                                                           | <b>What processes are involved for a request to access data/document</b>                                                                    |
| Availability period: From 6 months after publication of the study results for 5 years.                                                                                                                                                                                                                                | Requests should be submitted to the principal investigator. After review and approval, the study protocol will be shared with the requester |
| <b>To whom data/document is available</b>                                                                                                                                                                                                                                                                             | <b>Comments</b>                                                                                                                             |
|                                                                                                                                                                                                                                                                                                                       | None                                                                                                                                        |