

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### The effect of educational intervention by spaced retrieval method on pain perception in elderly with Alzheimer's disease

#### Protocol summary

##### Study aim

The effect of educational intervention by spaced retrieval method on reinforcing semantic pain memory in elderly with Alzheimer's disease

##### Design

A randomized controlled clinical trial was conducted on 40 elderly people between September 2018 and December 2018.

##### Settings and conduct

The statistical population included the elderly with mild to moderate Alzheimer's disease living in the nursing homes in Tehran. Samples were selected by non-probability purposive sampling and randomly assigned to two groups of intervention and control. Before and after the intervention, in the intervention and control groups the main variables of the study were measured.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 60 years and older; Mild and Moderate Alzheimer's Disease; Spoken in Farsi; Signed written consent by patient or legal guardian. Non-inclusion criteria: Blindness; Hearing loss; Aphasia; Drug abuse; Diabetes; Stroke; Psychiatric illnesses; Depression; Severe Alzheimer's Disease; Begin taking any pain medication during the study.

##### Intervention groups

Intervention group: target information that including pictures of painful situations, was provided to the elderly at the beginning of each session. The elderly were then asked to identify images at 45, 90, 180, 360, 720 intervals. The recovery time was increased by the correct response. This intervention was performed 2 times per week for 8 sessions. The images presented in each session were different from the previous one. Activities that do not require much memory function such as solving puzzles were used during data retrieval. Control group: free group discussion were held 2 times per week for 8 sessions.

##### Main outcome variables

Pain perception; Pain threshold; Pain Semantic memory;

General semantic memory

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190826044616N1**

Registration date: **2019-10-01, 1398/07/09**

Registration timing: **retrospective**

Last update: **2019-10-01, 1398/07/09**

Update count: **0**

##### Registration date

2019-10-01, 1398/07/09

##### Registrant information

##### Name

Marjan Haghi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8825 6336

##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-07-23, 1397/05/01

##### Expected recruitment end date

2018-09-23, 1397/07/01

##### Actual recruitment start date

2018-08-23, 1397/06/01

##### Actual recruitment end date

2018-11-22, 1397/09/01

##### Trial completion date

2018-12-21, 1397/09/30

### Scientific title

The effect of educational intervention by spaced retrieval method on pain perception in elderly with Alzheimer's disease

### Public title

Effect of spaced retrieval training in Alzheimer's disease

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

60 years and older Mild and Moderate Alzheimer's Disease Spoken in Farsi Signed written consent by patient or legal guardian

#### Exclusion criteria:

Unrecognized sensory deficits include blindness and hearing loss and aphasia Drug abuse History of diabetes because of the possibility of neuropathy Stroke history due to the possibility of paralysis and paresis Psychiatric illnesses such as schizophrenia and bipolar disorder GDS-15  $\geq$ 8 CDR=3 Begin taking any pain medication during the study

### Age

From **60 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **46**

Actual sample size reached: **40**

### Randomization (investigator's opinion)

Randomized

### Randomization description

In this study, block randomization was used to ensure equilibrium of participants in two groups (mild Alzheimer's block or moderate Alzheimer's block). For this purpose, four-membered blocks consisting of all four possible combinations were defined as having two A members (intervention group) and two B members (control group), and at the time of randomization, a block was randomly selected and the samples assigned to the intervention or control group based on the results. The six possible four combinations are: AABB, ABAB, ABBA, BAAB, BABA, BBAA One envelope was provided for each block, containing four cards, two cards marked A and two cards B. The order of the cards in each envelope was in accordance with one of the above patterns and we had a total of six envelopes (numbered from one to six). At the time of random allocation, one of the envelopes was randomly selected, and as a result, four patients entered the study and their assignment was identified. when the envelope was identified, all four cards were not pulled out together, but with each patient, one card (in the envelope, respectively) was removed and discarded. After inserting four samples into two groups, the cards were placed in the same order at the envelope, and the envelope was returned to its original location.

### Blinding (investigator's opinion)

Not blinded

### Blinding description

#### Placebo

Not used

#### Assignment

Single

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

##### Street address

Koodakyar Ave., Daneshjoo Blvd., Velenjak

##### City

Tehran

##### Province

Tehran

##### Postal code

1985713871

#### Approval date

2017-02-08, 1395/11/20

#### Ethics committee reference number

IR.USWR.REC.1395.351

## Health conditions studied

### 1

#### Description of health condition studied

Alzheimer's disease

#### ICD-10 code

G30

#### ICD-10 code description

Alzheimer's disease

## Primary outcomes

### 1

#### Description

Pain severity questionnaire score

#### Timepoint

Measurement of pain intensity before and after 8 sessions of intervention

#### Method of measurement

Pain Assessment checklist for Seniors with Limited Ability to Communicate

### 2

#### Description

The intensity of the electrical current that causes the

pain (Pain Threshold)

#### **Timepoint**

Measurement of pain intensity before and after 8 sessions of intervention

#### **Method of measurement**

Stimulator device amplitude

### **3**

#### **Description**

The number of painful situation images that are correctly identified (Pain semantic memory)

#### **Timepoint**

Measurement of pain intensity before and after 8 sessions of intervention

#### **Method of measurement**

Valid images of painful situations

### **4**

#### **Description**

The number of animals / fruits that the elderly can name in 60 seconds (semantic memory)

#### **Timepoint**

Measurement of pain intensity before and after 8 sessions of intervention

#### **Method of measurement**

Verbal Fluency test

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: In this study, educational intervention with spaced retrieval - errorless method was used. The target information provided to the elderly at the beginning of each session consisted of 16 images, of which 8 were images of painful situations, 5 were images of non-painful situations, and 3 were unrelated. These images were randomly selected from 128 images validated in previous studies. All images were related to familiar daily activities, and the photograph was taken in such a way that the situation was recognizable at first glance. Different types of mechanical, thermal and pressure pain have been depicted and these images are of different age and gender. These images have been used in similar studies to assess pain semantic memory. The elderly were asked to remember the target information. Then, at 45, 90, 180, 360, 720 seconds intervals, the elderly were asked to identify images of painful situations. The retrieval time was increased, if of the responses were correct. Every time the elderly failed to identify the images correctly, the time interval was reduced to a previous step, and the painful images were trained again. The images presented at each session were different from the previous session, and at the end, the elderly participants were introduced to 64 painful situations. Activities that do not require much memory

function such as solving puzzles were used during data retrieval.

#### **Category**

Rehabilitation

### **2**

#### **Description**

Control group: Eight free group discussion sessions were held twice a week. Meetings were held with easy, comprehensible, and interesting topics. The sessions lasted up to one hour.

#### **Category**

Rehabilitation

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Alborz Kahrizak Charity

##### **Full name of responsible person**

Dr Afshin Vojdani

##### **Street address**

Esfahaniha Ave., Golestanak Blvd.,

##### **City**

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<http://kahrizak.com/>

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

University of social welfare and rehabilitation sciences

##### **Full name of responsible person**

Dr Mohamadreza Khodaie Ardakani

##### **Street address**

Koodakyar Ave., Daneshjoo Blvd., Velenjak

##### **City**

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##### **Province**

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Kh.ardakani@uswr.ac.ir

**Web page address**

https://www.uswr.ac.ir

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

Yes

**Title of funding source**

University of social welfare and rehabilitation 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**

University of social welfare and rehabilitation sciences

**Full name of responsible person**

Marjan Haghi

**Position**

Phd Candidate

**Latest degree**

Master

**Other areas of specialty/work**

Geriatrics

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**Latest degree**

Master

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**Person responsible for updating data****Contact****Name of organization / entity**

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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**

There is no further information

**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