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)

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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 ęducational 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 ≥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

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Province
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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

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Sponsors / Funding sources

1

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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
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
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Person responsible for updating data

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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