

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### The effect of facial and head massage on agitation in elderly with Alzheimer's Disease

#### Protocol summary

##### Summary

This study was conducted to investigate efficacy of head and face massage on agitation improvement in elderly .This work is a clinical trial research for which random sampling process was carried out on 70 samples using software. The instrument applied in this research involves a demographic questionnaire and VAS pain score, CMAI questionnaire , which are filled out by the researcher for each patient at the beginning of the study to find out their qualification for entering to the study. Then, for subjects in test group, acupressure was performed 10 days and every day for ten minutes (The period of Evening ) for patients in the intervention group will be implemented. For the control group, no intervention will be done . For each research trial, 13 Brawn massage therapy techniques (which are a combination of effleurage and pressure) would be performed by a trained agent for 10 minutes on the head and face of patients. At the end of 10 meeting participants using questionnaires agitation immediately Cohen - Mansfield (CMAI), visual pain scale (VAS) are evaluated. Inclusion criteria for this study were diagnosed Alzheimer's disease by a neurologist, mild or moderate Alzheimer's disease, the age of 60 years and older, nursing home residents Mehriz and Taft Cities , being restless. Exclusion criteria include: unwillingness of elders to participate in the study, having mental retardation and a wound in the head and face, going to a brief release, discharge from the facility.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016062728673N1**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-09, 1395/11/21

##### Registrant information

###### Name

Saeed Keshavarz

###### Name of organization / entity

Rafsanjan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 3428 0040

###### Email address

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##### Recruitment status

###### Recruitment complete

##### Funding source

Rafsanjan University Medical of Science

##### Expected recruitment start date

2016-07-22, 1395/05/01

##### Expected recruitment end date

2016-09-20, 1395/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of facial and head massage on agitation in elderly with Alzheimer's Disease

##### Public title

Determine the effect of agitation facial and head massage

##### Purpose

Supportive

## **Inclusion/Exclusion criteria**

Inclusion criteria for this study :Alzheimer's disease dignosed by a neurologist, mild or moderate Alzheimer's disease, the age of 60 years and older, nursing home residents and city Mehriz Taft, restless exclusion criteria include: Unwillingness of elders to participate in the study, having mental retardation and a wound in the head and face, going to a brief release, discharge from the facility.

### **Age**

From **60 years** old to **103 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **70**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

Randomization method: After the selection of eligible, patients with random assignment method using the software, Random Allocation will be divided into two groups.

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Rafsanjan University of Medical Sciences

##### **Street address**

Central Intelligence Agency, Imam Ali Blvd, Rafsanjan

##### **City**

Rafsanjan

##### **Postal code**

##### **Approval date**

2016-07-02, 1395/04/12

##### **Ethics committee reference number**

IR.RUMS.REC.1395

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Agitation in Alzheimer's disease

#### **ICD-10 code**

G00, G99

#### **ICD-10 code description**

Agitation in Alzheimer's disease

## **Primary outcomes**

### 1

#### **Description**

agitation

#### **Timepoint**

During the two weeks before and immediately after intervention

#### **Method of measurement**

Cohen Mansfield questionnaire

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

In the control group, the intervention is not done.

#### **Category**

N/A

### 2

#### **Description**

In the intervention group, facial and head massage for ten minutes every day for ten days and will be implemented in the course of the evening.

#### **Category**

Other

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Nursing Home Center Of Mehriz City

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

Ahmad Abooe

##### **Street address**

Home for the elderly and disabled vitality Mehriz, next to Green Hall , Mehriz, Yazd

##### **City**

Mehriz

### 2

#### **Recruitment center**

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

Charity Fatemeh Zahra Taft City  
**Full name of responsible person**  
Alireza Ghorbani  
**Street address**  
Next Payame Noor University, Taft, 10 km road Yazd,  
Yazd  
**City**  
Taft

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice Chancellor for Research Rafsanjan University of  
Medical Sciences  
**Full name of responsible person**  
Hamid Hakimi  
**Street address**  
Central Organization for Medical Sciences, Building  
No. 3, Department of Education and Research  
**City**  
Rafsanjan

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Vice Chancellor for Research Rafsanjan University of  
Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Rafsanjan University of Medical Sciences  
**Full name of responsible person**  
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## Person responsible for scientific inquiries

#### Contact

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## Person responsible for updating data

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## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*

#### Informed Consent Form

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*