

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

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Iran (Islamic Republic of)

Phone

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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
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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