

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effect of facial and head massage on improving Delirium in elderly women hospitalized in Coronary Care units

Protocol summary

Summary

Delirium causes hospitalization of 2.3 million people annually, which amounts to 17.5 million days of hospitalization leading to about 4 billion dollars of medical care cost. Treatment of delirium involves medications and supplementary drugs. Massage therapy is among the complimentary traditional medicine, which is recommended as an effective and safe treatment, according to many works. This study was conducted to investigate efficacy of head and face massage on delirium improvement in elderly inpatient women in CCU. This work is a clinical trial research for which random sampling process was carried out on 88 samples through the coding approach; i.e., the odd and even numbers indicate members of test and control groups, respectively. The instrument applied in this research involves a demographic questionnaire and standard Neecham 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 four times (twice at 10:00 a.m. and twice at 6:00 p.m.) each for 15 minutes. 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 15 minutes on the head and face of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015051922320N1**
Registration date: **2015-08-20, 1394/05/29**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-08-20, 1394/05/29

Registrant information

Name

Tayebeh Mirzaei

Name of organization / entity

Rafsanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

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Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2015-05-14, 1394/02/24

Expected recruitment end date

2015-07-15, 1394/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of facial and head massage on improving Delirium in elderly women hospitalized in Coronary Care units

Public title

The effect of facial and head massage on improving Delirium in elderly women hospitalized in Coronary Care units

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria are: no opium and alcohol dependency; no visual and auditory lesion; no history of cognitive impairment; no history of psychological disease; and no history of psychoeffective drug use. exclusion criteria are: head and face lesions

Age

From **60 years** old to **75 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rafsanjan University of Medical Sciences

Street address

Emam Ali Bolv

City

Rafsanjan

Postal code

Approval date

2015-05-13, 1394/02/23

Ethics committee reference number

IR.RUMS.REC.1

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05.9

ICD-10 code description

Delirium, unspecified

Primary outcomes

1

Description

Delirium

Timepoint

After 2 times of intervention

Method of measurement

Neecham questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

For subjects in test group, massage therapy was performed four times (twice at 10:00 a.m. and twice at 6:00 p.m.) each for 15 minutes.

Category

Treatment - Other

2

Description

Control group only received routine treatments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

kashani hospital

Full name of responsible person

Fakhri Torki

Street address

kashni street

City

Isfahan

2

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Neda Eslami

Street address

Sofeh Street

City

Isfahan

3

Recruitment center

Name of recruitment center

Chamran

Full name of responsible person

Dr MohamadReza Akhbari

Street address

Moshtagh second Street

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Tayebeh Mirzaei

Street address

Geriatric Care Research Center, Jomhoori Eslami Bolv

City

Rafsanjan

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

Yes

Title of funding source

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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr Tayebeh Mirzaei

Position

PhD, assistant professor

Other areas of specialty/work**Street address**

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Web page address**Person responsible for updating data****Contact****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*