Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effects of slow-stroke back massage on anxiety, depression, blood pressure and shoulder pain in stroke patients in physiotherapy ward of Kamkar hospital in 2010

Protocol summary

Summary

Stroke is a leading cause of disability in the worldwide. The prevalence of anxiety, depression and shoulder pain following stroke is relatively high and long lasting. This study explores the effect of slow-stroke back massage (SSBM) on blood pressure, anxiety, depression and shoulder pain of patients with stroke. An experimental method was used with a pre-test and post-test design. In this study 50 stroke patients experiencing shoulder pain were randomly divided into a massage group or a control group. The subjects were selected using the following inclusion criteria: 1- Stroke patients experiencing shoulder pain 2- Patients 40 years of age or older 3- No history of bradycardia, hypotension, spinal and skin disorders as well as malignancy of the spinal column 4- Able to assess the pain with visual analogue scale. Intervention in the study consists of ten minutes of SSBM for three consecutive days. Patients in the experimental group were given a SSBM in massage room. Systolic and diastolic blood pressure of each subject measured before and after the cessation of intervention. Patients were also asked to complete the hospital anxiety and depression scale (HADS) and VAS before and end of the third day, after the massage intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812232560N3**
Registration date: **2010-04-20, 1389/01/31**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2010-04-20, 1389/01/31

Registrant information

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research of Qom University of Medical Sciences

Expected recruitment start date

2010-04-04, 1389/01/15

Expected recruitment end date

2010-07-06, 1389/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of slow-stroke back massage on anxiety, depression, blood pressure and shoulder pain in stroke patients in physiotherapy ward of Kamkar hospital in 2010

Public title

The effects of slow-stroke back massage on anxiety, depression, blood pressure and shoulder pain in stroke patients

Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria: 1) Stroke patients experiencing shoulder pain, 2) Patients 40 years of age or older, 3) Had a stroke in the recent 6 month, 4) Had continuous pain in shoulder, 5) No history of bradycardia, hypotension, spinal and skin disorders as well as malignancy of the spinal column. 6) Not received sedative and depressive drugs 4 hours before complete questionnaires. 7) Ability of patient to speaking; Exclusive criteria : 1) Absence of collaboration, 2) Death or exit from study, 3) Had a hypotension and vertigo during massage intervention, 4) Received other complementary therapy for relieving of the pain, anxiety and depression.
Age
From **40 years** old to **80 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
The sample size of the study was calculated with power Of 80% and significance level of 5% according to the result of previous studies.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qom University of Medical Sciences and Health Services
Street address
Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran
City
Qom
Postal code
37185
Approval date
empty
Ethics committee reference number
19256/34/پ

Health conditions studied

1

Description of health condition studied
shoulder pain
ICD-10 code
M75.8
ICD-10 code description
Other shoulder lesions

Primary outcomes

1

Description
Decrease of anxiety
Timepoint
hospital anxiety and depression scale(HADS)before and end of the third day, after the massage intervention
Method of measurement
Hospital anxiety and depression scale(HADS)

2

Description
Decrease of blood pressure
Timepoint
Systolic and diastolic blood pressure of each subject measured before and after the cessation of intervention
Method of measurement
check list blood pressure

3

Description
Decrease of depression
Timepoint
hospital anxiety and depression scale(HADS) before and end of the third day, after the massage intervention
Method of measurement
Hospital anxiety and depression scale(HADS)

4

Description
Decrease of shoulder pain
Timepoint
VAS scale before and end of the third day, after the massage intervention.
Method of measurement
VAS scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: ten minutes of (slow-stroke back massage) SSBM for three consecutive days
Category
Rehabilitation

2

Description
Patients in the control group were not offered the SSBM intervention
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamkar- Arabnia Hospital
Full name of responsible person
Street address
City
Qom

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qom University of Medical Sciences and Health Services
Full name of responsible person
Salimi Ali
Street address
Qom University of Medical Sciences and Health Services, Saheli st., Qom., Iran.
City
Qom
Grant name
تحقیقات 10506
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qom University of Medical Sciences and Health Services
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