

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 2026

The effect of massage therapy and life style education on gastrointestinal complications of stroke patients

Protocol summary

Study aim

Determining the effect of massage and lifestyle education on gastrointestinal complications of stroke patients

Design

Clinical trial with community-based control and intervention group, with parallel groups, without blinding, randomized numbers.

Settings and conduct

Elderly people with stroke in Ghaem Hospital in Mashhad are divided into two groups: intervention and control. Lifestyle is taught to both groups. In the intervention group, Massage Scheme I LOVE U is also provided. The movement of the hand is in the form of the only one; L; O; V U is drawn along the colon and the narrow intestine on the abdomen. The duration of each abdominal massage is 15 minutes, for four weeks, performed by the patient.

Participants/Inclusion and exclusion criteria

Age 60 and older; Definitive diagnosis of ischemic stroke; Get 5 and more points from the CAS Constipation Assay; Lack of history of recent surgery and the development of disorders such as pancreatitis, ulcers and gastrointestinal lesions, gastrointestinal malignancies, liver and kidney failure; Not having ulcers, injuries and a clear infection on the abdomen; Guava diet; Having knowing along;

Intervention groups

In both groups, control and lifestyle interventions are taught. In the intervention group, in addition to lifestyle, I LOVE U abdominal massage training is also provided

Main outcome variables

distension, gastric residual, constipation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180721040547N1**

Registration date: **2018-11-02, 1397/08/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-11-02, 1397/08/11**

Update count: **0**

Registration date

2018-11-02, 1397/08/11

Registrant information

Name

zahra fekri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3273 0958

Email address

fekriz1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-23, 1397/08/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

2018-10-23, 1397/08/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-07-17, 1398/04/26

Scientific title

The effect of massage therapy and life style education on gastrointestinal complications of stroke patients

Public title

The effect of massage therapy and life style education on

gastrointestinal complications of stroke patients

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Age 60 and older Definitive diagnosis of ischemic stroke
Two days of stroke the patient has distention Lack of history of recent surgery and the development of disorders such as pancreatitis, ulcers and gastrointestinal lesions, gastrointestinal malignancies, liver and kidney failure Not having ulcers, injuries and a clear infection on the abdomen The level of consciousness is above 7 Having a family member to take care of him Not dialysis

Exclusion criteria:
the family member doesn't like to collaborate in research the patient's disability to be in sitting position existence of any deficit in patient's extremities cartilages that avoid patient to do the exercises

Age
From **60 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **52**
Actual sample size reached: **52**

Randomization (investigator's opinion)
Randomized

Randomization description
At the first the researchers used the www.randomization.com website to allocate 52 numbers from 1 to 52 randomly. The first 26 numbers considered to be in intervention group and the latter to be in control group. Then the patients will catch the number from 1 to 52. therefore according to the random numbers each patient will be allocated to intervention or control group by considering the number.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Mashhad University of Medical Sciences

Street address

Ebne sina

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2018-06-30, 1397/04/09

Ethics committee reference number

IR.MUMS.REC.1397.099

Health conditions studied

1

Description of health condition studied

Cerebro vascular Attack

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction Incl.: Cerebrovascular accident NOS

Primary outcomes

1

Description

distension

Timepoint

daily for 4 weeks

Method of measurement

Meter

2

Description

constipation

Timepoint

daily for 4 weeks

Method of measurement

Constipation Assessment Scale

3

Description

gastric residual

Timepoint

daily for 4 weeks

Method of measurement

Gavag syringe

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:I LOVE U Massage training is provided in a lifestyle approach and teaching (training for drinking, using fluids and vegetables, exercise, positioning during excretion)

Category

Lifestyle

2

Description

Control group: Lifestyle education includes training on how to cook, use fluids and vegetables, exercise, position during excretion.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Neurosurgery at Ghaem Hospital in Mashhad

Full name of responsible person

Nahid aghebati

Street address

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Email

fekriz1@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid aghebati

Street address

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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

Mashhad University of Medical 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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Aghebati

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Nahid aghebati
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Abn cina
City

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

No more 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