

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

Study of The effect of Implementation of the program based on transitional care model (TCM) on quality of life and activity of daily life of patients with stroke

Protocol summary

Study aim

The effect of transitional care model based program on quality of life and ability to perform daily activities of stroke patients hospitalized in Isfahan University of Medical Sciences

Design

Non-randomized clinical trial with a comparison group, without blinding, with 80 subjects

Settings and conduct

After obtaining the code of ethics and coordination with the authorities of the research centers, the researcher selects the eligible study samples using a quota sampling method. The control group is selected first, then the intervention (to ensure non-exchange of information). The intervention group received the required interventions from the second day of admission to 10 weeks after discharge and at the beginning and the end of the study both groups completed the questionnaires of quality of life and ability to perform daily activities.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Stroke diagnosis confirmed by neurologist-willing to participate in study-admitted for the first time with stroke diagnosis -contact telephone number-selected patient for intervention group residing in Isfahan. Exclusion criteria: Has another neurological condition - previously undergone brain or skull surgery - has global or perceptual aphasia.

Intervention groups

Group: Intervention: Includes patients who receive interventions from the second day of hospitalization until ten weeks after discharge by the researcher in accordance with a transitional care plan according to the needs of each of these patients Control group: Patients who receive routine hospital care from day 2 of hospitalization until discharge, and then meet with the researcher once a month, ten weeks after discharge, to

discuss their problems.

Main outcome variables

Determining the quality of life of stroke patients;
Determining the ability of daily living activities in stroke patients

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190712044181N3**
Registration date: **2019-11-07, 1398/08/16**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-07, 1398/08/16**

Update count: **0**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

shahla Abolhassani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7548

Email address

abolhasani@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-04-18, 1399/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of The effect of Implementation of the program based on transitional care model (TCM) on quality of life and activity of daily life of patients with stroke

Public title

Implementation of the program based on transitional care model (TCM) on quality of life and activity of daily life of patients with stroke

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

The diagnosis of stroke was confirmed by a neurologist who was selected to be a resident of the study group in Isfahan. Willingness to participate in the study. Be hospitalized for the first time with a stroke diagnosis. Phone number to call. Patients with at least GCS 13-15. Patients selected for the study group reside in Isfahan.

Exclusion criteria:

The patient should not have a decreased consciousness. Has no other neurological or mental illness. Has been hospitalized for the first time with a stroke diagnosis The patient has not undergone skull or brain surgery. Patients with perceptual or global aphasia are not included in the study.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 80

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

To prevent exchange of information between the control and intervention groups (because patients enter the study from the second day of admission); The control group and then the intervention group are included in the study, so the sample selection is not random and the study is quasi-experimental.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics in research Committee of Isfahan University of Medical Sciences

Street address

Hezar Jareeb Ave

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-09-22, 1398/06/31

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.374

Health conditions studied**1****Description of health condition studied**

Stroke

ICD-10 code

G46.4

ICD-10 code description

Cerebellar stroke syndrome

Primary outcomes**1****Description**

Primary outcome measure of quality of life in stroke patients

Timepoint

Before the intervention (pre-test), after the intervention in the tenth week after discharge (post-test)

Method of measurement

Specific standard questionnaire for quality of life after stroke (SS-QOL)

2**Description**

The ability to perform daily living activities in stroke patients

Timepoint

Before the intervention (pretest), after the intervention in the tenth week after discharge (post-test)

Method of measurement

Barthel questionnaire will be used.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: This group will be supported by the researcher in accordance with the transitional care program from the second day of hospitalization (after need assessment) to 10 weeks after discharge including: training in medicine, nutrition, disease complications, etc., In addition, daily care is provided during hospitalization and up to 10 weeks after discharge once a week for 3 hours for patients in this group. The researcher receives.

Category

Treatment - Other

2

Description

Control group: This group will receive the same routine care as the intervention group from the second day of hospitalization And up to 10 weeks after discharge, the researcher will meet with the control group in person once a month to discuss their problems. At the end of the study, the educational content provided to the patients in the intervention group during the study will be provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Medical Educational Center

Full name of responsible person

Mehdi Nasr Isfahani

Street address

Soffeh Blvd; Alzahra Hospital

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Web page address

2

Recruitment center

Name of recruitment center

Kashani Medical Educational Center

Full name of responsible person

Iman Adibi

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Web page address

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3

Recruitment center

Name of recruitment center

Amin Medical Educational Center

Full name of responsible person

Mohamad Ali Pourmirzaei

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Sonbolstan Alley; Ibne Sina Ave; Amin Hospital

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Web page address

<https://amin.mui.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjooy Javanmard

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Hezar jareeb Ave;

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research@mui.ac.ir

Web page address
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Shahla Abolhassani
Position
Assistant professor of nursing Education
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The original data can be shared after unidentifiable individuals have complied with the principle of confidentiality in the thesis file and extracted article.

When the data will become available and for how long

Start access to thesis file 6 months after student's final thesis defense; Start accessing the article file immediately after printing

To whom data/document is available

Anyone, whether academics or researchers working in other institutions, including the private sector, can apply for shared data.

Under which criteria data/document could be used

To use the results of this study to plan more comprehensive similar studies or to use the results of this study to design appropriate supportive educational

interventions for patients.

From where data/document is obtainable

Isfahan University of Medical Sciences; School of Nursing and Midwifery; Department of Adult Health Education; Shahla Abolhasani Phone 0098 913 109 5395
abolhasani.nm.mui.ac.ir

What processes are involved for a request to access data/document

Within 7 business days of receiving a written request by email and a full description of the applicant, together with the organization or institution in which they work and where the data is used; Documentation can be sent.

Comments