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

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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
Isfehan
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
City
Isfahan
Province
Isfehan
Postal code
81746757731
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Fax
Email
alzahra@mui.ac.ir
Web page address

2

Recruitment center
Name of recruitment center
Kashani Medical Educational Center
Full name of responsible person
Iman Adibi
Street address
Ayatollah Kashani Ave.Kashani Hospital
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8174673461
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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
Street address
Sonbolestan Alley; Ibne Sina Ave; Amin Hospital
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Email
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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
Street address
Hezar jareeb Ave;
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Postal code
8174673461
Phone
+98 31 3668 0048
Email
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

Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
Assistant Professor of Nursing Education

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Other areas of specialty/work
Nursery

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Web page address

Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

Full name of responsible person
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Position
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Latest degree
Ph.D.

Other areas of specialty/work
Nursery

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Email
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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