Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of self-management program based on the five A model on quality of life of patients with stroke.

Protocol summary

Study aim
Determine the Effect of Self-Management Program Based on five A Model on Quality of Life in Patients with Stroke.
Design
Clinical trial with community based and pragmatic control group, single, non-blind and non-random
Settings and conduct
Self-management training based on five A model on stroke patients referring to Rasoul-e-Akram Hospital in Tehran, which will be carried out in pre-test and post-test in two groups: intervention and control
Participants/Inclusion and exclusion criteria
People with stroke and their ability to be trained
Intervention groups
Self-management training based on the Five A model
The main goal of self-management education is based on the five A model: achieving maximum independence, self-decision making, health promotion based on individual's abilities and lifestyle, as well as improving quality of life. In this research, the Five A model has been used as a self-management framework in the intervention group to evaluate its effectiveness in improving the quality of life of stroke patients. The control group has routine health and rehabilitation care and at the end of the intervention will receive self-management training package.
Main outcome variables
Quality of life in stroke patients

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20190104042226N1**
Registration date: **2019-04-02, 1398/01/13**
Registration timing: **registered_while_recruiting**
Last update: **2019-04-02, 1398/01/13**
Update count: **0**
Registration date
2019-04-02, 1398/01/13

Registrant information
Name
Homa Khorsandi Sani
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-01-20, 1397/10/30
Expected recruitment end date
2019-08-22, 1398/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of self-management program based on the five A model on quality of life of patients with stroke.

Public title
The effect of self-management training on quality of life of patients with stroke.
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:

Diagnosis of a stroke by a neurologist Possibility of self-care and training The absence of another known chronic disease, such as cancer, MS, Parkinson Research units are not from the medical group Not participating in the same study Consent to participate in research Having a score of 8 or higher in abbreviated mental test.

Exclusion criteria:

Having any disabling physical and psychological disorder. Any changes in the patient's condition that require emergency measures.

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Not randomized

Randomization description

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 the University of Social Welfare and Rehabilitation Sciences

Street address

University of Social Welfare and Rehabilitation Sciences Tehran,Childhood Deadend, Evin, Student Blvd,

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2018-12-21, 1397/09/30

Ethics committee reference number

IR.USWR.REC.1396.404

Health conditions studied

1

Description of health condition studied

Quality of life for patients with stroke

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Quality of life in stroke patients

Timepoint

At the beginning of the study (before the intervention) and at the end of intervention (after 45 days)

Method of measurement

Specific Quality of Life Questionnaire for Patients with Stroke

Secondary outcomes

empty

Intervention groups

1

Description

1.Intervention group: Self-management training 5 A model :(1.Assess 2. Advise 3.Agree 4.Assist 5. Arrange) The five steps include: 1. Assessing the patient's behavioral level, beliefs and motivations; 2. Guide the patient about personal hygiene and risk factors; 3. Interact with the patient on the actual selection of objective goals; 4. Estimate barriers and program predictions, Practical 5. Track and support and setup . This program will run for 45 days.In the first week, the first three sessions are run in a 1.5 hour session individually. At this stage, the patient's health and lifestyle issues are being studied and goals are addressed to address the problems and improve the quality of life of patients .And the self-management training program will be tailored to the needs of each patient. In the second week, the fourth stage will be implemented. This stage will be held in a session of 30 to 60 minutes to help with the practical program, and the patient's problems will be resolved in relation to the self-management program.In the next four weeks, the fifth step is to follow the patient's performance and support them by telephone. Educational contents include information on patient needs, problem-solving skill training and time management skills, as well as stress management skills and crisis management in life, and ultimately self-confidence promotion strategies that are tailored to the needs of the patients.

Category

Lifestyle

2

Description
Control group:The control group did not receive a Five A Self-Management Training Program during the 45 days and received only a routine rehabilitation and treatment center program. At the end of the program, the five A self-management training package was provided to the control group.

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Rasool Akram Hospital

Full name of responsible person
Homa khorsandi sani

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Rasoul Akram Hospital,.Niyayesh Ave.,Statarkhan Ave.,Tehran Town

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
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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
University of social welfare and rehabilitation sciences

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
University of social welfare and rehabilitation sciences

Full name of responsible person
homa khorsandi sani

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available