

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Effectiveness of Motivational Interview on Self-Efficacy for CVA Survivors: A Randomized Controlled Trial

Protocol summary

Study aim

Determining the effect of motivational interviewing on the self-efficacy of people with stroke

Design

A controlled, parallel-group, single-blind, randomized clinical trial on 34 patients. For randomization, 6 block manual randomization method is used.

Settings and conduct

Sampling is done as available among those who referred to the occupational therapy department of Rofeideh Hospital in Tehran in 1401 with a history or diagnosis of stroke.

Participants/Inclusion and exclusion criteria

Entry Requirements: Having informed consent to participate in the research; People with a history or diagnosis of Ischemic stroke by doctor's approval; Scores 5-18 in the Beck's Depression Inventory (Short Form)
Non-entry Requirements: Inability to follow verbal commands; Scoring less than 18 in the Mini-Mental State Examination

Intervention groups

After the initial evaluation and randomization, the people in the intervention group will receive 4 individual motivational interview sessions in 4 weeks by a trained therapist, in addition to the usual stroke occupational therapy interventions that the control group also receives. The measurements of the post-test stage in both groups are done 8 weeks after the last motivational interview session, and in this stage the tester visits the home of each participant in the study and again Brunnstrom recovery level, general self-efficacy scale, the quality of life scale and functional independence scale as a post-test.

Main outcome variables

Self-Efficacy; CVA Recovery Level; Functional Independence; Severity of depression; Quality of Life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220520054936N1**

Registration date: **2022-09-07, 1401/06/16**

Registration timing: **prospective**

Last update: **2022-09-07, 1401/06/16**

Update count: **0**

Registration date

2022-09-07, 1401/06/16

Registrant information

Name

Sina Gholipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3346 8391

Email address

sinaghlpr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness of Motivational Interview on Self-Efficacy for CVA Survivors: A Randomized Controlled Trial

Public title

Effect of Motivational Interview on Self-Efficacy in CVA

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Having informed consent to participate in the research
People with history or diagnosis of Ischemic stroke by doctor's approval Scoring 5-18 in the Beck's Depression Inventory (Short Form)

Exclusion criteria:

Inability to follow verbal commands Scoring less than 18 in the Mini-Mental State Examination

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

Assigning participants to two intervention groups is done by simple randomization and lottery. After selecting all the eligible patients, two envelopes containing cards A (representative of the intervention group) or B (representative of the control group) are given to each patient by a therapist, who is not aware of the contents of the envelopes, to choose one envelope.

Blinding (investigator's opinion)

Single blinded

Blinding description

After selecting all eligible patients, the initial evaluation and re-evaluation are done by a therapist who is not one of the study researchers and is unfamiliar with the grouping of patients. Assigning participants to two intervention groups is done by a therapist unaware of the contents of the envelopes. The usual occupational therapy interventions for both groups are performed by an occupational therapist unaware of the group allocation. Motivational Interview sessions for intervention group A will be held by the study researcher, who will be informed about the grouping of patients using envelopes after randomizing the patients. Data analysis is also done by an analyst unfamiliar with the grouping of patients.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of social welfare and rehabilitation

Street address

Evin, Daneshjoo Blvd, Koodakyar Street

City

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Province

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Postal code

1985713871

Approval date

2022-05-20, 1401/02/30

Ethics committee reference number

IR.USWR.REC.1401.025

Health conditions studied

1

Description of health condition studied

Cerebral Vascular Accident (Stroke)

ICD-10 code

I63.9

ICD-10 code description

Cerebral infarction, unspecified

Primary outcomes

1

Description

Self-efficacy score in the General Self-efficacy Scale

Timepoint

Measuring Self-efficacy at the beginning of the study and 60 days after the start of motivational interview.

Method of measurement

General Self-efficacy Scale

Secondary outcomes

1

Description

Quality of life score in the Quality of Life Scale

Timepoint

Measuring quality of life at the beginning of the study and 60 days after the start of the motivational interview.

Method of measurement

Quality of Life Scale

2

Description

Functional Independence Score in the Functional Independence Scale

Timepoint

Measuring functional independence at the beginning of the study and 60 days after the start of motivational interview.

Method of measurement

Functional Independence Scale

3

Description

Brunnstrom Recovery Level

Timepoint

Determining Brunnstrom recovery level at the beginning of the study and 60 days after the start of the motivational interview.

Method of measurement

Brunnstrom Approach

Intervention groups

1

Description

Intervention group (A): In addition to routine Occupational Therapy interventions, including programs to increase the level of independence in daily life activities, facilitate muscle tone, inhibit reflexes, and increase flexibility based on Brunnstrom and Bobath techniques, the recipient of 4 sessions of 30-60 minute individual Motivational Interview over four weeks by a trained therapist emphasizing the use of open-ended questions, giving feedback, counseling, validation, emphasis on control, reflection, reframing, and support conducted by the researcher in the interview room. The first session emphasizes familiarity with stroke, the causes of its occurrence, and progress, and the second session describes a day of daily life and emphasizes the examination of short-term and long-term problems, failure to observe adaptive behaviors, compensatory strategies, and increasing the quality of life. Third, with an emphasis on identifying the desired goals of the individual and the ways to achieve them to create internal motivation and also create changes to achieve favorable conditions, and the fourth session to review the talks made in the previous sessions, reminding the identified goals and Rewards are offered for achievements. It should be noted that three months before the start of the sessions, the researcher has received the necessary training under the supervision of a clinical psychologist and an Occupational Therapy specialist in the field of psychiatry who is in the research team and has obtained sufficient qualifications.

Category

Rehabilitation

2

Description

Control group (B): Receiving routine Occupational Therapy interventions, including programs to increase the level of independence in daily life activities, facilitate muscle tone, control reflexes and more flexibility based on Brunnstrom and Bobath techniques.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofeideh Rehabilitation Hospital

Full name of responsible person

Nazila Akbar Fahimi

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Email

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Web page address

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

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

University of social welfare and rehabilitation sciences

Full name of responsible person

Sina Gholipour

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Occupational Therapy

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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared after de-identifying people in the form of participant data file, study protocol, statistical analysis map, informed consent form, clinical study report, codes used in analysis and data dictionary.

When the data will become available and for how long

The access period starts 1 year after the results are published

To whom data/document is available

The data obtained from the current research can be sent to treatment centers and occupational therapy

Departments if needed.

Under which criteria data/document could be used

Apart from the analysis done by the research team on the data, no one is allowed to do any further analysis on the data.

From where data/document is obtainable

Nazila AkbarFahimi: n-fahimi@uswr.ac.ir

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

On average, to perform tasks related to sending files and considering the volume of files, a period of at least 2 weeks should be considered for sending data files.

Comments