Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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
Tehran
Province
Tehran
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
Brunnestrom Recovery Level

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

Method of measurement
Brunnestrom 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

Street address
Gheytarieh, shahid Baradaran Soleymani Street

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2220 5326

Fax
+98 21 2223 2741

Email
rofeideh.hospital@uswr.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

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

Full name of responsible person
Hamidreza Khankeh

Street address
Daneshjoo Blvd, Koodakyar Street

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0083

Fax
+98 21 2218 0109

Email
pr@uswr.ac.ir

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

Street address
Evin, Daneshjoo Blvd, Koodakyar Street

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 44 3346 8391

Fax

Email
sinaghlpr@gmail.com

Person responsible for scientific inquiries

Contact

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

Full name of responsible person
Nazila Akbar Fahimi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Occupational Therapy

Street address
Evin, Daneshjoo Blvd, Koodakyar Street

City
Tehran

Province
Tehran

Postal code
1985713871

Phone
+98 21 2218 0083

Fax
+98 21 2218 0109

Email
n-fahimi@uswr.ac.ir

Person responsible for updating data

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

Street address
Evin, Daneshjoo Blvd, Koodakyar Street

City
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Postal code
1985713871

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Fax

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sinaghlpr@gmail.com

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