

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Investigating the effect of empowerment program based on spirituality on care burden and health-related quality of life of stroke patients family caregivers

Protocol summary

Study aim

Determining the impact of empowerment program based on spirituality on care burden and quality of life related to the health of family caregivers of stroke patients

Design

A clinical trial with control and intervention groups, with cross-over groups, single-blind, randomized, phase 3 on 96 family caregivers, coin toss was used for randomization.

Settings and conduct

The research environment is the place and situation where the data collection of a study takes place. In this study, the research environment will be the neurology department of hospitals affiliated to Shahid Beheshti University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Having minimum literacy in Persian language: A family caregiver who is in the treatment team

Intervention groups

Spiritual intervention on family caregivers of stroke patients who will be divided into two intervention and control groups.

Main outcome variables

Caregiving burden; health-related quality of life

General information

Reason for update

Acronym

TSBQ

IRCT registration information

IRCT registration number: **IRCT20230810059109N1**

Registration date: **2023-08-15, 1402/05/24**

Registration timing: **prospective**

Last update: **2023-08-15, 1402/05/24**

Update count: **0**

Registration date

2023-08-15, 1402/05/24

Registrant information

Name

kosar pourhasan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3633 3128

Email address

kosarpourhasan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empowerment program based on spirituality on care burden and health-related quality of life of stroke patients family caregivers

Public title

Investigating the effect of empowerment program based on spirituality on care burden and health-related quality of life of stroke patients family caregivers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having minimum literacy in Persian language
Age above 18 years
Not taking drugs related to depression or psychosis according to the family caregiver
First or second degree family member including spouse, child, sister, brother, daughter-in-law, son-in-law
Having a smartphone and the possibility of installing internal messengers
Lack of family care as treatment staff
Failure to participate in similar training courses

Exclusion criteria:

Family caregivers should not be Muslim

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

The research samples will be entered into the study by the available method as individual units and by simple randomization and coin toss and will be allocated to two intervention and control groups. In order not to meet the control group with the intervention group for the purpose of concealment, we first sample the control group and then the intervention group.

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 Shahid Beheshti Faculty of Nursing and Midwifery

Street address

Tehran Province , Tajrish, Velenjak , 7 th Floor , Blong No.

City

Tehran

Province

Tehran

Postal code

1996835919

Approval date

2023-08-01, 1402/05/10

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.072

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

Z82.3

ICD-10 code description

Family history of ischaemic heart disease and other diseases of the circulatory system

Primary outcomes

1

Description

Caregiving burden of health-related quality of life

Timepoint

before the intervention and 3 weeks after the intervention

Method of measurement

In this study, the care burden variable is the burden of burden questionnaire and the health-related quality of life variable is the 12-question quality of life questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention is carried out in the form of educational content, pamphlets, educational videos in the form of one-on-one sessions for 30 minutes once a week

Category

Rehabilitation

2

Description

Control group: In this group, after the end of the intervention in the test group, which will last for 3 months. After 3 months, the educational content will be provided to the control group.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofaydeh Rehabilitation Center

Full name of responsible person

Kosar Pourhasan

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Phone

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Email

Kosarpourhasan@sbm.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Vahid Zamanzade

Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

shahid beheshti medical university

Proportion provided by this source

50

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Kosar Pourhasan

Position

Master Of Student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Kosar Pourhasan

Position

Master Of Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Master of Community Health Nursing

Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Demographic and clinical questionnaire

When the data will become available and for how long

month 3

To whom data/document is available

reaserchers

Under which criteria data/document could be used

controlled conditions

From where data/document is obtainable

Kosarpourhasan's email, contact number 09147882954 and email: kosarpourhasan@sbmu.ac.ir

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

Letter Writing

Comments