

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Evaluating the effect of family-centered empowerment model on persons with SCI on quality of life and health behaviors

Protocol summary

Study aim

effect of family-centered empowerment model in person with Spinal cord injury on quality of life and health behaviors

Design

Initially, profiles of people with spinal cord injury are reviewed, which are in Brain and spinal cord research center and the telephone numbers of eligible individuals are written. Persons with SCI and their caregivers are invited to the Research Center for initial assessment in accordance with the Consort flowchart. It should be noted that subjects are divided into two groups according to the randomization table. The researcher does not have any interference with which group to which it belongs. the sample size is 48 person in each group.

Settings and conduct

The study site is at the brain and spinal cord injury research center. It is going to use single blinding that In this way, the intervention is planned in such a way that the participant does not understand which of the two control or test groups belong.

Participants/Inclusion and exclusion criteria

Inclusion criteria for Individual with Spinal Cord Injury (SCI): Participants who had SCI from type of paraplegia by the diagnosis of a specialist physician; those who had age of more than 18 years; those who had SCI more than one year to 5 years; those who had mental and cognitive ability and ability to read and write. Inclusion criteria for family caregivers: Participants who were aware of the Individual with SCI's condition and those who were not a member of the medical team; those who had a mental and cognitive ability and they will be chosen as the caregiver with the confirmation of a SCI person. Exclusion criteria for SCI person: having fractures in the bones and amputations; pregnancy and/or surgery and coma from the past year

Intervention groups

family-centered empowerment program in Intervention

group Routine program in Control group

Main outcome variables

Quality of life/health behaviors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120804010488N3**

Registration date: **2018-04-25, 1397/02/05**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-25, 1397/02/05**

Update count: **0**

Registration date

2018-04-25, 1397/02/05

Registrant information

Name

Maryam Shabany

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-16, 1397/01/27

Expected recruitment end date

2018-07-22, 1397/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluating the effect of family-centered empowerment model on persons with SCI on quality of life and health behaviors

Public title
The effect of family-centered empowerment model on persons with SCI on quality of life and health behaviors

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria for Individual with Spinal Cord Injury (SCI): Participants who had spinal cord injury from type of paraplegia by the diagnosis of a specialist physician those who had age of more than 18 years those who had spinal cord injury more than one year and less than 5 years those who had mental and cognitive ability those who had the ability to read and write Inclusion criteria for family caregivers: Participants who were family caregiver that being aware of the Individual with SCI's condition those who were not a member of the medical team those who had mental and cognitive ability those who had ability for reading and writing
Exclusion criteria:
Participants who had fractures in the bones and amputations; Participants who had pregnancy and / or surgery and coma from the past year

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
Initially, profiles of people with spinal cord injury are reviewed, which are in Brain and spinal cord research center and the telephone numbers of eligible individuals are written. individual with SCI are invited to the Research Center for initial assessment in accordance with the Consort flowchart. It should be noted that subjects are divided into two groups according to the randomization table. The researcher does not have any interference with which group to which it belongs.

Blinding (investigator's opinion)
Single blinded

Blinding description
the one who evaluates the outcome (statistician) dose not know which data belongs to which of the two control or test groups.

Placebo

Not used

Assignment
Parallel

Other design features
Those who evaluate the outcome (statistician) do not know which data belongs to which of the two control or test groups.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of the Vice-Chancellor of Research Tehran University of Medical Sciences

Street address

Brain and spinal cord research center, emam khomeini hospital, Keshavarz Blvd, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1419733139

Approval date

2015-12-26, 1394/10/05

Ethics committee reference number

IR.TUMS.REC.1394.1493

Health conditions studied

1

Description of health condition studied

Individual with Spinal Cord Injury (Paraplegia)

ICD-10 code

S24.1, S34

ICD-10 code description

Other and unspecified injuries of thoracic spinal cord,
Other and unspecified injury of lumbar and sacral spinal cord

Primary outcomes

1

Description

Quality of life for spinal cord injury person

Timepoint

At the beginning of the study; one month later; three months later

Method of measurement

Quality of life questionnaire for the person with spinal cord injury (Frans and Powers) and general quality of life questionnaire (Frans and Powers).

2

Description

Health behaviors

Timepoint

At the beginning of the study; one month later; three months later

Method of measurement

Health behavior questionnaire

3

Description

Quality of life for family caregivers

Timepoint

At the beginning of the study; one month later; three months later

Method of measurement

General quality of life questionnaire (Frans and Powers).

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: are individuals with spinal cord injury and their family caregivers. Interventions include the pre-test, multiple educational interventions through two sessions of the classroom, instructional films (physical empowerment in person with SCI), instruction booklet (include physical, mental and psychological care tips for a person with SCI and their caregivers), education by telegram and follow up by telephone, run post tests one month later and three months later

Category

Rehabilitation

2

Description

Control group: person with spinal cord injury and their family caregivers that they receive rehabilitation routine programs.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Brain and spinal cord injury research center

Full name of responsible person

Dr. Ali Reza Nikbakht Nasrabadi

Street address

Brain and Spinal Cord Injury Research Center, Neuroscience Institute, Tehran University of Medical Sciences, Tehran, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Brain and spinal cord injury reseach center

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

Brain and spinal cord injury reseach center

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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Shabany

Position

Ph.D candidate

Latest degree

Master

Other areas of specialty/work

Nursery

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Student

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Master

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Professor in Tehran university

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Ph.D.

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Maryam Shabany

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

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

It is going to publish of study' s results.

When the data will become available and for how long

Start the access period from 1398

To whom data/document is available

Only for researchers working in academic and scientific institutions will be available.

Under which criteria data/document could be used

Record the information in this dissertation and usable for the next study

From where data/document is obtainable

The Central Library in Tehran University of Medical Sciences

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

Refer the Central Library of Tehran University of Medical Sciences and study the dissertation using a valid ID card.

Comments