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)
Phone
+98 21 7736 1961
Email address
mshabani@qums.ac.ir

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.
City
Tehran
Province
Tehran
Postal code
1419733139
Phone
+98 21 6658 1560
Email
nikbakht@tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Brain and spinal cord injury reseach center
Full name of responsible person
Dr.Mohammad Ali Sahraeian
Street address
Brain and Spinal Cord Injury Research Center, Neuroscience Institute, Tehran University of Medical Sciences, Tehran, Iran.
City
Tehran
Province
Tehran
Postal code
1419733139
Phone
+98 21 6670 6142
Email
msahrai@sina.tums.ac.ir
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
Street address
Brain and Spinal cord injury, Neurosciences institute, Tehran University of Medical Sciences, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14419733139
Phone
+98 21 6658 1560
Email
mshabani@razi.tums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Alireza Nikbakht Nasrabadi
Position
Professor in Tehran university
Latest degree
Ph.D.
Other areas of specialty/work
Nursery
Street address
Satarkhan
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6690 4252
Email
nikbakht@tums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Maryam Shabany
Position
Student
Latest degree
Master
Other areas of specialty/work
توانبخشی و سلامت
Street address
Keshavarz Blvd
City
Tehran
Province
Tehran
Postal code
1419733139
Phone
+98 21 6658 1560
Email
maryamshabanyi@yahoo.com

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