Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

The effect of self-efficacy training using the BASNEF model method on the quality of life of patients with spinal cord injury

Protocol summary

Study aim

This study aims to determine the effect of self-efficacy training using the Bezenef model on the quality of life of patients with Spinal cord injury will be done in Rafidah Rehabilitation Hospital in 1402.

Design

The selection of participants will be available and the patients with SCI hospitalized in Rafideh Rehabilitation Hospital in 1402 will be included in the study. In order to prevent the participants of the two intervention and control groups from contacting each other, sampling will be done asynchronously and at two separate times.The samples are randomly divided into two intervention and control groups of 40 people

Settings and conduct

This study will be conducted in Rafidah Rehabilitation Hospital.

Participants/Inclusion and exclusion criteria

Entry conditions: age >20, not participating in similar educational programs, no history of brain disorder, no pressure ulcer and mental disorders, access to the Internet and messengers, history of spinal cord injury for six months or more. Conditions of non-entry: unwillingness to participate in the study, use of psychoactive drugs and neuropsychiatric drugs, causing complications that the patient is unable to continue participating in the test.

Intervention groups

Completion questionnaires in the intervention and control groups. For the intervention group, it includes self-efficacy training based on the steps of the Bezenef model according to the training program designed in 7 sessions of 60 minutes for 6 weeks, in the form of group sessions, with the active participation of the patient and one of the The family members will be interviewed by the researcher in the conference hall of the center using educational aids. Also, the implementation of routine treatments . In both The telephone counseling group will be accepted immediately.

Main outcome variables

Change in the quality of life and self-efficacy of people with spinal cord injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230529058326N1**
Registration date: **2023-06-03, 1402/03/13**
Registration timing: **prospective**

Last update: **2023-06-03, 1402/03/13**
Update count: **0**

Registration date

2023-06-03, 1402/03/13

Registrant information

Name

zohreh karimi oragh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5633 0177

Email address

zohrehkarimi0211@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-07-21, 1402/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-efficacy training using the BASNEF model method on the quality of life of patients with spinal cord injury

Public title

Effect of self-efficacy training using the BASNEF model method on the quality of life of patients with spinal cord injury

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

history of spinal cord injury for six months or more Age above 20 years Failure to participate in similar educational programs No history of brain disorder or disease such as stroke Absence of pressure sores Internet access and messengers Not suffering from mental disorders (according to the initial consultation)

Exclusion criteria:

Unwillingness to participate in the study Use of psychoactive drugs and neuropsychiatric drugs causing complications that make the patient unable to continue participating in the test

Age

From **20 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Individual randomization will be done by block method using Graphpad software and concealment will be done by SPONE method.

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 in research of pharmacy, nursing and midwifery faculties of SBMU

Street address

Valiasr Ave

City

Tehran

Province

Tehran

Postal code

0000000000

Approval date

2023-05-23, 1402/03/02

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1402.011

Health conditions studied

1

Description of health condition studied

Spinal Cord Injury

ICD-10 code

T09.3

ICD-10 code description

Injury of spinal cord, level unspecified

Primary outcomes

1

Description

Quality Of Life

Timepoint

7 weeks

Method of measurement

SIP-68 Quality Of Life Questionnaire

Secondary outcomes

1

Description

Self-Efficacy

Timepoint

7 weeks

Method of measurement

GSE-17 Sherer Self-Efficacy

Intervention groups

1

Description

Intervention group: Questionnaires will be filled before the intervention to be compared at the end of the study when they are filled again. The self-efficacy training intervention is based on the steps of the Bezenf model and will be implemented according to the designed training program in 7 60-minute sessions with the titles of reforming ideas, attitudes, mental norms 1 and 2,

enabling factors, behavioral intention and behavioral structures. Training includes definitions, goals, disease complications, prevention, treatment, diet, physical activity, self-care, lifestyle improvement, anxiety and stress control, problem solving and adaptation, etc.

Category

Behavior

2

Description

Control group: The control group will fill the questionnaires 2 times with an interval of 7 weeks and will receive only routine care in the meantime.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Rofaydeh Rehabilitation Hospital

Full name of responsible person

Fatemeh Neiseh

Street address

Rofaydeh hospital, Andarzgoo Ave

City

Tehran

Province

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Postal code

0000000000

Phone

+98 21 8865 5366

Email

sarah.neiseh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Sepideh Hajian

Street address

Valiasr

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 8865 5366

Email

Hajian74@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Neiseh

Position

0

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

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Phone

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Email

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Neiseh

Position

0

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Fatemeh Neiseh

Position

0

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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

0

When the data will become available and for how long

0

To whom data/document is available

0

Under which criteria data/document could be used

0

From where data/document is obtainable

0

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

0

Comments