

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of self-management program on self-efficacy and life satisfaction of patients with spinal cord injury (SCI)

Protocol summary

Summary

aim : This research aims to determine the effect of self-management program on self-efficacy and life satisfaction of patients with spinal cord injury (SCI).
Design: This research is a randomized clinical trial study do on 66 patients with SCI. **Population:** The study populations include patients with spinal cord injury patients referred to the Iran Spinal Cord Disability Support Center and eligible to enter the study. **Inclusion criteria:** Aged 65-18 years; history of spinal cord injury from 3 months to 6 years; Spinal cord injury leading to paraplegia; not having trouble communicating (like deafness and blindness); Making phone calls. **Exclusion criteria:** Unwilling to participate in the study; the deterioration of the patients' condition prevents them from participating in the program. **Method:** The available sampling is done among Spinal Cord Injury patients referred to the Iran Spinal Cord Disability Support Center base on inclusion criteria. Then, random allocation of patients is done in two groups of intervention and control using random numbers. **Intervention:** The control group receive routine care. For the intervention group, self-management program is implement based on five self-management skills. Patients in both groups will complete moorong self-efficacy (MSES) and life satisfaction (SWLS) questionnaires before intervention. In intervention group, self-management sessions will be performed in 4 sessions of 2 hour, two session a week. After completing the intervention, a follow-up program is conducted for 12 weeks each week by the researcher for samples. **Main outcome measures (variables):** self-efficacy and life satisfaction.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201710306314N3**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Soraya Nejati

Name of organization / entity

Tehran University Medical of Science

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Recruitment status

Recruitment complete

Funding source

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Expected recruitment start date

2017-10-07, 1396/07/15

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of self-management program on self-efficacy and life satisfaction of patients with spinal cord injury (SCI)

Public title

The effect of self-management program on self-efficacy and life satisfaction of patients with spinal cord injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Aged 65-18 yrs, The history of spinal cord injury from 3 months to 6 yrs; Spinal cord injury leading to paraplegia; Not having trouble communicating (like deafness and blindness; Making phone calls.
exclusion criteria: Unwilling to participate in the study; The deterioration of the patients' condition prevents them from participating in the program.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Ethicsl Committee of Tehran Faculty of Nursing and Midwifery and rehabilitation

Street address

Faculty of Nursing and Midwifery, Nosrat Sharghi Street, Tohid Square, Tehran

City

Tehran

Postal code

Approval date

2016-12-27, 1395/10/07

Ethics committee reference number

IR.TUMS.FNM.REC.1395.1328

Health conditions studied

1

Description of health condition studied

spinal cord injury

ICD-10 code

G95.2

ICD-10 code description

Cord compression, unspecified

Primary outcomes

1

Description

self-efficacy

Timepoint

Before the intervention, one month and three months after the end of the intervention

Method of measurement

Morong Self-Efficacy Questionnaire (MSES)

2

Description

Satisfaction of life

Timepoint

Before the intervention, one month and three months after the end of the intervention

Method of measurement

Life satisfaction questionnaire (SWLS)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: : The control group receive routine care.

Category

N/A

2

Description

For the intervention group, self-management program is implement based on five self-management skills, including: 1. Problem-solving skills. 2. Decision-making skills. 3. Use of resources. 4. Formation of therapeutic communication between caregiver and patient. 5. Operational program. In intervention group, self-management sessions will be performed in 4 sessions of 2 hour, two session a week.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Spinal Cord Disability Support Center

Full name of responsible person

Masoumeh Taghizadeh

Street address

Rehabilitation and Educational Center for Spinal Cord Injury Shohada Jalayipour, Fire Department Street, behind the Shahid Akbar Abadi Hospital, Mowlavi Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammadali Sahraian

Street address

Central building of Tehran University of Medical Sciences, Qhds street, Keshavarz Blvd.

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Faculty of Nursing and Midwifery, Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Taghizadeh

Position

Msn student in Medical-Surgical Nursing

Other areas of specialty/work

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty