Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of a program based on family-centered empowerment model on perceived threats and care burden in family carers of spinal cord injured patients

Protocol summary

Study aim
Determining the impact of a program based on a family-centered empowerment model on perceived threats and care burden in family carers of spinal cord injured patients referring to the Spinal Cord Injury Society of Isfahan Selected Centers of the University of Medical Sciences in 2018

Design
A three stage clinical trial with an intervention group and a control group, and 35 patients in each group

Settings and conduct
A study is conducted at the Isfahan Spinal Cord Injury Association and the Tavana Rehabilitation and Training Center for the Spinal Cord Injury in Shahre-kord. After implementation of the empowerment program on caregivers of patients in four stages, evaluation is performed one and three months later.

Participants/Inclusion and exclusion criteria
Inclusion criteria: the caregiver is required to be between 18-60 years old; have taken care of a patient with spinal cord injury for at least 6 months; have reading and writing skills in the caregiver Non-inclusion criteria: The caregiver suffers from any acute or chronic physical disorders and psychological disorders; Membership of the caregiver in the health care team

Intervention groups
Intervention group: In this group, the family-centered empowerment program is four-step. Step 1: Perceived threats that is include perceived severity and perceived sensitivity. Step Two: This step is about improving self-efficacy in which caregivers is trained their skills in practice. Step Three: This step is to increase self esteem or self confidence through educational participation. Step Four: Includes process evaluation and final evaluation. Control group: This group receive the same training as the intervention group in a general, in summary and in two sessions. The evaluation of this group will be one and three months after the intervention, as in the intervention group.

Main outcome variables
Severity of perceived threat; burden of care

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20171216037895N3**
Registration date: **2019-06-04, 1398/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-04, 1398/03/14**
Update count: **0**

Registration date
2019-06-04, 1398/03/14

Registrant information

Name
Mohsen Torabi Khah

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-01, 1397/12/10

Expected recruitment end date
2019-08-21, 1398/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a program based on family-centered empowerment model on perceived threats and care burden in family carers of spinal cord injured patients

Public title

The impact of empowerment on perceived threat and care burden in caregivers of spinal cord injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The caregiver is required to be at least 18 and maximally 60 years old Have directly and actively taken care of a patient with spinal cord injury for at least 6 months and deserve to make decisions concerning the treatment of the injured person Have obtained the informed written consent for participation in the research Have no hearing or vision impairment for participation in the training sessions for caregiver Have reading literacy for caregiver Have no mental disorders or chronic physical illness and also have no history of taking medication and psychoactive substances for caregiver Have no history of participation in any training session or any research related to the subject of this study for caregiver Living the caregiver with a patient suffering from injured spinal cord injury Have obtained a Barthel Index (King's version) score less than and equal to 90 in Injured

Exclusion criteria:

Having other acute or chronic physical disorders and psychological disorders in the caregiver Caregiver membership in the healthcare team

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Among the injured and the caregivers who meet the inclusion criteria of the study, the caregiver is asked to randomly pick one of the two balls from the bag. People who pick the Ball 1 will be put into the intervention group and those who take the number 2 will be allocated to the control 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 Isfahan University of Medical Sciences

Street address

Hezarjarib

City

Isfahan

Province

Isfehan

Postal code

8174673461

Approval date

2019-02-27, 1397/12/08

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.490

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

Severity of perceived threat

Timepoint

One and three months after the intervention

Method of measurement

Questionnaire

2

Description

Burden of care

Timepoint

One and three months after the intervention

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, the family-centered empowerment program is implemented through four steps. Step 1: the Perceived threats including perceived severity and perceived sensitivity. In perceived severity, related to the complications and risks of the disease, a questionnaire, having 14 questions and Likert responses will be used. Based on the results of this survey, for the five most common issues, five one-hour training sessions, along with discussion will be held in the group. Each group includes 9 people. Before the start of the first session, an examination on the provided care amount and the threat perceived by caregivers will be taken to compare the grades obtained in one and three months after the implementation of the family-centered empowerment program. In this section, the concepts are also provided to caregivers through pamphlets and booklets. For perceived sensitivity, a questionnaire having 14 questions, along with Likert responses will be used. At this part, in three one-hour sessions, the management of the anxiety, depression and the stress associated with the care of the patients injured in his/her spinal cord will be taught in group. The concepts in this section are also given to caregivers in using pamphlets and booklets. Step Two: This step is on improving self-efficacy through which caregivers are trained with practical skills. In a group session, and via problem solving method, caregivers' problems will be identified and prioritized, then solutions will be discussed by themselves. Each skill will then be taught in a practical way and will be taught taking self-efficacy steps. In three one-hour sessions, caregivers are provided with the method/s of controlling vital signs, physiotherapy of limbs and Kegel and Crede's exercises. The concepts in this section are also provided to caregivers through pamphlets and booklets. Step Three: This step is to increase self-esteem or self-confidence through educational participation. At this stage, caregivers are asked to convey the materials acquired through group discussion, as well as the lessons learnt on self-efficacy, into their own patients. Training cards, containing the materials presented in each session, will also be given to family caregivers to deliver to their patients. In case questions or problems raise, caregivers will write down the related questions and submit them or those of their patients to the nurses in the next sessions attending the center of the spinal cord injury. Given that patients may not be empowered through the training provided to family caregivers and studying the training cards, in order to discuss the materials provided by the family caregivers and what the patients have been learnt using the card, they and their family caregivers are invited to the center. Step Four: It includes process evaluation and the final assessment. To evaluate the process, at the beginning of each session, caregivers are asked to verbally respond to 5 questions on the concepts contained in the training session on the day the session held. The answers to this section will be compared at the end of the session. For the final evaluation, a written test will be carried out by the caregivers who will calculate the score of the care amount and perceived threat within one and three months after the intervention.

Category

Other

2

Description

Control group: The same materials, i.e., the whole materials and their summary, are given to this group (like those provided for the intervention group) in two sessions. This group, as the same as the intervention group, will be evaluated at one and three months after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and Rehabilitation Center for Injured Spinal Cord Injury

Full name of responsible person

Fatemeh Karami-Zadeh

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2

Recruitment center

Name of recruitment center

Isfahan Spinal Cord Association

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Esfahan 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
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Person responsible for updating data

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

Clinical Study Report
Undecided - It is not yet known if there will be 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