

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

The effect of nurse counseling and telephone follow-up on anxiety and care burden of family caregivers of patients with spinal cord injury

Protocol summary

Study aim

Determining the effect of nurse counseling and telephone follow-up on anxiety and care burden of family caregivers of patients with spinal cord injury after discharge from educational and medical centers

Design

Clinical trial with control group, with parallel groups, one-way blind, randomized. Then, in a randomized permutation block, a list of random numbers is prepared and based on that, the samples are assigned to two groups of control and intervention.

Settings and conduct

In welfare centers affiliated to Shiraz University of Medical Sciences - Iran (education and counseling (about anxiety and coping strategies, crisis and ways to deal with it, urinary tract infection, skin care and bed sore prevention, training on moving people with lesions) Spinal, proper nutrition) during absentee sessions. One-way blindness: outcome assessor, data analyst and participants

Participants/Inclusion and exclusion criteria

Family caregivers of patients with spinal cord injury aged 18 to 70 years with at least six months of spinal cord injury care, No mental illness and acute cognitive disorders, Ability to understand, speak, read and write Persian No entry: Failure to answer the researcher's phone three times in a row, Severe hearing problems Patient care

Intervention groups

Members of the intervention group, within 4 weeks (12 absentee and telephone sessions) The topics are taught in six sessions and then followed up in the next six sessions based on a checklist. In the control group, no intervention is performed and the patients' families will receive only routine training, routine care and as needed. At the end of the study, in order to observe ethical considerations, a booklet will be provided to the control group in line with all the materials presented during the educational intervention.

Main outcome variables

Anxiety and care burden of family caregivers of patients with spinal cord injury

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220603055068N1**

Registration date: **2022-07-12, 1401/04/21**

Registration timing: **prospective**

Last update: **2022-07-12, 1401/04/21**

Update count: **0**

Registration date

2022-07-12, 1401/04/21

Registrant information

Name

Leyla Barani kazeruni

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 17 3573 6059

Email address

leyla.barani28@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-06, 1401/05/15

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of nurse counseling and telephone follow-up on anxiety and care burden of family caregivers of patients with spinal cord injury

Public title
The effect of counseling and telephone follow-up on anxiety and the burden of care

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Ability to access the phone (fixed and mobile)
Willingness to collaborate in the study Care age between 18 and 65 years Caring for a person with any spinal cord injury Lack of mental illness and acute cognitive disorders in caregivers Have at least six months of care for a patient with a spinal cord injury Have the ability to understand, speak, and read and write Persian
Exclusion criteria:
Incomplete completion of the questionnaire information Failure to answer the researcher's phone three times in a row Severe hearing problems Patient care Reluctance to continue cooperation

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The random allocation method in this study will be permutation block method. This method is implemented by considering blocks of 2 so that the total number of possible binary permutations is equal to 2. The desired random list of 60 which includes 30 blocks of 2 is produced and the order of allocation of each of the methods to the samples participating in the study is determined. The way to use the table of random numbers is that the starting point is random 30 numbers will be chosen randomly (row or column) and the permutation assigned to each number will be noted down and the method of allocating 60 people to two intervention and control groups will be determined.

Blinding (investigator's opinion)
Single blinded

Blinding description
The method of blinding will be that the questionnaires will be distributed and collected with the help of a

researcher who is not aware of the control and intervention group, and also the statistician who analyzes the data will not know the groups and the patients' family caregivers. They will also be unaware of the control and intervention group.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Namazi Square, Namazi Hospital, Fatemeh School of Nursing and Midwifery

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2022-05-31, 1401/03/10

Ethics committee reference number

IR.SUMS.NUMIMG.REC.1401.035

Health conditions studied

1

Description of health condition studied

Family caregivers of patients with spinal cord injury

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score in Spielberger questionnaire

Timepoint

Assess the level of caregivers' anxiety before the intervention and after the intervention

Method of measurement

State-Trait Anxiety Inventory

Secondary outcomes

1

Description

Caregiver care load score

Timepoint

At the beginning of the study and after the end of the intervention

Method of measurement

Zarit Burden Inventory

Intervention groups

1

Description

Intervention group: The participants of the intervention group, after completing the questionnaires, within 4 weeks (12 absentee and telephone sessions) in connection with topics including: 1- Anxiety and strategies to deal with it 2- Crisis and ways to deal with it 3- Urinary tract infection 4- Skin care and prevention of bed sores 5 - Training related to moving people with spinal cord injury 6- Proper nutrition is taught in the first six absentee and telephone sessions, and then in the next six absentee and telephone sessions, based on the checklist prepared by the researcher, the patients' family caregivers are followed up. At the end of 4 weeks, they will complete the anxiety and care burden questionnaires in person again.

Category

Behavior

2

Description

Control group: They will first complete a informed consent form, demographic and medical information questionnaires, and a caregiver. In the control group, there is no intervention and the family caregivers of the patients will receive only the usual care and routine training as needed. At the end of 4 weeks, they will complete the anxiety and care burden questionnaires in person again. At the end of the study, in order to observe ethical considerations, a booklet will be provided to the control group in line with all the materials presented during the educational intervention.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shiraz city welfare office

Full name of responsible person

Mohammad Reza Hoshyar

Street address

Shiraz, Airborne Crossroads, Sarbaz St., corner of Shahid Etemadi St.

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7174667566

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

Street address

Shiraz, Zand St., in front of Palestine St., the central building of Shiraz University of Medical Sciences

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71348-14336

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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

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Malazam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shiraz, Namazi Square, Hazrat Fatemeh School of Nursing

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Email

molazemzah@yahoo.com

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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Malazam

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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

Shiraz University of Medical Sciences

Full name of responsible person

Leila Barani Kazeruni

Position

Nursing Graduate Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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leyla.barani28@gmail.com

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

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Obtaining an official letter of introduction from Hazrat Fatemeh School of Midwifery and Nursing in Shiraz and obtaining permission from the officials of Shiraz University of Medical Sciences Obtaining written consent from the samples to participate in the study - Assuring the research units about the confidentiality of the information received - Participate freely and completely voluntarily in the research samples and considering the right to withdraw from the research - Creating a private environment for interviewing the patient and completing a questionnaire Provide the results of the research if desired by the training center where the researcher has sampled.

When the data will become available and for how long

After studying and printing the results

To whom data/document is available

The results of the research will be provided to the participants and relevant organizations upon request.

Under which criteria data/document could be used

Obtaining permission from the relevant authorities in the faculty, university and welfare centers. Keeping participants' information confidential

From where data/document is obtainable

Shiraz. Zand St., Shiraz School of Nursing and Midwifery Library. Mr. Ghasemi's library manager. Phone: 00987136474254

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

The request for the results will be sent to the library of Shiraz School of Nursing and Midwifery. It will be provided to them with the coordination done.

Comments

