Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)
Phone
+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.
City
Shiraz
Province
Fars
Postal code
7174667566
Phone
+98 71 3838 1242
Email
Info@behzisti-fars.ir

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
City
Shiraz
Province
Fars
Postal code
71348-14336
Phone
+98 71 3212 2713
Email
info@sums.ac.ir
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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Province
Fars
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71345-1978
Phone
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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
Street address
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City
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71345-1978
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Email
molazemzah@yahoo.com

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
Street address
Shiraz, Namazi Square "Namazi Hospital" Fatemeh School of Nursing and Midwifery
City
Shiraz
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Postal code
71936-13119
Phone
+98 38 3257 3907
Email
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