Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The investigation The effect of psycho-educational interventions on quality of life of family caregivers

Protocol summary

Summary

The present clinical trial was conducted on 62 family caregivers who had the primary responsibility of taking care of the patients with spinal cord injury. The participants were randomly divided into intervention (n=33) and control groups (n=29). The intervention group was involved in 90-minute educational sessions held once a week for four weeks. Both groups completed SF-36 questionnaire before and 2 and 6 weeks after the intervention. Then, the data were analyzed through independent t-test, Chi-square, and repeated measures ANOVA tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070811388N2**
Registration date: **2013-07-20, 1392/04/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-20, 1392/04/29

Registrant information

Name

Taybeh Falahati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1647 4251

Email address

falahatit@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellar for research of Shiraz University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-06-21, 1391/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigation The effect of psycho-educational interventions on quality of life of family caregivers

Public title

The effect of psycho-educational interventions on quality of life of family caregivers of patient with spinal cord injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: The individuals who had been the primary caregiver of a patient for one year and were willing to take part in the study were recruited into the research. Having access to telephone. Exclusion criteria of the study were having a history of hospitalization, suffering from known mental disorders, and being under treatment by psychiatric medications.

Age

To **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University of Medical Sciences

Street address

Shiraz, Zand street

City

Shiraz

Postal code

71345-1978

Approval date

2012-10-07, 1391/07/16

Ethics committee reference number

91/6266

Health conditions studied

1

Description of health condition studied

Spinal cord injury

ICD-10 code

G90-G99

ICD-10 code description

Other disorders of the nervous system

Primary outcomes

1

Description

Quality of life

Timepoint

Before, two & six weeks after the end of study

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

No intervention in control group

Category

Other

2

Description

Psycho-educational intervention for intervention group

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatholmobine Welfare center of Shiraz

Full name of responsible person

Ms.Ebrahimi

Street address

Shiraz, Cuie Zahra

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellar for research of Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

Street address

Shiraz University of Medical Sciences, Zand Street

City

Shiraz

Grant name

91/243010

Grant code / Reference number

91/6266

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

Yes

Title of funding source

Vice chancellar for research of Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Dr.Zahra Molazem

Position

PH.D, faculty member, Nursing Department

Other areas of specialty/work

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Web page address

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