

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The investigation of effect of psycho-educational interventions on mental health of family caregivers of patient with spinal cord injury

Protocol summary

Summary

This research was a clinical trial which was done on 72 family caregivers of patients with spinal cord injury who had referred to Fatholmobine welfare center of Shiraz city. Caregivers were selected with convenient sampling then randomized to experimental & control groups. Caregivers of experimental group participated in psycho-educational interventions program but caregivers of control group didn't participate in this program. psycho-educational intervention 4 session were performed one day a week, each session would 90 min. The purpose of this study was determining & comparing caregivers mental health before, two & six weeks after execution of psycho-educational interventions program in intervention & control group and between groups. The data were collected by GHQ-28 questionnaire which completed by caregivers of both groups before, two & six weeks after executing psycho-educational interventions.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012110611388N1**

Registration date: **2013-03-24, 1392/01/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-24, 1392/01/04

Registrant information

Name

Taybeh Falahati

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1647 4251

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falahatit@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor 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 of effect of psycho-educational interventions on mental health of family caregivers of patient with spinal cord injury

Public title

The effect of psycho-educational interventions on mental health of family caregivers of patient with spinal cord injury

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Having the primary role of caregiver, Responsible for caregiving of patient with SCI over a year, Having access to telephone, Having the tendency to participate in the study. Exclusion criteria: Having history of identified mental disorder or hospitalization and use psychotropic drugs.

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

Mental health

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

N/A

2

Description

The psycho-educational intervention that was performed in this research consisted of four consecutive weekly sessions, each session would 90 min. Providing information about strategies of coping with stress & depression, teaching effective communication, strategies of coping with crisis, teaching proper cares of patient with spinal cord injury.

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 chancellor for research of Shiraz University of Medical Sciences

Full name of responsible person

Gholamreza Hatam

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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 chancellor 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

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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