

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 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 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 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 chancellor 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 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*

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molazemzah@yahoo.com

**Web page address**

## 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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Nursing & midwifery school, Zand Street

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## Person responsible for updating data

### Contact

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Taybeh Falahati

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Postgraduate nursing student

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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Dr.Zahra Molazem

**Position**  
PH.D, faculty member, Nursing Department

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13119-71936

**Phone**

## 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*