

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of psycho-educational interventions on resilience of mothers who have 1-3 year old children with chronic liver diseases leading to cirrhosis

Protocol summary

Summary

1) Aims: To examine the effect of educational-psychological interventions on the resilience of mothers with children aged 1-3 years with chronic liver disease leading to cirrhosis. 2) Design: in this clinical trial study, 83 mothers with children with chronic illness led to cirrhosis of the liver, who were eligible for inclusion in the study, were selected by multi-permutational block method and randomly divided into two groups Test (n = 41) and control (n = 42). 4) Inclusion and exclusion criteria: mothers with children aged 1 to 3 years with chronic liver disease leading to cirrhosis; Absence of a crisis or stressful event such as divorce, separation from husband, imprisonment, death of a family member, loss of job and family disputes during the past year and during the study. 5) Interventions: The test group participated in six sessions of 45 minutes three times a week, and the control group did not receive intervention. 6) Main outcome variables: Maternal resilience score before, immediately after and one month after intervention

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017062434732N1**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name

Minoolaleh Haghshenas

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Deputy of Research of Shiraz University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of psycho-educational interventions on resilience of mothers who have 1-3 year old children with chronic liver diseases leading to cirrhosis

Public title

The effect of psycho-educational interventions on resilience of mothers who have 1-3 year old children with chronic liver diseases leading to cirrhosis referring to centers related to Shiraz University of Medical Sciences 2015

Purpose

Supportive

Inclusion/Exclusion criteria

Criteria for entering the study: - Age of the mother older than 18 years; - Inclination to participate in the study; - Completion of the consent form; - Farsi language proficiency and at least reading and writing literacy; - Non-emergence of a crisis or stressful event such as divorce, separation from the spouse, Imprisonment, death of a family member, loss of job and family disputes over the past year and during the study - the lack of use of sedative and anti-anxiety drugs according to the mother - no physical or mental illness that participated in the intervention Mother interferes, according to her mother - No participation in other educational programs during the study - No chronic disease. Air of children or family - Absence of a member of the medical and care staff - Confirmation of chronic liver disease leads to cirrhosis of the child by a specialist - age of the child is between 1-3 years of age - Non-hospitalization of the child during the study period Exit criteria: - Lack of Desire to cooperate during the study - Absence of more than 2 sessions in classes - Severe illness or child death

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **83**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee Shiraz University of Medical Sciences

Street address

Zand street, Shiraz

City

Shiraz

Postal code

71345-1978

Approval date

2015-11-29, 1394/09/08

Ethics committee reference number

IR.SUMS.REC.1394.139

Health conditions studied

1

Description of health condition studied

Chronic liver disease leads to cirrhosis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

resilience

Timepoint

before, immediately and one month after intervention

Method of measurement

Conner-Davidson Resilience Questionnaire (CD-RISC)

Secondary outcomes

1

Description

No

Timepoint

No

Method of measurement

No

Intervention groups

1

Description

Control group: After completing the questionnaires, the control group is given a booklet

Category

Behavior

2

Description

intervention group: face to face education in accordance with the educational booklet for mothers of children with chronic liver disease leading to cirrhosis

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person
Street address
City
Shiraz

2

Recruitment center
Name of recruitment center
Imam Reza Clinic
Full name of responsible person
Street address
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
Dr. Seyed Basir Hashemi
Street address
Fars Province, Shiraz, Zand
City
Shiraz
Grant name
Grant code / Reference number
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

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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