

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

The effect of resilience training for mothers on pain intensity of burned children hospitalized in Burn Hospital in Shiraz

Protocol summary

Study aim

Determining the effect of resilience training for mothers on the pain of children with burns referred to burn hospitals in Shiraz

Design

Clinical trial with control group, with consecutive groups, double-blind, on 50 patients.

Settings and conduct

Research environment in this research, Amir Al-Momenin Burn Hospital is located in Shiraz. To select the samples, the files of patients admitted to the burn hospital are identified and then the files that meet the inclusion criteria are separated. Participants in the experimental group participate in 6 training sessions every morning. Participants in the control group receive routine care. Participants, the person evaluating the questionnaires and analyzer of the data did not know the type of patient grouping. After obtaining informed consent, mothers complete a resilience questionnaire before the start of the first session, before the start of the fourth session, and immediately after the last session (day 6). Children fill in the visual pain scale every day until discharge. Participants in the control group also complete the questionnaires on the same days.

Participants/Inclusion and exclusion criteria

Inclusion criteria: diagnosis of burns in a child by the treating physician; age 6-12 years old in a child. Literacy in the mother; willingness to participate in research in children and mothers. Exclusion criteria: if the mother or child has a chronic physical or mental illness.

Intervention groups

Participants in the experimental group participate in 6 training sessions every morning with the topics: stress management (2 sessions), recognizing cognitive errors and how to manage it (2 sessions), positive psychology techniques (2 sessions). Trainings are held in groups of 3 to 6 people. Participants in the control group receive routine care.

Main outcome variables

Resilience; pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201001048893N2**

Registration date: **2020-12-08, 1399/09/18**

Registration timing: **retrospective**

Last update: **2020-12-08, 1399/09/18**

Update count: **0**

Registration date

2020-12-08, 1399/09/18

Registrant information

Name

Maryam Shaygan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3626 7345

Email address

m2620.shaygan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-23, 1398/08/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

2019-11-24, 1398/09/03

Actual recruitment end date

2020-04-08, 1399/01/20

Trial completion date

2020-04-14, 1399/01/26

Scientific title

The effect of resilience training for mothers on pain intensity of burned children hospitalized in Burn Hospital in Shiraz

Public title

The effect of resilience training for mothers on pain intensity of burned children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosis of burns in children by the treating physician
Age 6-12 years old in the child
Literacy in the mother
Willingness to participate in research in children and mothers

Exclusion criteria:

If the mother or child has a chronic physical or mental illness

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Everyone involved in the study thought that all participants received the intervention. Thus, the experimental group assumed that all participants in the study received these trainings, and the control group assumed that all participants received educational information through the booklet after discharge. It should be noted that in order to prevent data contamination, patients were assigned to experimental and control groups in a sequential manner. In addition, outcome assessors were unaware of patient grouping.

Placebo

Not used

Assignment

Other

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

School of Nursing and Midwifery, Nemazee Square, Zand St., Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71936-13119

Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.SUMS.REC.1398.1098

Health conditions studied

1

Description of health condition studied

Burn pain

ICD-10 code

G89.11

ICD-10 code description

Acute pain due to trauma

Primary outcomes

1

Description

Resilience

Timepoint

Mothers complete the resilience questionnaire before the first session, before the fourth session (fourth day) and immediately after the last session (sixth day).

Method of measurement

Connor Davidson Resilience Scale

2

Description

Pain Intensity in children

Timepoint

Daily

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: participants in the experimental group participate in 6 training sessions every morning with the topics: stress management (2 sessions), recognizing cognitive errors and how to manage it (2 sessions), positive psychology techniques (2 sessions). Trainings are held in groups of 3 to 6 people.

Category

Behavior

2

Description

Control group: participants in the control group receive routine care. For ethical considerations, at the end of the intervention, trainings in the form of pamphlets are provided to the control group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Al-Momenin Burn Hospital

Full name of responsible person

Maryam Shaygan

Street address

Faculty of Nursing and Midwifery, Namazi Sq. Shiraz, Iran

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713451359

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+98 71 3647 4254

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m2620.shaygan@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Abbas Rezaeianzadeh

Street address

Administration Building of Shiraz University of Medical Sciences Zand St., Shiraz, Iran

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Postal code

71348-14336

Phone

+98 71 3230 5410

Email

vcrdep@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

Maryam Shaygan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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School of Nursing and Midwifery, Nemazee Square, Zand St., Shiraz, Iran

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Fax**Email**

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Anonymous study data will be shared in correspondence
with the project manager

When the data will become available and for how long

Access period starts 6 months after the results are
published

To whom data/document is available

Researchers working in academic and scientific
institutions

Under which criteria data/document could be used

Systematic reviews and meta-analyses

From where data/document is obtainable

Contact via email

What processes are involved for a request to access data/document

After obtaining permission from the security unit and the
university's vice chancellor for research, the data will be
made available to the individual.

Comments