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

City
Shiraz

Province
Fars

Postal code
713451359

Phone
+98 71 3647 4254

Email
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

City
Shiraz

Province
Fars

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

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

City
Shiraz

Province
Fars

Postal code
713451359

Phone
+98 71 3626 7345

Fax

Email
m2620.shaygan@gmail.com

Person responsible for scientific inquiries

Contact

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Shiraz University of Medical Sciences

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Associate professor

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Person responsible for updating data

Contact
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Shiraz University of Medical Sciences
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Maryam Shaygan
Position
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Psychology
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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