Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

The effectiveness of a family-centered care on the aggression and Post-traumatic stress disorder (PTSD) in parents with congenital anomalies' infants

Protocol summary

Study aim

Determining and comparing the mean scores of post-traumatic stress disorder and aggression in parents of babies with congenital anomalies before, immediately and one month after the intervention in two experimental and control groups

Design

A clinical trial with an intervention and control group will be conducted as a block randomization, a blind strain, phase 3 on 74 parents

Settings and conduct

Chamran, Al-Zahra and Imam Hossein hospitals in Isfahan. The revised event impact of event and trait anger questionnaire on the first day and the perceived social support questionnaire, coping with stress and parents' stress measurement in the neonatal intensive care unit will be answered by the parents on the third day after the end of the intervention and one month after the end of the intervention. After collecting the questionnaires, the intervention will be implemented for the parents of the intervention group.

Participants/Inclusion and exclusion criteria

Entry criteria for post-traumatic stress disorder score above 24 and exclusion criteria for congenital anomalies requiring emergency surgery, absence and non-participation of parents in 1 or more sessions

Intervention groups

The intervention of the family-centered support educational program based on four steps (information exchange, self-efficacy promotion, self-confidence (self-esteem) and evaluation) during 5 daily sessions to parents in the form of teaching care for babies with abnormalities, participation in baby care, facilitating communication and mutual support Couples and psychoeducation about stress will be provided, and the control group will receive usual routine care

Main outcome variables

The independent variable of the educational support program for parents is of qualitative and nominal type, the dependent variables of psychological consequences of parents (PTSD and aggression) are of quantitative type

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220605055080N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Fateme Vaez

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 902 936 8800

Email address

fateme0vaez@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effectiveness of a family-centered care on the aggression and Post-traumatic stress disorder (PTSD) in parents with congenital anomalies' infants

Public title
The effectiveness of a family-centered care on the aggression and Post-traumatic stress disorder (PTSD) in parents with congenital anomalies' infants
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Post-traumatic stress disorder score above 24 Parents with a baby with any congenital abnormality requiring hospitalization in the neonatal intensive care unit Literate to read and write Parents without any mental disorder or history of taking psychiatric drugs Absence History of substance abuse in parents
Exclusion criteria:
Death of the baby during the intervention Congenital abnormalities requiring emergency surgery Discharge of the baby during the intervention Occurrence of a stressful incident while studying Absence and non-participation of parents in 1 or more sessions Dissatisfaction and unwillingness of the baby's family to continue cooperating with the researcher at every stage of the study
Age
No age limit
Gender
Both

Phase
4
Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **74**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Before starting the study, we will refer to the samples and explain the study to them, and after obtaining informed consent, they will be randomly assigned to the control or intervention group. Participants will not be informed whether the participant is currently in the intervention or control group. Also, the data will be coded so that the statistician will not be informed of the control or intervention group of the data.
Placebo
Not used
Assignment
Other
Other design features
The selected samples will be assigned to the control or intervention group by block randomization. This method will continue until the number of samples reaches the desired number of samples.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Central headquarters, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.
City
Isfahan
Province
Isfehan
Postal code
81746-73461
Approval date
2022-08-27, 1401/06/05
Ethics committee reference number
IR.MUI.NUREMA.REC.1401.067

Health conditions studied

1

Description of health condition studied
Post-traumatic stress disorder
ICD-10 code
F43.1
ICD-10 code description
Post-traumatic stress disorder (PTSD)

Primary outcomes

1

Description
The average score of post-traumatic stress disorder changes in parents of babies with congenital malformation is different in the control and test groups after the intervention.
Timepoint
before the start of the intervention and one month after the end of the intervention
Method of measurement
Revised Weiss and Marmer Impact of Event Questionnaire (IES-R)

Secondary outcomes

1

Description
The average score of aggression changes in the parents of babies with congenital anomalies is different in the control and test groups after the intervention.

Timepoint
before the start of the intervention and one month after the end of the intervention

Method of measurement
Spielberger Trait Anger Questionnaire (STAXI-2)

Intervention groups

1

Description
Intervention group: This group will be subjected to the intervention of the family-oriented educational-support program based on four steps (information exchange, self-efficacy promotion, self-confidence (self-esteem) and evaluation) during 5 sessions; In this way, providing daily training to parents in the form of caring for babies with abnormalities, participation in baby care, facilitating communication and mutual support of couples, and psychological training regarding the stress associated with the presence of fathers and mothers of babies with abnormalities hospitalized in the intensive care unit. will be. In addition, an educational pamphlet will be provided to them. Family-centered care will be done with the presence of parents and the researcher in the breastfeeding room and the neonatal intensive care unit next to the baby. The researcher will receive the necessary training for counseling from the research consultant. The phone and SMS system will be used during the study period to resolve the questions and concerns of the parents.

Category
Other

2

Description
Control group: Parents of infants in the control group will receive routine care from the neonatal intensive care unit of Chamran, Al-Zahra and Imam Hossein (AS) hospitals in Isfahan, and no intervention will be performed on them. After the end of the intervention and one month after the end of the intervention, the Revised Weiss and Marmer Event Impact Questionnaire (IES-R) and the Spielberger Trait-State Anger Questionnaire (STAXI-2) will be completed for mothers in each control group. The phone and SMS system will be used during the study period to solve the questions and concerns of parents.

Category
N/A

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran Hospital, Isfahan

Full name of responsible person
Alireza Hosseini

Street address
Shahid Chamran Heart Training and Research Center, After Shahristan Bridge, Third Mushtaq St.

City
Isfahan

Province
Isfehan

Postal code
81583-88997

Phone
+98 31 3260 0961

Email
chamran@mui.ac.ir

Web page address
https://chamran.mui.ac.ir/

2

Recruitment center

Name of recruitment center
Isfahan, Imam Hossein Hospital

Full name of responsible person
Mehrdad Memarzadeh

Street address
Imam Hossein (AS) Children's Educational and Therapeutic Center, Before Esteghlal Square, Imam Khomeini Street (RA), Isfahan.

City
Isfahan

Province
Isfehan

Postal code
8195163381

Phone
+98 31 3386 6266

Fax
+98 31 3386 8286

Email
emamhossein_hospital@mui.ac.ir

Web page address
https://ehuch.mui.ac.ir/

3

Recruitment center

Name of recruitment center
Isfahan, Al-Zahra Hospital

Full name of responsible person
Mehrdad Nowrozi

Street address
Al-Zahra Medical Education Center, Safeh Blvd, Shahid Kishori Highway, Isfahan.

City
Isfahan

Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Fax
+98 31 3669 1510
Email
alzahra@mui.ac.ir
Web page address
https://alzahra.mui.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Kianpour
Street address
Research Centers of the Faculty of Nursing and Midwifery, Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hazar Jarib Street, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 7621
Fax
+98 31 3669 9398
Email
nmrc@nm.mui.ac.ir
Web page address
https://mui.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fateme Vaez
Position
Master's degree student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Forozan 8th Alley, Arghvan St, Ferdowsi Square, Goldasht East.
City
Khorramabad
Province
Lorestan
Postal code
6819765996
Phone
+98 66 3341 8247
Email
fateme0vaez@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Faramarz Kalhor
Position
science Committee
Latest degree
Master
Other areas of specialty/work
Nursery
Street address
Nursing and Midwifery College, Isfahan University of Medical Sciences and Health Services, Hazar Jarib St.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 7153
Email
kalhor.faramarz@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fateme Vaez

Position
Master's degree student
Latest degree
Bachelor
Other areas of specialty/work
Nursery
Street address
Forozan 8th Alley, Arghvan St, Ferdowsi Square, Goldasht East.
City
Khorramabad
Province
Lorestan
Postal code
6819765996
Phone
+98 66 3341 8247
Email
fateme0vaez@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The analyzed data is usable
When the data will become available and for how long
The analyzed data can be used after printing the results
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
there is no access to the raw data
From where data/document is obtainable
there is no access to the raw data
What processes are involved for a request to access data/document
there is no access to the raw data
Comments