Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Investigating the effect of psychological education on mothers' self-efficacy and their anxiety before their children's surgery

Protocol summary

Study aim
This study assesses how psychological education reduces mothers' preoperative anxiety and boosts self-efficacy, guiding development of hospital preoperative protocols.

Design
This RCT employs a pretest-posttest design allocating 62 mothers of pediatric surgery patients (31/group) via web-based randomization to intervention or control arms at Imam Ali (AS) Hospital, Karaj, following eligibility screening.

Settings and conduct
Study Population: Mothers of children under 7 years undergoing urologic surgery at Imam Ali (AS) Hospital, Karaj (2025) Intervention Group: Session 1: Surgical education + maternal anxiety analysis (DTR) + cognitive restructuring Session 2: Decatastrophizing techniques + progressive muscle relaxation + stress coping strategies Session 3: Post-operative challenge visualization + child care techniques Control Group: Standard surgical education

Participants/Inclusion and exclusion criteria
Inclusion criteria Mothers of children <7 years old scheduled for pediatric urologic surgery; No comorbid psychiatric disorders in either mother or child; Maternal score >43 on the Spielberger State Anxiety Inventory; Child's first surgical procedure; Mother's literacy (ability to read/write);Willingness to participate (signed consent form) Conditions of exclusion Mothers of children undergoing emergency or non-urologic surgeries; Diagnosis of any psychiatric disorder in either mother or child; Maternal Spielberger score <43; Children with previous surgical experience; Illiterate mothers or those unable to complete questionnaires; Refusal to consent or incomplete baseline data

Intervention groups
Experimental Group: Three virtual psychological education sessions for mothers Control Group: One educational session providing surgery-related information for mothers

Main outcome variables
Mothers' anxiety; Mothers' self-efficacy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250222064815N1**
Registration date: **2025-04-06, 1404/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2025-04-06, 1404/01/17**
Update count: **0**

Registration date
2025-04-06, 1404/01/17

Registrant information

Name
Maryam Hafez

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3253 5919

Email address
maryamhafez78@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-02-24, 1403/12/06

Expected recruitment end date
2025-05-20, 1404/02/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of psychological education on mothers' self-efficacy and their anxiety before their children's surgery

Public title

Investigating the effect of psycho education on mothers' self-efficacy and anxiety before their children's surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Mothers of children under 7 years of age on the verge of pediatric urological surgery Absence of comorbid psychiatric disorders in children Absence of major psychiatric disorders such as mood and psychotic disorders in mothers Mothers with a Spielberger State Anxiety Scale score above 43 First-time surgery in children Mothers having the ability to read and write Willingness to participate in the research and signing the consent form

Exclusion criteria:

Mothers of children undergoing emergency or non-urologic surgeries Diagnosis of any psychiatric disorder in either mother or child Maternal Spielberger State Anxiety score <43 Children with previous surgical experience Illiterate mothers or those unable to complete questionnaires Refusal to participate or incomplete baseline data

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **62**

Randomization (investigator's opinion)

Randomized

Randomization description

In this randomized controlled trial, we assign 62 participants to intervention or control groups using computerized randomization. Eligible mothers of children referred to Imam Ali (AS) Hospital’s pediatric surgery clinic are enrolled after meeting inclusion criteria. Allocation is based on the order of enrollment.

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 of Isfahan University of Medical Sciences

Street address

No. 33, Zanbaq 20, Zanbaq Blvd., Azimieh, Karaj Town

City

Karaj

Province

Alborz

Postal code

3155888856

Approval date

2024-12-14, 1403/09/24

Ethics committee reference number

IR.MUI.MED.REC.1403.394

Health conditions studied

1

Description of health condition studied

Anxiety and self-efficacy of mothers before their children's surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anxiety score on the Spielberger Anxiety Inventory

Timepoint

Before the start of psychoeducation sessions and after the sessions are completed until before surgery

Method of measurement

Spielberger State-Trait Anxiety Inventory

2

Description

Dumka Parenting Self-Efficacy Scale Score

Timepoint

Before the start of psychoeducation sessions and after the sessions are completed until before surgery

Method of measurement

Domka Parenting Self-Efficacy Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group:Three preoperative psychological education sessions for mothers:Session 1:Surgical education (admission process, procedure duration, recovery, hospitalization) Anxiety analysis using DTR technique Cognitive restructuring (information provision, probability evaluation, problem-solving) Session 2 :Surgery education review (if needed)Cognitive restructuring using de-catastrophizing Stress management:Progressive muscle relaxation training (with audio guide)Coping strategies for stressful situations. Session 3: Guided imagery for post-operative concerns Child care techniques:Distraction methods Pleasant stimulus provision.

Category

Treatment - Other

2

Description

The control group will participate in a single preoperative education session providing comprehensive information about the surgical process, including hospitalization procedures, expected duration of surgery and recovery, postoperative care requirements, and necessary hospitalization items. The session also includes a therapist-facilitated discussion where mothers can share concerns and questions about their child's surgery. This discussion is guided by the therapist but does not include any specialized psychological education or intervention, while providing a platform for participants to exchange experiences.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Ali (AS) Hospital
Full name of responsible person
Maryam Hafez
Street address
No. 33, Zanbaq 20, Zanbaq Blvd, Azimieh.
City
Karaj
Province
Alborz
Postal code
3155888586
Phone
+98 26 3253 5919
Email
maryamhafez78@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Asgari
Street address
Hezar Jerib Street, Isfahan University of Medical Sciences and Health Services, Building No. 4, Vice President for Research and Technology
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
askari@mui.ac.ir
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
Fatemeh Zargar
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Hezar Jerib Street, Isfahan University of Medical Sciences and Health Services, Faculty of Medicine
City
اصفهان
Province
Isfehan

Postal code
8174673461
Phone
+98 31 3792 8101
Email
fatemehzargar@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Zargar
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
Hezar Jerib Street, Isfahan University of Medical Sciences and Health Services, Faculty of Medicine
City
اصفهان
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 8101
Email
fatemehzargar@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Maryam Hafez
Position
Master's student
Latest degree
Bachelor
Other areas of specialty/work
Psychology
Street address
No. 33, Zanbagh 20 Ave., Zanbagh Blvd., Karaj Town
City
Karaj
Province
Alborz
Postal code
3155888586
Phone
+98 26 3253 5919
Fax
Email
maryamhafez78@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable