

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The Effect of a Supportive- Educational Program on Anxiety and Satisfaction of Mothers of Children undergoing the Lumbar puncture: compared to non-receipt of such intervention as control group

Protocol summary

Summary

Study objective: The aim of this study was to determine the effect of supportive - educational program on the anxiety and satisfaction of mothers of children undergoing Lumbar puncture. Design: This study was a semi-experimental clinical trial, with two groups (intervention and control), pre-posttest design, and single not-blind. Sample size: This study was conducted on 60 children's mothers (30 mothers per each group) hospitalized in pediatric emergency department of Quaem, Dr Sheikh, and Imam Reza hospitals of Mashhad. The main outcome variables in this study included: Anxiety and satisfaction. Inclusion criteria: Mother's age between 18 years to 55 years old; not experienced major stressors (such as divorce) within 6 month before; lack of sedatives and anti-anxiety drugs within 2 days before the test, and children's age between 1 month to 14 years old. Exclusion criteria: Children required emergency lumbar puncture test and, lack of cooperation mother to participate in the post test. Sampling was conducted via convenience sampling method, at the beginning of sampling; in order to avoid from information distribution between two groups, the first group was selected by a simple draw, and the intervention group was selected as first group. The mothers in the experimental group received an educational-supportive program (that included: Informational and emotional supports for 70 minutes), and an information booklet. The control group did not receive any intervention. Data were collected by demographic and spielburger questionnaires. The anxiety level was measured before and after the intervention (immediately before the LP) in two groups. Also, the satisfaction of mothers from preparation before the lumbar puncture test in their children were measured by the researcher-made questionnaire at 3 hours after Lumbar puncture test in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110224845N1**

Registration date: **2016-02-13, 1394/11/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-13, 1394/11/24

Registrant information

Name

Akhtar Nejat Mohammad

Name of organization / entity

Mashhad Faculty of Nursing and Midwifery, Mashhad
University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

University of Medical Sciences Mashhad, Vice chancellor
for research

Expected recruitment start date

2015-07-18, 1394/04/27

Expected recruitment end date

2015-09-29, 1394/07/07

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effect of a Supportive- Educational Program on Anxiety and Satisfaction of Mothers of Children undergoing the Lumbar puncture: compared to non-receipt of such intervention as control group

Public title
Effect of a Supportive- Educational Program on Anxiety and Satisfaction of Mothers of Children undergoing the Lumbar puncture (LP)

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Mother's age between 18 years to 55 years old; not experienced major stressors (such as divorce) within 6 month before; not receiving sedatives and anti-anxiety drugs within 2 days before the test, and children's age between 1 month to 14 years old.
Exclusion criteria: Children required emergency lumbar puncture test, and lack of cooperation mother to participate in the post test.

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Not 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 of Mashhad University of Medical Sciences

Street address

University of Medical Sciences Mashhad, Vice chancellor for research, Ghoraiшы Building,

University St
City
Mashhad
Postal code
Approval date
2015-06-22, 1394/04/01
Ethics committee reference number
IR.MUMS.REC.1394.212

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41

ICD-10 code description

Disorders in which manifestation of anxiety is the major symptom

Primary outcomes

1

Description

Mother anxiety

Timepoint

Spielberger state trait anxiety inventory (STAI)

Method of measurement

Before intervention and immediately before lumbar puncture test for child in two groups (experimental and control)

2

Description

Mother satisfaction

Timepoint

Three hours after the intervention in two groups (experimental and control)

Method of measurement

Researcher-made questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group in this study was received a supportive program by the researcher (70 minutes). This program was conducted in two stages. Stage1: The first part was about the informational support (30 minute), that included, talking and giving adequate information about lumbar puncture test, (method test, benefits, side effects lack of testing, and necessary cares after the test) and, answering the mother's questions about lumbar puncture test. Then,

the mother was given ten minute rest break. After rest break, stage 2: The second part program was about emotional support (30 minute), that included: At first, showing a supportive movie the mother for (15 minute) that content of movies: interview whit parents which the lumbar puncture test were performed for their children. After showing film, encouraging the mother to talk about concerns and fears; expressing feelings about lumbar puncture test, and ensuring her about the safety test (15 minute). In the end supportive program, the mothers given an information booklet about lumbar puncture test.

Category

Behavior

2

Description

Control group: in this study, no intervention was administered to the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Quaem Hospital

Full name of responsible person

Mina Delghandi

Street address

Pediatric Emergency Department, Quaem Hospital, Ahmad Abad St, Dr Shariati Square, Mashhad

City

Mashhad

2

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Manizheh Vazifedost Khalaj

Street address

Pediatric Department, Imam Reza Hospital, Ebne Sina St, Imam Reza Square, Mashhad

City

Mashhad

3

Recruitment center

Name of recruitment center

Dr Shaikh Hospital

Full name of responsible person

Nadia Tavakolian

Street address

Pediatric Emergency Department, Dr Shaikh Hospital, Taheri Street, Tohid Square, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of Medical Sciences Mashhad, Vice chancellor for research

Full name of responsible person

Mohsen Tafaghodi

Street address

University of Medical Sciences Mashhad, Vice chancellor for research, Ghorashy Building, University St

City

Mashhad

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

University of Medical Sciences Mashhad, Vice chancellor for research

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

Contact

Name of organization / entity

Mashhad Faculty of Nursing and Midwifery

Full name of responsible person

Akhtar Nejat Mohammad

Position

Master of Science student in pediatric Nursing

Other areas of specialty/work

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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