Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Compare the effectiveness of educative story book with face-to-face education on anxiety of hospitalized children and their mothers

Protocol summary

Summary

(1) Objectives: Compare the effectiveness of educative story book with face-to-face education on anxiety of hospitalized children and their mothers. (2) Design: The research project is a quasi-experimental design with pretest and post test. The subjects consist of 81 hospitalized children 6-9 years old and their mothers in Sabzevar, who are selected by availability method. (3) Setting and conduct: The subjects are selected by availability method, and then are randomly are allocated in educative story book, face-to-face education and routine method groups. (4) Participants including major eligibility criteria: The subjects consist of 81 hospitalized children 6-9 years old in Sabzevar that had been admitted for the first time at hospital; none-use of sedatives and anti-anxiety drugs. Exclusion criteria: Administration of sedatives and anti-anxiety drugs; discharge with personal satisfaction; hospitalized more than a week. (5) Intervention: In one group orientation program is done by educative story book, in two group orientation program is face to face and other is routine. Intervention time: When patients and their mothers enter the ward. (6) Main outcome measures variables: Anxiety of hospitalized children and their mothers

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015091021663N2**
Registration date: **2015-10-22, 1394/07/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-10-22, 1394/07/30

Registrant information

Name
Shahrbano Talebi
Name of organization / entity
Sabzevar University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2015-08-23, 1394/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effectiveness of educative story book with face-to-face education on anxiety of hospitalized children and their mothers

Public title

Compare the effectiveness of educative story book with face-to-face education on anxiety of hospitalized children and their mothers

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Hospitalized children between 6 to 9

years old that had been admitted for the first time at hospital; Children and mothers without any mental retardation, malignancy and other chronic diseases; none-use of sedatives and anti-anxiety drugs; parental and child consent. Exclusion criteria: Administration of sedatives and anti-anxiety drugs; discharge with personal satisfaction; hospitalized more than a week.

Age
From **6 years** old to **48 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **81**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Children with their mothers are divided by lottery method into two groups of intervention and one group of control

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Sabzevar University of Medical Sciences

Street address
Ethics Committee of Sabzevar University of Medical Sciences, Sabzevar University of Medical Sciences, 5 km road Sabzevar - Tehran, Sabzevar, Khorasan Razavi, Iran

City
Sabzevar

Postal code

Approval date
2014-12-29, 1393/10/08

Ethics committee reference number
Medsab.Rec.93.64

Health conditions studied

1

Description of health condition studied
Anxiety

ICD-10 code
F41.1

ICD-10 code description
Anxiety that is generalized and persistent but not restricted to, or even strongly predominating in, any particular environmental circumstances (i.e. it is

Primary outcomes

1

Description
Anxiety

Timepoint
Patient admission and discharge time

Method of measurement
Questionnaire: The scale of facial self-reported anxiety for children and questionnaire: The state anxiety for mothers

Secondary outcomes

1

Description
-

Timepoint
-

Method of measurement
-

Intervention groups

1

Description
Intervention: Education is done by educative story book from admission until discharge time

Category
Behavior

2

Description
Intervention: Education is done by face to face method from admission until discharge time

Category
Behavior

3

Description
Control: Education is done by routine method from admission until discharge time

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Pediatric ward of Sabzevar Vasei hospital

Full name of responsible person
Shahrbano Talebi

Street address
Pediatric ward, Vasei hospital, Tovhid boulevard, Sabzevar, Khorasan Razavi, Iran

City
Sabzevar

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Sabzevar University of Medical Sciences

Full name of responsible person
Mohammad Mohammadzadeh

Street address
Vice Chancellor for Education, Building number two, Sabzevar University of Medical Sciences and Health Services, 5 km road Sabzevar – Tehran, Sabzevar, Khorasan Razavi, Iran

City
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Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for research, Sabzevar University of Medical Sciences

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
Sabzevar University of Medical Sciences

Full name of responsible person
Javad Ganjloo

Position
Nursing instructor

Other areas of specialty/work

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School of Nursing and Midwifery, Sabzevar University of Medical Sciences, 5 km road Sabzevar - Tehran, Sabzevar, Khorasan Razavi, Iran

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Person responsible for updating data

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Student

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