

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 51 4464 4351

Email address

talebi.sh@medsab.ac.ir

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

Street address

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

City

Sabzevar

Postal code

9613873136

Phone

+98 51 4444 5994

Fax**Email**

jganj@yahoo.com

Web page address

medsab.ac.ir

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

Sabzevar

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Shahrbano Talebi

Position

Nursing postgraduate student

Other areas of specialty/work**Street address**

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

City

Sabzevar

Postal code

9617868311

Phone

+98 51 4464 4351

Fax**Email**

shtslebi12@yahoo.com

Web page address

medsab.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Sabzevar university of medical sciences

Full name of responsible person

Shahrbano Talebi

Position

Student

Other areas of specialty/work**Street address**

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

City

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Postal code

9617868311

Phone

+98 51 4464 4351

Fax

Email

shtslebi12@yahoo.com

Web page address

medsab.ac.ir

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