

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Comparison of the effect of the admission introduction program used by visual concept map and face to face method on fear and anxiety of hospitalized children 6-9 years old in Sabzevar

Protocol summary

Summary

(1) Objectives: The aim of this study is Comparison of the effect of the admission introduction program used by visual concept map and face to face method on fear and anxiety of hospitalized children 6-9 years old. (2) Design: The study quasi-experimental design with pre-test and post-test (3) Setting and conduct: The subjects select no randomly by method, Then are randomly allocated in two groups. (4)) Participants including major eligibility criteria: The subjects consist of 44 hospitalized children 6-9 years old in Sabzevar Inclusion criteria: hospitalized children between 6 to 12 years old that had been admitted for the first time at hospital; Children without any mental retardation, malignancy and other chronic diseases; none-use of sedatives and anti-anxiety drugs; parental and child consent. Exclusion criteria: children requiring emergency surgery; administration of sedatives and anti-anxiety drugs; discharge with personal satisfaction; hospitalized more than a week. (5) Intervention: In one group orientation program used by visual concept maps and other orientation program was face to face. Intervention time: When patients enter the ward. (6) main outcome measures variables: Fear and anxiety

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040821663N1**

Registration date: **2015-07-26, 1394/05/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-07-26, 1394/05/04

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

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sabzevar University of Medical Sciences

Expected recruitment start date

2014-01-01, 1392/10/11

Expected recruitment end date

2015-04-04, 1394/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Comparison of the effect of the admission introduction program used by visual concept map and face to face method on fear and anxiety of hospitalized children 6-9 years old in Sabzevar

Public title

The Comparison of the effect of the admission introduction program used by visual concept map and face to face method on fear and anxiety of hospitalized children 6-9 years old in Sabzevar

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: hospitalized children between 6 to 12 years old that had been admitted for the first time at hospital; Children without any mental retardation, malignancy and other chronic diseases; none-use of sedatives and anti-anxiety drugs; parental and child consent. Exclusion criteria: children requiring emergency surgery; administration of sedatives and anti-anxiety drugs; discharge with personal satisfaction; hospitalized more than a week.

Age

From **6 years** old to **9 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

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 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

fear

ICD-10 code

Z71.1

ICD-10 code description

Feared condition not demonstrated, Problem was normal state

2

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

fear

Timepoint

Before intervention and after intervention

Method of measurement

Broom's Hospital Fear

2

Description

anxiety

Timepoint

Before intervention and after intervention

Method of measurement

State - Trait Anxiety Inventory for Children

Secondary outcomes

1

Description

Satisfaction

Timepoint

Before intervention and after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Intervention: Education used by visual concept maps from admission until discharge the patient.

Category

Behavior

2

Description

Control : Education used by face to face from admission until discharge the patient.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Part pediatric of Sabzevar Vasei hospital

Full name of responsible person

Shahrbano Talebo

Street address

Part pediatric, Vasei hospital, Tovhid shahr Blvd, 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 Mohammad-Zadeh

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 Ganjlo

Position

Lecture

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Sabzevar University of Medical Sciences

Full name of responsible person

Shahrbano Talebi

Position

Nursing postgraduate student

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

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Position

student

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

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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