

# 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

talebi.sh@medsab.ac.ir

#### 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

#### 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

## 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

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shtslebi12@yahoo.com

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## 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

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**Postal code**

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**Phone**

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**Fax****Email**

shtalebi12@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*