

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of the Dress and Doll clothes on the anxiety and fear child

Protocol summary

Study aim

Compare the effect of Dress and Teddy Bear on the admission anxiety and fear child age 3-6 years old

Design

Seventy five children transferred from the emergency department to the pediatric ward. Qualified children were made unpredictable by choosing and distributing children to a group of Teddy Bear, Dress and control with simple random assignment. Data were collected by a questionnaire containing two parts. The first part was personal information, and the second part included a self-report tool for fear and anxiety.

Settings and conduct

This research was conducted in Imam Reza Hospital, Mashhad, Iran. Children from the emergency department were transferred to the pediatric ward during a phase. A researcher with Dress and Teddy Bear was in the process of admitting with the child at the same time. The Blind was one-sided, and the children were unaware of the results of the research. At the end, the child was placed in the bed and the anxiety and fear were measured by the self-report tool.

Participants/Inclusion and exclusion criteria

Qualifying children aged 3-6 years and not having chronic disease and anxiety, having no severe pain during the intervention.

Intervention groups

The Teddy Bear group was "Saturday and Sunday", The Dress group was "Monday and Tuesday," Dress and Teddy Bear program was for an hour such as featuring initial engagement: A researcher say hello with the child, The department and the Interventions were be recognized to the child. Accompaniment with the child will be continued and all procedures were initiated with the help of the researcher. In the final stage, the researcher takes the child to his room for placement on the bed, and afterwards the child score for the self-report tool and then researcher say goodbye to him. "The control group was" Wednesday and Thursday ".The researcher wears the normal uniform and then the child

score the scale. " At the end, fear and anxiety were compared in control and intervention groups.

Main outcome variables

The study of child anxiety and fear at the end of the admission process using the self-report tool in all three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160709028849N1**

Registration date: **2017-12-02, 1396/09/11**

Registration timing: **retrospective**

Last update: **2017-12-02, 1396/09/11**

Update count: **0**

Registration date

2017-12-02, 1396/09/11

Registrant information

Name

Farzaneh Abbasian

Name of organization / entity

Mashhad University of Medical Science

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2016-10-22, 1395/08/01

Actual recruitment start date

2016-07-22, 1395/05/01

Actual recruitment end date

2016-10-22, 1395/08/01

Trial completion date

empty

Scientific title

The effect of the Dress and Doll clothes on the anxiety and fear child

Public title

The effect of the Dress and Doll clothes on the anxiety and fear child

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Have informed consent to participate in the intervention
Has been moved from Hospital emergency department of Imam Reza to the pediatric ward
One of the parents has been present
Is not have growth and mental retardation
Is not suffering from chronic diseases
Is not suffering from separation anxiety and phobia
Has not severe pain before intervention
Parents not associated with hospital staff
The child' age is 6-3 years
Anti-anxiety medication is not used

Exclusion criteria:

Do not want to continue research for any reason
Children requiring emergency intervention
Pain during the intervention

Age

From **3 years** old to **6 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **75**

Actual sample size reached: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

The groups randomly assigned two days each week using random numbers. Teddy Bear group was specially assign to on Saturday and Sunday. Dress group was specially assign to on Monday and Tuesday and the control group was specially assign to on Wednesday and Thursday, and then the children arrived in the group on the basis of arrival each day.

Blinding (investigator's opinion)

Single blinded

Blinding description

After obtaining consent from the parents of children, interventions were carried out and children were enrolled in the study and at the end they scored the self-report instrument. Children only chose the shape in the video self-monitoring tool that was close to their state of affairs and was unaware of its impact on the results of the

research.

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 Science

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Faculty of Nursing and Midwifery, Ibn Sina Avenue, Doctora Square, Mashhad, Iran

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Razavi Khorasan

Postal code

99191-91778

Approval date

2016-06-20, 1395/03/31

Ethics committee reference number

IR.MUMS.REC.1395.163

Health conditions studied**1****Description of health condition studied**

Anxiety and Fear of admitting children

ICD-10 code

F40-F48

ICD-10 code description

Neurotic, stress-related and somatoform disorders

Primary outcomes**1****Description**

Fear

Timepoint

After intervention

Method of measurement

Fear self report

Secondary outcomes**1****Description**

Anxiety

Timepoint

After intervention
Method of measurement
Anxiety self-report scale

Intervention groups

1

Description

"Control group: Nurse using form dressing white is from the child's admission to staying with her on the bed. "

Category

N/A

2

Description

"Intervention group: A nurse with a Teddy Bear will do all the work at the child's reception, and until he stays with him on the bed."

Category

N/A

3

Description

"Intervention group: A nurse with a colorful dress will do all the work for the child and she will be with her on the bed"

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Vazifiedust

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Sponsors / Funding sources

1

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Grant name

941825

Grant code / Reference number

IR.MUMS.REC.1395.163

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

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available