

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of dear child presence on anxiety and depression caused by hospitalization in children aged 6 to 12 years in Dezful

Protocol summary

Study aim

check the effect of dear child on depression and anxiety in hospitalized children between 6 and 12 years

Design

80 selected children are randomly divided into 2 groups of 40 control and intervention

Settings and conduct

in the pediatric ward of Dr. Ganjavian Hospital, children aged 6 to 12 years admitted to the pediatric ward are selected based on inclusion and exclusion criteria. Then 80 selected children are randomly divided into 2 groups of 40 control and intervention. A dear child is considered for the intervention group. she is with the child every morning until noon and performs all aggressive procedures and supportive measures. she also approaches the child using communication technique, play therapy, storytelling and painting, and no intervention is performed for the control group. The collection tools in this study were the Demographic Information Questionnaire, the standard Reynolds & Richmond Children's Revealed Anxiety Scale (RCMAS), the Maria Kwas Children's Depression Inventory (CDI) . which was completed 3 times by the patient or with help. will be (When admitted to the ward ,48 hours after admission, at discharge) Data will be analyzed using SPSS statistical software.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient is hospitalized in the pediatric ward. The patient is conscious, has mental stability and is between 6 and 12 years old.

Intervention groups

A dear child is considered for the intervention group. she is with the child every morning until noon and performs all aggressive procedures and supportive measures. she also approaches the child using communication technique, play therapy, storytelling and painting, and no intervention is performed for the control group

Main outcome variables

Depression rate, anxiety rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170607034381N6**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **prospective**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

Registration date

2022-05-02, 1401/02/12

Registrant information

Name

Ferdos Pelarak

Name of organization / entity

Dezful Azad University

Country

Iran (Islamic Republic of)

Phone

+98 916 941 7091

Email address

pelarak.f@dums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-24, 1401/03/03

Expected recruitment end date

2022-07-25, 1401/05/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of dear child presence on anxiety and depression caused by hospitalization in children aged 6 to 12 years in Dezful

Public title

The effect of dear child on depression anxiety in hospitalized children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient is hospitalized in the pediatric ward. The patient is conscious and has mental stability between 6 to 12 years old.

Exclusion criteria:

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Gachsaran Islamic Azad University

Street address

Islamic Azad University of Gachsaran

City

Gachsaran

Province

Kohgiluyeh-va-Boyerahmad

Postal code

7581863876

Approval date

2021-12-15, 1400/09/24

Ethics committee reference number

IR.IAU.IAUG.REC.1400.006

Health conditions studied

1

Description of health condition studied

Anxiety

ICD-10 code

F41.9

ICD-10 code description

Anxiety disorder, unspecified

2

Description of health condition studied

Depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

Primary outcomes

1

Description

Anxiety

Timepoint

when admitted, 48 hours after admission, at discharge

Method of measurement

Revised Reynolds and Richmond Children's Manifest Anxiety Scale

2

Description

Depression

Timepoint

when admitted, 48 hours after admission, at discharge

Method of measurement

Maria Kwas Children's Depression Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:A dear child is considered for the intervention group.she is with the child every morning until noon and performs all aggressive procedures and supportive measures .she also approaches the child using communication technique, play therapy, storytelling and painting

Category

Behavior

2

Description

Control group: no intervention is performed for the control group

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Ganjavian hospital

Full name of responsible person

Fateme Mohtadi

Street address

Gangavian Hospital, Andimesh road to Dezful

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Province

Khouzestan

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6461643981

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bbd@dums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Vice Chancellor for Research, Islamic Azad University of Dezful

Street address

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Fateme Mohtadi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentifiable individuals

When the data will become available and for how long

12 months after the results are published

To whom data/document is available

Researchers working in scientific and academic institutions

Under which criteria data/document could be used

According to the terms and conditions of Dezful Azad University, the data can be used

From where data/document is obtainable

Fateme Mohtadi fatememohtadi713@gmail.com

What processes are involved for a request to access data/document

Written request and consent of the Executor of the project and colleagues

Comments