

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The Effect of Spiritual Care on the Adaptive Behavior of Parents with hospitalized children in the Pediatric Intensive Care Unit

Protocol summary

Registration timing: **retrospective**

Study aim

Comparison of adaptive behaviors of parents with children in the intensive care unit before and after spiritual care in two groups of control and intervention

Last update: **2019-01-29, 1397/11/09**

Update count: **0**

Registration date

2019-01-29, 1397/11/09

Design

Two arm parallel group randomized, unblinded trial

Registrant information

Name

Mina Mohammady

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3500 2117

Email address

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Settings and conduct

After obtaining the code of ethics and obtaining a referral letter and coordinating with the children's intensive care unit at Imam Hussein Hospital in Isfahan, the researcher recruit the eligible parents. They will complete the written informed consent then will complete the demographic information and pretest.

Participants/Inclusion and exclusion criteria

All parents with hospitalized children in a pediatric intensive care unit

Recruitment status

Recruitment complete

Funding source

Intervention groups

In the intervention group, a pretest will be carried out by completing the Parental Health Compliance Questionnaire; then, To provide optimal spiritual care to the participants, the need assessment will be done by completing the Spiritual Needs Assessment Form. Based on the needs assessment, a spiritual care program consisting of supporting protection, support for family religious ceremonies, use of supportive systems is provided for 4 weeks. Then the post-test will be performed. In the control group, we will first have a pretest, and the participants will receive only routine hospital care and post-test will be done after 4 weeks.

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

2017-10-23, 1396/08/01

Actual recruitment end date

2018-05-05, 1397/02/15

Trial completion date

2018-05-05, 1397/02/15

Main outcome variables

Coping Health manners of Parents

Scientific title

The Effect of Spiritual Care on the Adaptive Behavior of Parents with hospitalized children in the Pediatric Intensive Care Unit

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180629040279N1**

Registration date: **2019-01-29, 1397/11/09**

Public title

The Effect of Spiritual Care on the Adaptive Behavior of Parents

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Children who hospitalized to the pediatric intensive care unit for at least 2 weeks and the presence of at least one parent (father or mother) in the hospital All children admitted from infancy to 18 years old The desire of parents to participate in research

Exclusion criteria:

children who do not live with their parents

Age

From **1 month** old to **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

To generate random sequences and assigning the participants to the intervention and control groups, simple randomization was used on each participant. To generate random sequences, random sequencing software was used and individuals were randomly assigned to two groups.

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 Islamic Azad University,
Khorasgan branch

Street address

Arghavanieh

City

Isfahan

Province

Isfahan

Postal code

۸۱۵۵۱-۳۹۹۹۸

Approval date

2018-05-26, 1397/03/05

Ethics committee reference number

IR.IAU.KHUISF.REC.1397.016

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

Adaptive behavioral of parents

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Parental adaptive behavior

Timepoint

Before the intervention begins and after 4 weeks

Method of measurement

Coping Health Inventory for Parents (CHIP)

Secondary outcomes

empty

Intervention groups**1****Description**

The intervention group will select the type and method of spiritual care, based on the needs expressed by them and the need for the researcher, as requested and agreed upon by the researcher. Within the two weeks during the period of hospitalization, the program was implemented during 3 sessions of 60 minutes in the mother's room and on the bedside of the child. The intervention included receiving advice and spiritual support in the form of supporting presence, support for religious ceremonies The family is using supportive systems.

Category

Behavior

2**Description**

Control group: receiving routine hospital care for 2 weeks

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital, Isfahan

Full name of responsible person

Mina Mohammady

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Emam Khomini street
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Sponsors / Funding sources

1

Sponsor

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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

1

Public or private sector

Private

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
Mina Mohammady
Position

Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Fax**Email**

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

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

We will try to decide upon completion of the project

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

All data is shareable

When the data will become available and for how long

4 months after publication

To whom data/document is available

All researchers can access the data

Under which criteria data/document could be used

For review in systematic review studies

From where data/document is obtainable

Dr. Narges Sadeghi n45sadeghi@yahoo.com

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

Satisfaction of all research team

Comments