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

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
Design
Two arm parallel group randomized, unblinded trial
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
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.
Main outcome variables
Coping Health manners of Parents

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180629040279N1**
Registration date: **2019-01-29, 1397/11/09**
Registration timing: **retrospective**

Last update: **2019-01-29, 1397/11/09**
Update count: **0**
Registration date
2019-01-29, 1397/11/09

Registrant information
Name
Mina Mohammady
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

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

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

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
Isfehan
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

Street address
Emam Khomini street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
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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
Master
Other areas of specialty/work
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Person responsible for updating data

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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