Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effectiveness of an educational-supportive program for fathers and routine care program on outcomes of hospitalized pediatrics with pneumonia

Protocol summary

Study aim
Determining the effect of a fathers education-support program for fathers on outcomes of hospitalized pediatrics with pneumonia including nutritional behavior, children's sleep and maternal stress

Design
A clinical trial with the control group, single-blind, randomized, On 40 sick pediatric. Random allocation software (RAS) will be used for randomization.

Settings and conduct
Research environment of Imam Hossein Children's Hospital, Isfahan University of Medical Sciences.During the 4 days (twice a day) before communicating with the child, the father will be contacted through video and social networks and will be given the necessary training and support such as sleep hygiene and nutrition training and proper communication with mothers.The fathers will then participate in the video call will implement the lessons learned.

Participants/Inclusion and exclusion criteria
Entry requirements: Age of the child 12 to 36 months, hospitalization with a diagnosis of pneumonia, not receiving specific medication for insomnia, oral nutrition, ability of parents to use video calling, consent of the child's family to participate in the study, lack of Mood disorder in the mother, presence of the father No entry conditions:Inability of the father to study educational program, If communication device is not available (video call), Change the diagnosis of the child's disease

Intervention groups
Education and support for fathers with hospitalized children and their mother as the patient's primary caregiver. The fathers will do the seen educations by making a video communication with the video call for their child. control group:Will receive routine care. Questionnaires will be completed at the time of admission and 7 days after admission.

Main outcome variables
The effect of fathers on improving nutritional performance and sleep quality of children and mothers' stress levels

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210421051029N1**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **retrospective**

Last update: **2021-05-31, 1400/03/10**
Update count: **0**

Registration date
2021-05-31, 1400/03/10

Registrant information
Name
sajjad khaksar
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 4572 4532
Email address
sajjadkhaksar1997@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-11-14, 1399/08/24
Expected recruitment end date
2021-01-13, 1399/10/24
Actual recruitment start date

2020-11-14, 1399/08/24

Actual recruitment end date

2021-03-19, 1399/12/29

Trial completion date

2021-04-19, 1400/01/30

Scientific title

Comparison of the effectiveness of an educational-supportive program for fathers and routine care program on outcomes of hospitalized pediatrics with pneumonia

Public title

Effect of fathers on outcomes of hospitalized pediatrics with pneumonia

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the child is in the age range of 12 to 36 months The first day of hospitalization of a child with a diagnosis of pneumonia in the hospital Do not receive specific medicine for insomnia problems Have oral nutrition and do not receive complete intravenous feeding or gavage Parents' ability to use video call The child's family is willing and satisfied to participate in the study The mother does not have a mood disorder (not taking medication and not experiencing other stressful conditions other than discussing the child's hospitalization during the child's hospitalization) Father's presence in the family (not dead, etc.)

Exclusion criteria:

Inability of the father to study educational program If communication device is not available (video call) Change the diagnosis of the child's disease

Age

From **12 months** old to **36 months** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

At first, one of the existing hospitals that treat children with pneumonia was selected by lottery. Children will be selected by available sampling method and finally each of the selected samples will be assigned to the control or intervention group with Random allocation software(RAS). In this way, the software determines the sample size and equal blocks and the software output will be used for random allocation. This method will continue until the number of samples reaches the desired number of samples.

Blinding (investigator's opinion)

Single blinded

Blinding description

The patient participates in the study and is explained that he is in the study, but does not know which group he is in

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Isfahan University of Medical Sciences

Street address

No. 545,dead end 3 ,Modares Alley, Shahid Kharazi St., Moallem Blvd.,Gaz Borkhar,Isfahan

City

isfahan

Province

Isfehan

Postal code

8344117875

Approval date

2021-01-02, 1399/10/13

Ethics committee reference number

IR.MUI.RESEARCH.REC.1399.630

Health conditions studied

1

Description of health condition studied

Pneumonia

ICD-10 code

J18.9

ICD-10 code description

Pneumonia, unspecified organism

Primary outcomes

1

Description

Sleep quality score

Timepoint

Measurement of sleep quality at the beginning of the study and one week after admission

Method of measurement

Brief Infant Sleep Questionnaire-R

2

Description

Eating Behavior score

Timepoint
Measurement of Eating Behavior score at the beginning of the study and one week after admission
Method of measurement
Children’s Eating Behavior Questionnaire

3

Description
Stress score
Timepoint
Measurement of stress score at the beginning of the study and one week after hospitalization
Method of measurement
stress response inventory (SRI) Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:The educational-supportive program will include education and support for fathers with hospitalized children and the mother as the patient's primary caregiver.The education with the participation of parents in social networks will be held virtually for 4 consecutive days by sharing the educational content prepared for the fathers of the intervention group.Fathers will do the lessons seen by video communication twice a day for 15 to 30 minutes each time with a video call for their child. To receive information and promote knowledge, some information by the researcher about the child at toddler age (behaviors and physical symptoms) and the child's illness, the effect of hospital conditions on the child and mother, and teaching the role of the father in physical and emotional support and care of Child and spouse support in critical situations and understanding and knowing each other and working together to solve problems and not blame each other and about the child, as well as tips on how to interact with children through video calls. An educational package (including an education booklet and CD with instructions) will be given to fathers to use. Accordingly, to exchange information and transfer information between parents and the researcher, the father will be contacted through video calls and social networks within 4 days (twice a day) and with prior coordination with the researcher, before communicating with the child.They will be given the necessary training and support such as sleep hygiene and nutrition training and proper communication with mothers, and they will be asked to read the educational content shared in the virtual group before making a video communication.The fathers, with the cooperation of the researcher and under the supervision of the researcher, will participate in the video call and will implement the lessons learned.The educational content provided will include information on normal sleep patterns, children's sleep needs, signs and consequences of sleep disorders, sleep hygiene information, and anticipated tips on sleep and nutrition during hospitalization.The father will be asked to use relaxing behaviors and skills to prevent or reduce sleep problems.In addition, fathers will be asked to bring with them material as well as storybooks that include colorful pictures and fun characters, musical instruments, their child's latest artwork such as a painting, or whatever they want to show him. This not only allows the child to continue to communicate with the parents with interest but also increases comfort.It will also be planned in advance to share a snack or a meal with the child so that people have the same snack or meal on both sides of the screen and adults can pretend to enjoy it from the camera. They deliver the child. At the end of the video, people can play music and sing with each other or play age-appropriate games.
Category
Behavior

2

Description
Control group: The control group will receive routine care. Questionnaires for this group will be completed at the time of admission and 7 days after admission. The educational content will be provided to the control group after the completion of the research.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Hossein Hospital
Full name of responsible person
Faramarz Kalhor
Street address
Imam Khomeini St., before Esteghlal Square, Imam Hossein Children's Educational and Medical Center
City
Isfahan
Province
Isfehan
Postal code
۸۱۹۵۱۶۳۳۸۱
Phone
+98 31 3386 6266
Email
emamhossein_hospital@mui.ac.ir
Web page address
http://www.ehuch.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person
Shaghyegh Hagh Jooye Javanmard

Street address
No. 54, Dead End 3, Modares Alley, Shahid Kharazi St., Moallem Blvd., Gazborkhar, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8344117875

Phone
+98 31 4572 4532

Email
sajjadkhaksar1997@gmail.com

Grant name

Grant code / Reference number

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

Title of funding source
Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Sajjad Khaksar

Position
Master student of Pediatric Nursing, Department of Pediatrics, School of Nursing and Midwifery, Isfa

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 54, Shahid Kharazi St., Modares Alley, Shahid Kharazi Street

City
Isfahan

Province
Isfehan

Postal code
8344117875

Phone
+98 31 4572 4532

Email
sajjadkh@nm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Faramarz Kalhor

Position
Clinical Instructor, Faculty of Nursing and Midwifery

Latest degree
Master

Other areas of specialty/work
Nursery

Street address
No. 485,Side Alley 2., Marefat St., Janbazan Blvd

City
Isfahan

Province
Isfehan

Postal code
6037697491

Phone
+98 31 3778 2166

Email
faramarz@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Sajjad Khaksar

Position
Master student of Pediatric Nursing

Latest degree
Bachelor

Other areas of specialty/work
Nursery

Street address
No. 54, Shahid Kharazi St., Modares Alley, Shahid Kharazi Street

City
Isfahan

Province
Isfehan

Postal code
8344117875

Phone
+98 31 4572 4532

Email
sajjadkh@nm.mui.ac.ir

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

Participant data file: If the results of the study indicate the need for this work, part of the data will be published after it becomes unidentifiable (demographic characteristics) and will be available to other researchers after being unidentifiable by sending an email. Study protocol: The study protocol will be displayed in articles for researchers and for citation by other researchers only citation of the article is sufficient. Informed consent form : It does not need to be published and only its title will be given in the articles and if necessary, the readers and the competent inspection authorities will be provided to them, but its raw form will be provided to the journals to publish the results of the study. Statistical analysis map: In the method section, the work will be provided and if used by other researchers, citing the article will suffice and no license will be required. Clinical study report: The results of the study will be published in the form of an article after the end of the study, and only citation to the article is sufficient to use the results. If needed more information will be available by email after being unidentified.

When the data will become available and for how long

After publishing the results in the article

To whom data/document is available

The data will be available to researchers

Under which criteria data/document could be used

Can be used for secondary studies

From where data/document is obtainable

The person in charge of research - sending email

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

Will be sent after receiving the email

Comments