

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of a supportive educational program on anxiety in children with kidney disease and burden of mothers' care

Protocol summary

Study aim

Effect of a supportive educational program on anxiety in children with kidney disease and burden of mothers' care

Design

The research is a clinical trial study in two groups and three stages to evaluate the effect of independent variable of supportive training program on two dependent variables including the grade of children's anxiety as well as the score of the burden of their mothers' care. Sampling will be done with continuous easy method from all children referred to the Alzahra and Emam Hosein hospital in Isfahan. So 120 children with their mothers, which have inclusion criteria, would randomly selected and assigned to two groups: test and control groups. Accidental assignment of samples in two groups of test or control will be using a numbers packet. The test group will attend in supportive educational program that will be held simultaneously for mothers and children as 5 daily 45-50 minutes sessions. The control group will participate in one question and answer session which held by researcher. Data collection in this research will be done using a 3-part questionnaire including demographic profile of the child and mother, visual anxiety measurement tool for children and the Zarit scale questionnaire to assess caregiver burden for mothers. Before beginning the study, the Holmes and Rahe scale was also completed by mothers for individuals' inclusion into the research. Both groups will answer questionnaires before and immediately after the intervention and also one month after the intervention. Data of this research will be collected before and immediately after the intervention as well as one month later

Settings and conduct

This study will be done on children referred to Al-Zahra and Emam Hossein Hospital in Isfahan. So 120 children with their mothers, which have inclusion criteria, would randomly selected and assigned to two groups: test and control groups. The test group will attend in supportive

educational program that will be held simultaneously for mothers and children as 5 daily 45-50 minutes sessions. The control group will participate in one question and answer session which held by researcher. Data collection in this research will be done using a 3-part questionnaire including demographic profile of the child and mother, visual anxiety measurement tool for children and the Zarit scale questionnaire to assess caregiver burden for mothers. Before beginning the study, the Holmes and Rahe scale was also completed by mothers for individuals' inclusion into the research. Both groups will answer questionnaires before and immediately after the intervention and also one month after the intervention. Data of this research will be collected before and immediately after the intervention as well as one month later

Participants/Inclusion and exclusion criteria

Inclusion criteria for children: Suffering from kidney disease (kidney failure, Glomerulonephritis, Nephrotic syndrome, Urinary tract infection, ESRD and other diseases of renal system); It was passed at least three months from diagnosis; Being accompanied by mother during the hospitalization; Living in Isfahan; Having mental health; Not being diagnosed with known psychiatric diseases and necessary consciousness to the extent that does not hinder the research (referring to medical documents and records of the disease); Not using medicine to reduce anxiety and pain except for kidney disease (referring to the doctors' recorded orders); The lack of experience of critical events over the past year including: death of a parent, sister or brother's death, parental divorce and severe accident based on the questions which were asked from the patients' mothers. Inclusion criteria for the mother: Considered as having at least elementary education; Not being as medical staff (Physician, nurse and ...); Not being diagnosed with known psychiatric diseases and lack of taking psychedelic drugs by mother based on the questions which were asked from the mothers; Lack of experience of a critical event over the past year with using Holmes-Rahe scale. Exclusion criteria: Child and their family's

unwillingness to continue the research at each stage; Deterioration of child's health condition in the course of the disease during the study and then referring to the physician; Prescribing and taking anxiolytic and tranquilizing drugs during hospitalization of child and according to the doctor's order and according to medical records for some reasons except for kidney disease; Discharge of the child before the end of the curriculum of supportive education; Child affliction due to infectious diseases; Lack of child and her or his mother's regular attendance at meetings (absence more than two sessions)

Intervention groups

The test group will attend in supportive educational program that will be held simultaneously for mothers and children as 5 daily 45-50 minutes sessions. The control group will participate in one question and answer session which held by researcher. Data of this research will be collected before and immediately after the intervention as well as one month later

Main outcome variables

The proposed non-pharmacological application to children's treatment centers based on a supportive educational program is based on findings to improve the anxiety of children with chronic renal diseases and reduce the maternal care burden

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171028037045N1**

Registration date: **2018-01-21, 1396/11/01**

Registration timing: **retrospective**

Last update: **2018-01-21, 1396/11/01**

Update count: **0**

Registration date

2018-01-21, 1396/11/01

Registrant information

Name

niloofar bahrami

Name of organization / entity

isfahan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3680 5498

Email address

n.bahrami@nm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Research center of Isfahan University of Medical Sciences

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of a supportive educational program on anxiety in children with kidney disease and burden of mothers' care

Public title

Effect of a supportive educational program on anxiety in children with kidney disease and burden of mothers' care

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for children: Suffering from kidney disease (kidney failure, Glomerulonephritis, Nephrotic syndrome, Urinary tract infection, ESRD and other diseases of renal system); It was passed at least three months from diagnosis; Being accompanied by mother during the hospitalization; Living in Isfahan; Having mental health; Not being diagnosed with known psychiatric diseases and necessary consciousness to the extent that does not hinder the research (referring to medical documents and records of the disease); Not using medicine to reduce anxiety and pain except for kidney disease (referring to the doctors' recorded orders); The lack of experience of critical events over the past year including: death of a parent, sister or brother's death, parental divorce and severe accident based on the questions which were asked from the patients' mothers. Inclusion criteria for the mother: Considered as having at least elementary education; Not being as medical staff (Physician, nurse and ...); Not being diagnosed with known psychiatric diseases and lack of taking psychedelic drugs by mother based on the questions which were asked from the mothers; Lack of experience of a critical event over the past year with using Holmes-Rahe scale.

Exclusion criteria:

Exclusion criteria: Child and their family's unwillingness to continue the research at each stage; Deterioration of child's health condition in the course of the disease during the study and then referring to the physician; Prescribing and taking anxiolytic and tranquilizing drugs during hospitalization of child and according to the doctor's order and according to medical records for some reasons except for kidney disease; Discharge of the child before the end of the curriculum of supportive education; Child affliction due to infectious diseases; Lack of child and her or his mother's regular attendance at meetings (absence more than two sessions)

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Accidental assignment of samples in two groups of test or control will be using a packet, in which there are pairs and odd numbers written on cardboard cards. So, for example, the researcher first specifies randomly that patients with a coupled number will be in the test group (intervention) and those whose have odd number will be in the control group. When the samples are entered into the study with the entry conditions in an easy way, the card for which he leaves the envelope, depending on whether he has a pair number or odd, he is in one of the two test group (intervention) and or control group, and random sampling and assignment will continue to complete the required number of samples.

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 Isfahan University of Medical Sciences

Street address

Hezarjarib Ave, Isfahan University of Medical Sciences, Faculty of nursing and midwifery, Isfahan City.

City

Isfahan

Province

Isfahan

Postal code

8144117625

Approval date

2017-09-23, 1396/07/01

Ethics committee reference number

IR.MUI.REC.1396.3.445

Health conditions studied

1

Description of health condition studied

chronic kidney diseases

ICD-10 code

N17-N19

ICD-10 code description

P96.0

Primary outcomes

1

Description

children anxiety

Timepoint

before the intervention, immediately after the intervention, one month after the intervention

Method of measurement

visual anxiety measurement tool

2

Description

caregiver burden for mothers

Timepoint

before the intervention, immediately after the intervention, one month after the intervention

Method of measurement

Zarit scale questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

The test group will attend in supportive educational program that will be held simultaneously for mothers and children as 5 daily 45-50 minutes sessions. The control group will participate in one question and answer session which held by researcher

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Dr. Mahdi Nasr Esfahani

Street address

Al-Zahra Medical Education Center- Safavi Boulevard- Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone
+98 31 3620 1250
Email
ari@mui.ac.ir
Web page address
<http://www.ari.mui.ac.ir>

2

Recruitment center

Name of recruitment center
Emam Hossein hospital
Full name of responsible person
Dr. Mehrdad Meemarzadeh
Street address
Emam Hossein Children's Therapeutic Hospital, Km 10
of Imam Khomeini Ave (RA) , Isfahan.
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Isfahan
Province
Isfahan
Postal code
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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
Research center of Isfahan University of Medical
Sciences
Full name of responsible person
Mrs Maryam Maroufi
Street address
Faculty of Nursing and Midwifery, Isfahan University
of Medical Sciences, Hezar jarib Avenue
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Isfahan
Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 0048
Email
n.bahrami@nm.mui.ac.ir
Web page address
<http://www.mui.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research center of Isfahan 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
Niloofer Bahrami
Position
MSc
Latest degree
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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