Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jul 2026

The effect of intervention based on health belief model on parent's anxiety, follow up examinations and velocity of retinal vascularization in retinopathy of prematurity

Protocol summary

Study aim

The effect of Health Belief Model based intervention on parental anxiety, follow-up examinations and retinal vascularization in neonates with retinopathy of prematurity.

Design

Randomized controlled trial, single-blind

Settings and conduct

This randomized controlled trial will be performed on preterm infants with ROP and their parents referring to Retinal Disease Clinic of Premature Infants of Khatam Al Anbia Hospital in Mashhad. After random assignment, the intervention will be presented in 4 sessions، 60-minute lecture-question-answer and slide shows in the form of health belief model.

Participants/Inclusion and exclusion criteria

Parent Criteria for Inclusion: Having written consent to participate in the study, having read and write literacy. Test scores above 30 in the Spiel Berger Situational Anxiety Questionnaire. Inclusion criteria for neonates: Research unit infants with gestational age of 34 weeks (33 weeks and 6 days or less), infants weighing 2000 g or less, neonates with zone 2 and stage 2 retina screening examination. Exclusion criteria for parents: unwillingness of the research unit to continue cooperating, having depression or anxiety disorder confirmed by a specialist physician during the study, participating in a similar training program during the study, more than one absenteeism session, history of maintenance An infant with retinopathy of prematurity, severe stressful events such as the death of first-degree relatives, divorces, or severe family disputes during the study. Exclusion criteria for neonates: Infant death or clinical instability of the infant during the study

Intervention groups

Premature infant with ROP and their parents

Main outcome variables

Parental Anxiety of Neonates with Retinopathy, Parent Adherence to the Neonatal Retinopathy Follow-Up Program, Retinal Vascularisation of Neonates with Retinopathy

General information

Reason for update

Acronym

ندارد

IRCT registration information

IRCT registration number: **IRCT20200130046307N1**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **prospective**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date

2020-02-08, 1398/11/19

Registrant information

Name

Azamsadat Salehnezhad

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-09, 1398/11/20

Expected recruitment end date

2020-04-08, 1399/01/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of intervention based on health belief model on parent's anxiety, follow up examinations and velocity of retinal vascularization in retinopathy of prematurity

Public title
The effect of intervention based on health belief model on parent's anxiety, follow up examinations and velocity of retinal vascularization in retinopathy of prematurity
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Parent Criteria for Inclusion: Having written consent to participate in the study, having read and write literacy. Test scores above 30 in the Spiel Berger Situational Anxiety Questionnaire. Inclusion criteria for neonates: Research unit infants with gestational age of 34 weeks (33 weeks and 6 days or less), infants weighing 2000 g or less, neonates with zone 2 and stage 2 retina screening examination.
Exclusion criteria:
Exclusion criteria for parents: unwillingness of the research unit to continue cooperating, having depression or anxiety disorder confirmed by a specialist physician during the study, participating in a similar training program during the study, more than one absenteeism session, history of maintenance An infant with retinopathy of prematurity, severe stressful events such as the death of first-degree relatives, divorces, or severe family disputes during the study. Exclusion criteria for neonates: neonatal death, clinical instability, and outpatient referral, such as hospitalization in the ICU, incidence of respiratory distress syndrome and need for mechanical ventilation during the study, severe asphyxia, and congenital major malformations
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced Block Randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
In terms of sampling method, infants will be included in the study in a non-random way. Randomization will be the Balanced Block Randomization method.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of School of Nursing and Midwifery-Mashhad University of Medical Sciences
Street address
School of Nursing and Midwifery, University of Medical Sciences, Mashhad, Khorasan Razavi, Mashhad
City
mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2019-11-12, 1398/08/21
Ethics committee reference number
IR.MUMS.NURSE.REC.1398.089

Health conditions studied

1

Description of health condition studied
retinopathy of prematurity
ICD-10 code
retinopath
ICD-10 code description
retinopathy of prematurity

2

Description of health condition studied
health belief model
ICD-10 code
health bel
ICD-10 code description
health belief model

3

Description of health condition studied
Situational anxiety
ICD-10 code
Situationa
ICD-10 code description
Situational anxiety

Primary outcomes

1

Description
Parental Anxiety of Neonates with Retinopathy
Timepoint
Parental anxiety of neonates with retinopathy of prematurity, at baseline (before intervention), immediately after intervention
Method of measurement
Standard Spellberger questionnaire

2

Description
Parental adherence to the follow-up screening program for infants with retinopathy of prematurity
Timepoint
According to the schedule prescribed by the treating physician
Method of measurement
Form made by the researcher

3

Description
velocity of retinal vascularization in retinopathy of prematurity
Timepoint
In accordance with Schedule of follow-up examinations in Retinopathy Executive Regulations
Method of measurement
Comparison of neonatal admission time to Posterior 2, Posterior 2, Anterior 2, Posterior 3 and Vascularization, respectively

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: This randomized controlled clinical trial will be performed on at least 60 infants with premature retinopathy and their parents referring to ROP Clinic of Khatam Al Anbia Eye Hospital in Mashhad, Iran, in 1389-99. Was. In terms of sampling method, infants will be admitted to the study in a non-random way. The sampling process will take approximately 2 months and the sample will be sampled 10% more than the specified number.The randomization method will be a balanced rendering block.After completing the selection form of research units and consenting to participate in the study, researcher-made questionnaires of Health Belief and Anxiety will be completed by intervention and control group and then it will be examined which parents have more problems in model model and structures. To emphasize that part at the planning stage. The intervention program will be implemented in 6 sessions of 45-60 minutes in the form of lecture, group discussion, question and answer and film and slide show. At the end of each session, the materials will be provided as educational pamphlets.The sessions will be held at the ROP Unit of Khatam Al Anbia Eye Hospital in Mashhad. The content of the training will include empowering parents to abide by treatment, timely follow-up examinations, care needs of the premature infant, control of the baby's pain at the time of eye examination, sleep patterns and nutrition of the infant, and parent stress management and anxiety. The intervention will be based on the constructs of the Health Belief Model as follows: In accordance with the Health Belief Model, the first step will be to create perceived sensitivity through speech, group discussion, poster and slide show, parents with retinopathy problems and problems Familiar with and highlighting the complications and risks of diseases of this period, relative to leprosy Periodic examinations and screenings will be sensitive.By constructing concrete examples and displaying photographs of infants who have been blinded by weakness and failure to care, the perceived structure will be highlighted. An instructional pamphlet and telephone reminder as well as the role of spouses (in building positive beliefs on the opposite side) will be used to build the practice guide. To create perceived benefits, parents will try to believe that they are capable of taking care of the premature baby themselves. Secondly, these cares are not difficult and will not cost them a lot (Structures perceived barriers). In order to construct self-efficacy, caring behaviors are divided into smaller components, practically demonstrated through parenting, and they will be encouraged to do so. Research units will be encouraged to discuss the obstacles and problems encountered in the group or to use the researcher's telephone guidance if necessary. The control group will receive routine ROP training. Research units will be given the opportunity to repeat and practice the training for one month and may need help and advice if needed during this period or by phone call to the researcher if necessary. To receive.During this one month, health messages will be sent to research units twice a week (re-highlighting the practice guideline). The Health Belief and Anxiety Questionnaires will be provided to the experimental and control groups immediately and one month after the intervention. Again, the questionnaires will be evaluated and compared with before the intervention. Also, compliance of the intervention and control groups with timely referral to the neonate will be assessed based on the State Regulatory Board of Retinopathy in the preterm infants. The first examination will be diagnosed by the retina stage and disease area specialist in the infant and will be followed by a follow-up examination in accordance with the National Regulatory Board for Retinopathy Care Schedule.Subsequent examinations will be performed until the neonatal retinal vascularization is completed. Considering that adherence to follow-up visits is one of the key elements in the treatment process, parental follow-up and follow-up are The intervention and control groups will be evaluated. How to follow-up examinations include, exactly on the day of examination, 1 to 2 days delayed phone recall, 3

weeks delayed phone recall, more than one week delayed recall, non-attendance despite phone reminders.It should be noted, in view of the importance of follow-up examinations if the intervention and control groups were delayed for more than one week despite telephone reminders, in accordance with the procedure in the premature neonatal clinic of Khatam Al Anbia Specialty Hospital Telephone reminders will continue for all clients, if no referral is made, correspondence with comprehensive health centers and if necessary visit the patient's home through comprehensive health centers to justify parents and ensure referral to the baby to continue the process. Treatment and examinations will be performed.Neonatal retinal vascularization in the intervention and control groups will be initially evaluated by an ophthalmologist. This evaluation will continue until the neonatal retinal vascularization is completed in both the intervention and control groups. In this study, premature neonates who are in stage 2 and area 2 will be enrolled in the study. Vascularization rates will be compared to neonatal arrival time to Posterior 2, Posterior 2, Anterior 2, Posterior 3, and Vascularization, respectively.The control group will receive all routine services and training of the premature neonatal clinic at Khatam Al Anbia Specialist Hospital, which will be provided to all clients. At the premature neonatal clinic, after obtaining the consent of the patient, screening examinations will be performed by the retina specialist. Subsequent examinations will be scheduled until the end of vascularization according to the stage and area of the eye involvement. Training provided to parents of premature infants will be performed by a skilled Nursing Expert with experience in the ROP unit who will answer parental questions and provide educational pamphlets.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam Ol-Anbia Eye Hospital

Full name of responsible person
Akbar Derakhshan

Street address
Khorasan Razavi Province, Mashhad, Qarani Boulevard, Khatam Ol-Anbia Eye Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
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Province
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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Azam Salehnezhad

Position
Nursing Graduate Student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available
Title and more details about the data/document
Information about the main outcome can be shared after unidentifiable people
When the data will become available and for how long
Start of access period 6 months after printing results
To whom data/document is available
researchers
Under which criteria data/document could be used
For academic studies, Information about the main outcome can be shared after unidentifiable people
From where data/document is obtainable
salehnezhada2@mums.ac.ir _ Azam Salehnezhad
What processes are involved for a request to access data/document
send mail
Comments
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