

# 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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##### Email address

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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**  
Seyed Mohammad Hossein Bahraini Tusi

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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

**Contact**

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Zahra Emami moghadam

**Position**

educational academic staff

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Master

**Other areas of specialty/work**

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## Person responsible for updating data

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**Latest degree**

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**Other areas of specialty/work**

Nursery

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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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