

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jul 2026

### The effect of Video Interaction Guidance of mother-infant interaction on stress in mothers with premature neonates in Neonatal Intensive Care Units".

#### Protocol summary

##### Study aim

The assess Video Interaction Guidance of mother- infant interaction in mothers with premature neonates in Neonatal Intensive Care Units".

##### Design

trial with intervention and control group -80 mother- in access

##### Settings and conduct

Nullipara mothers with preterm infant 34-37 week that hospitalized in NICU in Imam hkomaeini and booolisina hospital in sari depended to Mazandaran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

nullipara mothers with no history in preterm labour- mother with no difficult diseases- Iranian nationality- with lowest literacy of reading and writikg

##### Intervention groups

intervention group including 34 nullipara mothers who their preterm infant hospitalized in NICU. at first day,they filled pss questionnaire(pretest) and then,recieved VIG(Video Interaction Guidance).then, at fourth day,intervention group recieved VIG and then filled pss questionnaire(first posttest) and in seventh day, they recieved VIG and then filled pss questionnaire (secound posttest).control group including 40 mothers compeleted pss questionnaire in first day(pretest),fourth day(first posttest) and seventh day(secound posttest) and they recieved hospital routin care.

##### Main outcome variables

Mothers stress reducing who their preterm infant hospitalized in NICU

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170220032693N1**

Registration date: **2018-05-31, 1397/03/10**

Registration timing: **retrospective**

Last update: **2018-05-31, 1397/03/10**

Update count: **0**

##### Registration date

2018-05-31, 1397/03/10

##### Registrant information

###### Name

**Name of organization / entity**

###### Country

Iran (Islamic Republic of)

###### Phone

+98 11 4220 3877

###### Email address

maryambarzegar93@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-24, 1396/10/03

##### Expected recruitment end date

2018-02-01, 1396/11/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Video Interaction Guidance of mother-infant interaction on stress in mothers with premature neonates in Neonatal Intensive Care Units".

##### Public title

The effect of video interaction guidance of mother-infant interaction on stress in mother".

## **Purpose**

Other

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Nullipara- mothers with the lowest literacy in reading and writing Iranian nationality- married Not addiction with alcohol and extasia material NO associated with difficult diseases

### **Exclusion criteria:**

affected to depression having preterm labour before this reseach

## **Age**

From **21 years** old to **38 years** old

## **Gender**

Female

## **Phase**

N/A

## **Groups that have been masked**

*No information*

## **Sample size**

Target sample size: **80**

## **Randomization (investigator's opinion)**

Not randomized

## **Randomization description**

## **Blinding (investigator's opinion)**

Not blinded

## **Blinding description**

## **Placebo**

Not used

## **Assignment**

Other

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethic committee of iran university of Medical Science

##### **Street address**

Shahid beheshti alley,Edalat 41, Rezvan building

##### **City**

Ghaemshahr

##### **Province**

Mazandaran

##### **Postal code**

4765754536

#### **Approval date**

2018-03-02, 1396/12/11

#### **Ethics committee reference number**

R.IUMS.REC.1395.9311451002.

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

The effect of Video Interaction Guidance on preterm infants mother

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### **1**

#### **Description**

mother stress

#### **Timepoint**

The first, fourth and seventh day

#### **Method of measurement**

questionnaire-Likert

## **Secondary outcomes**

empty

## **Intervention groups**

### **1**

#### **Description**

Intervention group: Recieving Video Interaction Guidance.Intervention group compelete pss quesonaire(pretest) and then recieved Video Interaction Guidance in first day.then,theyrecieved Video Interaction Guidance in fourth day and filled pss questinaire(first posttest).in seventh day,mothers recieved Video Interaction Guidance and then filled pss questionnaire(second post test).

#### **Category**

N/A

### **2**

#### **Description**

Control group: control group recieved just hospital routin care and filled pss questionnaire in first day(pretest) and fourth day(first posttest) and seventh day(second posttest).

#### **Category**

N/A

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Booali sina and Imam khomeini hospital

##### **Full name of responsible person**

Barzegar ,Maryam

##### **Street address**

No41,Edalat 41Alley,Shahid beheshti Street,Ghaemshahr town

##### **City**

Ghaemshahr  
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maryambarzegar93@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Dr.Seid Kazem Malakouti.  
**Street address**  
Shahid beheshti alley,41 Edalat , Rezvan building  
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**Web page address**  
**Grant name**  
20000000Rial  
**Grant code / Reference number**  
**Is the source of funding the same sponsor organization/entity?**  
Yes  
**Title of funding source**  
Iran University of Medical Sciences  
**Proportion provided by this source**  
50  
**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**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Maryam Barzegar  
**Position**  
Nurse

**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
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Shahid beheshti Alley,Edalat 41, Rezvan Building  
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**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Barzegar, Maryam  
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Student  
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## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
**Full name of responsible person**  
Maryam barzegar  
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Nurse  
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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**

No - There is not a plan to make this available

**Title and more details about the data/document**

It possible some of data related to outcomes that intersect

**When the data will become available and for how long**

six month after resaults published

**To whom data/document is available**

Researcher who employed in association and university

**Under which criteria data/document could be used**

Useability of data should be with permitting responsible author.

**From where data/document is obtainable**

access to data by mobile phone

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

connecting with responsible author by electronic post and mobile

**Comments**