

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Aug 2026

### The effect of robotic training play on the mother-child relationship and stress of children hospitalized in hospital

#### Protocol summary

##### Study aim

The effect of robotic training on mother-child relationships and anxiety in children hospitalized

##### Design

Clinical trial with control and intervention group, sampling was based on purposeful and accessible, and by non-random method, 15 appointment children in the first group as an intervention group and 15 patients in the next group as control group, without substitution, December 2018 to October 2019 and followed for one month later

##### Settings and conduct

Robotics training sessions during 8 sessions in two weeks on improving child-parent relationship and anxiety in hospitalized children in a semi-experimental pre and post test in two groups of intervention and control in the pediatric ward of Shahid Motahari Hospital affiliated to Urmia University of Medical Science will be done in 2018.

##### Participants/Inclusion and exclusion criteria

Age

##### Intervention groups

The intervention group will receive robotic training sessions next to mothers in 8 sessions of 1 hour during the first two weeks of admission.

##### Main outcome variables

Mother-child relationships, Anxiety in hospitalized children

#### General information

##### Reason for update

Due to the completion of sampling, in order to prevent the transfer of information from the intervention group to the control, data collection was done through the convenience sampling and non-random manner in two separate units (one pediatric unit for the intervention group and another unit for the control group).

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181022041419N1**

Registration date: **2018-12-24, 1397/10/03**

Registration timing: **prospective**

Last update: **2021-02-17, 1399/11/29**

Update count: **1**

##### Registration date

2018-12-24, 1397/10/03

##### Registrant information

###### Name

Sima Pourteimour

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 44 3338 7708

###### Email address

simapure@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-12-22, 1397/10/01

##### Expected recruitment end date

2019-04-21, 1398/02/01

##### Actual recruitment start date

2019-02-01, 1397/11/12

##### Actual recruitment end date

2019-07-31, 1398/05/09

##### Trial completion date

2019-07-31, 1398/05/09

##### Scientific title

The effect of robotic training play on the mother-child relationship and stress of children hospitalized in hospital

##### Public title

The effect of robotic training play on the mother-child

|                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
|----------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------|
| relationship and stress of children hospitalized in Shahid Motahari Educational Centers of Urmia in 2018 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Urmia university of medical science         |
| <b>Purpose</b>                                                                                           | Education/Guidance                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <b>Street address</b>                       |
| <b>Inclusion/Exclusion criteria</b>                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Kashani Ave., Motahari Hospital, Urmia city |
| <b>Inclusion criteria:</b>                                                                               | The age of mothers over the age of 18 years is to be satisfied with the presence of the research. Mother must have hospitalized child. The mother is able to communicate in a different language. The mother has literacy to read and write. Mothers and children must be native to Orumiyeh city for the purpose of going to the outpatient clinic and performing the intervention and have a readiness and ability to visit one month later to follow up. During the time of admission, be sure the mother and the child are present for 60 minutes at the time of the game. The child has no educational background about the robotic training game. The child should have at least one week of hospitalization. A child with neurological diseases, such as seizures, mental and mental disabilities, mental problems, and history of taking fluids such as anxiolytics, are not based on a doctor's diagnosis and a child's medical record. Child ages 3 to 7 years. | <b>City</b>                                 |
| <b>Exclusion criteria:</b>                                                                               | Parental dissatisfaction for participation in the study. Missing children participating in more than two sessions of the robotics training program. Use of drugs that reduce children's anxiety and fear.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Urmia                                       |
| <b>Age</b>                                                                                               | From 3 years old to 7 years old                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Province</b>                             |
| <b>Gender</b>                                                                                            | Both                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      | West Azarbaijan                             |
| <b>Phase</b>                                                                                             | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <b>Postal code</b>                          |
| <b>Groups that have been masked</b>                                                                      | No information                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 5718673533                                  |
| <b>Sample size</b>                                                                                       | Target sample size: 60<br>Actual sample size reached: 59                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <b>Approval date</b>                        |
| <b>Randomization (investigator's opinion)</b>                                                            | Not randomized                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | 2018-09-21, 1397/06/30                      |
| <b>Randomization description</b>                                                                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | <b>Ethics committee reference number</b>    |
| <b>Blinding (investigator's opinion)</b>                                                                 | Not blinded                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | IR.UMSU.REC.1397.145                        |
| <b>Blinding description</b>                                                                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
| <b>Placebo</b>                                                                                           | Not used                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                             |
| <b>Assignment</b>                                                                                        | Parallel                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                             |
| <b>Other design features</b>                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
| <b>Secondary Ids</b>                                                                                     | empty                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |                                             |
| <b>Ethics committees</b>                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
| <b>1</b>                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
| <b>Ethics committee</b>                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |
| <b>Name of ethics committee</b>                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                             |

## Health conditions studied

### 1

#### Description of health condition studied

hospitalized Children

#### ICD-10 code

F43.2

#### ICD-10 code description

Adjustment disorders

## Primary outcomes

### 1

#### Description

Average score of anxiety of hospitalized children

#### Timepoint

Before the intervention, immediately after the intervention

#### Method of measurement

Pre-school children's anxiety questionnaire of 28 items

## Secondary outcomes

### 1

#### Description

Average score of mother-child relationship

#### Timepoint

Before the intervention, immediately after intervention

#### Method of measurement

Parent-parent relationship questionnaire of 33 items

## Intervention groups

### 1

#### Description

Robotic training sessions (with the goals specified in each session) will be held for children admitted to mothers in 8 sessions of 1 hour in the evening shifts, during the two weeks of admission to the children's playroom Motahari Hospital in Urmia, use of 59 packages which produce from Robofa Iran Co. Affiliated with Sharif University of Technology, named Robot Warrior. Educational information will also be provided in the form

of pamphlets and educational CDs. The reason behind the use of this robot, according to a study by the Robotics Institutions, is the ultimate goal of making this robot an incentive to counteract the stresses and problems of children. In order to achieve the objectives of the plan, the 8 steps of the training session will be presented in the form of a structured structure.

#### Category

Other

## 2

#### Description

Control group: The routine nursing interventions of the children's department will be received.

#### Category

Treatment - Other

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Shahid Motahari Hospital in Urmia

##### Full name of responsible person

Sima Pourteimour

##### Street address

Motahari Hospital, Kashani Ave, Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5718673533

##### Phone

+98 44 3275 4963

##### Email

simapure@yahoo.com

## Sponsors / Funding sources

## 1

#### Sponsor

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Dr. Iraj Mohebi

##### Street address

Research and Technology Department, Headquarters  
University, Emergency cuticle end, Resalat  
Bldv,Urmia

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5714783734

##### Phone

+98 44 3193 7224

##### Email

mohebbi\_iraj@yahoo.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

##### Full name of responsible person

Sima Pourteimour

##### Position

faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

##### Street address

Nazlou Campus Building Faculty of Nursing and  
Midwifery - 11 km Sero - Urmia - West Azarbaijan -  
Iran

##### City

Urmia

##### Province

West Azarbaijan

##### Postal code

5756115111

##### Phone

+98 44 3275 4963

##### Email

simapure@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Oroumia University of Medical Sciences

##### Full name of responsible person

Sima Pourteimour

##### Position

Faculty member

##### Latest degree

Master

##### Other areas of specialty/work

Nursery

**Street address**

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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**

Not applicable

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

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

Only part of the information, such as information on the  
main outcome or the like, can be shared.

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

6 months after publish results

**To whom data/document is available**

Researchers working in academia and academia

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

After permission from the responsible author, any  
analysis may be possible.

**From where data/document is obtainable**

simapure@yahoo.com Sima Pourteioumr Faculty Member  
of Urmia Nursing and Midwifery Faculty

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

Within a week of sending the email, the documentation  
will be available with the preservation of spirituality.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Oroumia University of Medical Sciences

**Full name of responsible person**

Sima Pourteimour

**Position**

Faculty member

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

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