

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	
Purpose	Education/Guidance	Street address	Kashani Ave., Motahari Hospital, Urmia city
Inclusion/Exclusion criteria		City	Urmia
Inclusion criteria:	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.	Province	West Azarbaijan
Exclusion criteria:	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.	Postal code	5718673533
Age	From 3 years old to 7 years old	Approval date	2018-09-21, 1397/06/30
Gender	Both	Ethics committee reference number	IR.UMSU.REC.1397.145
Phase	N/A	Health conditions studied	
Groups that have been masked	No information	1	
Sample size	Target sample size: 60 Actual sample size reached: 59	Description of health condition studied	hospitalized Children
Randomization (investigator's opinion)	Not randomized	ICD-10 code	F43.2
Randomization description		ICD-10 code description	Adjustment disorders
Blinding (investigator's opinion)	Not blinded	Primary outcomes	
Blinding description		1	
Placebo	Not used	Description	Average score of anxiety of hospitalized children
Assignment	Parallel	Timepoint	Before the intervention, immediately after the intervention
Other design features		Method of measurement	Pre-school children's anxiety questionnaire of 28 items
Secondary Ids	empty	Secondary outcomes	
Ethics committees		1	
1		Description	Average score of mother-child relationship
Ethics committee		Timepoint	Before the intervention, immediately after intervention
Name of ethics committee		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

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

+98 44 3275 4963

Email

simapure@yahoo.com

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

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

City

Urmia

Province

West Azarbaijan

Postal code

5756115111

Phone