

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The Effect of Supportive Program on Anxiety and Attachment in Infants of Mothers With Digestive Anomalies:A Randomized Controlled Clinical Trial

Protocol summary

Summary

The aim of present study is to investigate the effects of supportive programs on interest and anxiety level of mothers of infants suffering from gastrointestinal disorders. In this study 60 term infant mothers who Having no history of abnormal infant were included randomly into two control and observation groups. Before and after intervention, Koren mother-infant interest questioner was used to evaluate interest level and Eschpel Burger anxiety questioner was filled by mothers to measure anxiety level in both control and observation groups. The supportive program in observation group, with mental and psychological aspects, started by clinical psychologist or scholar for 2 sessions of 30 minutes during 2nd- 4th courses after admission infant. During this period, some issues were explained about the importance of emotional relationship between mother and infant and the mother was prepared psychologically to accept caring role, anxiety reduction and interest to infant. Then a caring program was started by the scholar, for 2 sessions of 30 minutes during 2nd- 4th courses after infant's surgery. At this time interval, according to mother's knowledge of infant's abnormality and using training images some explanations were presented about infant's condition and booklet involving information about infant care was provided for each mother. Above mentioned items were administrated practically and in face to face method.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201409264617N10**

Registration date: **2015-02-13, 1393/11/24**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-13, 1393/11/24

Registrant information

Name

Mahnaz Jabraeili

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-17, 1393/09/26

Expected recruitment end date

2015-05-15, 1394/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Supportive Program on Anxiety and Attachment in Infants of Mothers With Digestive Anomalies:A Randomized Controlled Clinical Trial

Public title

The Effect of Supportive Program on Anxiety and Attachment in Infants of Mothers With Digestive Anomalies: A Randomized Controlled Clinical Trail

Purpose

Supportive

Inclusion/Exclusion criteria
Inclusion criteria: Mothers of infants with absolute diagnosis of gastrointestinal abnormalities(hidden or obvious); No reception of anti-depression drugs by mothers; No alcohol consumption or smoking; Having no history of abnormal infant Signing written consent by mother;Having knowledge of reading and writing by mother; Having no life threatening danger in infant;Not suffering from alcoholic infant syndrome. Exclusion criteria Infant's death or release during study time; Transferring infant to ICU; No tendency of mother to continue study.

Age
To 28 days old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tabriz University of Medical Sciences Ethics Committee

Street address

Deputy of Research, Tabriz University of Medical Sciences ,Golgasht street , Tabriz

City

Tabriz

Postal code

5138947979

Approval date

2014-11-09, 1393/08/18

Ethics committee reference number

93123

Health conditions studied

1

Description of health condition studied

Digestive Congenital Anomalies

ICD-10 code

Q38-Q45

ICD-10 code description

Other congenital malformations of the digestive systems

Primary outcomes

1

Description

Mother's Anxiety

Timepoint

After and Before

Method of measurement

Spilberger of Self Evaluation Questionnaire

2

Description

Attachment

Timepoint

Befor and After

Method of measurement

Maternal Attachment Inventory (MAI)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: support program that includes psychological support through clinical psychologist during the second and fourth days of the meeting for 30 minutes after birth in hospital admissions of children will be done. The second phase of support by the researcher during two 30-minute sessions on two consecutive days after surgery research at the neonatal unit will be done. At the First session about kind of anomalies and second meeting of the in newborn care based on practical, face-to-face training will be given.

Category

Prevention

2

Description

Control group: This group received usual care on the part of the psychologist and researcher did not receive supportive care. After completion of data collection to support their educational booklets will be at their disposal.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Educational Center Affiliated Medical Sciences University of Tabriz;Iran

Full name of responsible person

Masomeh Janetdoust

Street address

Next to the Pharmacy Mehan;Sheshgelan Street;Tabriz;Iran

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research,Tabriz University of Medical Sciences

Full name of responsible person

Dr Rashidi

Street address

Research Department,Central Building,Golgasht,Tabriz

City

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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

Deputy of Research,Tabriz University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Alehe Seyyedrasoli

Position

Ms, Faculty member

Other areas of specialty/work

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Person responsible for scientific inquiries

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MS, Faculty Member

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Nursing Student

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>