

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of counseling with behavioral approach on the infant's Colic of anxious mothers : a randomized controlled trial

Protocol summary

Study aim

Determining the effect of behavioral counseling on infants' colic in anxious mothers

Design

Randomized trial with control group and parallel groups, on 46 subjects who will be randomly divided into control and intervention groups by random.org site and random blocking method with 4 and 6 block sizes and 1: 1 allocation ratio.

Settings and conduct

This study will be performed in the pediatric clinics of Tabriz, and 46 anxious mothers whose infants have colic will be easily selected. Then, questionnaires of postpartum anxiety, demographic characteristics, infant colic and mother-infant attachment will be completed. Participants will be randomly assigned to the control and intervention groups, the intervention group will receive 8 counseling sessions and the control group will receive routine care. Two weeks after the intervention, post-test questionnaires will be completed again for both groups.

Participants/Inclusion and exclusion criteria

Mothers whose infants 2 to 6 weeks old had colic according to Wessel criteria and pediatrician diagnosis and scored 112 or higher on the Postnatal Specific Anxiety Questionnaire.

Intervention groups

For the intervention group mothers, according to the behavioral psychology approach , 8 counseling sessions will be held two days a week for 4 consecutive weeks, with some sessions to teach relaxation as well as the ordering of stress triggers. Training on breastfeeding, taking extra baby gastric air, and nutritional counseling will be conducted in groups and individually. The control group will only be offered breastfeeding training, extra gastric air intake and nutritional counseling.

Main outcome variables

infantile colic; maternal anxiety; mother-infant attachment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111219008459N14**

Registration date: **2020-10-08, 1399/07/17**

Registration timing: **prospective**

Last update: **2020-10-08, 1399/07/17**

Update count: **0**

Registration date

2020-10-08, 1399/07/17

Registrant information

Name

Shirin Hasanpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-21, 1399/09/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of counseling with behavioral approach on the infant's Colic of anxious mothers : a randomized controlled trial

Public title

The effect of counseling on the infant's Colic of anxious mothers

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Primiparous women with 2 to 6 weeks infants Anxiety Based on Postpartum Anxiety Questionnaire (PSAS) Diagnosis of infant colic based on Wessel criteria and approved by pediatrician Having at least intermediate Education Exclusive Breastfeeding Healthy term infant weighing at least 2500 grams and normal weight gain

Exclusion criteria:

Twin Use of all kinds of chemical and herbal remedies such as anti-flatulence to treat infant colic. Congenital autoimmune disease or infant nutritional problems. A history of mental illness requiring medication, including postpartum depression in previous deliveries (according to the individual). The mother's anxiety as much as she needs medication. Existence of mothers' drug abuse during pregnancy and in the postpartum period (according to the individual). Mother's education in research topic from other sources. Maternal formal education / training to reduce anxiety. Mother's uncertainty about attending all counseling sessions. Adverse events such as the death of loved ones or divorce and ... for the mother in the last 2 months. Mother's use of antibiotics.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 46

Randomization (investigator's opinion)

Randomized

Randomization description

Participants would be allocated into two groups (receiving counseling and control), using a randomized block method with a block size of four and six, and the allocation ratio of 1: 1.

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

Ethics Committee of Tabriz University of Medical Sciences

Street address

South Shariati Ave.

City

Tabriz

Province

East Azarbaijan

Postal code

5138947979

Approval date

2020-01-07, 1398/10/17

Ethics committee reference number

IR.TBZMED.REC.1398.1083

Health conditions studied

1

Description of health condition studied

Infantile Colic

ICD-10 code

R10.83

ICD-10 code description

Colic

2

Description of health condition studied

maternal anxiety

ICD-10 code

F06.4

ICD-10 code description

Anxiety disorder due to known physiological condition

Primary outcomes

1

Description

infantile colic

Timepoint

Measurement of infant colic score before the intervention and 2 weeks after the intervention.

Method of measurement

Infantile Colic scale (ICS)

2

Description

maternal anxiety

Timepoint

Measurement of maternal anxiety score before the intervention and 2 weeks after intervention.

Method of measurement

Postpartum Specific Anxiety scale (PSAS)

Secondary outcomes

1

Description

Maternal Postnatal Attachment

Timepoint

Measuring mother-infant attachment score before and two weeks after intervention

Method of measurement

Maternal Postnatal Attachment scale (MPAs)

Intervention groups

1

Description

Intervention group: For intervention group mothers, according to the behavioral psychology approach and regular desensitization technique, 8 counseling sessions will be held two days a week for 4 consecutive weeks. The intervention protocol is as follows: Session 1: Teaching how to breastfeed and get extra air in the baby's stomach and training relaxation for mothers with infants with colic, Session 2: Continuation of relaxation training for mothers with colic, Session 3: Identifying the anxiety hierarchy of mothers with infants with colic (from severe to mild), Session 4: Initiation of desensitization: clients will sit relaxed or lying down and will begin to visualize and deal with anxiety (from the least anxious to the most). The fifth, sixth, seventh and eighth sessions of desensitization continue until the person Minimize anxiety in the cases listed. Probiotic drops will be prescribed for both groups infants. Two weeks after the intervention, infants' colic questionnaires, postpartum anxiety and mother-infant attachment questionnaires will be completed again.

Category

Other

2

Description

Control group: The control group will be taught how to breastfeed and get extra air in the baby's stomach individually, and their babies will also receive probiotic drops.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Alzahra Hospital

Full name of responsible person

dr Shirin Hasanpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Reyhaneh Montazeri

Position

Ms.c student of counseling in Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available