

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of an educational- supportive- following program on burden of parental ' care with infantile colic

Protocol summary

Study aim

Determination of an educational- supportive- following program's effect on burden of parental ' care with infantile colic

Design

The clinical trial, parents of infants colic divided randomly into two groups of 32 peoples, intervention and control groups.

Settings and conduct

This research was done in Amin and Emam Hossein clinical centers of Isfahan. The test group received a three-cycle program during 2 weeks in 4 sessions. Both groups answered the caregiver's burden questionnaire before, immediately and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Parents of infant (Mother or Father); Wishing to participate in the study; Be able to communicate and Persian language; With no drug addiction; No history of taking any psychiatric drug; Have colicky baby in the age range from 2 weeks to 3 months old; Have a physical and mental ability to take care of colicky infants who had not previously participated in family education sessions (any other research project in the field).

Intervention groups

The experimental group received an intervention called a three-cycle program as an educational- supportive- following program during two weeks in 4 sessions while the control group received routine infant care.

Main outcome variables

Propose a three-cycle educational- supportive- following program to children's treatment centers to improve the parental care burden of colic infants.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190312043031N1**

Registration date: **2019-04-24, 1398/02/04**

Registration timing: **retrospective**

Last update: **2019-04-24, 1398/02/04**

Update count: **0**

Registration date

2019-04-24, 1398/02/04

Registrant information

Name

Zahra Alikhalili

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

2017-09-23, 1396/07/01

Actual recruitment end date

2018-02-22, 1396/12/03

Trial completion date

2018-02-22, 1396/12/03

Scientific title

Effect of an educational- supportive- following program on burden of parental ' care with infantile colic

Public title

Effect of an educational- supportive- following program on burden of parental ' care with infantile colic

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Parents of infant (Mother or Father) to be considered as primary caregiver and all have to assume his or her responsibilities Have a mental and physical ability to take care of colicky baby Wishing to participate in the study Be able to communicate and follow the rules of the training session Be able to speak, read and write in Persian language Must not be drug-addicted and not to be treated with psychiatric drug In family training sessions (any other research project in the field) have not participated in the past Parents for colicky baby who range in age from 2 weeks to 3 months

Exclusion criteria:

Parents are reluctant to continue cooperation in the training sessions There is any problem, so parents can not continue to participate in the study look out for a maximum of two sessions of the training sessions absence The physical and psychological problems in parents who can not presence in the meetings Parents have to take care of another patient in the family Infants have a diagnosis other than colic at the time of referral

Age

From **14 days** old to **3 months** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Actual sample size reached: **55**

Randomization (investigator's opinion)

Randomized

Randomization description

The random allocation of samples was done in two groups of test and control by simple random method and using the envelope in a package containing 32 cards with number one and 32 cards with number two. On the day of random allocation of the research units, parents were asked to choose a card. In this way, the parents who assigned the number one in the experimental group and those who were assigned number two were placed in the control group. .

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 Isfahan University of Medical Sciences

Street address

Faculty of Nursing and Midwifery, Isfahan University of Medical Sciences, Hezar jarib Street.

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Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-07-02, 1396/04/11

Ethics committee reference number

IR.MUI.REC.1396.3.224

Health conditions studied

1

Description of health condition studied

Colic in infants

ICD-10 code

R10.4

ICD-10 code description

Other and unspecified abdominal pain

Primary outcomes

1

Description

Caregiver burden for parents

Timepoint

Before the intervention, immediately after the intervention and one month after the intervention

Method of measurement

Zarit caregiver burden questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

In this study, for patients in the test group, educational- supportive- following program was held for 4 sessions, 30-45 minutes, during 2 weeks.

Category

Prevention

2

Description

Control group received routine infants cares.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Hossein hospital

Full name of responsible person

Dr. Mehrdad Meemarzadeh

Street address

Emam Khomeini St, Emam Hossein children's hospital

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emamhossein_hospital@mui.ac.ir

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2

Recruitment center

Name of recruitment center

Amin

Full name of responsible person

Dr Etminani

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Sponsors / Funding sources

1

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Name of organization / entity

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Zahra Alikhalili

Position

student

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available