

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of educating “care for child development guidelines” through a new method to mothers on developmental status of children: A randomized clinical trial

Protocol summary

Study aim

To evaluate the effect of educating "care for child development" guidelines through a new method to mothers on child development

Design

Two arm, parallel groups, randomised, double blinded

Settings and conduct

This trial will be held at Isfahan child development center

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women in the third trimester who have a healthy child based on clinical and ultrasound evaluations ; Exclusion criteria: Preterm birth (earlier than 37 weeks), birth asphyxia or seizure, Being absent for more than 2 sessions, lack of cooperation for the study, known metabolic or neurological disorders after birth, malnutrition

Intervention groups

The intervention group: The intervention group undergo 5 educational sessions, each lasting for almost 45 minutes. The session will be held during the third trimester of pregnancy (the first session) and 2-6 weeks, 2-6 months, 6-9 months and 9-12 months after delivery, respectively. The educational content of each session is adopted from the Farsi version of CCD manual. In each session, the mother would be trained on how to play and communicate with her child based on the child's age using training materials such as educational slides, toys, etc. The control group: The control group undergo routine educations on child care, suggested by WHO, which is currently implementing in most of the health centers in the country (through pamphlets and brochures, as well as two to three general skills training sessions such as breastfeeding).

Main outcome variables

BSID-III scores after 1 year

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190128042533N2**

Registration date: **2020-01-16, 1398/10/26**

Registration timing: **retrospective**

Last update: **2020-01-16, 1398/10/26**

Update count: **0**

Registration date

2020-01-16, 1398/10/26

Registrant information

Name

Omid Yaghini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3234 1294

Email address

yaghini@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-10-17, 1398/07/25

Expected recruitment end date

2019-12-29, 1398/10/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of educating “care for child development guidelines” through a new method to mothers on developmental status of children: A randomized clinical trial

Public title

Evaluating the effect of educating “care for child development guidelines” through a new method to mothers on developmental status of children: A randomized clinical trial

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women in the third trimester of pregnancy (days 196 to 280 of pregnancy). Having a healthy child based on clinical and ultrasound evaluations during pregnancy.

Exclusion criteria:

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **266**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers would be divided in to two control and intervention groups. Random numbers would be generated by random allocation software in four blocks. In this method, different conditions of being in the control or intervention group would be considered. Random numbers would be generated, and considering different conditions, patients' allocation to the control or intervention group would be determined.

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

Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8117673461

Approval date

2018-08-12, 1397/05/21

Ethics committee reference number

IR.MUI.RESEARCH.REC.1397.092

Health conditions studied

1

Description of health condition studied

child development at 12 months of age

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Bayley Scale for Infant Development (BSID)-III score at 1 years of age

Timepoint

when the child is 1 year old

Method of measurement

Bayley Scale for Infant Development (BSID)-III

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Pregnant women who are included in the study are invited to participate in a session, as the starting session of the study. In this session, general concepts will be discussed including the nutritional needs of children and their developmental status. Then, the intervention group is invited to attend 5 educational sessions, every session lasts 45 minutes. The educational content of each session is adopted from the Farsi version of CCD manual. In each session, mothers are trained to how to play and communicate with their children in each age group. In addition, toys that may be beneficial for children's development are introduced to mothers and they are encouraged to avoid punishing their children. The control group: The control group undergo routine educations on child care, suggested by WHO, which is currently implementing in most of the health centers in the country (through pamphlets and brochures, as well as two to three general skills training

sessions such as breastfeeding).

Category

Behavior

2

Description

Control group: this group take only rotin care in pregnancy and after that take rotin care in health center

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan city primary health care centers

Full name of responsible person

Omid Yaghini

Street address

Child Growth and Development Research Center, Research Institute for Primordial Prevention of Non-communicable Diseases, Isfahan University of Medical Sciences, Hezar Jarib Street, Isfahan, Iran

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yaghini@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan 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

Esfahan University of Medical Sciences

Proportion provided by this source

80

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

Omid Yaghini

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Neuroscience

Street address

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Associate professor

Latest degree

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Neuroscience

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Person responsible for updating data

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Full name of responsible person

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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

Yes - There is 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

Title and more details about the data/document

Have not decided yet.

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

Have not decided yet.

To whom data/document is available

Have not decided yet.

Under which criteria data/document could be used

Have not decided yet.

From where data/document is obtainable

Have not decided yet.

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

Have not decided yet.

Comments