

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of education based on the theory of planned behavior on supplementation of their fewer than two years children.

Protocol summary

Summary

The aim of this study is to evaluate the effect of educational intervention based on theory of planned behavior on mothers supplementation, of their under two-years children. In this randomized controlled trial, from 251 mothers with children under two years who had referred to the health centers of Mashhad, 70 Mothers were chosen with multi-stage cluster sampling and randomly divided into either experimental or control group.(35 in trial group and 35 in control group). The instructional sessions were carried out applying modified methods of the theory of planned behavior structure (attitudes, subjective norms,perceived behavioral control, intention and behavior). Inclusion criteria : Willingness to participate in research; Having children under two years. Exclusion criteria: Feeding children with infant formula more than 500 ml per day ;Whether the child has anemi ;Contraindications vitamins and iron in children; The absence of a training session. Main outcome measure: weekly dose number of supplementation (iron-vitamin). Data: weekly dose number of supplementation (iron-vitamin), health literacy and growth disorders in children, were analyzed during the three periods: before, immediately and three month after the intervension.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017031328863N14**

Registration date: **2017-05-21, 1396/02/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-21, 1396/02/31

Registrant information

Name

Nooshin Peyman

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

peymann@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Mashhad University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of education based on the theory of planned behavior on supplementation of their fewer than two years children.

Public title

Effect of education on supplementation of their fewer than two years children

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria : Willingness to participate in research; Having children under two years. Exclusion criteria:

Feeding children with infant formula more than 500 ml per day ;Whether the child has anemi ;Contraindications vitamins and iron in children; The absence of a training session.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 70

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**

Ethics committee of Mashhad University of Medical Sciences

Street address

Ghoraishy Building, University St, Mashhad

City

Mashhad

Postal code**Approval date**

2016-08-17, 1395/05/27

Ethics committee reference number

IR.MUMS.REC.1395.322

Health conditions studied**1****Description of health condition studied**

Supplementation

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Mothers' knowledge about supplementation

Timepoint

Before and three months after intervention

Method of measurement

The questionnaire was created by the researcher

Secondary outcomes**1****Description**

Frequency of supplementation(iron-vitamin) for children

Timepoint

before, immediately and three month after the intervention

Method of measurement

The questionnaire was created by the researcher

2**Description**

social cognitive theory constructs(attitudes, subjective norms,perceived behavioral control, intention and behavior)

Timepoint

before, immediately and three month after the intervention.

Method of measurement

The questionnaire based on theory of plane behavior, was created by the researcher

3**Description**

Mothers health literacy.

Timepoint

before, immediately and three month after the intervention.

Method of measurement

Test of Functional Health Literacy in Adults

Intervention groups**1****Description**

The implementation of three training sessions on supplementation(a total of 180 minutes)based on theory of plane behavior.

Category

Behavior

2**Description**

Control groupel: no action

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khamenei Health Center

Full name of responsible person

Saeedeh Fakehi Khorasani

Street address

Khorramshahr 14, Khorramshahr Street

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2

Recruitment center

Name of recruitment center

Shahid Bahooar Health Center

Full name of responsible person

Saeedeh Fakehi Khorasani

Street address

Musa Ibn Ja'far 16, Hor 86, HorBoulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Ghoroishy Building, University St, Mashhad

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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

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Saeedeh Fakehi Khorasani

Position

Masters of Health Education and Health Promotion

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty