Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of combined counseling and face-to-face on mothers self-efficacy in complementary nutrition and growth index of 6-10 month infants

Protocol summary

Study aim

Comparison of the effect of combined counseling and face-to-face on mothers self-efficacy in complementary nutrition and growth index of 6-10 month infants

Design

The present study is a clinical trial with two groups. Which will be conducted on 120 mothers with a 6-month-old healthy baby who will go to health centers in Mashhad for health care and have entry requirements. Five centers of health in Mashhad will be selected by drawing a center. And from the selected center, two centers or a covered base are selected by lottery method, which is a center of intervention group 1 and another center of intervention group 2, mothers with a 6 month old child having easy access to the study file They will be selected at the centers and will be informed by telephone and will be included in the study if they consent.

Settings and conduct

The place of sampling is in the selected health centers. The method of counseling is face-to-face in the intervention group 1, in the intervention group, the first 2 sessions are face-to-face and follow-up podcast links provided to mothers. To be done.

Participants/Inclusion and exclusion criteria

The informed consent of the parent, Iranian and resident of Mashhad, the lack of speech, audio or dialectal problems that prevent contact with the researcher, is the first birth, the gestational age is between 38 and 40, has at least fifth grade primary education, the mothers of the intervention group 2 have access to the Android device and the internet. The infant has no history of being admitted to infancy, term, IUGR, no metabolic and metabolic problems, and FTT.

Intervention groups

The intervention groups consist of two groups of maternity counseling and podcast counseling, which are the same in the two groups.

Main outcome variables

Improved child nutrition counseling, saving time.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180613040088N1**
Registration date: **2018-11-12, 1397/08/21**
Registration timing: **registered_while_recruiting**

Last update: **2018-11-12, 1397/08/21**
Update count: **0**

Registration date

2018-11-12, 1397/08/21

Registrant information

Name

Elahe Moghadasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3604 3299

Email address

moghadasie1@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-01, 1397/08/10

Expected recruitment end date

2019-03-01, 1397/12/10

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of combined counseling and face-to-face on mothers self-efficacy in complementary nutrition and growth index of 6-10 month infants

Public title
Comparison of the effect of combined counseling and face-to-face on mothers self-efficacy in complementary nutrition and growth index of 6-10 month infants
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Have written informed consent to participate in the research. Iranian and resident of Mashhad. Do not have spoken, audible or dialectal problems that prevent communication with the researcher. The age of the mother is between 18 and 45 years old. Have at least fifth grade elementary education. The mother has no medical condition. (medical illness includes diabetes, cardiovascular disease, hypertension, epilepsy, migraine, history of head trauma, thyroid disease, connective tissue disease, asthma, respiratory disorders, kidney disease, anemia and stroke Brain) Mother is prenatal. Moms have access to Android and the Internet in a combination group. The age of the infant is 6 months, the growth curve between the 15th and the 85th percentile, has no metabolic and medical problems, low birth weight and hospitalization history.
Exclusion criteria:
Unwilling to continue studying. In the compilation group, they did not follow the tutorials and podcast files in a meeting, nor would they attend a face-to-face meeting in a counseling session, they would be excluded from the research process. Medical problems have occurred during the study for infants (listed in clause 6 of entry requirements). Do things like travel and change during the study, which leads to lack of follow up counseling sessions and missed infant formula. The infant has a history of hospitalization during the study period.
Age
From **6 months** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the randomization method is simple and draw Use the random numbers table. First, a center is selected from the five centers of Mashhad and then by drawing the centers covered by the center, two centers for intervention group 1 and 2 Selected.
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 Nursing and Midwifery
Street address
Doktora Crossroads
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Approval date
2018-10-24, 1397/08/02
Ethics committee reference number
IR.MUMS.NURSE.REC.1397.047

Health conditions studied

1

Description of health condition studied
Infant Growth Index
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Self-efficacy of mothers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Mothers self-efficacy in complementary nutrition
Timepoint
Before intervention and 1 and 3 months after intervention
Method of measurement
Researcher-made questionnaire on maternal nutritional

self-efficacy

2

Description
Infant growth index of 6 to 10 months
Timepoint
Before the intervention, 1, 2 and 3 months after the intervention
Method of measurement
Balance and meter

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: In face-to-face group, 4 supplementary nutritional counseling sessions will be held during 4 weeks from 6 months to 7 months, each session including counseling, question and answer, and exchange of views, the content of the sessions will be based on the results of the required measurement. The preparation will consist mainly of erroneous false beliefs and nutritional behaviors, as well as creativity in the mother to prepare new, tasty and tasty foods for the infant. The duration of each session is 40 to 60 minutes.
Category
Other

2

Description
Intervention group 2: In the consolidated group, we will have four counseling sessions from sixth to seventh for four weeks, with a face-to-face consultation and question-and-answer session, and three sessions for submitting podcast files, the content of the sessions will be prepared based on the results of the need assessment and will include the refinement Nutrition beliefs and nutritional behaviors, along with creativity in the mother to cook new and tasty and tasty foods for the infant, will be discussed at the first session (in person) and in the next sessions through the podcast link provided to mothers as well as Q & A and chat through an internet messenger program, the duration of each session 40 Or 60 minutes
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Vahdat Health Center
Full name of responsible person
Dr . Mahdi sayad
Street address
Mirza Kuchak Khan Square
City
Mashhad
Province
Razavi Khorasan
Postal code
9153913153
Phone
+98 51 3259 6531
Email
ETG@mums.ac.ir

2

Recruitment center
Name of recruitment center
Velayat Health center
Full name of responsible person
Sedighe Barat
Street address
Mirza Kuchak Khan Square , Emet Blvd.
City
Mashhad
Province
Razavi Khorasan
Postal code
9153913153
Phone
+98 51 3259 6534
Email
ETG@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Nursing and Midwifery
Full name of responsible person
Dr Rabab Latifnejad Roodsari
Street address
Mashhad University of Nursing and Midwifery, Daneshgah Street, Doktora Crossroads
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
NMS.IT@MUMS.AC.IR
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source

Mashhad University of Nursing and Midwifery

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

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Moghadasi

Position

ResponsibleMidwife (Base)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.38 , Imahat52 , Imamat Blvd.

City

Mashhad

Province

Razavi Khorasan

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9188796789

Phone

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Email

Moghadasie1@Mums.Ac.Ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Moghadasi

Position

Health Center Employee

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.38, Floor 3, Imamate 52, Imamate Blvd

City

Mashhad

Province

Razavi Khorasan

Postal code

9188796789

Phone

+98 51 3604 3299

Fax

Email

Moghadasie1@Mums.Ac.Ir

Person responsible for updating data

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Elahe Moghadasi

Position

Responsible Midwife (Base)

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

No.38 , Imahat52 , Imamat Blvd.

City

Mashhad

Province

Razavi Khorasan

Postal code

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Phone

+98 51 3604 3299

Email

Moghadasie1@Mums.Ac.Ir

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