Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Sep 2026

Smartphone-based maternal education directed at complementary feeding versus treatment as usual among malnourished children below 3 years of age in food-secure contexts: Randomized controlled trial in Urmia, Iran

Protocol summary

Study aim

The aim of this study was to assess the effect of smartphone-based maternal nutritional education directed at complementary feeding on malnourished children below 3 years of age in a food-secure context

Design

Six-month single-centre randomized controlled trial with one intervention (smartphone application) arm and one control (treatment-as-usual) arm.

Settings and conduct

The study used a randomized controlled trial design with one intervention and one control arm (n=110; 1:1 ratio). 860 children seen at one well-child clinic in Urmia, Iran, were assessed for study eligibility. An educational smartphone application was delivered to the intervention group for a 6-month period while the control group received treatment-as-usual (TAU). The primary outcome and Secondary outcome measures were pre-post intervention changes in malnutrition indices and mothers' nutritional health literacy. The randomization was performed by a researcher with no access to participant information and who did not participate in the enrollment process. also, the participants in control group were blinded to the smartphone application provided to the intervention group.

Participants/Inclusion and exclusion criteria

inclusion criteria Child aged < 3 years with moderate or severe malnourishment exclusion criteria Child or mother diagnosed with a medical disorder requiring treatment. Mother did not possess a smartphone.

Intervention groups

in the intervention group, the application provided the mothers of newly-born children with an interactive healthy-child care guide structured into a set of learning topics. In the control arm, mother and child pairs received routine health service treatment.

Main outcome variables

weight-for-height (WFH), weight-for-age (WFA) and height-for-age (HFA) z scores mothers nutritional health literacy (critical knowledge, feeding attitudes, and nutrition practice)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190705044103N1**
Registration date: **2019-07-14, 1398/04/23**
Registration timing: **retrospective**

Last update: **2019-07-14, 1398/04/23**
Update count: **0**

Registration date

2019-07-14, 1398/04/23

Registrant information

Name

Navisa Seyyedi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 44 3345 0459

Email address

ns.seyyedi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-01, 1397/01/12

Expected recruitment end date
2018-05-15, 1397/02/25
Actual recruitment start date
2018-04-01, 1397/01/12
Actual recruitment end date
2018-05-31, 1397/03/10
Trial completion date
2018-12-31, 1397/10/10

Scientific title
Smartphone-based maternal education directed at complementary feeding versus treatment as usual among malnourished children below 3 years of age in food-secure contexts: Randomized controlled trial in Urmia, Iran

Public title
Smartphone-based maternal education directed at complementary feeding among malnourished children below 3 years of age in Urmia, Iran
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Child aged < 3 years with moderate or severe malnourishment with regard to wasting (WFH < -2),and/or underweight (WFA < -2), and/or stunting (HFA < -2)
Exclusion criteria:
Child or mother diagnosed with a medical disorder requiring treatment Mother diagnosed with a medical disorder requiring treatment Mother did not possess a smartphone
Age
To **3 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Care provider
- Investigator

Sample size
Target sample size: **110**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
The mothers having consented to participate in the study were allocated using Random Allocation Software 1.0 (https://random-allocation-software.software.informer.com/1.0/) to intervention or control groups in a 1:1 ratio. The randomization was performed by a researcher with no access to participant information and who did not participate in the enrollment process. The permuted block method of randomization for a block size of four was used. Based on the limited size of the trial, this procedure was preferred to simple randomization in order to maintain an adequate balance in the number of participants allocated to each of the study groups
Blinding (investigator's opinion)
Double blinded
Blinding description
For avoiding the study bias it is required that the control and intervention have no access to each other. because in this intervention as an educational mobile App, it is possible the control group by identifying the opposite group could access to the app however this probability is low in our study but for avoiding this bias the investigation on participants were conducted quit separately in an isolated room. (Dear admin, please let us know if this is blinding) Data collectors and care providers were blinded to group assignment and they just investigated the inclusion criteria in the defined clinic. The randomization was performed by a researcher with no access to participant information and who did not participate in the enrollment process.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Urmia University of Medical Science
Street address
Urmia University of Medical Sciences, Nazloo Campus, Sero Road
City
Urmia
Province
West Azarbaijan
Postal code
571478334
Approval date
2017-12-13, 1396/09/22
Ethics committee reference number
IR.UMSU.REC.1396.291

Health conditions studied

1

Description of health condition studied
moderate malnutrition
ICD-10 code
E44.0
ICD-10 code description
Moderate protein-calorie malnutrition

2

Description of health condition studied

severe malnutrition

ICD-10 code

E41

ICD-10 code description

Nutritional marasmus

Primary outcomes

1

Description

Pre-post intervention change with regard to wasting status measured by the weight-for-height (WFH) z score (< -2 standard deviations (SDs)) indicator

Timepoint

before intervention and 6 month after intervention

Method of measurement

The weight of the child was obtained using a calibrated electronic scale and infant digital scale and stadiometer were used for measuring the height

Secondary outcomes

1

Description

Underweight status (measured by the WFA indicator), practice

Timepoint

before intervention and 6 month after intervention

Method of measurement

calibrated electronic scale

2

Description

stunting status (the HFA indicator),

Timepoint

before intervention and 6 month after intervention

Method of measurement

infant digital scale and stadiometer were used for measuring the height

3

Description

wasting caseness (WFH < -2; yes/no),

Timepoint

before intervention and 6 months after intervention

Method of measurement

(WFH < -2; yes/no)

4

Description

underweight caseness (WFA < -2; yes/no),

Timepoint

calibrated electronic scale

Method of measurement

(WFA < -2; yes/no)

5

Description

stunting caseness (HFA < -2; yes/no),

Timepoint

before intervention and 6 month after intervention

Method of measurement

(HFA < -2; yes/no)

6

Description

mothers nutritional health literacy (critical knowledge, feeding attitudes, and nutrition practice)

Timepoint

before intervention and 6 month after intervention

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: A smartphone application and educational content were developed based on the Maternity Guidelines for maternal and child health services issued by the Iranian Ministry of Health and delivered to the intervention group for a 6-month period. The application provided the mothers of newly-born children with an interactive healthy-child care guide structured into a set of learning topics. The topics included nutrition principles based on child age, behavioral methods for child feeding, child weaning time, the introduction of complementary feeding, and mother health. All learning materials in the application were cross-examined by expert nutritionists to ensure that they complied with the national guidelines on infant feeding in the first 3 years of life. The user interface and functions of the smartphone application were developed using participatory design methods involving software developers, clinicians, medical informaticians, and end users in a process where functions were step wise added and revised. Following repeated field tests, a final version of the application was implemented for the Android operative system for smartphones. The final application had two major features: (1) providing mothers with evidenced-based education of how to feed their child divided by the child's age group, and (2) a chat function where clinicians answered the mothers' questions regarding nutrition through the application.Mothers in the intervention arm had the application installed on their smartphones at the start of the 6 months intervention period.

Category

Behavior

2

Description

Control group:In the TAU arm, mother and child pairs received routine health service treatment.Mother and child pairs were visited by MCH clinicians for

assessments to determine the age-related ability of the child. Developmental screening tests were performed by asking mothers checklist-based questions about their child's play, learning, speech, behaviour, and motor abilities.

Category
Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center
Urmia Well-child clinic

Full name of responsible person
Hamid Reza Farrokh Eslamlou

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Oroumia University of Medical Sciences

Full name of responsible person
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mohebbi_iraj@yahoo.co.uk

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Oroumia 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
Oroumia University of Medical Sciences

Full name of responsible person
Bahlol Rahimi

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Informatics

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Results will be presented in an article to be published in a leading scientific journal during 2019

When the data will become available and for how long
Intention to publish date 15/10/2019

To whom data/document is available
All researchers

Under which criteria data/document could be used
Results will be presented in an article to be published in a leading scientific journal during 2019 so after publishing the data could be used

From where data/document is obtainable
Results will be presented in an article to be published in a leading scientific journal during 2019 and the applicant could use the researchers email to communicate bahlol.rahimi@gmail.com

What processes are involved for a request to access data/document
Results will be presented in an article to be published in a leading scientific journal during 2019 and the applicant could use the researchers email to communicate bahlol.rahimi@gmail.com

Comments