

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of education based on behavioral intention model on the feeding behaviors of mothers of children with Phenylketonuria

Protocol summary

Summary

The purpose of this study is evaluation the effectiveness of educational interventions on feeding behavior of mothers of children with phenylketonuria. Inclusion criteria are residency in Tehran; having children with phenylketonuria in age from 6 months to 8 years; having at least literate; have the desire and ability to participate in training sessions. Exclusion criteria are participation in other sessions (with feeding children with phenylketonuria (PKU)) too; absence of in one or two sessions; unwilling to continue work with the researcher. This study is a quasi-experimental intervention study. The study population consisted of mothers of children with phenylketonuria (PKU) who referred to Iran is center of phenylketonuria and they will be allocated to intervention and control group using randomized sampling by randomization table. Intervention is education with lecture, Ask and answering, group discussion method. Content development and design will be addressed in the context of behavioral intention model. Control group wont participate in educational sessions. data will be collected using self reported questionnaire before and one month after education. Primary outcome of this is study mothers nutritional behavior

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013020612382N1**
Registration date: **2013-08-29, 1392/06/07**
Registration timing: **na**

Last update:

Update count: **0**

Registration date

2013-08-29, 1392/06/07

Registrant information

Name

Zahra Rahnavard

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6105 4206

Email address

zrahnavard@sina.tums.ac.ir

Recruitment status

Not enough for processing

Funding source

Tehran University of Medical Sciences, Nursing school

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2013-04-21, 1392/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of education based on behavioral intention model on the feeding behaviors of mothers of children with Phenylketonuria

Public title

Investigating the effect of education based on behavioral intention model on the feeding behaviors of mothers of children with Phenylketonuria

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Residency in Tehran; Having children with phenylketonuria in age from 6 months to 8 years;

Having at least literate! have the desire and ability to participate in training sessions Exclusion criteria: Participation in the other sessions (with feeding children with phenylketonuria (PKU)) too! Absence of in one or two sessions! Unwilling to continue work with the researcher

Age

From **1 year** old to **4 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Nursing faculty, Nosrat St, Tohid Sq, Tehran

City

Tehran

Postal code

Approval date

2013-01-02, 1391/10/13

Ethics committee reference number

91/130/2528/3

Health conditions studied

1

Description of health condition studied

Phenylketonuria

ICD-10 code

E70

ICD-10 code description

Classical phenylketonuria

Primary outcomes

1

Description

Mothers Nutritional Behavior

Timepoint

Before After

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Education with lecture, ask and answering , group discussion method. Content development and design will be addressed in the context of behavioral intention model

Category

Other

2

Description

Control group: No intervention

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Phenylketonuria center

Full name of responsible person

Zahra Rahnavard

Street address

Nursing School, East Nosrat St, Tohid Sq, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences, Nursing school

Full name of responsible person

Dr. Ziba Taghizadeh

Street address

Nursing school, East Nosrat st, Tohid sq, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences, Nursing school

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences, Nursing School

Full name of responsible person

Zahra Rahnavard

Position

PHD

Other areas of specialty/work

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Person responsible for updating data

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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