

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Effect of maternal empowerment program on burden of care in mothers of children with PKU

Protocol summary

Summary

The purpose of this study is evaluating the effect of maternal empowerment program on burden of care in mothers of children with PKU and also the Phenylalanine serum level in the suffering children. 50 mothers that have inclusion criteria participated in the study in two groups (each group consist of 25 mother). Before intervention the mothers completed the questionnaires. Inclusion criteria for mothers consist of: having children with established diagnosis of Phenylketonuria, living in Qazvin province or its surrounding villages. Exclusion criteria were the family's unwillingness to participation in the research. The intervention based on the family-centered empowerment pattern with 4 steps is conducted during 9 sessions, duration of each is 60 to 90 for mothers. The final evaluation will be taken 1 month after the intervention by using the Zarit burden interview for mothers and evaluating the serum phenylalanine in children in both groups. For considering the research ethical issues, after the final evaluation, 1-2 training sessions were held for control group and pamphlets and booklets were placed at their disposal. The intervention began on July 5th, and ended on September 12th, 2016.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016071828975N1**

Registration date: **2017-04-21, 1396/02/01**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-21, 1396/02/01

Registrant information

Name

Tahereh Sojoodi

Name of organization / entity

University of Social Welfare and Rehabilitation Sciences (USWR)

Country

Iran (Islamic Republic of)

Phone

00982833359224, 00982122180036

Email address

tsojodi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Funding source : University of social welfare and rehabilitation sciences es - - Dr. Abolfazl Rahgoui

Expected recruitment start date

2016-07-05, 1395/04/15

Expected recruitment end date

2016-11-12, 1395/08/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of maternal empowerment program on burden of care in mothers of children with PKU

Public title

Effect of maternal Empowerment Program on Decreasing the Burden of Caring in mothers of Children with Phenylketonuria and Controlling Phenylalanine (in Children)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Mothers of children with established

diagnosis of Phenylketonuria, living in Qazvin province or its surrounding villages. Exclusion criteria: The family's unwillingness to participation in the research

Age

From **5 days** old to **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

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

university of social welfare and rehabilitation sciences(USWR)

Street address

kodakyar street- daneshjo blv. - evin

City

Tehran

Postal code

1985713834

Approval date

2016-06-26, 1395/04/06

Ethics committee reference number

IR.USWR.REC.1395.227

Health conditions studied

1

Description of health condition studied

phenylketonuria

ICD-10 code

E70.0

ICD-10 code description

Classical phenylketonuria

Primary outcomes

1

Description

Burden of care

Timepoint

Before and 1 month after intervention

Method of measurement

zarit interview and determining the serum level of phenylalanine

2

Description

Burden of care

Timepoint

Before and 1 month after intervention

Method of measurement

zarit interview and determining the serum level of phenylalanine

Secondary outcomes

1

Description

Laboratory parameters

Timepoint

before intervention -after intervention

Method of measurement

serum level of phenylalanine

2

Description

Laboratory parameters

Timepoint

before intervention -after intervention

Method of measurement

serum level of phenylalanine

3

Description

Laboratory parameters

Timepoint

before intervention -after intervention

Method of measurement

serum level of phenylalanine

4

Description

Laboratory parameters

Timepoint

before intervention -after intervention

Method of measurement

serum level of phenylalanine

Intervention groups

1

Description

Mothers in intervention group participated in family-centered empowerment program in four steps over nine sessions, each session lasting 60-90 minutes twice a week.

Category

Behavior

2

Description

Mothers in control group only received the routine care. After the final evaluation, 1-2 training sessions were held and pamphlets and booklets were placed at their disposal

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

qods hospital

Full name of responsible person

mother

Street address

City

qazvin

2

Recruitment center

Name of recruitment center

qods hospital

Full name of responsible person

Dr. abolfazl rahgoi

Street address

University of social welfare and rehabilitation science(USWR)

City

Kodakyar street- daneshjo blv.evin- tehan

3

Recruitment center

Name of recruitment center

qods hospital

Full name of responsible person

Dr. abolfazl rahgoi

Street address

qazvin Iran, Islamic Republic of

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

univerUniversity of social welfare and rehabilitation sciences(USWR)

Full name of responsible person

Dr. abolfazl rahgoi

Street address

kodakyar street - daneshjo blv. - evin - tehran Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

univerUniversity of social welfare and rehabilitation sciences(USWR)

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

university of social welfare and rehabilitation science(USWR)

Full name of responsible person

Dr. abolfazl rahgoi

Position

PhD

Other areas of specialty/work

Street address

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Person responsible for scientific

inquiries

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Web page address

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