Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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 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