

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of training on depression, anxiety and stress in mothers with phenylketonuria child

Protocol summary

Study aim

Determining the effect of training on depression, anxiety and stress in mothers with phenylketonuria child

Design

Experimental study with control group with parallel and one-blind groups

Settings and conduct

Among the mothers with phenylketonuria child referring to the phenylketonuria clinic of Ahvaz's children's hospital in Abouzar, the mothers who are willing to participate in the research and who meet the criteria for entry, sampling was done in an accessible manner and then by random allocation of units. The research is done in two groups: intervention and control.

Participants/Inclusion and exclusion criteria

Only mothers are allowed to enter the study, that children having phenylketonuria and willing to participate in the study. And refer to the Phenylketonuria Association.

Intervention groups

For the intervention group, a 5-session class on Wednesday, every week, and every 1 hour and ten minutes for each session, the intervention group will first have a lecture and then a Q & A session, and at the end of each session, mothers will raise their concerns about the affected child. At the end of the sessions, an educational package containing an overview of the training given will be provided to the intervention sample. Immediately after training and 4 weeks after the completion of the training, the mothers of the intervention group will be interviewed and their anxiety will be measured by a questionnaire for the second and third times. The content of these training sessions will be in 5 sections. At the end of the study, in order to observe the ethics in the research, the content of the training will be provided to the control group and, if desired, individual training will be given.

Main outcome variables

The effect of education on stress, anxiety and depression

in mothers with phenylketonuria child

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181013041324N1**

Registration date: **2018-12-05, 1397/09/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-12-05, 1397/09/14**

Update count: **0**

Registration date

2018-12-05, 1397/09/14

Registrant information

Name

Forouzan Khodabakhshi Ardali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 0888

Email address

khodabakhshi.f@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-10-16, 1397/07/24

Expected recruitment end date

2019-01-04, 1397/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty	to prevent information exchange, first the control group will complete the demo questionnaire and the DASS 21 questionnaire immediately and one month later.
Scientific title	Blinding (investigator's opinion)
Effect of training on depression, anxiety and stress in mothers with phenylketonuria child	Single blinded
Public title	Blinding description
Effect of training on depression, anxiety and stress in mothers with phenylketonuria child	In this study, we have two groups of intervention and control that none of the participating groups will know which intervention is, and which is the control group, and is in fact a blind one.
Purpose	Placebo
Education/Guidance	Not used
Inclusion/Exclusion criteria	Assignment
Inclusion criteria:	Parallel
The mother has the main role of keeping the child affected. The person caring for the patient should not have a history of phenylketonuria. Mother is not a member of the health professional team. The mother has not participated in a class or any kind of special education for the disabled child. Mother has no tense experiences in the last 3 months The mother has no known mental illness and does not use sedative medications Parents do not have addiction. Parents are not exposed to the process of separation The mother of the child is married and lives with her husband The mother has no chronic long-term illness. The age of the affected child is 9 years or less. The child has a classical phenylketonuria disease 3 to 6 months from the diagnosis of the disease.	Other design features
Exclusion criteria:	
Mothers who are not willing to enter the study. Mothers who are being treated with anti-anxiety drugs. Mothers who have anxiety disorders. Mothers who are being treated with anti-depressant drugs.	Secondary Ids
Age	empty
No age limit	Ethics committees
Gender	1
Female	Ethics committee
Phase	Name of ethics committee
N/A	Ethics committee of Iran University of Medical Sciences
Groups that have been masked	Street address
• Participant	Shahid Hemmat West Highway, between intersection of Sheikh Fazlollah Noori and Shahid Chamran
Sample size	City
Target sample size: 74	Tehran
Randomization (investigator's opinion)	Province
Randomized	Tehran
Randomization description	Postal code
Among the mothers with phenylketonuria child referring to the phenylketonuria clinic of Ahvaz's children's hospital in Abouzar, the mothers who are willing to participate in the research and who meet the criteria for entry, sampling was done in an accessible manner and then by random allocation of units The research is done in two groups: intervention and control. the sample size is 74 people. They were selected by available sampling method and randomly divided into two groups: intervention and control (37 cases, 37 controls); we have a list of patients' names and Calling the mothers with the affected patient. To prevent contamination between the two intervention and control groups, allocation of research units to the two groups will be in the form of a timetable and through a lottery (throwing coins). In order	1449614535
	Approval date
	2018-08-25, 1397/06/03
	Ethics committee reference number
	IR.IUMS.REC.1397.266
	Health conditions studied
	1
	Description of health condition studied
	Effect of training on depression, anxiety and stress in children with phenylketonuria
	ICD-10 code
	ICD-10 code description
	Primary outcomes
	1
	Description
	Anxiety and Stress Scale in questionnaire Depression Anxiety Stress Scale 21
	Timepoint
	Measure the stress score, depression and anxiety before the intervention, immediately after training and four

weeks after completion of the training.

Method of measurement

Questionnaire Depression Anxiety Stress Scale 21

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: For the intervention group, a 5-session class on Wednesday, every week, and every 1 hour and ten minutes for each session, the intervention group will first have a lecture and then a Q & A session, and at the end of each session, mothers will raise their concerns about the affected child. At the end of the sessions, an educational package containing an overview of the training given will be provided to the intervention sample. Immediately after training and 4 weeks after the completion of the training, the mothers of the intervention group will be interviewed and their anxiety will be measured by a questionnaire for the second and third times. The content of these training sessions will be in 5 sections

Category

N/A

2

Description

Control group: There will be no training in the control group. At the end of the study, in order to observe the ethics in the research, the content of the training will be provided to the control group and, if desired, individual training will be given.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Abuzar hospital

Full name of responsible person

Forouzan Khodabakhshi Ardali

Street address

unit 6, floor 2, building Arg2, Day st, Ordibehesht st, Farvardin st, Golestan

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ahvaz

Province

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malakouti

Street address

Hemmat West, between Sheikh Fazlollah Noori and Shahid Chamran

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Leila Neisani Samani

Position

Instructor-faculty of the university

Latest degree

Master

Other areas of specialty/work

Midwifery

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Person responsible for updating data

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Full name of responsible person

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Bachelor
Other areas of specialty/work
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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

Not applicable

Data Dictionary

Not applicable