

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

The effect of family-centered empowerment model on family function and care burden of primary caregivers of children with glucose-6-phosphate dehydrogenase enzyme deficiency

Protocol summary

Study aim

Determining the effect of family-centered empowerment model on family function and care burden of the main caretaker of children with glucose-6-phosphate dehydrogenase enzyme deficiency

Design

The clinical trial has two groups of control and intervention, with parallel groups, without blindness, simple randomization, in which 30 individuals will be included in the study. At first, children with favism admitted to the Iranian hospital were randomly selected based on the purpose of the selected patients and classified according to age group in three floors (6 to 8 years) - (9 to 11 years) - (12 to 14 years) In each step, patients will be randomly assigned to intervention and control groups. In this way, pre-made white cards will be randomly assigned to each patient, and a color card is written that the green color represents the intervention group and the blue color representing the control group.

Settings and conduct

Population under study: The population of the study consisted of the main carers of children aged 6 years and older who lacked the glucose-6-phosphate dehydrogenase enzyme present at or admitted to the Iran Iran Hospital Environment and Research Time: Iran Hospital, Iranshahr City, Bahar 1398

Participants/Inclusion and exclusion criteria

Having a child with glucose-6-phosphate dehydrogenase deficiency ages 6 to 14 years Having reading and writing skills and the ability to complete a questionnaire in the main caregiver There is no history of formal education about favic disease before studying The ability to speak and listen in the main caregiver Having the right to decide on the prevention and treatment of childhood illness

Intervention groups

The implementation of the family-centered

empowerment model on the intervention group consists of 4 steps in 5 sessions of 90 minutes

Main outcome variables

care burden Family function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043936N1**

Registration date: **2019-07-18, 1398/04/27**

Registration timing: **prospective**

Last update: **2019-07-18, 1398/04/27**

Update count: **0**

Registration date

2019-07-18, 1398/04/27

Registrant information

Name

Saeed Kalkali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 7253 2085

Email address

saeedkalkali@bums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2019-08-22, 1398/05/31

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of family-centered empowerment model on family function and care burden of primary caregivers of children with glucose-6-phosphate dehydrogenase enzyme deficiency

Public title
The effect of family-centered empowerment model on family function and care burden of primary caregivers of children with favism

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 Completion of written consent form to participate in the study Having a child with glucose-6-phosphate dehydrogenase deficiency ages 6 to 14 years Literacy and ability to complete the questionnaire in the main caregiver The main caregiver is not a member of the medical and nursing group Lack of chronic disease in other family members There is no history of formal education about favic disease before the study The ability to speak and listen to the patient and the main caregiver Being responsible for the maximum daily care of the child Having the right to decide on the prevention and treatment of childhood illness
Exclusion criteria:
 Not willing to continue participating in the scheme Absence for any reason two consecutive sessions that can not attend meetings Not available for communicating and informing sessions To create a special event affecting the quality of life and the specific mental illness in the main caregiver

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
 Target sample size: **60**
 More than 1 sample in each individual
 Number of samples in each individual: **60**
 The main guardian and the child

Randomization (investigator's opinion)
Randomized

Randomization description
Preset White Cards will be randomly assigned to each patient and will be written on a color card representing the color of the intervention group and the blue color of the control group.

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

Birjand University of Medical Sciences

Street address

Ghaffari street

City

Birjand

Province

South Khorasan

Postal code

9717853577

Approval date

2019-07-01, 1398/04/10

Ethics committee reference number

IR.BUMS.REC.1398.107

Health conditions studied

1

Description of health condition studied

Glocos 6 phospat dehydrogenaz enzim definenshe

ICD-10 code

D55.0

ICD-10 code description

Anaemia due to glucose-6-phosphate dehydrogenase [G6PD] deficiency

Primary outcomes

1

Description

Care load score in Zarit questionnaire

Timepoint

Before the intervention and a month later

Method of measurement

caring-burden-inventory-CBI-Zarit

2

Description

McMaster family functioning score in the questionnaire.

Timepoint

Before the intervention and a month later

Method of measurement

Family Assessment Device (FAD) McMaster

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Family-based empowerment model was implemented based on four perceived threat, self-efficacy, educational participation and evaluation.

Category

Lifestyle

2

Description

Control group: Routine care and a training session

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran hospital

Full name of responsible person

saeed kalkali

Street address

Shahid Moradi Highway, 3 km from Iranshahr,
Bampour Road

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Province

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Irshums@irshums.ac.ir

Web page address

<http://iranhospital.irshums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr Miri Moghadam

Street address

Ghaffari street

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public_r@bums.ac.ir

Web page address

<https://www.bums.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

saeed kalkali

Position

Masters Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Full name of responsible person

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Position

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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

Not applicable

Title and more details about the data/document

All individual data can be shared with researchers and the medical team after unidentifiable individuals. The method and outcome of the work in the form of an article can be shared for all researchers and the medical and medical team

When the data will become available and for how long

After completing the work and obtaining the result

To whom data/document is available

Researchers, medical team, medical education team, students

Under which criteria data/document could be used

For use in other research

From where data/document is obtainable

Library of Birjand University of Medical Sciences

What processes are involved for a request to access data/document

Referring to the library of Birjand University of Medical Sciences and using it or sending an e-mail to scientific research officer Mr. Ali Mohammad Izadpanah

Comments

Person responsible for updating data

Contact

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Saeed kalkali

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

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City

Birjand

Province