Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 54 7253 2085

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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
City
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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
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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
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Other areas of specialty/work
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Position
Master of Science (MSc) Nursing and Scientific Staff

Latest degree
Master

Other areas of specialty/work
Nursery

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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