

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of Family-Centered Empowerment on Quality of Life of Children with hemophilia and the care burden of caregivers

Protocol summary

Study aim

Comparison of quality of life of children and care burden in two groups of intervention and control.

Design

50 pairs of children with hemophilia and their main caregiver and randomly selected blocks, which consists of 6 blocks and 4 groups and divided into two groups (25 persons).

Settings and conduct

Obtaining informed consent, the quality of life questionnaire by the child, and the Zarit care burden questionnaire will be completed by the primary caregiver. In order to intervene, family-empowerment will be used. The intervention includes self-care behaviors training based on the family-centered empowerment model, which was conducted by a researcher in the conference hall during nine sessions of 60-90 minutes twice a week based on four steps in understanding the threat, problem solving, educational participation and evaluation. The hospital will be attended by primary caregivers and children with hemophilia. Face-to-face meetings with slideshows and films and pamphlets will be provided face-to-face and face-to-face meetings. The control group will receive only a routine treatment and care program, and again after the 9th week (one month after the intervention group training program) The quality of life questionnaire for Hemophilia children and the Zarit care burden questionnaire for the control group will be completed.

Participants/Inclusion and exclusion criteria

The desire to participate in the research and diagnosis of a child's illness and having a case in the hematologic clinic and not having any other chronic disease other than hemophilia.

Intervention groups

Family-based empowerment training for parents in two groups: intervention and control.

Main outcome variables

The results of this study, if positive, can be a way to

improve self-care behaviors and consequently, in addition to reducing the family care burden, it can improve their quality of life.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181123041733N1**

Registration date: **2018-12-21, 1397/09/30**

Registration timing: **retrospective**

Last update: **2018-12-21, 1397/09/30**

Update count: **0**

Registration date

2018-12-21, 1397/09/30

Registrant information

Name

Soulmaz Namaki KHameneh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-03, 1397/08/12

Expected recruitment end date

2018-12-11, 1397/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of Family-Centered Empowerment on Quality of Life of Children with hemophilia and the care burden of caregivers

Public title
The effect of Family-Centered Empowerment on Quality of Life of Children with hemophilia and the care burden of caregivers

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 The desire to participate in research. Diagnosis of a child with hemophilia by a physician and having a case at hematologic clinic of Baghaee Hospital, Ahvaz, Iran There is no other chronic disease other than hemophilia, such as diabetes, asthma, thalassemia. Age range 12-8 years
Exclusion criteria:
 Lack of record of participation in previous training programs

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
At first, qualified individuals, including their main carers and their children, are selected according to entry criteria and then divided into two groups of 25 pairs, using randomized block random method, and randomly assigned random numbers. Then the study questionnaires will be completed for both groups. . The quality of life questionnaire will be completed by the child. The Persian version of Zarit's Care Weight Questionnaire will be completed by the primary caregiver of the child and, if necessary, by the interviewer's method, will be completed by the researcher at the Hepatitis Clinic of Baqaee Hospital 2. In order to intervene, the researcher in this study will use a family-centered empowerment model based on its comprehensive approach among all types of empowerment approaches. This template was designed by Alhani et al. In 2003 (38). It should be noted that the intervention group will be divided into 2 groups of 8 pairs and 1 pairs of 9 pairs (including the main caregiver and the affected child).

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
 The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences
Street address
 Padada lands, avenue of knowledge, Complex Yazdan 5, Plot 62, Unit 2
City
 Ahvaz
Province
 Khuzestan
Postal code
 5154550888
Approval date
 2018-11-05, 1397/08/14
Ethics committee reference number
 IR.AJUMS.REC.1397.571

Health conditions studied

1

Description of health condition studied
Family-centered empowerment education on the quality of life of children with hemophilia and caring burden.

ICD-10 code
D68.0

ICD-10 code description
Von Willebrand's disease

Primary outcomes

1

Description
Quality of life for children with hemophilia

Timepoint
Before the intervention and 37 days after the intervention began

Method of measurement
Hemophilia quality of life questionnaire

2

Description
Caregivers for carers of children with hemophilia

Timepoint
Before the intervention and 37 days after the intervention began

Method of measurement

Zarit's Care Bar Questionnaire

Secondary outcomes**1****Description**

Improving the quality of life

Timepoint

45 days

Method of measurement

Hemophilia Quality of Life Questionnaire, Zarit's Care Weight Inventory

Intervention groups**1****Description**

Intervention group: In order to intervene, the researcher in this study will use a family-centered empowerment model based on its comprehensive approach among all types of empowerment approaches. This template was designed by Alhani et al. In 2003 (38). It should be noted that the intervention group will be divided into 2 groups of 8 pairs and 1 pairs of 9 pairs (including the main caregiver and the child). The intervention will include the implementation of a self-care behaviors training program based on a family-centered empowerment model that during 9 sessions of 90- A 60-minute sessions a week, based on four steps in understanding the threat, problem solving, educational participation and evaluation, will be carried out by a researcher at the hospital conference hall with the presence of primary carers and children with hemophilia. These face-to-face and face-to-face meetings will be conducted with group discussions and questions and answers between researcher, primary caregivers and children, with slideshows and films, and presentation of pamphlets.

Category

Lifestyle

2**Description**

Control group: The control group will receive the routine treatment and care program only. After the 9th week (one month after the intervention group program), the quality of life questionnaire for hemophilia children and the Zarit care burden questionnaire will be completed for the control group.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hospital Baghaee 2 Ahvaz

Full name of responsible person

Dr. Shahnaz Rostami

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Padada lands, avenue of knowledge, license plate 62, unit 2

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badawi

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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

Ahvaz 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**

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Shahnaz Rostami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Position

Student

Latest degree

Bachelor

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

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Associate professor

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Person responsible for updating data**Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Soulmaz Namaki KHameneh

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Data can not be shared.

When the data will become available and for how long

Start the access period 6 months after printing the results.

To whom data/document is available

Researchers and Academic Staff

Under which criteria data/document could be used

Access to tools and how to analyze tools is possible.

From where data/document is obtainable

namakikhameneh.s@ajums.ac.ir Rostami-sh@ajums.ac.ir

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

One month after receiving a request.

Comments