

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Family-Centered Empowerment Model on Quality of Life and Self-Efficacy in Children with Rheumatoid Arthritis.

Protocol summary

Study aim

Determining the Effect of Family-Based Empowerment Model on Quality of Life and Self-efficacy in Children with Rheumatoid Arthritis.

Design

Clinical trial with control and intermediate group, randomized with sample size 60 (30 controls and 30 intervention groups)

Settings and conduct

This study was a randomized controlled clinical trial. Sixty children with rheumatoid arthritis were randomly divided into two groups, randomly and in the rheumatology department of Akbar Children Hospital in Mashhad. Four phases of family-centered empowerment model (knowledge upgrading, self-efficacy, self-esteem and evaluation) through Face-to-face education, practical demonstration, educational participation and presentation of a training book were conducted for six 45-minute sessions for the experimental group. After one month, the questionnaire Quality of life and self-efficacy were completed by children.

Participants/Inclusion and exclusion criteria

The criteria for entering the study: the children and their parents tend to participate in the study; ages 8 to 12 years old; diagnosis of rheumatoid arthritis according to the physician (at least 3 months ago); lack of specific mental illness; the child's ability to complete the questionnaire and participate in the study. The empowerment plan has no other chronic disease other than rheumatoid arthritis. Incapacity: the child and parents' desire to leave the study; creating a special incident affecting the quality of life and the underlying illness and mental disorder.

Intervention groups

Children with rheumatoid arthritis

Main outcome variables

Family-centric empowerment model

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180319039131N1**

Registration date: **2019-03-27, 1398/01/07**

Registration timing: **retrospective**

Last update: **2019-03-27, 1398/01/07**

Update count: **0**

Registration date

2019-03-27, 1398/01/07

Registrant information

Name

Nahid Pilehvar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3766 5593

Email address

pilehvarn941@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2019-02-20, 1397/12/01

Actual recruitment start date

2018-07-23, 1397/05/01

Actual recruitment end date

2019-03-20, 1397/12/29

Trial completion date

2019-04-03, 1398/01/14

Scientific title

Effect of Family-Centered Empowerment Model on Quality of Life and Self-Efficacy in Children with Rheumatoid Arthritis.		The Ethics Committee of Mashhad University of Medical Sciences	
Public title	Effect of Family-Centered Empowerment Model on Quality of Life and Self-Efficacy in Children with Rheumatoid Arthritis.	Street address	Khorasan Razavi, Mashhad, Blvrshahid Fakori, Shahid Javan Square and Shahidi Square, Science and Welfare
Purpose	Education/Guidance	City	Mashhad
Inclusion/Exclusion criteria		Province	Razavi Khorasan
Inclusion criteria:	The tendency of the child and their parents to participate in the study Aged 8 to 12 years old Diagnosis of rheumatoid arthritis according to the physician (at least 3 months ago) Lack of specific mental illness The child's ability to complete the questionnaire Absence of other chronic disease other than arthritis rheumatoid	Postal code	99191-91778
Exclusion criteria:	The desire of the child and parents to leave the study Creating a special incident that affects the quality of life and the development of a known mental and psychological disorder	Approval date	2018-02-09, 1396/11/20
Age	From 8 years old to 12 years old	Ethics committee reference number	IR.MUMS.REC.1396.391
Gender	Both	Health conditions studied	
Phase	N/A	1	
Groups that have been masked	No information	Description of health condition studied	
Sample size	Target sample size: 60 Actual sample size reached: 60	Juvenile Rheumatoid Arthritis	
Randomization (investigator's opinion)	Randomized	ICD-10 code	
Randomization description	The assignment of research units to random and control groups was intervention and control. In order to prevent data leakage in the two groups after the draw, the sampling from the control group first began. After sampling in this group, the intervention group sampling was started	M08.0	
Blinding (investigator's opinion)	Not blinded	ICD-10 code description	
Blinding description		Juvenile rheumatoid arthritis	
Placebo	Not used	Primary outcomes	
Assignment	Single	1	
Other design features		Description	
Secondary Ids	empty	Quality of Life	
Ethics committees		Timepoint	
1		Measurement of quality of life in the beginning of the study (before the beginning of the study) and one month after the implementation of the family-centered empowerment model	
Ethics committee		Method of measurement	
Name of ethics committee		PedsQL Questionnaire; Quality of life for children ages 8 to12	
		2	
		Description	
		Self-efficacy	
		Timepoint	
		Measurement of self-efficacy in the beginning of the study (before the beginning of the study) and one month after the implementation of the family-centered empowerment model	
		Method of measurement	
		Self-efficacy questionnaire SEQ-C	
		Secondary outcomes	
		empty	
		Intervention groups	

1

Description

Intervention group: the implementation of the family-centered empowerment model consists of four steps (knowledge upgrading, self-efficacy, self-esteem and evaluation) on children with rheumatoid arthritis

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Rheumatology, Akbar Hospital

Full name of responsible person

Abdolreza Malek (Head of Department of Rheumatology)

Street address

No. 14 , Shahid Kaveh Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Zare (Deputy of Finance), Faculty of Nursing

Street address

Ebne Sina Street, Faculty of Nursing and Midwifery, Mashhad

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13944-91388

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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

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

Mashhad University of Medical Sciences

Full name of responsible person

Nahid Pilehvar

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

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Other areas of specialty/work

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Postal code

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
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable