

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jun 2026

Investigating the effect of self-care training on self-efficacy and quality of life of children with nephrotic syndrome and their parents

Protocol summary

Study aim

Self-care training can be effective in reducing the length of hospitalization of patients and, as a result, reducing the cost of treatment, reducing mortality, and improving the outcome of the disease. Therefore, the present study aims to determine the effect of self-care training on the self-efficacy and quality of life of children with nephrotic syndrome and their parents.

Design

This randomized clinical trial with a control group, pre-test-post-test design, without blinding, was conducted on 60 children with nephrotic syndrome along with their parents who referred to Mofid Children's Hospital in Tehran. In order to randomize, the table of random numbers was used to determine the number of research samples that should enter the intervention group.

Settings and conduct

This study was conducted on 60 children with nephrotic syndrome along with their parents who referred to Mofid Children's Hospital in Tehran. Blinding methods were not used. The table of random numbers was used for simple randomization.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include the age of the child between 7 and 18 years, having been treated for at least one year, parents having the ability to read and write. Also, children and parents should not have a history of mental disorders, the child should not have a history of kidney transplant. Exclusion criteria included absence of parents in educational sessions and unwillingness to participate in the study.

Intervention groups

The intervention group in this study received face-to-face training sessions. The control group received routine measures and no new intervention.

Main outcome variables

Parents' self-efficacy, parents' quality of life, children's quality of life, children's self-efficacy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230816059164N2**

Registration date: **2024-01-09, 1402/10/19**

Registration timing: **retrospective**

Last update: **2024-01-09, 1402/10/19**

Update count: **0**

Registration date

2024-01-09, 1402/10/19

Registrant information

Name

Mohammad Mehdi Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

2019-01-21, 1397/11/01

Actual recruitment end date

2020-11-21, 1399/09/01

Trial completion date

2020-12-21, 1399/10/01

Scientific title

Investigating the effect of self-care training on self-efficacy and quality of life of children with nephrotic syndrome and their parents

Public title

Investigating the effect of self-care training on self-efficacy and quality of life of children with nephrotic syndrome and their parents

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The age of the child between 7 to 18 years The child has received treatment for at least one year Parent's ability to read and write The diagnosis of nephrotic syndrome of the child has been confirmed by a specialist doctor

Exclusion criteria:

Having a history of mental or physical disorders in parents or children The child has a history of kidney transplant

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A person, who was unaware of the study, determined 36 numbers from 1 to 72 using a table of random numbers. These numbers were the numbers of samples that should be included in the intervention group. These numbers were provided to the research team. Thus, after sampling according to the available method, according to the number of samples, they entered the control or intervention 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

School of Nursing and Midwifery & Rehabilitation -

Tehran University of Medical Sciences (Ethics Com

Street address

School of Nursing and Midwifery, Tehran University of Medical Sciences, Nusrat Sharghi Street, Tohid Square, Tehran

City

Tehran

Province

Tehran

Postal code

1419733171

Approval date

2019-12-23, 1398/10/02

Ethics committee reference number

IR.TUMS.FNM.REC.1398.159

Health conditions studied

1

Description of health condition studied

Nephrotic syndrome

ICD-10 code

N04

ICD-10 code description

Nephrotic syndrome

Primary outcomes

1

Description

Quality of life of the child

Timepoint

Before the start of the intervention, 4 weeks after the start of the intervention

Method of measurement

Pediatric's Quality of Life Questionnaire (PedsQL)

2

Description

Quality of life of parents

Timepoint

Before the start of the intervention, 4 weeks after the start of the intervention

Method of measurement

World Health Organization Quality of Life Summary Questionnaire (WHOQOL-BREF)

3

Description

Self-efficacy of parents

Timepoint

Before the start of the intervention, 4 weeks after the start of the intervention

Method of measurement

General Self-Efficacy Questionnaire (GSES)

4

Description

Children's self-efficacy

Timepoint

Before the start of the intervention, 4 weeks after the start of the intervention

Method of measurement

Children's Self-Efficacy Questionnaire (SEQ-C)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention consisted of "self-care training", derived from Orem's self-care theory, which was carried out in two 60 minute face-to-face training sessions and the presentation of a training booklet containing the topics presented in the training sessions with the presence of children with nephrotic syndrome and their parents. The interval between the sessions was two weeks, the researcher had telephone and face-to-face contact with the samples of the intervention group during this time period.

Questionnaires of self-efficacy and quality of life were completed by children and parents in the intervention group, before the beginning of the training sessions and 4 weeks later.

Category

N/A

2

Description

Control group: The control group received routine training by the medical center personnel after completing the pre-test at the same time as the test group. In this group, routine hospital follow-ups were done. Self-efficacy and quality of life questionnaires were completed by children and parents in the control group at the same time as the intervention group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Children's Hospital

Full name of responsible person

Shamsullah Nouripour

Street address

Mirdamad St, Above Hosseinieh Irshad, Dr. Ali Shariati St., Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotohi

Street address

6th floor of Research and Technology Vice-Chancellor, Central Organization of the University, corner of Quds St., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Mehdi Rajabi

Position

Master's student in pediatric nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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

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Position

Master's student in pediatric nursing

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Other areas of specialty/work

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

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Position

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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

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