

# 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)

##### Phone

+98 939 811 2685

##### Email address

mmehdirajabi1379@gmail.com

##### 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

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

15514- 15468

##### **Phone**

+98 21 2222 7021

##### **Email**

info-mch@sbmu.ac.ir

## **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.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1417613151

##### **Phone**

+98 21 6105 4567

##### **Email**

vcr@tums.ac.ir

##### **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

**Street address**

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mmehdirajabi1379@gmail.com

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

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

Master's student in pediatric nursing

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Bachelor

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**Email**

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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