

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 2026

### Comparison of the effect of self-care training using conceptual mapping and feedback-based methods on the self-concept of children with nephrotic syndrome

#### Protocol summary

##### Study aim

The purpose of this study is to improve the self-concept of children with nephrotic syndrome through conceptual mapping and feedback-based educational methods, which will lead to an increase in the child's adaptation to her/his illness and quality of life.

##### Design

A clinical trial with a control group, with parallel groups, a blind strain, randomized, with a sample size of 70 patients, a simple method was used for randomization.

##### Settings and conduct

The purpose of this research is to provide educational content to deal with problems in order to improve self-concept, which in turn improves health. The location of the study is Akbar Children's Nephrology Clinic and Dr. Sheikh Mashhad, and the method of conducting the study is four 45-minute individual sessions. These training sessions are in the form of lectures (feedback) depending on the child's placement in the intervention or control groups. axis) or written and visual (conceptual maps). This research is one-sided blind and the statistical analyst will analyze the data without knowing the study groups.

##### Participants/Inclusion and exclusion criteria

Children enter the study according to the criteria of entry and exit

##### Intervention groups

Intervention groups: the first group: self-care training using concept maps, the second group: self-care training using feedback-based method, both intervention groups during 4 days and 4 45-minute individual sessions, the necessary training in the field of self-care and self-concept improvement according to the type The group will receive (concept map, feedback-based), so that at the end, the effectiveness of each of the educational methods on improving self-concept will be measured.

##### Main outcome variables

On the fourth day of VSM, after the training, the self-concept questionnaire of Pirzaharis will be completed, checked and recorded by the researcher by asking the children under study.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221219056869N1**

Registration date: **2023-04-08, 1402/01/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-04-08, 1402/01/19**

Update count: **0**

##### Registration date

2023-04-08, 1402/01/19

##### Registrant information

##### Name

Nazanin Kazar

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 5725 8395

##### Email address

kazarn971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-03-11, 1401/12/20

##### Expected recruitment end date

2023-04-19, 1402/01/30

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of self-care training using conceptual mapping and feedback-based methods on the self-concept of children with nephrotic syndrome

**Public title**  
Comparison of the effect of self-care training using conceptual mapping and feedback-based methods on the self-concept of children with nephrotic syndrome

**Purpose**  
Education/Guidance

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Informing the child about her/his illness Age between 7 and 12 years One year has passed since the diagnosis of nephrotic syndrome for the child The child should be able to read and write at a low level  
**Exclusion criteria:**  
The child has another physical disease in addition to nephrotic syndrome The child or the parents have a type of mental illness

**Age**  
From **7 years** old to **12 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  

- Data analyser

**Sample size**  
Target sample size: **70**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this research, randomization will be done in a simple way. Patients will be selected by convenience sampling and based on inclusion criteria, and then assigned to the intervention or control group by coin toss.

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
In this research, the statistical analyst will analyze the data without knowing the study groups.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of school of Nursing and Midwifery- Mashhad University of Medical Science

##### Street address

No. 12, 5 Shahrestani St, Shahrestani Blvd., Mashhad.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913199

#### Approval date

2023-01-24, 1401/11/04

#### Ethics committee reference number

IR.MUMS.NURSE.REC.1400.100

## 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

Self-concept score in Piers-Harris questionnaire

#### Timepoint

At the beginning of the study (before the start of the intervention), 4 days after the start of the intervention and 30 days after the end of the study.

#### Method of measurement

Piers Harris self-concept questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Children suffering from nephrotic syndrome who receive training in four 45-minute individual sessions daily in the field of (nutrition, self-concept improvement, happy living, routine care of the disease) by the method of concept maps (drawn on paper appropriate to the age of the children ) and at the end of the sessions in Venice, 30 days after the end of the study, self-concept variable will be measured by

Pirzaharis self-concept questionnaire.

**Category**

Behavior

**2**

**Description**

The second intervention group: children with nephrotic syndrome who will receive training in four 45-minute individual sessions daily in the field of (nutrition, self-concept improvement, happy living and routine care of the disease) in a feedback-oriented method (speech and question and answer). At the end of the sessions in Venice, 30 days after the end of the study, self-concept variable is measured by Pirzaharis self-concept questionnaire.

**Category**

Behavior

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Dr. Sheikh Hospital

**Full name of responsible person**

Hamid Reza behnam voshani

**Street address**

No. 12, 5 Shahrestani St, Shahrestani Blvd., Mashhad.

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+98 51 3859 1511

**Email**

Kazarn971@mums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Akbar Hospital

**Full name of responsible person**

Hamid Reza behnam voshani

**Street address**

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**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Majid Ghayor Moberhan

**Street address**

No. 12, 5 Shahrestani St, Shahrestani Blvd., Mashhad.

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**Email**

Ramresearch@mums.ac.ir

**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**

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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Nazanin Kazar

**Position**

Master's student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Nursery

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Mashhad University of Medical Sciences

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**Position**

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**Latest degree**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not 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**

No - There is not a plan to make this available