

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

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

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Mashhad

Province

Razavi Khorasan

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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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2

Recruitment center

Name of recruitment center

Akbar Hospital

Full name of responsible person

Hamid Reza behnam voshani

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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

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

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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

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

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Position

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Person responsible for updating data

Contact

Name of organization / entity

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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