

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

The Effectiveness of Self-Care Skills Training on Self-Esteem and Quality of Life in 8-12 Year Old Children with Stoma of Hospitals in Tehran in 1395

Protocol summary

Study aim

General purpose: Determining the effectiveness of self-care skills training on self-esteem and quality of life in children aged 12-8 years with ostoma in Tehran hospitals in 1395
Dedicated purposes: 1. Determine the self-esteem level of children aged 12-8 years with ostoma, before, immediately and one month after intervention in the case and control group
2. Determination of the quality of life of children aged 12-8 years with ostoma, before, immediately and one month after intervention in the case and control group
3. Compare the rate of self-esteem level of children aged 12-8 years with ostoma, before, immediately and one month after intervention in the case and control group
4. Compare the rate of quality of life level of children aged 12-8 years with ostoma, before, immediately and one month after intervention in the case and control group

Design

The research is a clinical trial with community-based and pragmatic control group, with parallel and randomized groups. A total of 36 samples were randomly divided into two groups (case and control) of 18 patients according to the patient's case number

Settings and conduct

This research was conducted in Tehran hospitals in 1395-1396. Having received the code of the Ethics Committee (1395.233) and the introductory letter, the researcher presented to the selected centers. In three working sessions, after obtaining written consent from the parents of children, demographic questionnaires, Cooper Smith's self-esteem and Kindle Life Quality by two The case and control groups were completed and then were trained in 6 sessions in the case group with self-care training stoma. The data were collected using a questionnaire completed three times before, after and one month after the intervention

Participants/Inclusion and exclusion criteria

Participants of the study, 36 children aged 8-12 years with stoma were randomly assigned to two groups of 18 patients based on case number. Entry criteria: • Children aged under 12 and over 8 years old. • Samples have not recently participated in courses on self-care skills in the field of stoma. • According to parents, there is no illness, physical disability, mental retardation or other behavioral disorder. • Have informed consent to participate in the study
Exit criteria: Children who had absent more than two sessions

Intervention groups

Intervention in this study was the teaching of self-care skills in the field of stoma. The participants of the study, 36 children aged 8 to 12 years old with stoma, were divided into two groups of 18 case and control. The case group was trained in 6 sessions of 45 minutes with the Stoma self-care training package (film and pamphlet)

Main outcome variables

quality of life, self-esteem, self-care skills

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160802029166N2**

Registration date: **2018-04-19, 1397/01/30**

Registration timing: **retrospective**

Last update: **2018-04-19, 1397/01/30**

Update count: **0**

Registration date

2018-04-19, 1397/01/30

Registrant information

Name

nazanin shahedijoghan

Name of organization / entity

shahidbeheshtiuniversity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
20,000,000Rials

Expected recruitment start date
2016-08-22, 1395/06/01

Expected recruitment end date
2017-07-23, 1396/05/01

Actual recruitment start date
1986-08-23, 1365/06/01

Actual recruitment end date
2017-09-23, 1396/07/01

Trial completion date
empty

Scientific title
The Effectiveness of Self-Care Skills Training on Self-Esteem and Quality of Life in 8-12 Year Old Children with Stoma of Hospitals in Tehran in 1395

Public title
The Effectiveness of self-care skills training on self-esteem and quality of life in children with stoma

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Children under the age of 12 and over 8 years old
Samples have not recently participated in ostoma self-care training courses
Parents said that they have no illness, physical disability, mental retardation or other behavioral disorder
Conscious informed consent to participate in the study
Exclusion criteria:
Children who had absent more than two sessions
Individuals who participated in self-care sessions at the same time in the field of stoma.

Age
From **8 years** old to **12 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **36**
Actual sample size reached: **36**

Randomization (investigator's opinion)
Randomized

Randomization description
Sample file number was written on small paper and was packed in a packet and 18 case files were randomly selected as case group and 18 were randomly assigned

to the control 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

College of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences and Health Services

Street address

Tehran, Valiasr Ave., Shahid Abbaspour Street, next to Paul Hemmat, No. 19

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tehran

Province

Tehran

Postal code

ib@sbmu.ac.ir

Approval date

2016-06-21, 1395/04/01

Ethics committee reference number

IR.SBMU.RETECH.REC.1395.233

Health conditions studied

1

Description of health condition studied

Hirschsprung disease

ICD-10 code

Q43.1

ICD-10 code description

Hirschsprung's disease

2

Description of health condition studied

Other congenital functional disorders of colon

ICD-10 code

Q43.2

ICD-10 code description

Other congenital functional disorders of colon

3

Description of health condition studied

Other congenital malformations of bladder and urethra

ICD-10 code

Q64.7

ICD-10 code description

Other congenital malformations of bladder and urethra

Primary outcomes**1****Description**

Quality of Life

Timepoint

Before, immediately and one month after the intervention

Method of measurement

Kindle Children's Quality of Life Questionnaire

2**Description**

Self esteem

Timepoint

Pre-intervention, immediately and one month after intervention

Method of measurement

Cooper Smith Self-Esteem Questionnaire

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention as self-care skills training sessions including referral, familiarity with osteoporosis, exchange of colostomy bag, diet in osteoporosis patients, exercise and daily activity, and practical evaluation of interventional group for replacing osteoarthritis in 6 training sessions of 45 minutes prior to Surgery was conducted with pamphlets and educational videos

Category

Lifestyle

2**Description**

Control group: The control group consisted of 18 children with ostoma (8-12 years old) admitted to selected hospitals in Tehran who did not receive any training on self care skills.

Category

N/A

3**Description**

Intervention group: The intervention group consisted of 18 children with ostoma (8-12 years old) admitted to selected hospitals in Tehran who were trained in self-care skills in 6 sessions of 45 minutes (familiarity with ostoma, how to exchange colostomy bag, diet in ostomates, exercise and Daily activities)

Category

Lifestyle

Recruitment centers**1****Recruitment center****Name of recruitment center**

mofid hospital

Full name of responsible person

Maryam Momeni

Street address

Mofid hospital,before Mirdamad Street, above Hosseiniyeh Ershad, Dr. Ali Shariati Avenue, Tehran, Iran

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences and Health Services

Full name of responsible person

Dr. Mohammad Aqajani

Street address

Tehran - Shahid Chamran Highway - Yemen Ave. - Taleghani Hospital - Shahid Beheshti University of Medical Sciences

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Province

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Grant name**Grant code / Reference number**

IR.SBMU.RETECH.REC.1395.233

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences and Health Services

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**

Self-governing pardis of Shahid Beheshti University of
Medical Sciences and Health Services

Full name of responsible person

Nazanin Shahedi Joghhan

Position

Bachelor of Nursing

Latest degree

Bachelor

Other areas of specialty/work**Street address**

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Shahid Beheshti University of Medical Sciences and
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Full name of responsible person

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Position

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Other areas of specialty/work

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Full name of responsible person

Dr. Jamile Mohtashami

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work**Street address**

Tehran - Vale Asr Ave. - Intersection of Prayer - In
front of Shahid Rajae Heart Hospital - Faculty of
Nursing and Midwifery

City

Tehran

Province

Tehran

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

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

Not applicable

Data Dictionary

No - There is not a plan to make this available