

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Assessing Effects of Educating Bowel Management Program On Quality Of Life In Children With Fecal Incontinence at Mofid hospital

Protocol summary

Registration timing: **prospective**

Study aim

Determination of the effect of bowel management program on the quality of life of children with fecal incontinence in Mofid children hospital of Shahid Beheshti University of Medical Sciences

Last update: **2018-12-12, 1397/09/21**

Update count: **0**

Registration date

2018-12-12, 1397/09/21

Design

Clinical trial with control group

Registrant information

Name

Shiva Hojjati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3314 1838

Email address

shivahojjati@sbmu.ac.ir

Settings and conduct

Obtaining permission from the Ethics Committee Receive written consent from the helpful authorities Identify eligible children Introduce yourself and express the purpose of the research to children and their parents Putting them randomly in the intervention and control group Written Consent Completion of children's quality of life questionnaire Run intestinal management training program in seven days A month later, a re-examination and completion of the QOL of the child

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

- Involve in research. - Between the ages of 4 and 16. - A definitive diagnosis of stool incontinence by the surgeon. - Be able to understand Persian language

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

In this research, children were selected through goal-based sampling and according to the criteria for entering the study, and then randomly divided into two groups of intervention and control. The intervention will be the same as the training of the intestinal management program within a week that will be conducted orally and accompanied by educational pamphlets.

Main outcome variables

quality of life

Scientific title

Assessing Effects of Educating Bowel Management Program On Quality Of Life In Children With Fecal Incontinence at Mofid hospital

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181113041644N1**

Registration date: **2018-12-12, 1397/09/21**

Public title

Assessing Effects of Educating Bowel Management Program On Quality Of Life In Children

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

their willingness to participate in research Between the ages of 4 and 16 A definitive diagnosis of incontinence by surgery Be able to understand Persian language

Exclusion criteria:

The caretakers are constantly changing In a family, there is no other child with chronic illness.

Age

From **4 years** old to **16 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Children who come to a Mofid hospital clinic are selected by specialist confirmation and divided into two intervention and control groups according to their file number in the way that the odd numbers become the intervention group. We do not have blindness in this study.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Valiasr street

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-11-15, 1397/08/24

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1397.150

Health conditions studied

1

Description of health condition studied

Fecal incontinence

ICD-10 code

R15

ICD-10 code description

Fecal incontinence

2

Description of health condition studied

Patients with fecal incontinence

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

quality of life

Timepoint

Measurement of quality of life before intervention and one month after the end of intervention

Method of measurement

Using the quality of life questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Children who are referred to us by a specialist from the clinic and have an odd file number will be assessed by a pediatrician and nurse then the education program starts. the education program will be as follows: The first session will be orientation. The student will communicate with them by introducing themselves and asking questions such as the name and surname of the children. The student will explain the purpose of the research and the method of intervention to be completely clear to children and their parents. After obtaining written consent from the children and their parents, complete examination of the patient by examining the pattern and frequency of excretion and consistency and form of the stool, the study of diet and fluid intake, behavioral examination and abnormal habits and examination of the abdomen and perinea in cooperation with the physician. The quality of life questionnaire will then be provided to their parents during the same session to complete and deliver them during the same session or next meeting. At the next session on the second day, the curriculum will be performed on the basis of a survey conducted individually and within an hour, as well as a presentation

of the pamphlet, and will be evaluated with questions from them and, if necessary, will be repeated again and will be available to all Questions for the child and parents will also be answered. In the next sessions that are on a daily basis, the child will first have a graph for the assessment of the bowel and, according to the physician's permission, the training program will continue or change, in which case the training will be carried out again by the nurse. . And by asking questions, the performance of the program is evaluated by him. Finally, on the seventh day, the final program of the gut management will be described and will be explained to the child and parents, and they will be asked to come back to the clinic one month later to re-examine and complete the quality of life questionnaire in the clinic. Tracking will be done by the student. During this time, the researcher's contact number will be provided to answer questions in the morning shift

Category

Other

2**Description**

Control group: who receives even file number receives routine care and does not additional work for them anymore.

Category

Other

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

Mofid children's hospital

Full name of responsible person

Dr. Iman Zadeh

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Shariati street

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Mahrokh Dolatian

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mhdolatian@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Hojjati

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact**

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Hojjati

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Fax**Email**

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shiva Hojjati

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Not applicable

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

Undecided - It is not yet known if there will be a plan to make this available