Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Impact of the nurse led approaches on functional chronic constipation in 3 to 14 year old children referred to Imam Reza clinic, Shiraz University of Medical Sciences

Protocol summary

Summary

Objective: Determining the impact of nurse led approaches on functional chronic constipation in 3 to14 year old children referred to Imam Reza clinic. inclusion criteria :Having aged 3 to 14 years old;Having constipation during the 2 months prior to entrance to the study;Children with the diagnosis of functional chronic constipation based on Rome 3 criteria and physician`s approval. Exclusion criteria:Children diagnosed with IBS;Children with mental retardation or metabolic disorders (such as hypothyroidism);children with drugs affecting gastrointestinal motility or any kind of traditional medicine or other conventional medical treatment . Method: Randomized clinical trial with intervention and control group. Study population:3 to14 year old patients having functional chronic constipation referred to Imam Reza clinic in Shiraz. Sample: 95 patients (47 patients in experimental group and 48 patients in control group). Intervention and time of the study:nurse led approaches which is based on two main components: training and following up. Training sessions were presented to patients and their parents in three ninety minute sessions in lecture,question and answer, and educational pamphlets.follow up was done during three months after intervention. primary consequence is the percentage of improvement in functional chronic constipation and secondary consequences of this study are 6 items of Rome 3 criteria

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014062918270N1**
Registration date: **2014-07-22, 1393/04/31**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-07-22, 1393/04/31

Registrant information

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Zohre Faramarzian
Name of organization / entity
Shiraz University of Medical Science
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Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for Research and Technology of Shiraz University of Medical Sciences

Expected recruitment start date

2013-11-18, 1392/08/27

Expected recruitment end date

2014-03-22, 1393/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of the nurse led approaches on functional chronic constipation in 3 to 14 year old children referred to Imam Reza clinic, Shiraz University of Medical Sciences

Public title

The impact of nurse led approaches on functional chronic constipation of children

Purpose
Treatment

Inclusion/Exclusion criteria
inclusion criteria: Having aged 3 to 14 years old; Having constipation during the 2 months prior to entrance to the study;Children with diagnosis of functional chronic constipation based on Rome 3 criteria and physician`s approval; Having informed consent and willingness to participate in the study;Parents are literate enough to read and write Farsi; The participation of parents and children in all training and counseling sessions. Exclusion criteria: Children diagnosed with IBS;Children with mental retardation or metabolic disorders (such as hypothyroidism);Children with diagnosis of spinal anomalies or Hirschsprung's disease or anorectalpathology;Children who have undergone gastrointestinal surgery; children who receive drugs affecting gastrointestinal motility or any kind of traditional medicine or other conventional medical treatment; Lack of desire to continue the study

Age
From **3 years** old to **14 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **95**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences

Street address
Seventh floor, Shiraz University of Medical Sciences and Health Services, Next to Red Crescent Organization, Zand blvd

City
Shiraz

Postal code
1978-71345

Approval date
2013-11-18, 1392/08/27

Ethics committee reference number
6775-92 -CT

Health conditions studied

1

Description of health condition studied
constipation

ICD-10 code
k59.0

ICD-10 code description
constipation

Primary outcomes

1

Description
improvement of constipation

Timepoint
1month,2months and 3 months after intervention

Method of measurement
bowel dairy

Secondary outcomes

1

Description
two or fewer defecation in the toilet per week

Timepoint
Before starting the study,1month,2months and 3 months after intervention

Method of measurement
bowel dairy

2

Description
at least one episode of fecal incontinence per week

Timepoint
before starting the study,1month,2 months and 3 months after intervention

Method of measurement
bowel dairy

3

Description
history of retentive posturing or excessive volitional stool retention

Timepoint
Before starting the study,1month,2months and 3 months after intervention

Method of measurement
bowel dairy

4

Description
history of painful or hard bowel movement
Timepoint
Before starting the study,1month,2months and 3 months after intervention
Method of measurement
bowel dairy

5

Description
presence of a large fecal mass in the rectum
Timepoint
Before starting the study,1month,2months and 3 months after intervention
Method of measurement
bowel dairy

6

Description
history of large diameter stools that may obstruct the toilet
Timepoint
Before starting the study,1month,2months and 3 months after intervention
Method of measurement
bowel dairy

Intervention groups

1

Description
Intervention group: routine treatment plus nurse led approaches which consists of 2 main components education and follow up. Training sessions were presented to patients and their parents in three ninety minute sessions in lecture, question and answer, and educational pamphlets.follow up was done during three months after intervention .
Category
Behavior

2

Description
control group:routin treatment
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Clinic related to Shiraz University of Medical Science
Full name of responsible person
Dr Safi lari
Street address
Namazi square
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-Chancellor for Research and Technology of Shiraz University of Medical Sciences
Full name of responsible person
Dr Gholamreza Hatam
Street address
Seventh floor, Shiraz University of Medical Sciences and Health Services, Next to Red Crescent Organization, Zand blvd
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellor for Research and Technology of Shiraz University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty