

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 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 to 14 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 to 14 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

###### Name

Zohre Faramarzian

###### Name of organization / entity

Shiraz University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1230 5410

###### Email address

faramarziz@sums.ac.ir

##### 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 anorectal pathology; 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 diary

**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 diary

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 diary

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 diary

#### 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 Iari

**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**

Marzie Kargar

**Position**

MS in Nursing

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

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

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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Pediatric Gastroenterologist  
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## Person responsible for updating data

### Contact

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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*