# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 2026

## Investigating the effects of tecar therapy with biofeedback in comparison with biofeedback alone on the treatment of fecal incontinence in children (4-16 years): a randomized clinical trial

## Protocol summary

**Study aim**

In this randomized clinical trial, the effects of tecar therapy with biofeedback in comparison with biofeedback alone on the treatment of fecal incontinence in children (4-16 years) will be investigated.

**Design**

Clinical trial in phase 2 on 81 volunteers with control and intervention groups with parallel groups, single-blind, randomization by simple randomization method

**Settings and conduct**

This study will be done in the physiotherapy clinic of Mashhad University Rehabilitation Center. The participants will complete the questionnaire of constipation and incontinence and children's quality of life and the frequency of incontinence per week , then the patients will be randomly divided into three intervention groups . Control group: routine medical care including diet and lifestyle modification and laxative consumption Intervention group 1: biofeedback therapy , 2 sessions a week Intervention group 2, biofeedback therapy along with tecar therapy ,2 sessions a week This study will have a 6-week intervention time and 6 weeks follow-up.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: children age range from 4 to 16 years fecal incontinence for 6 months according to the diagnosis of the referring specialist doctor Exclusion criteria: traumatic sphincter injury with/or following surgery anorectal and anatomical abnormalities of the excretory system with/or digestive system and sexual disorders psychological and psychiatric disorders comprehension problems and children who are unable to cooperate with a physiotherapist for any reason Spine with/or nerve diseases that lead to fecal incontinence patients with sensory disorders in the anus and perineum

**Intervention groups**

Control group: routine medical care Intervention group 1: biofeedback therapy alone Intervention group2: biofeedback with tecar therapy.

**Main outcome variables**

The number of bowel incontinence per week

## General information

**Reason for update**

At the beginning of the study, the researchers decided to add the usual medical treatment group, so the randomization was changed to three groups, including two physiotherapy intervention groups and one usual medical intervention group.

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20140811018760N9**
Registration date: **2023-06-15, 1402/03/25**
Registration timing: **prospective**

Last update: **2024-09-08, 1403/06/18**
Update count: **1**

**Registration date**

2023-06-15, 1402/03/25

**Registrant information**

**Name**
Fariba Ghaderi
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Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-07-05, 1402/04/14
**Expected recruitment end date**
2023-12-22, 1402/10/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigating the effects of tecar therapy with biofeedback in comparison with biofeedback alone on the treatment of fecal incontinence in children (4-16 years): a randomized clinical trial

**Public title**
The effects of tecar therapy with biofeedback on the treatment of fecal incontinence in children
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
The age range of children is 4 to 16 years Fecal incontinence for 6 months according to the diagnosis of the referring specialist
**Exclusion criteria:**
Children under 4 years old and over 16 years old Traumatic sphincter injury or following surgery Anorectal and anatomical abnormality of the excretory system or digestive system and sexual disorders Psychological and psychiatric disorders Understanding problems and children who are not able to cooperate with the physiotherapist for any reason. Diseases of the spine or nerves that lead to fecal incontinence Patients with sensory disorders in the anus and perineum
**Age**
From **4 years** old to **16 years** old
**Gender**
Both

**Phase**
N/A
**Groups that have been masked**

- Outcome assessor

**Sample size**
Target sample size: **81**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Randomization will be done by simple randomization method with table of random numbers assigned to three groups.
**Blinding (investigator's opinion)**
Single blinded
**Blinding description**
To hide the allocation of the type of intervention received, it will be written on a piece of paper and placed inside sealed envelopes, consecutively numbered. The envelopes will be opened in the order in which the participants enter the study and the type of group of people will be determined. Due to the nature of the treatment, it is not possible to blind the patient and the researcher, so only the evaluator will be blind to the grouping.
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Tabriz University of Medical Sciences
**Street address**
Daneshgah Ave, Tabriz University of Medical Sciences, Rehabilitation Faculty
**City**
Tabriz
**Province**
East Azarbaijan
**Postal code**
5167654455
**Approval date**
2023-05-28, 1402/03/07
**Ethics committee reference number**
IR.TBZMED.REC.1402.195

## Health conditions studied

### 1

**Description of health condition studied**
Children fecal incontinence
**ICD-10 code**
F98.1
**ICD-10 code description**
Fecal incontinence

## Primary outcomes

### 1

**Description**
The number of bowel incontinence per week
**Timepoint**
6 weeks of treatment period, 6 weeks of follow-up
**Method of measurement**
Report of the patient or the child's parents

### 2

**Description**

Severity of fecal incontinence
**Timepoint**
6 weeks of treatment period, 6 weeks of follow-up
**Method of measurement**
Rintala questionnaire

**3**

**Description**
Quality of Life
**Timepoint**
6 weeks of treatment period, 6 weeks of follow-up
**Method of measurement**
Pediatrics Quality of life questionnaire for fecal incontinent

**4**

**Description**
Severity of constipation
**Timepoint**
6 weeks of treatment period, 6 weeks of follow-up
**Method of measurement**
Pediatrics constipation questionnaire

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group 1: biofeedback therapy
**Category**
Rehabilitation

**2**

**Description**
Intervention group 2: biofeedback along with tecar therapy
**Category**
Rehabilitation

**3**

**Description**
Control group: routine medical care
**Category**
Treatment - Other

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Physiotherapy Clinic, Comprehensive Rehabilitation Center, Faculty of Paramedical Sciences and Rehab
**Full name of responsible person**
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## Sponsors / Funding sources

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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**
Tabriz 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**
Tabriz University of Medical Sciences
**Full name of responsible person**
Fariba Ghaderi

**Position**
Professor, PhD of physiotherapy
**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

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