

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of using *Salvadora Persica* toothbrush on the intensity of constipation in the elderly referred to specialized gastroenterology clinic.

#### Protocol summary

##### Study aim

To determine the effect of using *Salvadora Persica* toothbrush on intensity of constipation in elderly referred to Golestan Gastroenterology Clinic

##### Design

Randomized trial with two parallel groups on 60 elderly, no blinding, using computer software to generate random codes in form of permuted blocks.

##### Settings and conduct

Elderly people who refer to the gastroenterology clinic and are eligible for study will be allocated to control and intervention groups based on random codes. After receiving necessary instruction, participants in the intervention and control groups will use the *Salvadora Persica* toothbrush, and regular toothbrush, respectively. Constipation intensity will be evaluated at study onset, week 3, and week 6.

##### Participants/Inclusion and exclusion criteria

Being over 60 years old. Being fully conscious and teachable. Having natural teeth and degrees of constipation. Being a city resident. Being able to perform the intervention protocol independently or with the help of their caregiver. Using C-Lax pill for their constipation. Not using narcotics or medications such as iron tablets or calcium, that cause constipation.

##### Intervention groups

In the intervention group, participants after receiving necessary instruction will use *Salvadora Persica* toothbrush 3 times a day, at morning, noon, and night, 5 minutes each time, for 6 weeks. In control group, participants will use their regular toothbrush 3 times a day, at morning, noon, and night, 5 minutes each time, for 6 weeks.

##### Main outcome variables

Constipation intensity will be assessed using the Constipation Assessment Scale (CAS) and with the scores ranging from 0 to 16; with higher scores denote more severe constipation. Measurements will be done at study onset, week 3, and week 6. Also, to increase the validity

of data the Bristol Stool Scale (BSS) that evaluates the stool appearance will be used during the study.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201023049119N1**

Registration date: **2021-04-10, 1400/01/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-04-10, 1400/01/21**

Update count: **0**

##### Registration date

2021-04-10, 1400/01/21

##### Registrant information

##### Name

Raheleh Yousefzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3328 6734

##### Email address

r.yousefzadeh@nkums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-03-05, 1399/12/15

##### Expected recruitment end date

2021-08-06, 1400/05/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of using *Salvadora Persica* toothbrush on the intensity of constipation in the elderly referred to specialized gastroenterology clinic.

**Public title**

The effect of using *Salvadora Persica* toothbrush on elderly constipation intensity

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being over 60 years old. Being fully conscious and teachable. Having natural teeth. Having degrees of constipation (too mild to severe). Being a city resident. Being able to perform the intervention protocol independently or with the help of their caregiver. Being able to do activities of daily living. Using C-Lax pill for their constipation.

**Exclusion criteria:**

Being on treatment for heart disease, hypertension, respiratory diseases and gastrointestinal ulcers. Being addicted to drugs. Use of medications causing constipation.

**Age**

From **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

First, a purposive sampling will be done; then eligible subjects will be randomly allocated into two groups, using permutation blocks randomization approach and the codes generated by the relevant software. Subjects will be randomized individually.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

In this trial, participants in control group will use a regular plastic toothbrush, and in intervention group will use *Salvadora Persica* toothbrush 3 times a day, at morning, noon, and night, 5 minutes each time, for 6 weeks. Participants will receive information on how to use toothbrushes.

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

**Street address**

Central Library. School of Medicine. south side of the hospital. Shahriar St. Bojnourd.

**City**

Bojnurd

**Province**

North Khorasan

**Postal code**

9414974877

**Approval date**

2021-02-01, 1399/11/13

**Ethics committee reference number**

IR.NKUMS.REC.1399.126

**Health conditions studied****1****Description of health condition studied**

Constipation

**ICD-10 code**

K59.00

**ICD-10 code description**

Constipation, unspecified

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

Constipation intensity based on the score of Constipation Assessment Scale (CAS).

**Timepoint**

Study onset (before starting the intervention), week 3, and week 6 after starting the intervention.

**Method of measurement**

Using of Constipation Assessment Scale: This questionnaire was published by McMillan in 2001 and contains 8 questions; each question has three answer options with scores from zero to 2; Total score ranges from zero to 16, with the higher score denotes more severe constipation.

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Control group: participants in this group will use their regular plastic toothbrush 3 times a day, at morning after breakfast, noon after lunch, and night after dinner, 5 minutes each time, for 6 weeks. Participants will receive necessary instruction on appropriate use of the toothbrush .

### Category

Treatment - Drugs

## 2

### Description

Intervention group: participants in this group will use *Salvadora Persica* wood as toothbrush. Participants and their caregivers will receive instructions on how to prepare, use, and maintain this toothbrush by description and showing video. Participants will use the toothbrush 3 times a day, at morning after breakfast, noon after lunch, and evening after dinner, 5 minutes each time, perpendicular to teeth and gums with rotating movements. Before using, the toothbrush is placed in tepid water to soften the fibers, and then about 1 cm of the stem skin is peeled and the fibers inside are unbraided using a hammer or with teeth. The toothbrush is held like a pen in hand, rubbed on teeth and the gums. After finishing, the used part is cut and disposed. The toothbrush is washed and dried after each use to prevent contaminants. This protocol will be done for 6 weeks.

### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Specialized gastrointestinal clinic

##### Full name of responsible person

Dr. Peyman Sanjari

##### Street address

3rd floor. Bozorgmehr Doctors Building. East Taleghani St.

##### City

Gonbad-e Qabus

##### Province

Golestan

##### Postal code

4971889711

##### Phone

+98 17 3323 5835

##### Email

Dr.p.sanjari@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

#### Name of organization / entity

Bojnourd University of Medical Sciences

#### Full name of responsible person

Dr. Amir Amani

#### Street address

South side of Imam Ali Hospital. Shahriar Street. Bojnourd.

#### City

Bojnurd

#### Province

North Khorasan

#### Postal code

94176-96786

#### Phone

+98 58 3229 7182

#### Email

research@nkums.ac.ir

#### Web page address

<http://nkums.ac.ir/index.aspx?Catid=508>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Bojnourd 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

Bojnourd University of Medical Sciences

##### Full name of responsible person

Raheleh Yousefzadeh

##### Position

Graduate student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Plaque12. Alley 30. South Danesh

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Bojnourd University of Medical Sciences

**Full name of responsible person**

Raheleh Yousefzadeh

**Position**

Graduate student

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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