

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 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

City

Gonbad-e Qabus

Province

Golestan

Postal code

4971889711

Phone

+98 17 2238 6734

Email

susfzd76@gmail.com

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

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Plaque12. Alley 30. South Danesh

City

Gonbad-e Qabus

Province

Golestan

Postal code

4971889711

Phone

+98 17 2238 6734

Email

susfzd76@gmail.com

Person responsible for updating data

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

City

Gonbad-e Qabus

Province

Golestan

Postal code

4971889711

Phone

+98 17 2238 6734

Email

susfzd76@gmail.com

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