

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The assessment of the efficacy of commercial charcoal tooth floss and conventional tooth floss in Periodontal indices: randomized clinical trial

Protocol summary

Study aim

Determining the effect of commercial charcoal floss and ordinary floss on periodontal indices

Design

This study will be performed in the center of the Faculty of Dentistry of Ardabil University of Medical Sciences, as a double-blind (researcher and study analyst) and as a randomized clinical trial.

Settings and conduct

Among students studying at dental school, 50 people who meet the criteria will participate in the study after receiving written consent. Each person will be given the necessary training and they will be asked to use the given tooth floss as a split-mouth. After a period of time, the studied indicators will be evaluated. Finally, the effect of commercial charcoal floss and conventional floss in reducing gingivitis will be investigated.

Participants/Inclusion and exclusion criteria

Exclusion criteria: systemic diseases that cause changes in periodontal health such as diabetes, hormonal problems, patients at risk for endocarditis, pregnant and lactating women; visual diagnosis of any malocclusion such as crowding, cross-bite, open bite, etc; history of chronic use of any antibiotics or drugs that affect the condition of the periodontium such as phenytoin or cyclosporine at least the last 3 months; chronic use of NSAIDs; history of any harmful oral habits such as bruxism, clenching; chewing with the one side mouth. Inclusion criteria: at least 5 teeth in each quadrant; at least one dental space in each quadrant of bleeding during the probe (BOP); maximum depth of the envelope is 2 mm and there is no gingival resorption; maximum space between the teeth should be 1 mm.

Intervention groups

Intervention group: Charcoal dental floss Control group: normal dental floss

Main outcome variables

plaque index; gingival index; bleeding on probing index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210305050584N2**

Registration date: **2021-12-04, 1400/09/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-04, 1400/09/13**

Update count: **0**

Registration date

2021-12-04, 1400/09/13

Registrant information

Name

Sheida Fazlalizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 45 3324 9753

Email address

sh.fazlalizadeh@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-10, 1400/08/19

Expected recruitment end date

2022-03-17, 1400/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The assessment of the efficacy of commercial charcoal tooth floss and conventional tooth floss in Periodontal indices:randomized clinical trial		Due to the distinction between charcoal and normal floss, there is no ability to blind the participant.The analyst of the study data and the person measuring the indexes (researcher) do not know in which group the samples are.	
Public title	The assessment of the efficacy of commercial charcoal tooth floss and conventional tooth floss in Periodontal indices	Placebo	Not used
Purpose	Health service research	Assignment	Parallel
Inclusion/Exclusion criteria	Inclusion criteria: At least 5 teeth in each quadrant. At least one dental space in each quadrant of bleeding during the probe (BOP). The maximum depth of the pocket equal to 2 mm and no gingival resorption. A maximum interdental space of 1 mm. Exclusion criteria: Systemic diseases that cause changes in periodontal health,such as diabetes,hormonal problems,patients at risk for endocarditis,pregnant women and nursing mothers. Malocclusion. Use of systemic antibiotics in the last 3 months before the start of the study. History of any harmful oral habits such as bruxism, clenching. Chewing with the one side of mouth. Consumption of mouthwash in the last 6 months. Smoking. Pregnancy. Periodontal surgery: In case of periodontal surgery within 6 months before the study in the study area. Oral mucosal diseases (such as vesiculosis-bullous diseases). Periodontal disease: If attachment loss more than 2 mm. Any type of dental prosthesis appliances, orthodontics, cavities or any plaque blocking agent other than calculus.	Other design features	
Age	No age limit	Secondary Ids	empty
Gender	Both	Ethics committees	
Phase	N/A	1	
Groups that have been masked	- Investigator - Outcome assessor - Data analyser	Ethics committee	
Sample size	Target sample size: 51	Name of ethics committee	Ardabil University of Medical science-Dentistry Faculty
Randomization (investigator's opinion)	Randomized	Street address	Daneshgah alley, Ardebil University of Medical science
Randomization description	Randomization of samples will be done by lottery method. Inside the sealed envelopes, half of the samples will contain an A card and half of the samples will contain a B card, and the samples will randomly pick up a card from the envelope. Each specimen that removes card A will floss its right quadrant (quadrant) with charcoal floss and its two left quadrants with conventional floss, and each specimen that removes card B will floss its two right quadrants with conventional floss and two left quadrants will floss with charcoal floss	City	Ardabil
Blinding (investigator's opinion)	Double blinded	Province	Ardabil
Blinding description		Postal code	5618985991
		Approval date	2021-10-26, 1400/08/04
		Ethics committee reference number	IR.ARUMS.REC.1400.221
		Health conditions studied	
		1	
		Description of health condition studied	gingivitis
		ICD-10 code	K05
		ICD-10 code description	Gingivitis and periodontal diseases
		Primary outcomes	
		1	
		Description	plaque index
		Timepoint	Start of study and the second, fourth and eighth week after the intervention
		Method of measurement	Turesky modified Quigley-hein index
		2	
		Description	

Bleeding on probing index
Timepoint
Start of study and the second, fourth and eighth week after the intervention
Method of measurement
Ainamo & Bay bleeding on probing index

3

Description
gingival index
Timepoint
Start of study and the second, fourth and eighth week after the intervention
Method of measurement
Loe Silness index

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Use charcoal floss once a day before bed for 2 months.
Category
Prevention

2

Description
Control group: Use conventional toothfloss once a day before bed for 2 months.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ardabil University of Medical science-Dentistry Faculty
Full name of responsible person
Dr. Sheida Fazlalizadeh
Street address
Daneshgah alley, Ardebil University of Medical science
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Sheida Fazlalizadeh
Street address
Daneshgah alley, Ardebil University of Medical science
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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
Ardabil 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
Ardabil University of Medical Sciences
Full name of responsible person
Dr. Sheida Fazlalizadeh
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Daneshgah alley, Ardebil University of Medical science
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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Amirreza Rakhshanpour

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

part of datas

When the data will become available and for how long

access period starts 6 months after the results are published

To whom data/document is available

researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutes can request access to data and documents only for the purpose of scientific and research work and in order to improve scientific resources.

From where data/document is obtainable

Dr. Sheida Fazlalizadeh : sh.fazlalizade@gmail.com

Amirreza Rakhshanpour : amir_rakhsh@yahoo.com

What processes are involved for a request to access data/document

Dr. Sheida Fazlalizadeh : sh.fazlalizade@gmail.com

Amirreza Rakhshanpour : amir_rakhsh@yahoo.com

Comments

Requests will be answered via email as soon as possible.