

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effectiveness of school orthodontic screening, specific referral letter and orthodontic advice on treatment rate in patients who need timely treatment: a cluster-randomized controlled trial

#### Protocol summary

##### Study aim

Evaluating the effectiveness of school orthodontic screening, specific referral letter and orthodontic consultation on treatment rate in patients who need timely treatment

##### Design

Cluster-randomized controlled trial, parallel group with 198 patients in each group. Stratified randomization is done. The unit of randomization is the school(cluster).

##### Settings and conduct

Second grade students(in gorgan, Aqqala, Kordkuy and Bandar-e-Gaz) with reversed overjet, one or two anterior teeth crossbite, and/or posterior crossbite and Fifth grade students with increased overjet (more than 6mm), one or two anterior teeth crossbite, and/or posterior crossbite will be examined. In intervention group orthodontic screening along with specific referral and orthodontic consultation will be done. in control group no intervention will be done after examination for 6 month. attendance at orthodontist will be compared after 6 month. Three last year dentistry students who perform orthodontic school screening are kept blind. intervention will be done the day after screening by independent person. Data analyst is kept blind to the allocation.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All elementary schools in Gorgan, Aqqala, Kordkuy and Bandar-e-Gaz Second grade students with reversed overjet, one or two anterior teeth crossbite, and/or posterior crossbite Fifth grade students with increased overjet (more than 6mm), one or two anterior teeth crossbite, and/or posterior crossbite  
Exclusion criteria: Schools does not agree to participate in the study Children who refuse to be examined Parents refusal to give informed consent

##### Intervention groups

Intervention group: screening in schools along with specific referral letter and orthodontic consultation

Control group: Without orthodontic screening, specific referral letter and orthodontic consultation

##### Main outcome variables

attendance at orthodontist

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240119060731N1**

Registration date: **2024-02-12, 1402/11/23**

Registration timing: **prospective**

Last update: **2024-02-12, 1402/11/23**

Update count: **0**

##### Registration date

2024-02-12, 1402/11/23

##### Registrant information

##### Name

Mohammad Damavandi Kamali

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 911 375 8032

##### Email address

dr.damavandi@goums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-02-19, 1402/11/30

##### Expected recruitment end date

2024-08-20, 1403/05/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
The effectiveness of school orthodontic screening, specific referral letter and orthodontic advice on treatment rate in patients who need timely treatment: a cluster-randomized controlled trial

**Public title**  
The effectiveness of school orthodontic screening, specific referral letter and orthodontic advice on treatment rate in patients who need timely treatment

**Purpose**  
Health service research

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

All elementary schools in Gorgan, Aqqala, Kordkuy and Bandar-e-Gaz Second grade students with reversed overjet, one or two anterior teeth crossbite, and/or posterior crossbite Fifth grade students with increased overjet (more than 6mm), one or two anterior teeth crossbite, and/or posterior crossbite

**Exclusion criteria:**

Schools does not agree to participate in the study  
Children who refuse to be examined Parents refusal to give informed consent

**Age**  
From **7 years** old to **13 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**

- Investigator
- Data analyser

**Sample size**  
Target sample size: **396**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Stratified randomization is done by gender, type of school and city The unit of randomization is the school (cluster) Allocation concealment will be achieved with sequentially numbered, opaque, sealed envelopes

**Blinding (investigator's opinion)**  
Single blinded

**Blinding description**  
Three last year dentistry students who perform orthodontic school screening are kept blind. intervention will be done after screening by independent person. Data analyst is kept blind to the allocation.

**Placebo**  
Not used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Golestan University of Medical Sciences

**Street address**

shahriar town

**City**

Gorgan

**Province**

Golestan

**Postal code**

4881844999

**Approval date**

2023-09-26, 1402/07/04

**Ethics committee reference number**

IR.GOUMS.REC.1402.266

## Health conditions studied

### 1

#### Description of health condition studied

timely treatment of patients in need of orthodontic treatment

**ICD-10 code**

K07.2

**ICD-10 code description**

Anomalies of dental arch relationship

## Primary outcomes

### 1

#### Description

attendance at orthodontist

**Timepoint**

6 month after intervention

**Method of measurement**

parents complete a survey which inquired whether they took the child to the orthodontist

## Secondary outcomes

### 1

#### Description

Commencing orthodontic treatment

**Timepoint**

6 months after intervention

**Method of measurement**

parents complete a survey which inquired whether orthodontic treatment has been commenced

## Intervention groups

### 1

#### Description

Intervention group: screening in schools along with specific referral letter and orthodontic consultation. In this group of patients, orthodontic problems are diagnosed, and the referral letter (includes an explanation of the type of problem, the right time for treatment, and by whom they should be treated will be given to them ). Moreover, they are invited to visit the Faculty of Dentistry for orthodontic consultation.

#### Category

Early detection

### 2

#### Description

Control group: Without screening, specific referral letter and orthodontic consultation. In this group of patients, orthodontic problems are diagnosed and no other intervention will be done for 6 month

#### Category

Early detection

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

elementary schools in Gorgan, Aqqala, Kordkuy and Bandar-e-Gaz

##### Full name of responsible person

Mohammad Damavandi Kamali

##### Street address

Unit 17, 2nd floor, Yademan building, Edalat Alley 21, Valiasr street

##### City

Gorgan

##### Province

Golestan

##### Postal code

4917748855

##### Phone

+98 17 3232 7923

##### Email

dr.damavandi@goums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Gorgan University of Medical Sciences

##### Full name of responsible person

Narges beigom Mirbehbahani

##### Street address

Central organization of Golestan university of medical sciences, Hirkan BLVD

##### City

Gorgan

##### Province

Golestan

##### Postal code

4918936316

##### Phone

+98 17 3243 0310

##### Email

info@goums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Gorgan 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

Gorgan University of Medical Sciences

##### Full name of responsible person

Mohammad Damavandi Kamali

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Dentistry

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Damavandi Kamali

**Position**

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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

**Person responsible for updating data****Contact****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mohammad Damavandi Kamali

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

**Street address**