Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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

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

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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
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Dentistry
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Person responsible for updating data

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dr.damavandi@goums.ac.ir

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