Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Assessment of the effectiveness of dental occlusion on postural position of body in students of semester 8 to semester 12 at Shahid Beheshti School of dentistry

Protocol summary

Study aim

The aim of this study was to asses the effects of occlusal splints on controlling the postural position of the body in students of semester 8 to semester 12 at Shahid Beheshti School of dentistry

Design

Clinical trial with control group, with parallel, non-blind, randomized groups, on 40 patients. Randomization.com website was used.

Settings and conduct

In this study, 40 volunteers with dental occlusion problems were examined in two groups of intervention and control (20 people in each group). First, using Alginate molding material, the impressions of upper and lower jaws were taken, and after recording the CR and face bow, the casts were mounted in a semi-adjustable articulator, and then a CR splint was made with transparent acrylic material based on patient's centric realation. The Balance indicators was measured by Biodex device before the first session, after the first session and after one month.

Participants/Inclusion and exclusion criteria

The inclusion criteria included Non-compliance of the central relationship with the maximum intercuspation, the ability to walk at least 10 meters independently without the use of auxiliary equipment, having the ability to stand independently on the level 8 of Biodox balance device ; the exclusion criteria included having previous Neurological, Equilibrium and Labyrinth Diseases and having history of falling or fractures of the lower limbs in the last year

Intervention groups

The intervention group included those who received treatment for occlusal splints. This treatment, without any irreversible effect, leads the mandible to the position of the central relationship. The control group also included those who did not receive any treatment.

Main outcome variables

OSI, APSI and MLSI These indexes, measured by the Biodex device, are oscillation the center of gravity of the body relative to the zero point in different axes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200516047458N1**
Registration date: **2020-06-17, 1399/03/28**
Registration timing: **retrospective**

Last update: **2020-06-17, 1399/03/28**
Update count: **0**

Registration date

2020-06-17, 1399/03/28

Registrant information

Name

amirfarhang poureini

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-23, 1397/12/04

Expected recruitment end date

2019-10-23, 1398/08/01

Actual recruitment start date

2019-02-25, 1397/12/06

Actual recruitment end date

2020-01-13, 1398/10/23

Trial completion date

2020-02-12, 1398/11/23

Scientific title

Assessment of the effectiveness of dental occlusion on postural position of body in students of semester 8 to semester 12 at Shahid Beheshti School of dentistry

Public title

Effect of dental occlusion on posture of the body

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Non-compliance of the central relationship with the maximum intercuspation Ability to walk at least 10 meters independently without the use of auxiliary devices Ability to stand independently on the highest level of stability of the Biodox device

Exclusion criteria:

Having a history of neurological disease, systemic disease, equilibrium or labyrinthine disease Having acute or major orthopedic problems, especially in the pelvis, lower limbs and spine Existence of acute uncorrected vision problems The presence of sensory disturbances or vascular pathology in the lower extremities Have a history of falling in the last year History of heart attack in the last 6 months History of fractures of the lower limbs in the last year

Age

From **22 years** old to **24 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: block randomization Randomization unit: individual Used the website https://www.Randomization.com 40 subjects randomized into 5 blocks. in order to reproduce this plan, used the seed 9580 . the number of subjects per block were 8 , number of blocks were 5 and treatment labels were case and control as entered originally.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti Research Institute for Dental Sciences

Street address

5th Floor, Shahid Beheshti,Dental School, Evin, Tehran-IRAN

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Province

Tehran

Postal code

1983963113

Approval date

2019-02-18, 1397/11/29

Ethics committee reference number

IR.SBMU.DRC.REC.1398.023

Health conditions studied

1

Description of health condition studied

Occlusal problems

ICD-10 code

M26.69

ICD-10 code description

Other specified disorders of temporomandibular joint

Primary outcomes

1

Description

Medial-lateral stability index (MLSI)This number, calculated by the device, is the oscillation of the center of gravity of the body relative to the zero point on the medial-lateral axis. Naturally, the lower the number of index indicates the better the stability and lower postural deviation.

Timepoint

1. Before the intervention of the first session 2. After the intervention of the first session 3.One month after the first session

Method of measurement

The variable was collected by the Biodex system as a result of the sample performances.

2

Description

Anterior-posterior stability index (APSI)This number, calculated by the device, is the oscillation of the center of gravity of the body relative to the zero point on the

anterior-posterior axis. Naturally, the lower the number of index indicates the better the stability and lower postural deviation.

Timepoint

1. Before the intervention of the first session 2. After the intervention of the first session 3.One month after the first session

Method of measurement

The variable was collected by the Biodex system as a result of the sample performances.

3

Description

Overall stability index (OSI)This number, calculated by the device, is the oscillation of the center of gravity of the body relative to the zero point on the overall axis. Naturally, the lower the number of index indicates the better the stability and lower postural deviation.

Timepoint

1. Before the intervention of the first session 2. After the intervention of the first session 3.One month after the first session

Method of measurement

The variable was collected by the Biodex system as a result of the sample performances.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Those who have received occlusal splint treatment. Occlusal splint is a prosthetic appliance that is made using transparent acrylic (made in Acropars Factory, Iran) in the laboratory. This device directs the mandible to the centric jaw position.All samples in this group use this occlusal splint for one month.

Category

Treatment - Devices

2

Description

Control group: Those who have not received any treatment. The members of this group only participate in the balance study sessions with the other group.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti university of medical sciences and health services , school of dentistry

Full name of responsible person

Yeganeh Memari

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Mahmood Khodadoost

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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Assistant professor
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not 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
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available