

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 assess 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 relation. 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 Biodex 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8868 8093

##### Email address

amirfarhang374@gmail.com

##### 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 Biodex 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

##### City

Tehran

##### 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

#### **Street address**

Shahid Beheshti university of medical sciences, School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

#### **City**

Tehran

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#### **Postal code**

1983969411

#### **Phone**

+98 21 2240 3075

#### **Email**

DentIt@sbmu.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Dr. Mahmood Khodadoost

##### **Street address**

5th Floor, Bldg No.1 Shahid Beheshti university of medical sciences, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.

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1985717443

##### **Phone**

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##### **Email**

info@sbmu.ac.ir

#### **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**

Seyed Majid Hosseini

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Physiotherapy

**Street address**

Shahid Beheshti university of medical sciences, School of Rehabilitation Sciences, Damavand St, Across from Bu Ali Hospital

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

Shahid Beheshti University of Medical Sciences

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Majid Hosseini

**Position**

Assistant professor

**Latest degree**

Ph.D.

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**Province**

Tehran

**Postal code**

1616913111

**Phone****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