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Dental splint effect in bruxism (condition where a person grinds, clenches, or gnashes their teeth, either while awake or asleep)

Submission date
07/10/2024

Recruitment status
No longer recruiting

Registration date
10/10/2024

Overall study status
Completed

Last Edited
14/10/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Bruxism is defined as an activity of the masticatory muscles (MMA) that can be rhythmic (phasic) or non-rhythmic (tonic), which can occur during sleep (sleep bruxism) or during awake period of the day (awake bruxism). Bruxism can occur with teeth contact (clenching of the teeth, grinding of the teeth), that could be manifested both during awake and sleep periods, or without teeth contact (mandibular bracing and thrusting) manifested especially during the awake period of the day.
Both sleep bruxism and awake bruxism have tooth wear, tooth fractures and abfractions as consequences. The only recognized method of preventing them is considered dental splint or oral appliance, which can be done by different methods, from traditional to fully digital ones. A standard oral appliance is occlusal appliance worn on maxillary arch, at sleep, which act as a functional appliance to reduce the intensity of masticatory muscles force during clenching and grinding. The printed occlusal appliances are used more and more in dentistry. The aim of the study is to determine if wearing every night the occlusal appliance for a period of 12 months in a group of subjects with low sleep bruxism has the same effects as in a group of subjects with moderate sleep bruxism.

Who can participate?
Adults diagnosed with sleep bruxism and teeth lesions like tooth wear or tooth fractures.

What does the study involve?
Participants with sleep bruxism from dental students and faculty were screened and randomly selected to participate in the study. After a first evaluation of the EMG activity with Dia-Bruxo, participants were allocated to 2 groups: one with mild or low bruxism (2-4 no of bruxism events per sleep hour) and one with moderate bruxism (equal or higher than 4 events of bruxism per h of sleep). The follow up periods are after 2 weeks, after one month, after 3 months. Dia-Bruxo registrations were done initially and at 3 months .

What are the possible benefits and risks of participating?
Participants may benefit from being protected against the impacts of sleep bruxism (i.e. tooth

wear, dental fractures and dental sensitivity). There are no notable risks involved with participating.

Where is the study run from?
Dental School, University of Medicine and Pharmacy of Craiova (Romania)

When is the study starting and how long is it expected to run for?
July 2022 to October 2024

Who is funding the study?
University of Medicine and Pharmacy of Craiova (Romania)

Who is the main contact?
Dr. Adrian Marcel Popescu, sanda.popescu@umfcv.ro

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
Ethics Committee No of UMF Craiova 156 from 25.07.2022

Study information

Scientific Title
Electromiographic evaluation of masseter muscle activity before and after wearing an occlusal appliance for sleep bruxism

Acronym
EMG-MMA-OA-SB

Study objectives
Occlusal appliance wearing in sleep bruxism is effective in normalization of the electromyographic activity of the masseter muscle in bruxism individuals

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 25/07/2022, University and scientific ethics and deontology commission of University of Medicine and Pharmacy of Craiova (Bd. 1 Mai no 66, Craiova, 200638, Romania; +40 744523754; cristea_csmn@yahoo.com), ref: 156

Study design
Single-centre randomized interventional trial

Primary study design
Interventional

Study type(s)
Prevention, Treatment

Health condition(s) or problem(s) studied
Bruxism (sleep/awake)

Interventions
The randomization process was conducted by computer, assigning a number to each potential participant from a larger group of students with sleep bruxism. This randomization occurred in the initial phase of the study, before the intervention.

The study group of bruxism subjects was investigated before and after the intervention, which involved wearing a 3D-printed occlusal appliance each night for three months. Surface electromyography (sEMG) was used to record the masseter muscle activity over a 24-hour period.

The intervention consisted of a 3D-printed maxillary occlusal appliance made of hard acrylic, a treatment for sleep bruxism. After the initial sEMG recording, participants were allocated into one of two groups based on the severity of their sleep bruxism: Group 1 with low sleep bruxism (2-4 bruxism events per hour of sleep) and Group 2 with moderate sleep bruxism (4 or more bruxism events per hour of sleep).

Intervention Type
Other

Primary outcome(s)
1. Change in sleep bruxism activity is measured using surface electromyography (sEMG) at baseline and after 3 months
2. Comparison of sleep bruxism activity between low and moderate sleep bruxism groups is measured using surface electromyography (sEMG) at baseline and after 3 months
3. Change in awake bruxism indexes is measured using sEMG device software at baseline and

after 3 months
4. Comparison of awake bruxism indexes between low and moderate sleep bruxism groups is measured using sEMG device software at baseline and after 3 months

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
01/10/2024

Eligibility

Key inclusion criteria
1. Age over 18 years
2. Subjects with self-reported bruxism
3. Subject with changes in the dentition (presence of cracks, dental wear)
4. Subject willing to wear the dental splint
5. Subjects with good oral hygiene

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
50 years

Sex
All

Total final enrolment
38

Key exclusion criteria
1. Systemic diseases
2. Subjects wearing an orthodontic appliance
3. Subjects diagnosed with sleep apnoea
4. Subjects with sleep bruxism treated with medication
5. Subjects wearing a dental splint already

Date of first enrolment
01/10/2022

Date of final enrolment
01/06/2024

Locations

Countries of recruitment
Romania

Study participating centre
University of Medicine and Pharmacy of Craiova
Petru Rares 2-4
Craiova
Romania
200349

Sponsor information

Organisation
University of Medicine and Pharmacy of Craiova

ROR
https://ror.org/031d5vw30

Organisation
Romanian Society for Dental Research

Funder(s)

Funder type
University/education

Funder Name
University of Medicine and Pharmacy of Craiova

Results and Publications

Individual participant data (IPD) sharing plan

The dataset generated during and analyzed during the current study will be available upon request from Adrian Marcel Popescu smpopescu@mail.com

IPD sharing plan summary

Available on request