

UNIVERSIDADE DE SÃO PAULO
FACULDADE DE ODONTOLOGIA DE BAURU

DYANNE ADENEA MEDINA FLORES

Evaluation of awake bruxism behaviour with ecological momentary assessment (EMA) and its impact in muscle sensitivity tenderness and endogenous analgesia

Avaliação do comportamento do bruxismo de vigília com avaliação momentânea ecológica (AME) e a sua relação com fatores de mensuração da dor.

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Orientador: Prof. Dr. Paulo Cesar Conti Rodrigues

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*“Escuta e serás sábio,
o começo da sabedoria
é o silêncio.”*

Pitágoras

ABSTRACT

The aim of this study was to evaluate awake bruxism (AB) behaviors for one week in a sample of healthy young adults using an ecological momentary assessment (EMA) and the relationship of different AB behaviors with muscle tenderness and pain modulation (CPM) **Methods:** One hundred and twenty-two healthy postgraduate students were given a smartphone application that sends 10 alerts at random intervals every day, for one-week. Subjects had to report in real time what represented their current condition between these options: Relaxed jaw muscles, teeth contact, teeth clenching, teeth grinding and jaw bracing. Before the first day of alerts, the subjects also underwent recordings of the masticatory muscles pressure pain threshold (PPT) and the paradigm of conditioned pain modulation (CPM). The PPT recording was repeated in the last day of study. **Results:** Data were considered valid if compliance was of at least 60% of responses. The total compliance was of 75.9%. The average frequency of relaxed jaw muscles was 54.5%, 29.4% for teeth contact, 5.8% for jaw bracing, 9.7% for teeth clenching and 0.6% for teeth grinding. Teeth contact was found to be the most prevalent behaviour, 69% of participants showed at least one bruxism behaviour during the one-week evaluation period. Any significant gender difference was detected on the sample. The PPT values were within the normality parameters, for the anterior temporalis, 2.52 kg/cm² and 2.26 kg/cm² for right and left. The masseter muscle presented a pain threshold of 1.93 kg/cm² and 1.84 kg/cm² for the right and left side, respectively. Statistically significant difference ($p > 0.000$) were noted on CPM test with the difference between the PPT before (2.5 ± 1.07) and after (2.9 ± 0.96) the cold-water immersion, demonstrating a positive modulation on these young healthy patients. **Conclusion:** The most prevalent behavior was the teeth contact with an average frequency of 29.4%, where 69.6% of the participants presented at least once this behavior. AB is not an important factor of masticatory muscle tenderness on the orofacial pain area in young healthy adults. No association was found between AB behaviors with masticatory muscle tenderness and endogenous analgesia.

Keywords: Awake bruxism, Ecological momentary assessment, conditioned pain modulation

RESUMO

O objetivo do estudo foi avaliar o comportamento de bruxismo da vigília (BV) em adultos jovens, usando a avaliação momentânea ecológica (AME) e avaliar a associação dos diferentes comportamentos do AB com o LDP e CPM. **Métodos:** Cento e vinte e dois estudantes de pós-graduação saudáveis usaram um aplicativo no smarthphone, o qual enviava 10 alertas em intervalos aleatórios todos os dias, durante uma semana. Os sujeitos tiveram que relatar em tempo real sua condição atual entre as seguintes opções: “Músculos da mandíbula relaxados”, “dentes levemente encostados”, “apertando os dentes”, “rangendo os dentes” ou “músculos da mandíbula contraídos sem contato dentário”. Antes da semana de avaliação com o AME, os participantes foram submetidos a testes de limiar de dor à pressão (LDP) e de modulação de dor condicionada (CPM), no último dia da avaliação o LDP foi repetido. **Resultados:** A taxa de resposta foi de 75.9%. Os dados foram considerados válidos com um mínimo de 60% de respostas. A taxa de resposta da frequência de músculos relaxados da mandíbula foi de (54.5%), dentes levemente encostando (29,4%), apertando dentes (9.7%), rangendo dentes (0.6%) e músculos da mandíbula contraídos, mas sem contato dentário de (5.8%). O comportamento mais prevalente foi dos “dentes levemente encostados”; o 69% dos participantes pelo menos em algum momento teve algum comportamento de bruxismo durante a semana de avaliação. Não foi encontrada nenhuma diferença significativa de gênero na amostra. Os valores de LDP se encontraram dentro dos níveis normais, no temporal anterior com 2.53 kg/cm² e 2.26 kg/cm² para direita e esquerda correspondentemente. No músculo masseter se obteve 1,93 kg/cm² e 1,4 kg/cm², para o lado direito e esquerdo. Na amostra total foi encontrada diferença estatística significativa ($p > 0,000$) entre o PPT antes da imersão em água fria (2,5+- 1,07) e depois (2,9 +-0.96), demonstrando uma modulação positiva nos participantes durante o teste de CPM. **Conclusão:** O comportamento mais prevalente foi o contato dentário com (29.4%). O BV não é um fator importante de sensibilidade nos músculos estudados em jovens adultos saudáveis. Não foi encontrada nenhuma associação do BV com a sensibilidade da musculatura nem com a analgesia endógena.

Palavras chave: Bruxismo de vigília, Avaliação momentânea ecológica, Modulação de dor condicionada.

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LIST OF ABBREVIATIONS AND ACRONYMS

AB	Awake Bruxism
SB	Sleep Bruxism
EMA	Ecological momentary assessment
PPT	Pressure pain threshold
CPM	Conditioned pain modulation
TMD	Temporomandibular disorder
TMJ	Temporomandibular joint
DC/TMD	Diagnostic Criteria for Temporomandibular Disorder
SMS	Short message service
TS	Test stimulus
CS	Conditioning stimulus

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1 INTRODUCTION

1 INTRODUCTION

Bruxism is an oral condition that have been gaining interest recently, different features of this behavior have already been studied, such as etiology, definition, prevalence, physiopathological mechanism and its possible association with Temporomandibular Disorders (TMD) (MANFREDINI; WINOCUR; GUARDA-NARDINI; PAESANI *et al.*, 2013). For a long time, bruxism was considered a risk factor for different oral diseases (BADER; LAVIGNE, 2000).

Bruxism can be divided into sleep bruxism (SB) and awake bruxism (AB) (LOBBEZOO; AHLBERG; RAPHAEL; WETSELAAR *et al.*, 2018). A previous study of general bruxism estimates a prevalence of 8% to 31.4%, the major percentage represented by AB (22 to 31%), while SB prevalence was minor but more consistent ($12 \pm 3.1\%$) in adults (MANFREDINI; WINOCUR; GUARDA-NARDINI; PAESANI *et al.*, 2013). There are notably no differences between men and woman, and prevalence decreases with increasing age. High prevalence are also found in children and adolescents (MANFREDINI; SERRA-NEGRA; CARBONCINI; LOBBEZOO, 2017).

Recently, some studies described that bruxism etiology does not have any origin on occlusal factors, as was believed formerly. Biologic (e.g. neurochemicals such as dopamine and other neurotransmitter, genetics, sleep arousals), psychologic (e.g. stress sensitivity, personality traits, anxiety), and exogenous factors (e.g. smoking, alcohol, caffeine, certain medications such as selective serotonin reuptake inhibitors, illicit drugs) are involved in the etiology of bruxism, leaving in the past the occlusal paradigms (MANFREDINI; SERRA-NEGRA; CARBONCINI; LOBBEZOO, 2017)(LAVIGNE; KHOURY; ABE; YAMAGUCHI *et al.*, 2008)(MANFREDINI; LOBBEZOO, 2009).

Based on a recent expert's consensus, sleep bruxism was defined as a masticatory muscle activity during sleep that is characterized as rhythmic (phasic) or non-rhythmic (tonic), and awake bruxism was described as repetitive or sustained tooth contact and/or bracing or thrusting of the mandible during wakefulness. It is important to emphasize that any type of bruxism is not considered a movement disorder, especially in healthy individuals (LOBBEZOO; AHLBERG; RAPHAEL; WETSELAAR *et al.*, 2018).

Clinical consequences of bruxism were evaluated in different systematic reviews, describing the effects on temporomandibular joints (TMJ), jaw muscles, (i.e. TMD and orofacial pain) (SIERWALD; JOHN; SCHIERZ; HIRSCH *et al.*, 2015), natural teeth (i.e. tooth wear and failing restorative treatments) and/or restored implant-supported dentitions (MANFREDINI; AHLBERG; WINOCUR; LOBBEZOO, 2015). It seems to be a consensus that bruxism does not need treatment in the absence of signs and symptoms as it is not considered as a disorder nowadays. In healthy patients, bruxism should rather be considered as a behavioral risk factor (and/or protective) for certain clinical consequences. The protective/risk characteristic of each factor will depend on the presence or extension of other risk factors as well (LOBBEZOO; AHLBERG; RAPHAEL; WETSELAAR *et al.*, 2018).

For the diagnosis and bruxism assessment, different tools such as electromyography, polysomnography, self-reported, questionnaires and different signs or clinical symptoms are available (LOBBEZOO; AHLBERG; RAPHAEL; WETSELAAR *et al.*, 2018). Sleep bruxism have been diagnosed specifically by polysomnography and surface electromyography. On the other hand, these evaluations are not practical for the diagnosis of awake bruxism due to the long periods that participants would have to be connected to the equipment during the entire day. Another limitation of this method is that collecting data in a different environment than the participant is used to, would modify the results, giving possibly false positives (BRACCI; DJUKIC; FAVERO; SALMASO *et al.*, 2018) (YAP; CHUA, 2016).

To facilitate the assessment of AB, an ecological momentary assessment (EMA) can be performed. EMA are collections of repeated momentary evaluations of participants on their natural environment (STONE, 1994). The participants answer how they feel at the exact moment, instead of being asked to summarize their feelings and behaviors along the day. By this methodology, the sample more accurately represents the participant's behavior in a real world (SHIFFMAN, 1998) (STONE; SHIFFMAN, 2002). Laboratory studies, while affording a good deal of control, may not faithfully capture real-world phenomena and thus may not generalize to real-world settings (STONE, 1994). EMA has been already proven reliable in the research setting to assess a variety of oral behaviors (KAPLAN; OHRBACH, 2016), including AB behaviors, where the participant is able to express how they feel and how they manage these behaviors every day (BRACCI; DJUKIC; FAVERO; SALMASO *et al.*, 2018).

Participants relate these events through the use of some cuing device (A, 1998), in the past were used beepers (JOHNSON; LARSON, 1982), a wristwatch with a programmed alarm (LITT; COONEY; MORSE, 1998) or a palmtop computer (STONE, 1994).

Most often the assessments are scheduled at random intervals to avoid any bias in the sampling moments (A, 1998). Recent studies in the orofacial pain field have shown efficacy using EMA as a tool to evaluate oral behaviors, including one study where the jaw muscle tension was shown as predictor for orofacial pain (GLAROS; MARSZALEK; WILLIAMS, 2016). On these recent studies the devices used were short message service (SMS) or e-mails by smartphones (FUNATO; ONO; BABA; KUDO, 2014).

In this way, EMA can be used for epidemiological studies about AB behaviors and can evaluate characteristics associated with those behaviors, as well as the response rate (COLONNA; LOMBARDO; SICILIANI; BRACCI *et al.*, 2020). A first study conducted in healthy young adults evaluating awake bruxism frequency behaviors, used smartphones for a real-time report. Forty-six students received alerts during a week to collect AB events (BRACCI; DJUKIC; FAVERO; SALMASO *et al.*, 2018). Little variability was found of the mean frequency of behaviors compared with the literature, confirming EMA as a reliable method for epidemiologic research of oral behaviors. This research introduced EMA as a viable methodology for awake bruxism assessment (BRACCI; DJUKIC; FAVERO; SALMASO *et al.*, 2018) and will be taken as a reference to continue evaluating related conditions.

Several studies have examined the role of bruxism on alterations of pain sensitivity on masticatory muscles ((MACHADO; COSTA; QUEVEDO; STUGINSKI-BARBOSA *et al.*, 2020), (CONTI; STUGINSKI-BARBOSA; BONJARDIM; SOARES *et al.*, 2014), (MANFREDINI; LOBBEZOO, 2010), (COMMISSO; MARTINEZ-REINA; MAYO, 2014)). This association has been questioned due to the unclear knowledge of the etiology and diagnosis of both bruxism and TMD. (MANFREDINI; LOBBEZOO, 2010) A study by Machado *et al.* 2018, examined orthodontic patients without signs and symptoms of TMD pain and found no relationship between self-reported awake bruxism and changes on masticatory muscles' sensitivity. To more accurately determine the association of muscle pain sensitivity and bruxism, a well-rounded

bruxism diagnosis comprised of a positive self-report, clinical inspection and some complementary tool such as EMA should be realized. Muscle sensitivity could be assessed with a test of pressure pain thresholds (PPT) considering the level of endogenous analgesia to evaluate possible patterns of somatosensory abnormality. (LOBBEZOO; AHLBERG; RAPHAEL; WETSELAAR *et al.*, 2018) (SVENSSON; BAAD-HANSEN; PIGG; LIST *et al.*, 2011)

The German Research Network on Neuropathic Pain (DFNS) has developed a standardized Quantitative sensory testing (QST) protocol (ROLKE; MAGERL; CAMPBELL; SCHALBER *et al.*, 2006). QST is a reliable, noninvasive psychophysical test which allows to determine comprehensive somatosensory profile in the orofacial region (ROLKE; BARON; MAIER; TOLLE *et al.*, 2006). One simple test of the QST protocol is the pressure pain threshold (PPT), which is performed by a pressure algometer that is easy and convenient QST instrument to use, carry and work with (FUTARMAL; KOTHARI; AYESH; BAAD-HANSEN *et al.*, 2011). PPT shows levels of pressure sensitivity on the orofacial region, for mechanical sensitivity mapping in the masseter muscle and TMJ region. The algometer has an excellent reliability and can assess spatial aspects of mechanical sensitivity in a specific anatomical region (TANG; CHEN; ZHOU; ZHANG *et al.*, 2018)(LIN; ZHOU; YU; WAN *et al.*, 2020).

To assess the function of endogenous pain inhibitory pathways in humans the conditioned pain modulation is used (CPM) (LEWIS; RICE; MCNAIR, 2012). CPM refers to the phenomenon where strong tonic painful stimulation (the conditioning stimulation) when applied to one body region reduces pain evoked by a phasic noxious stimulus (test stimuli) in a remote body region (YARNITSKY, 2010). It is known that several individual and environmental factors influence CPM, including age, gender, menstrual cycle phase, psychosocial factors, intake of pharmacological substances, diseases, and chronic pain (EDWARDS; FILLINGIM; NESS, 2003) (GOFFAUX; REDMOND; RAINVILLE; MARCHAND, 2007) (MIYAZAKI; WANG; INUI; DOMINO *et al.*, 2010) (SANDRINI; SERRAO; ROSSI; ROMANIELLO *et al.*, 2005) (TOUSIGNANT-LAFLAMME; MARCHAND, 2009). Still, it is not clear the association of awake bruxism in this pain modulation phenomena, therefore our study will be evaluating its relation using the EMA assessment.

Most studies about bruxism have studied SB, it has been decades defining clinical protocols, characteristics and diagnosis of this type of bruxism. In contrast, AB has scarce studies available for research, and only few clinical protocols and data. More research is still needed, and this study will highly contribute with more information about EMA assessment on this masticatory activity. The present study aims to quantify the frequency of AB behaviors with EMA assessment, and to define the potential association of these behaviors with pain pressure threshold of the masticatory muscles and with the level of endogenous analgesia, as measured by the CPM in healthy young adults.

2 ARTICLE

2 ARTICLE

The article presented in this dissertation was written in accordance with the instructions and guidelines of the Journal of Oral Rehabilitation.

EVALUATION OF AWAKE BRUXISM BEHAVIORS IN ASYMPTOMATIC INDIVIDUAL WITH ECOLOGICAL MOMENTARY ASSESSMENT (EMA) AND ITS IMPACT OVER THE PPT OF MASTICATORY MUSCLES, CONSIDERING THE LEVEL OF ENDOGENOUS ANALGESIA.

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ABSTRACT

The aim of this study was to evaluate awake bruxism (AB) behaviors for one week in a sample of healthy young adults using an ecological momentary assessment (EMA) and the relationship of different AB behaviors with muscle tenderness and pain modulation (CPM) **Methods:** One hundred and twenty-two healthy postgraduate students were given a smartphone application that sends 10 alerts at random intervals every day, for one-week. Subjects had to report in real time what represented their current condition between these options: Relaxed jaw muscles, teeth contact, teeth clenching, teeth grinding and jaw bracing. Before the first day of alerts, the subjects also underwent recordings of the masticatory muscles pressure pain threshold (PPT) and the paradigm of conditioned pain modulation (CPM). The PPT recording was repeated in the last day of study. **Results:** Data were considered valid if compliance was of at least 60% of responses. The total compliance was of 75.9%. The average frequency of relaxed jaw muscles was 54.5%, teeth contact 29.4%, jaw bracing 5.8%, teeth clenching 9.7% and teeth grinding 0.6%. Teeth contact was found to be the most prevalent behaviour, 69% of participants showed at least one bruxism behaviour during the one-week evaluation period. Any significant gender difference was detected on the sample. The PPT values were within the normality parameters, for the anterior temporalis, 2.52 kg/cm² and 2.26 kg/cm² for right and left. The masseter muscle presented a pain threshold of 1.93 kg/cm² and 1.84kg kg/cm² for the right and left side, respectively. Statistically significant difference ($p>0.000$) were noted on CPM test between the PPT before (2.5 ± 1.07) and after (2.9 ± 0.96) the cold-water immersion, demonstrating a positive modulation on these young healthy patients. **Conclusion:** The most prevalent behavior was the teeth contact with an average frequency of 29.4%, where 69.6% of the participants present at least once this behavior. AB is not an important factor of masticatory muscle tenderness on the orofacial pain area in young healthy adults. No association was found between AB behaviors with masticatory muscle tenderness and endogenous analgesia.

Keywords: Awake bruxism, Ecological momentary assessment, conditioned pain modulation

INTRODUCTION

Bruxism is an oral condition that have been deeply studied recently, some characteristics of this oral behavior have already been studied, such as etiology, definition, prevalence, pathophysiological mechanism and its possible association with temporomandibular disorders (TMD).¹ For a long time, bruxism was considered a risk factor for different oral diseases.²

Bruxism is classified in sleep bruxism (SB) and awake bruxism (AB).³ A previous study estimate a total bruxism prevalence of 8% to 31%, the major percentage is represented by AB (22 to 31%), SB prevalence is minor but more consistent ($13 \pm 3\%$) in adults.¹ Biologic (e.g. neurochemicals such as dopamine and other neurotransmitter, genetics, sleep arousals), psychologic (e.g. stress sensitivity, personality traits, anxiety), and exogenous factors (e.g. smoking, alcohol, caffeine, certain medications such as selective serotonin reuptake inhibitors, illicit drugs) are involved in the etiology of bruxism, leaving in the past the occlusal paradigms.^{4,5,6}

Awake bruxism is defined, as a masticatory muscle activity during wakefulness that is characterized by repetitive or sustained tooth contact and/or bracing or thrusting of the mandible.³ Clinical consequences of bruxism were evaluated in different systematic reviews, describing effects on the temporomandibular joints (TMJ) and jaw muscles (i.e. TMD and orofacial pain),⁷ natural teeth (i.e. tooth wear and failing restorative treatments) or restored implant-supported dentitions.⁸

For the diagnosis and bruxism assessment, different tools such as electromyography, polysomnography, self-reported, questionnaires and different signs or clinical symptoms are available³. On awake bruxism is not possible to practice these evaluations with those devices due to the long periods that participants would have to be connected with them during the entire day. Another fault of this method is that collecting data in a different environment than the participant is used to, could modify the results, giving possibly false positives.^{9,10}

To facilitate the assessment, a technique named ecological momentary assessment (EMA) can be done. EMA are collections of repeated momentary evaluations of participants on their natural environment.¹¹ The participants answer how do they feel at the exactly moment, instead of being asked to summarize their feelings and behaviors along the day, the sample will represent the participants behavior in a real world.^{12,13} Laboratory studies, while affording a good deal of control, may not faithfully capture real-world phenomena and thus may not generalize to real-world settings.¹¹ EMA has been already proven reliable in the research setting to assess variety of oral behaviors.^{9,14,15}

With all these background, EMA can be used for epidemiological studies about AB behaviors and the evaluation of different characteristics associated with those behaviors, as well as the response rate can be assessed.¹⁴ A first study made in healthy young adults evaluating awake bruxism frequency behaviors, was utilizing EMA and smartphones for a real-time report, was obtained the average frequency of 28.3%.⁹ This study will be taken as a reference to continue evaluating EMA with related conditions. Somatosensory profile and mechanical sensitivity on the orofacial region are conditions that had not been previously related with AB frequency using EMA as a tool for diagnosis, possible patterns of somatosensory abnormality could be related with AB.

Several studies have examined the role of bruxism on alterations of pain sensitivity on masticatory muscles.^{16,17,18,19} This association has been questioned due to the unclear knowledge of the etiology and diagnosis of both bruxism and TMD.¹⁸ A study by Machado et al. 2018, examined orthodontic patients without signs and symptoms of TMD pain and found no relationship between self-reported awake bruxism and changes on masticatory muscles' sensitivity.¹⁶ To more accurately determine the association of muscle pain sensitivity and bruxism, a well-rounded bruxism diagnosis comprised of a positive self-report, clinical inspection and some complementary tool such as EMA should be realized. Muscle sensitivity could be assessed with a test of pressure pain thresholds (PPT) considering the level of endogenous analgesia to evaluate possible patterns of somatosensory abnormality.^{3,20}

Quantitative sensory testing is a reliable, noninvasive psychophysical test which allows to determine comprehensive somatosensory profile in the orofacial region.²¹ Pressure pain thresholds (PPT) is part of the protocol of QST tests. This test shows levels of pressure sensitivity on the orofacial region for mechanical sensitivity mapping the masseter muscle and TMJ region. Pressure algometer has an excellent reliability and can assess the spatial aspects of mechanical sensitivity in a specific anatomical region.^{22,23} A pressure algometer is commonly used to quantify local PPT).^{24,25}

To assess the function of endogenous pain inhibitory pathways in humans the conditioned pain modulation (CPM) is used.²⁶ CPM refers to the phenomenon where strong tonic painful stimulation (the conditioning stimulation) when applied to one body region reduces pain evoked by a phasic noxious stimulus (test stimulus) in a remote body region.²⁷ It is known that several individual and environmental factors influence CPM. In this sense, will be associated AB on the response to painful sensory stimuli on the CPM test in the orofacial region.

Due to the lack of design studies assessing awake bruxism with EMA and somatosensory profile, more research is still needed, and this study will highly contribute with more information about EMA assessment on this masticatory activity. The present manuscript pretends to quantify the prevalence of AB behaviors with EMA assessment and figure out its relationship with the masticatory muscle's tenderness and the level of endogenous analgesia in healthy young adults.

METHODS

Study population

This study was approved by the local ethics committee (Certificate of presentation for ethical consideration #99729118.6.0000.5417). A signed informed consent in accordance with the Helsinki guidelines was obtained from all the participants.

The sample was constituted of 150 young adults between 20 and 35 years old (101 females, 49 males), from April 2019 until December 2019. All subjects were graduated

dental surgeons and postgraduate dentistry students attending different areas (Orthodontics, Prosthodontics, Anatomy, Histology, etc.) at the Bauru School of dentistry, University of Sao Paulo, São Paulo, SP, Brazil.

All individuals were healthy, without orofacial pain complaint or symptoms. Exclusion criteria for all individuals were: the presence of any type of temporomandibular disorder (TMD); present or previous pathology or any skin lesion on the face; history of trauma in the orofacial area that interferes with normal somatosensory function, any acute or chronic pain (e.g. fibromyalgia); any systemic disease (e.g. metabolic, cardiovascular); neurologic disturb, women during menstrual cycle phase and participants who were going under orthodontic treatment were also excluded. In addition, all participants were asked to avoid any analgesic medication during a week of the study prior to the results.

Study design

Initially, all participants were informed about the purpose of the study and confirmed they understood. Patients were evaluated by an orofacial pain specialist with the TMD pain screener from the international diagnostic criteria of temporomandibular disorders (DC/TMD)²⁸ to discard any possibility of disorder. All the tests and evaluations were performed by two experienced specialists with the same instrument and tests were repeated by the same specialist after one week.

EMA

A website called Mentimeter® was used for EMA evaluation, where an interactive platform to receive the feedback from the participants was created, and all answers received were automatically saved in an EXCEL tab. The platform sent a link (at randomized hours during the day) to a free multi-platform messaging app: Whatsapp®, where participants were redirected to the interactive platform to answer the questions. The subjects had to answer in real time on their smartphones the next question: which of the following options better described your teeth contact at this moment?; they had to choose their current oral behavior among the following options: relaxed jaw muscles; jaw bracing without teeth contact; teeth contact; teeth clenching; teeth grinding. They also had to answer which type of daily activity they were performing when responding the alert. Activities such as eating or talking are not reliable to

evaluate teeth contacts related to bruxism, therefore these answers were excluded during the evaluation.

Participants received a code during the training session about EMA, for individualized handling. They were instructed how to use the platform (click on the received link on WhatsApp® and choose the current behavior) and were informed the exact definition of each condition to be aware of the relevance of their answers. They were also instructed to answer as they noticed the message, each alert had time to expire: 5, 10 or 15 minutes (randomized time); after that period was not possible to get into the options. In addition, alerts were simulated during the training session, to train the participant to recognize different conditions. They were asked to communicate any doubt or concern during the one-week period to the assigned investigator.

The alerts initiated the day after the tests and training session, starting between 8am to 12pm and from 2pm to 8pm. Rest hours were implemented during lunch and dinner times to avoid alerts while the participants were eating. The platform was programmed to send 10 alerts per day on randomized hours, to avoid the participant from getting used to a standardized hour. After the 7-day protocol, the platform generated an excel file with all the feedback of the participants. (Figure 1)

A minimum of appliance considered was of the 60%, the participants who did not reach the minimum were excluded of the sample.¹⁴ They were represented in percentages according to the alerts answered. Mean values, standard deviation and 95% of confidence intervals, were reported too. All the behaviors that influence on bruxism was grouped as “total awake bruxism”

QST and CPM

To assure quality of QST, two examiners were trained in the Physiology laboratory of the Bauru School of dentistry with experts, following the recommendations established by the DFNS.²⁹

Initially the participant was submitted to a pressure pain threshold (PPT) test. The PPT recording was made with a digital algometer (KRATOS, Cotia, Brazil) with a 1-cm² flat

circular-shaped tip and a display with a visual feedback of the force rate. First, it was localized the proper site to be examined (bilateral anterior temporalis; bilateral masseter), the algometer was applied vertically to the test site and pressure linearly increased while the individual's head was firmly supported by the other operator's hand. The participants were sitting upright and were instructed to press a button at the first painful sensation. Each site was tested three times with ascending stimulus intensities, each applied with an increasing ramp of 0.5 kgf/cm², in a previously defined randomized sequence. The mean threshold for each site was calculated.²⁹

The following test was the conditioned pain modulation (CPM). The test stimulus (TS) was applied on the area of anterior temporalis from the dominant side of the participant, meanwhile the conditioning stimulus (CS) was on the contralateral hand. The first PPT obtained was used as the baseline, and then the patient was asked to immerse the contralateral hand in a noxious conditioning cold stimulus, a circulating cold-water bath maintained for one minute (10-12 C°; enough temperature to evoke pain).^{30,31} Immediately after the application of the CS, PPT was assessed again (on the same site as the baseline assessment). During the hand immersion participants were also asked to rate pain intensity using the NRS scale from 0-10, where 0 indicated "no pain" and 10 indicated "most intense pain imaginable".³² Protocol deviations were considered when the participant did not keep the hand submerged at least for 30s or did not rate at least a mild pain (NRS=3) after 30s. In this way, CPM was calculated as a percentage of the variation between PPT before and after conditioned stimuli.³³ After these tests, the participants received instruction on how to use the EMA technique for 7 days.

Statistical Analysis

Descriptive analysis of PPT and CPM was made, as well as a comparisons test to evaluate if there is any significant difference between the first and last day of PPT test after one-week of EMA alerts. Correlations between the total awake bruxism and clenching behavior with the PPT and CPM, to evaluate the association of the awake bruxism with the muscle sensitivity of the orofacial region in healthy young adults were also addressed. Finally, a correlation between the PPT and CPM was performed.

For this reason, data were organized in an excel spreadsheet and the analyses were performed on a personal computer using the Statistical Package for the Social Sciences (SPSS for MacOS, version 29.0; SPS Inc., Chicago, IL, US).

An interclass correlation coefficient ICC was made to confirm the reliability between the examiners. Descriptive statistics of behaviors (Relax jaw; jaw bracing; teeth contact, teeth clenching; teeth grinding), PPT and CPM (measure of central tendency and dispersion, frequency, range and 95% confidential intervals) were performed. Additionally, a *t* test comparing the first PPT test with the last PPT made after one-week EMA evaluation was realized for each muscle with a significance level at $p < 0.05$.

The *t* student test for unpaired data with a significance level at $p < 0.05$ was performed for gender comparison.

Pearson and Spearman tests were performed to evaluate the association between: a) total awake bruxism and initial PPT; b) clenching behavior and initial PPT; c) clenching and CPM; d) total awake bruxism with CPM; e) total awake bruxism and the difference between first and last day PPT; f) clenching and the difference between first and last day PPT; and g) CPM with the difference between first and last PPT. A level of significance of $p < 0.05$ was adopted.

RESULTS

Sample characterization

The total sample consisted of 122 individuals (64% women, 35% men), and 28 participants were not included in the sample due to failed reporting, some had no access to internet sometimes or were on clinical activities while the alerts arrived. The mean age was 27.39 for women and 28.07 for men. The majority of participants were Brazilian (78%) and single (90,16%).

The reliability between the examiners for the PPT test was confirmed on the ICC test, with results of 0,851; 0,832; 0.818; 0,810 for all the muscles (right anterior temporalis; left anterior temporalis, right masseter; left masseter), which was considered high (Table 1).

Awake Bruxism Frequency

The average response rate of alerts was $76.4 \pm 10.37\%$ (range 60-100%). The frequency of the different behavior of AB over the study week were: relaxed jaw muscles 54.5%; jaw bracing without contact 5.8%; teeth contact 29.4%; teeth clenching 9.7%; and teeth grinding 0.6%. The total percentage of awake bruxism was 45.5%. (Table 2). Even though no significant statistical differences were found between gender and AB frequency, men presented three times more (1.14%) grinding behavior than women (0.29%). This apparent difference can be interpreted as a significant clinical finding (Table 3).

QST and CPM assessment

Descriptive data of PPT are shown on table 4. A mean of 2,52 kg/cm and 2.2 kg/cm for right and left anterior temporalis and 1.93 kg/cm and 1.84 kg/cm for right and left masseter were found on initial PPT. The paired *t* test comparing the PPT test before and after the one-week study, results with a significant statistical difference in two muscles: left anterior temporalis ($p < 0.001$) and left masseter ($p < 0.047$). (Table 5)

CPM values were classified by a -10% cutoff between the initial evaluation (control test stimulus) and the same measured test value after the conditioning stimulus was applied. The 29.5% ($n=36$) participants presented a significantly lower (impaired) CPM effect. Meanwhile the other 70,50% ($n=86$) of participants responded with an efficient endogenous analgesia. It was found a highly difference on the capacity of pain inhibition between these two types of participants ($p < 0.000$). To assess the effect directly to the effect of CPM were compared the TS before CS and the TS after. A significant difference ($p > 0.000$) between the 'TS before CS' (2.5 ± 1.07) and 'TS after CS' (2.9 ± 0.96) was found in the entire sample. The subjects who responded to the CPM test had a statistically significant increase ($p < 0.000$) between the 'TS before CS' (2.4 ± 1.17) and the 'TS after the CS' ($3.0 \pm 0.97\text{kg}$). The other subjects, minority, non-responders had a statistically significant decrease ($p < 0.019$) of the 'TS before CS' (2.8 ± 0.75) compared with 'TS after the CS' (2.6 ± 0.86). (Table 6)

The NRS scores for pain of cold-water immersion had a mean of (73.32 ± 23.76), in all participants, the ones who respond (75.85 ± 22.42) or non-respond (67.36 ± 26.06)

with an efficient CPM effect. There wasn't any significant difference of the NRS scale between these participants ($p>0.087$)

As described before, correlations between variables were made. Total awake bruxism with initial PPT ($r = -0.0317$, $p=0.730$) did not reach any significance. Also, there was no statistical significance on total awake bruxism with the difference of the initial to the last PPT ($r=0.130$, $p=0,887$). Same on clenching with the correlation of clenching with the difference of the initial PPT to the last PPT ($r = 0.0978$; $p = 0.678$). There was no statistical significance ($p>0.05$) for all the correlations except for CPM with the difference of PPT (difference between the first and the last day PPT), that showed a moderate positive association ($r = 0.3417$; $p = 0.000$). The positive correlation is presented on figure 2.

DISCUSSION

In the present study, it was found that EMA is a reliable tool for diagnose of awake bruxism, due to a high compliance of response. In a population of healthy young adults, the average of total awake bruxism found was 45.5%. The most prevalent behaviors were teeth contact (light touch) (29.4%) and teeth clenching (9.7%). The PPT test on masseter ($1.93\text{kg}/\text{cm}^2$, $1.84\text{ kg}/\text{cm}^2$ for right and left respectively) and anterior temporalis ($2.52\text{ kg}/\text{cm}^2$, $2.26\text{ kg}/\text{cm}^2$ for right and left respectively), showed results within normality values on young healthy adults, with no mechanical sensitivity. On CPM test, the majority of subjects had the ability of inhibit pain. No significant correlations were found for AB with PPT or CPM.

These findings suggest that compliance levels of participants were high. The mean compliance recorded with the smartphone application was 76,4% of the total alerts. There is a unique study that assessed the compliance of EMA strategy on awake bruxism,¹⁴ where the minimum threshold defined were 60% responded alerts/day. Considering this reference, a total compliance of 76,4% is highly satisfactory and represents a positive and a relevant result of EMA assessment.

Results of the frequency of AB behaviors shows that in a sample of healthy young adults, the frequency average of the distinct behaviors of awake bruxism during one-week were 45.5% (jaw bracing without contact 5.7%; teeth contact 29.4%; teeth clenching 9.7%, teeth grinding 0.6%). The most frequent behavior was teeth contact with 29.4%, important detail to consider on these population since the third part of their oral behaviors in one-week study were represented by a light touch. At a clinical level, teeth clenching seem to be a relevant behavior due to the consequences it can cause on stomatognathic system.³⁴ The frequency of teeth clenching was 9.7%; 69.6% of participants at some point of the one-week study presented this behavior, showing that it was found in a large number of the young individuals. Even presenting a moderate frequency of this behavior, subjects were healthy and without any manifestation of pain.

All these findings are difficult to compare with previous studies, since most have been conducted with other methods of AB recording, as a single observation, questionnaires, self-report or via retrospective reports.^{1,35} There is an initial study evaluating AB behaviors with EMA that served as a model for this investigation.⁹ The authors found an average of 28.3% for all behaviors of AB (i.e. Teeth contact 14.5%; teeth clenching 3.7%; teeth grinding 0.1%; jaw clenching 10.0%). While in our study the average of AB behaviors was 45.5%. The difference of the higher prevalence of AB behaviors could be explained by the type of population of the sample and the higher number of participants on the present investigation. One hundred and twenty-two students participated and all of them were master students or PhD candidates, dealing with a huge kind of responsibilities every day and have an stressful life; details that could increase some concentration activities and consequently more masticatory movements.^{6,36,37,38,39} Other investigation described a prevalence of 37.0% of AB in a group of Italian students between 20-33 years old using self-report.⁴⁰ Similar study reported a prevalence of AB of 36.5% also with self-report as the method for detecting the AB, in participants between 17 and 46 years old.⁴¹ Considering age, authors described that self-reported awake bruxism increases from adolescence to young adulthood⁴², this could also contribute to the high prevalence of awake bruxism on this manuscript results. Is important to emphasize that all the participants of the present study were graduated dental students, familiar with bruxism behaviors and individual compromised with research. This can support the good level of compliance and the

higher prevalence of the different AB behaviors compared to other studies with a different sample.⁹

Regarding the methods, it has not been yet determined a gold standard tool for the diagnosis of awake bruxism.³ Researchers have done some studies performing EMG recording for several hours along the day, but these methods have shown limitations and difficulties.⁴³ Most of them need to keep a device in the masseter area during the day, showing discomfort and sometimes difficulties, such as set and remove the device by the participant at home.⁴⁴ Experts had proposed EMA as a reliable and valid diagnostic tool for awake bruxism, for clinical objectives and for research purposes.⁴⁵ This method has been recently used for bruxism in a few studies,^{9,14,15} during an observation period, and the feedback has allowed researchers get data gathering the association between tooth contact habits and masticatory muscle pain.^{3,28} These recent studies have shown that adopting EMA with reports of real time offer an excellent diagnostic tool, that allows to accompany the participant during several days.⁹ The present study strengthens the reliability and efficacy of EMA assessment. With the advances of the technology, internet and smartphones EMA can be optimized over the years, remembering that the first studies using this technique were with beepers on the area of psychology.¹¹

Experts suggested the introduction of this tool for self-report bruxism, emphasizing whether if it should be done in one or two weeks.³ On the medicine and psychosocial field most of studies using EMA as a tool of diagnosis, followed designs of collecting data during 6 or 7 consecutive days, with an average of 10 times per day.^{46,47,48,49} In the case to follow the evolution of treatments the amount of days was increased between 12 and 15 days^{50,51}, this is because EMA methods seem particularly vulnerable to reactivity with time, the assessments are repeatedly and in close proximity to the behavior of interest putting participants in a position to affect behavior. This reactivity is also enhanced when subjects are asked to record undesirable target events⁵², what promotes self-awareness and potentially induce positive changes to the capability to self recognizes and avoid the behavior.^{46,51} In this way, following treatments with EMA let the researchers or clinicians analyze if the participant is improving or failing on treatment. This idea has been theorized to be similar on AB

EMA assessment. Consequently, one-week period was chosen as the study design for the purpose of EMA as a tool diagnosis.

About pressure pain threshold, a previously investigation standardized the pressure of healthy patients, analyzing the sensitivity with a 90.8% of specificity, these PPT values of masseter and temporalis muscles were used as a reference of normality, the cut point for anterior temporalis is 1.50 kg/cm² and for masseter 2.47 kg/cm² ⁵³. Values of 2.52 kg/cm² and 2.26 kg/cm² for anterior temporalis (left and right respectively) and 1.93kg/cm² and 1.94 kg/cm² for masseter (left and right respectively) were found in the present investigation. The average of kg/cm² of both anterior temporalis and both masseters were within the normal ranges. No mechanical sensitivity findings were expected due to the condition of our participants, young, healthy and with no TMD disorders. PPT test after one-week EMA evaluation showed on left temporal and left masseter a statistically significance increase compared with the first day PPT test ($p<0.001$; $p<0.047$ for anterior temporalis and masseter respectively). This could possibly be explained by the intrinsic effect on the subject about remembering many times per day a certain behavior, the improvement of the threshold could be the result of a non-intended treatment by receiving the alerts. ^{46,51,52}

In the present study the endogenous analgesia was evaluated by CPM test. Somatosensory abnormalities weren't detected due to the healthy young participants condition. Majority of participants responded with an efficient endogenous analgesia response (70.5%), only a minor of participants had a significant lower (impaired) CPM effect (29.5%) what is expected on healthy young adult patients.²⁶ They have been reported some studies with impairments of CPM (reduce ability to inhibit pain) in chronic pain conditions, such as TMD,⁵⁴ chronic tension-type headache,⁵⁵ osteoarthritis and fibromyalgia.^{54,56,57} This explain how endogenous pain inhibitory systems react in a positive way on healthy patients and how CPM is impaired in other persistent pain conditions.⁵⁸

No correlations were found between AB with CPM or PPT. All participants were asymptomatic and solely presented AB behaviors without pain symptoms, so somatosensory abnormalities were not influenced by high or low masticatory activities. This explains why no association was found even between an intense behavior such as clenching and CPM. These findings where expected on the present study, as

bruxism cannot be labeled as a harmful dysfunction itself (ie, disorder)⁵⁹ and may not necessarily be the cause of pain. This association was made because there is evidence that leads to a simplistic cause-effect model based on the assumption that bruxism causes pain due to an overload of the masticatory system and also that higher bruxism activity leads to more pain.⁶⁰ Amorim et al concluded in their study that people with bruxism presented greater muscle pain, and that pain not only occurred in masticatory muscles but also in the craniofacial complex and cervical spine.⁶¹ Moreover, bruxers with low frequency of EMG activity have been shown to report craniofacial pain more frequently.⁶² In contrast, other investigation by Takeuchi and colleagues, suggested that “tooth clenching alone is insufficient to initiate longer lasting and self-perpetuating symptoms of TMD, which may require other risk factors”.⁶³ The majority of these studies were made with sleep bruxism or general bruxism. No AB association was found with CPM and PPT, this supports the evidence that AB behaviors may not be enough to develop pain, as it is not related with muscle tenderness and with endogenous pain inhibition.

CPM showed a correlation with the difference of PPTs (between the first PPT and after one-week EMA assessment PPT). This association can be due to the fact that if the muscle sensitivity improves, there is a high possibility that the CPM effects tends to elevate, as CPM is calculated by the difference of the PPT's (TS before and after the CS). This positive association confirms that they are highly related, and that a PPT within normal values should indicate a positive endogenous analgesia.

The present manuscript has some limitations. Despite the large sample, only graduated dental studies were included, and the probable stressful life and age could influence the AB behaviors. It is also important to consider their previous knowledge about masticatory system and the subject's commitment with research. This study encourages researchers to continue using EMA approaches to evaluate awake bruxism behaviors, in addition, platforms, smartphones and technologic devices must be considered, to have a good feedback. Future studies with more representative samples are required to confirm the findings reported on this study including some other aspects associated with AB behaviors. This is an initial study evaluating AB behaviors and the somatosensory profile (CPM and PPT) of healthy patients by an

experience of EMA report, therefore, researchers could go further, and more evaluations could be carried out considering other types of QST.

Conclusions

- The average frequency of the distinct AB behaviors (i.e., teeth contact; teeth clenching; teeth grinding; jaw clenching/bracing) over 1-week (7days) period, was 45.5%.
- The most prevalent behavior was the teeth contact with an average frequency of 29.4%, where 69.6% of the participants present at least once this behavior.
- No gender differences were found on AB behaviors.
- AB behaviors are not an important factor of muscle tenderness on the orofacial pain area in healthy young adults.
- Higher figures of PPT suggest a good modulation on healthy young people.

Conflict of interest statement

The authors of the manuscript declared no conflict of interest, financial or otherwise.

Ethical Approval

The study in the present manuscript were carried out with the approval of the responsible ethics committee and in accordance with the Helsinki Declaration of 1975. An informed consent was obtained from all the participants included on the study.

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Legend of tables:

Table 1 (ICC) test between examiners

Table 2 Frequency data expressed in percentage of positives observations (mean values, SD, range and 95% confidence intervals) for the different AB behaviors over the observation period.

Table 3 Descriptive statistics for male and female (mean value; standard deviation; range) and differences between gender using Student's t test for each parameter (statistical significance $p < 0.05$)

Table 4 Mean PPT (kgf/cm²), SD, min, max, variance and 95% CI for all muscles, on the first and the last day.

Table 5 PPT (kgf /cm²), paired t student initial vs after one-week EMA evaluation.

Table 6 CPM, descriptive data and "t" de student

Legend of illustrations:

Figure 1 Time course of the study.

Figure 2 Correlation between CPM and the difference between the first and the last PPT.

Table 1. ICC test between examiners

Muscle	<i>Interclass Correlation Coefficient</i>		
	ICC	CI95%	P
Anterior temporalis			
Right	0.851	(0.688 – 0.929)	0.000
Left	0.832	(0.647 – 0.920)	0.000
Masseter			
Right	0.818	(0.619 – 0.913)	0.000
Left	0.810	(0.598 – 0.910)	0.000

*(p<0.05)

Table 2. Frequency data expressed in percentage of positives observations (mean values, SD, range and 95% confidence intervals) for the different AB behaviors over the observation period.

Activity	Mean frequency	SD	CI95%	Range	P*
Relaxed Jaw muscles	54.5	26.0	49.8-59.1	0 - 100	0.026
Teeth contact	29.4	18.2	26.1 – 32.6	0 – 78.9	0,012
Jaw clenching/ bracing	5.8	11.0	3.7 – 7.7	0 - 63.4	0.000
Teeth clenching	9.7	14.0	7.2 – 12.2	0 – 72.7	0,000
Teeth grinding	0.6	2.8	0.08 – 1.1	0 – 26,5	0.000
Total awake bruxism	45.5	26.0	40.8 – 50.1	0 - 100	0.026

*Shapiro Wilk test, (p<0.05)

Table 3. Descriptive statistics for male and female (mean value; standard deviation; range) and differences between gender using Student's t test for each parameter (statistical significance $p < 0.05$)

Behavior	Male		Female		t - test
	Mean (SD)	Range	Mean (SD)	Range	
Relaxed Jaw Muscles	58.74(26,49)	0-100	52.17(25,67)	1.92-100	0.184
Teeth contact	26.26(16,11)	0-60.47	31.12(19,15)	0-78.95	0.160
Jaw bracing	5.08(9,86)	0-42.42	6.12(11,63)	0-63.46	0.621
Teeth clenching	8.75(11.74)	0-56.25	10.28(15,22)	0-72.73	0.570
Teeth grinding	1.14(4,31)	0-26.56	0.29(1,49)	0-12.07	0.216
Total awake bruxism	41.25(26,49)	0-100	47.82(25,67)	0-98	0.184

*Significance ($p < 0.05$)

Table 4. Mean PPT (kgf/cm²), SD, min, max, variance and 95% CI for all muscles, on the first and the last day.

BEFORE							
Muscle	Mean	SD	Min	Max	Variance	95%ic	P
Anterior temporalis							
Right	2.52	1.079	1.095	10.383	1.166	2.33 – 2.71	0.000
Left	2.26	0.781	.000	4.386	0.610	2.12- 2.40	0.053
Masseter							
Right	1.93	0.718	0.845	5.030	0.517	1.80 –2.06	0.000
Left	1.84	0.583	0.755	3.971	0.340	1.74- 1.952	0.000
AFTER							
Muscle	Mean	SD	Min	Max	Variance	95%ic	P
Anterior temporalis							
Right	2.67	1.219	1.243	12.488	1.487	2.45 – 2.89	0.000
Left	2.45	0.820	0.803	4.745	0.674	2.31- 2.60	0.012
Masseter							
Right	1.96	0.634	0.781	4.066	0.403	1.85 –2.08	0.004
Left	1.92	0.659	0.911	4.860	0.435	1.80- 2.04	0.000

*($p < 0.05$)

Table 5. PPT, paired t student initial vs after one-week EMA evaluation.

	BEFORE			AFTER			
Muscle	Mean	SD	95%IC	Mean	SD	95%ic	t-test
Anterior temporalis							
Right	2.52	1.079	2.33-2.71	2.67	1.219	2.45 – 2.89	0.183
Left	2.26	0.781	2.12-2.40	2.45	0.820	2.31- 2.60	0.001*
Masseter							
Right	1.93	0.718	1.80-2.06	1,96	0,634	1.85 –2.08	0.436
Left	1.84	0.583	1.74-1.952	1,92	0,659	1.80- 2.04	0.047*

*Significance (p<0.05)

Table 6. CPM, descriptive data and “t” de student.

	TS before CS		TS after CS		t test
	Mean (SD)	95%CI	Mean (SD)	05%CI	
Responders	2.4(1.17)	2.14-2.65	3.0(0.97)	2.86-3.28	0.000
Non responders	2.8(0.75)	2.57-3.08	2.6(0.86)	2.36-2.95	0.019
Total sample	2.5(1.07)	2.33-2.71	2.9(0.96)	2.77-3.12	0.000

- Significance (p<0.05)

Figure 1- The time course of the study.

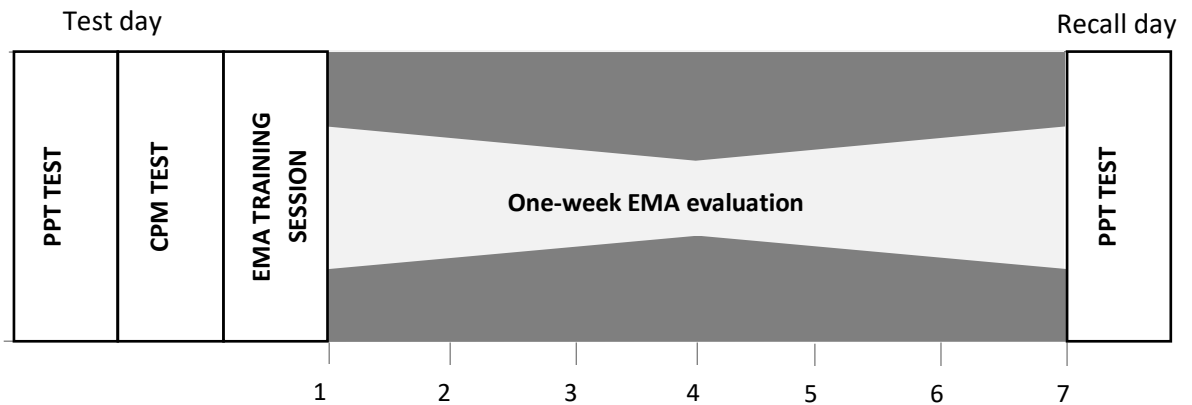
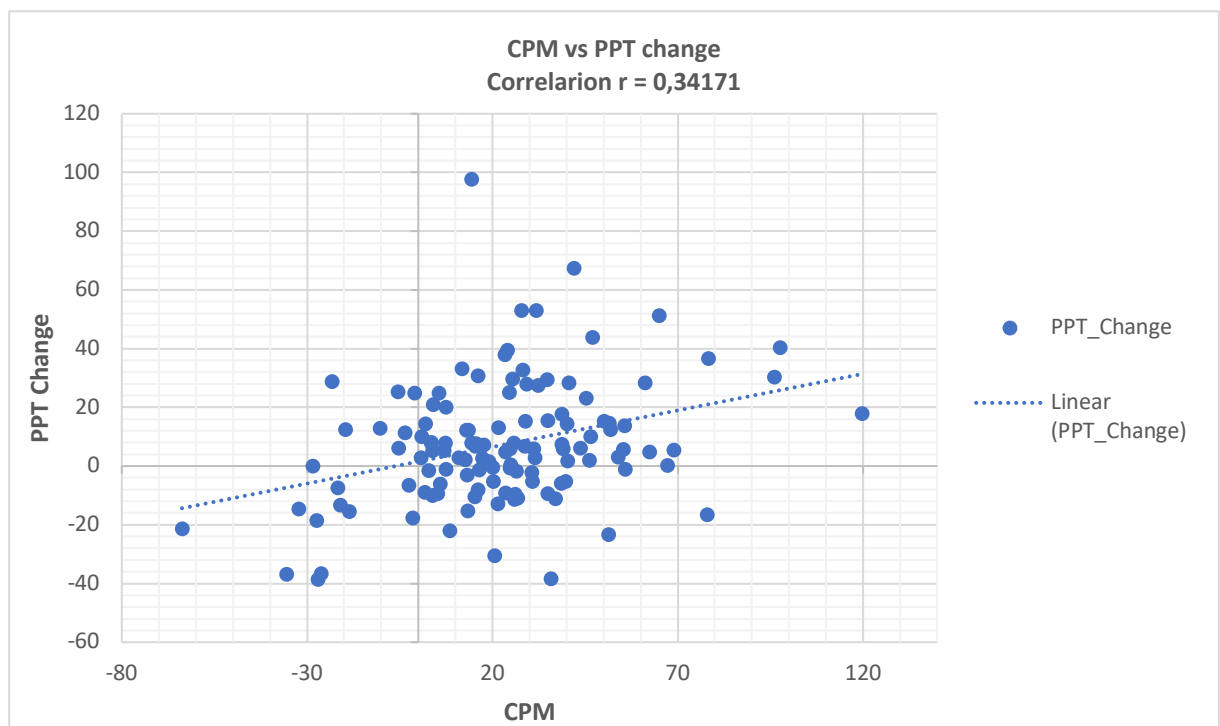


Figure 2 - Correlation between CPM and the difference between the first and the last PPT, $r = 0,3417$, $p = 0,000$



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APPENDIX

**DECLARATION OF EXCLUSIVE USE OF THE ARTICLE IN
DISSERTATION/THESIS**

We hereby declare that we are aware that the article **“EVALUATION OF AWAKE BRUXISM BEHAVIOURS WITH EMA AND THEIR RELATIONSHIP WITH PAIN MEASUREMENT FACTORS”** will be included on the dissertation of the student Dyanne Adenea Medina Flores, it wasn't and will not be use in other dissertation/thesis of Posgratuated programs at the Bauru School of Dentistry, University of São Paulo.

Bauru, July 10, 2020.

Author

Assinatura

Author

Assinatura

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ANNEXES

ANNEX A. Ethics Committee approval, protocol number

USP - FACULDADE DE
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USP

**PARECER CONSUBSTANCIADO DO CEP****DADOS DA EMENDA**

Título da Pesquisa: Comportamento do bruxismo de vigília e a sua relação com fatores psicológicos, funcionais e de mensuração da dor

Pesquisador: DYANNE MEDINA FLORES

Área Temática:

Versão: 3

CAAE: 99729118.6.0000.5417

Instituição Proponente: Faculdade de Odontologia de Bauru

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 3.284.735

Apresentação do Projeto:

Apresentação de emenda solicitando alteração de 3 para 7 dias de avaliação a distância por meio de um aplicativo baseado em estudos recentes.

Objetivo da Pesquisa:

sem alterações.

Avaliação dos Riscos e Benefícios:

não modificado e não necessária modificação.

Comentários e Considerações sobre a Pesquisa:

Apresentação de emenda solicitando alteração de 3 para 7 dias de avaliação a distância por meio de um aplicativo baseado em estudos recentes.

Considerações sobre os Termos de apresentação obrigatória:

Foi apresentada a emenda, alterado o projeto principal e o TCLE.

Conclusões ou Pendências e Lista de Inadequações:

aprovado.

****Corrigir a modificação de 3 para 7 dias na metodologia do projeto da plataforma brasil.**

Considerações Finais a critério do CEP:

A emenda apresentada pelo(a) pesquisador(a) foi considerada APROVADA na reunião ordinária do CEP de 17/04/2019, com base nas normas éticas da Resolução CNS 466/12. Ao término da

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USP - FACULDADE DE ODONTOLOGIA DE BAURU DA USP



Continuação do Parecer: 3.284.735

pesquisa o CEP-FOB/USP exige a apresentação de relatório final. Os relatórios parciais deverão estar de acordo com o cronograma e/ou parecer emitido pelo CEP. Alterações na metodologia, título, inclusão ou exclusão de autores, cronograma e quaisquer outras mudanças que sejam significativas deverão ser previamente comunicadas a este CEP sob risco de não aprovação do relatório final. Quando da apresentação deste, deverão ser incluídos todos os TCLEs e/ou termos de doação assinados e rubricados, se pertinentes.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_1312569_E1.pdf	11/03/2019 18:35:45		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLEEMENDA.pdf	11/03/2019 18:32:21	DYANNE MEDINA FLORES	Aceito
Outros	CARTADEEMENDA.pdf	11/03/2019 18:32:00	DYANNE MEDINA FLORES	Aceito
Projeto Detalhado / Brochura Investigador	PROJETOEMENDA.pdf	11/03/2019 18:30:39	DYANNE MEDINA FLORES	Aceito
Outros	PBCartaEncaminhamentocepresposta1.pdf	06/11/2018 14:55:45	DYANNE MEDINA FLORES	Aceito
Outros	PBQuestionarioTecnicoPesquisador.pdf	06/11/2018 14:30:19	DYANNE MEDINA FLORES	Aceito
Projeto Detalhado / Brochura Investigador	projetoCEP.pdf	06/11/2018 13:47:14	DYANNE MEDINA FLORES	Aceito
Outros	Cartaaquiescenciamentotratamento.pdf	06/11/2018 09:42:57	DYANNE MEDINA FLORES	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	Termodelivreconsentimientoesclarecido.pdf	30/10/2018 16:44:33	DYANNE MEDINA FLORES	Aceito
Cronograma	CRONOGRAMA2.pdf	30/10/2018 16:37:58	DYANNE MEDINA FLORES	Aceito
Folha de Rosto	FOLHAROSTROASSINADA.pdf	20/09/2018 12:55:00	DYANNE MEDINA FLORES	Aceito
Declaração de Pesquisadores	Declaracaocompromissopesquisador.pdf	12/09/2018 11:44:45	DYANNE MEDINA FLORES	Aceito
Outros	termodeaquiescencia.pdf	12/09/2018 11:24:02	DYANNE MEDINA FLORES	Aceito

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Continuação do Parecer: 3.284.735

Outros	termoaqueciescenciaexterno.pdf	12/09/2018 11:19:46	DYANNE MEDINA FLORES	Aceito
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Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

BAURU, 25 de Abril de 2019

Assinado por:**Ana Lúcia Pompéia Fraga de Almeida**
(Coordenador(a))

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ANNEX B. Patient's informed consent exoneration(front)



Universidade de São Paulo Faculdade de Odontologia de Bauru

Departamento de Prótese e Periodontia

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

O (A) Sr/Sra. está sendo convidado a participar da pesquisa **“COMPORTAMENTO DO BRUXISMO DE VIGÍLIA E A SUA RELAÇÃO COM FATORES PSICOLÓGICOS, FUNCIONAIS E DE MENSURAÇÃO DA DOR”** com orientação do Professor Dr. Paulo César Rodrigues Conti e Professor Dr. Leonardo Rigoldi Bonjardim. Esta pesquisa tem como objetivo avaliar a frequência dos comportamentos de apertar e ranger os dentes numa amostra de estudantes de pós-graduação da FOB-USP e a sua correlação com diferentes aspectos psicológicos, clínicos e de avaliação da dor. Este estudo clínico envolverá 150 participantes que serão avaliados por um período de nove dias, sendo dois presenciais e sete à distância. No primeiro dia, o pesquisador lhe fornecerá as informações sobre os objetivos do estudo, você será convidado a responder uma ficha clínica e alguns questionários que fornecerão informações sobre estresse, ansiedade, qualidade de vida, saúde geral, hábitos orais e desgaste dentário. Em seguida, você será avaliado pelos testes de mensuração da dor, a sessão do primeiro dia terá como duração aproximadamente 60 minutos. No final dessas avaliações, você será instruído sobre a utilização de uma ferramenta do celular onde você receberá alertas sonoros diariamente, durante sete dias sobre o estado da sua musculatura da face, nível de dor/cansaço/estresse e atividade de rotina que você esteja realizando naquele exato momento. As perguntas serão respondidas via telefone celular, você demorará aproximadamente um minuto em responder, não haverá necessidade de se encontrar com os pesquisadores do estudo, podendo serem respondidas no local onde você estiver naquele momento. No nono dia será repetido o exame de mensuração da dor e será avaliado a presença de fadiga muscular. Para todos os exames serão utilizados equipamentos amplamente seguros, no entanto, há de se considerar um risco mínimo de algum possível desconforto durante a realização dos testes de mensuração da dor e de fadiga muscular, como uma leve sensação de pressão e/ou cansaço muscular. A avaliação do (a) Sr./Sra. com esta sequência de testes e através do uso do telefone celular pode ser benéfica, pois podemos diagnosticar a presença de bruxismo e analisar a suas possíveis relações com diferentes fatores. O benefício dessa pesquisa será que se for diagnosticado o comportamento de bruxismo da vigília, se oferecerá um tratamento especializado com terapias atuais pelos pesquisadores responsáveis e pelos supervisores da pesquisa. Os riscos relacionados ao presente estudo são mínimos, nenhuma dessas avaliações trará qualquer tipo de dano físico (apenas um pequeno desconforto relacionado ao teste de sensibilidade e de fadiga como relatado anteriormente), moral ou material para o (a) Sr/Sra. As informações fornecidas serão mantidas confidenciais, respeitando sua privacidade, sem serem divulgadas inapropriadamente. Os resultados obtidos serão analisados e publicados em meios de informação científicos, sem a sua identificação, de qualquer forma. O (A) Sr/Sra. não terá nenhum gasto ou ganho financeiro por participar na pesquisa, caso haja algum dano decorrente de sua participação nesta pesquisa, será lhe garantido o direito à indenização, bem como haverá o ressarcimento de qualquer possível gasto por participar da pesquisa. Você é livre para deixar de participar a qualquer momento sem nenhum prejuízo. Caso não concorde em participar desta pesquisa, sua vontade será respeitada, seu nome será preservado e você não será penalizado física ou psicologicamente por isso, pois não é de nosso interesse causar constrangimentos ou danos à sua imagem. Uma via deste Termo de Consentimento Livre e Esclarecido ficará com você e outra conosco. Qualquer dúvida a respeito da pesquisa poderá entrar em contato com Maria Isabel Barragan Nuñez, e-mail:

Rubrica do Participante da Pesquisa:

Rubrica do Pesquisador Responsável:

ANNEX B. Patient's informed consent exoneration(verso)

maisabel_barragann@hotmail.com, telefone (14) 991132777 ou Dyanne Medina Flores e-mail:dmedinafl@gmail.com, telefone (11) 944452185. Para reclamações e denúncias faça contato pelo Comitê de Ética e Pesquisa desta faculdade pelo telefone (14) 3235-8356 ou e-mail: cep@fob.usp.br.

Pelo presente instrumento que atende às exigências legais, o Sr. (a)

_____, portador da cédula de identidade _____, após leitura minuciosa das informações constantes neste TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO, devidamente explicada pelos profissionais em seus mínimos detalhes, não restando quaisquer dúvidas a respeito do lido e explicado, DECLARA e FIRMA seu CONSENTIMENTO LIVRE E ESCLARECIDO concordando em participar da pesquisa proposta. Fica claro que o participante da pesquisa, pode a qualquer momento retirar seu CONSENTIMENTO LIVRE E ESCLARECIDO e deixar de participar desta pesquisa e ciente de que todas as informações prestadas tornar-se-ão confidenciais e guardadas por força de sigilo profissional (Cap. III, Art. 9º do Código de Ética Odontológica (Res. CFO-118/2012)), ou (Cap. IV, Art. 23. do Código de Ética da Fonoaudiologia (Res. CFFa nº 490/2016)) – para outras profissões verificar o Código de Ética do sigilo profissional correspondente).

Por fim, como pesquisador(a) responsável pela pesquisa, DECLARO o cumprimento do disposto na Resolução CNS nº 466 de 2012, contidos nos itens IV.3 e IV.4, este último se pertinente, item IV.5.a e na íntegra com a resolução CNS nº 466 de dezembro de 2012.

Por estarmos de acordo com o presente termo o firmamos em duas vias igualmente válidas (uma via para o participante da pesquisa e outra para o pesquisador) que serão rubricadas em todas as suas páginas e assinadas ao seu término, conforme o disposto pela Resolução CNS nº 466 de 2012, itens IV.3.f e IV.5.d.

Bauru, SP, _____ de _____ de _____.

Assinatura do Participante da Pesquisa
Principal

Nome/Assinatura do Responsável

O **Comitê de Ética em Pesquisa – CEP**, organizado e criado pela **FOB-USP**, em 29/06/98 (**Portaria GD/0698/FOB**), previsto no item VII da Resolução CNS nº 466/12 do Conselho Nacional de Saúde do Ministério da Saúde (publicada no DOU de 13/06/2013), é um Colegiado interdisciplinar e independente, de relevância pública, de caráter consultivo, deliberativo e educativo, criado para defender os interesses dos participantes da pesquisa em sua integridade e dignidade e para contribuir no desenvolvimento da pesquisa dentro de padrões éticos.

Qualquer denúncia e/ou reclamação sobre sua participação na pesquisa poderá ser reportada a este CEP:

Horário e local de funcionamento:

Comitê de Ética em Pesquisa

Faculdade de Odontologia de Bauru-USP - Prédio da Pós-Graduação (bloco E - pavimento superior), de segunda à sexta-feira, no horário das **14hs às 17 horas**, em dias úteis.

Alameda Dr. Octávio Pinheiro Brisolla, 9-75

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