**MANAGEMENT OF AWAKE BRUXISM USING A MOULDED THERMOPLASTIC TOOTH COVER TO ALTER AWARENESS OF THE BEHAVIOR; AN INVESTIGATION OF ITS USE IN A GROUP OF MUSICIANS.**

**A MANAGEMENT STRATEGY FOR AWAKE BRUXISM**

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# STATEMENT OF COMPLIANCE

This document is a protocol for a clinical research study. The study will be conducted in compliance with all stipulations of this protocol, the conditions of ethics committee approval, the NHMRC National Statement on Ethical Conduct in Human Research (2007) and the Note for Guidance on Good Clinical Practice (CPMP/ICH-135/95).

Contents

[**STATEMENT OF COMPLIANCE** 1](#_Toc520786356)

1.  **STUDY MANAGEMENT**……………………………………………………………………………………………………………….4

 1.1 Principal Investigator…………………………………………………………………………………………………….4

 1.2 Associate Investigators……………………………………………………………………………………………….…4

 1.3 Statistician………………………………………………………………………………………………………………….…5

 1.4 Sponsor………………………………………………………………………………………………………………………...5

 1.5 Funding and resources………………………………………………………………………………………………..…5

[2. **INTRODUCTION AND BACKGROUND**](#_Toc520786359)……………………………………………………………………………………….…5

 2.1 Background……………………………………………………………………………………………………………………5

 [2.2 Research Question](#_Toc520786360)………………………………………………………………………………………………………...6

 [2.3 Rationale for Current Study](#_Toc520786361) 7

[**3.** **STUDY OBJECTIVES**](#_Toc520786363) 7

 [3.1 Primary Objective](#_Toc520786364) 7

 3.2 Secondary Objective………………………………………………………………………………………………………7

[4. **STUDY DESIGN**](#_Toc520786365) 7

 4.1 Type of study………………………………………………………………………………………………………………..7

 4.2 Study design…………………………………………………………………………………………………………………8

 4.3 Number of Participants………………………………………………………………………………………….……10

 4.4 Study sites…………………………………………………………………………………………………………………..10

 4.5 Expected duration of study…………………………………………………………………………………………10

 4.6 Primary and secondary outcome measures………………………………………………………………..11

[**5.** **PARTICIPANT ENROLLMENT AND RANDOMISATION**](#_Toc520786366) 11

 5.1 Recruitment…………………………………………………………………………………………………………………11

 5.2 Eligibility criteria………………………………………………………………………………………………………….11

 5.2.1 Inclusion criteria……………………………………………………………………………………….…11

 5.2.2 Exclusion criteria…………………………………………………………………………………….…..11

 5.3 Informed Consent Process………………………………………………………………………………………….11

 5.4 Enrolment and Randomisation Procedures…………………………………………………………………11

 5.5 Blinding arrangements………………………………………………………………………………………………..12

 5.6 Participant withdrawal……………………………………………………………………………………………….12

 5.7 Trial closure………………………………………………………………………………………………………………..12

 5.8 Continuation of therapy……………………..………………………………………………………………………12

[**6.** **STUDY VISITS AND PROCEDURES SCHEDULE** 12](#_Toc520786367)

[**7.** **ADVERSE EVENT REPORTING** 1](#_Toc520786369)3

 [7.1 Definitions 1](#_Toc520786370)3

[8. **STATISTICAL METHODS** 1](#_Toc520786375)3

 [8.1 Sample Size Estimation 1](#_Toc520786376)3

 [8.2 Statistical Analysis Plan 1](#_Toc520786377)4

 8.3 Interim analysis…………………………………………………………………………………………………………..15

[**9.** **DATA MANAGEMENT** 1](#_Toc520786379)5

 9.1 Data Collection……………………………………………………………………………………………………………15

 9.2 Data Storage……………………………………………………………………………………………………………….15

 9.3 Data Confidentiality……………………………………………………………………………………………………15

 9.4 Study Record Retention……………………………………………………………………………………….……..15

[**10.** **ADMINISTRATIVE ASPECTS** 1](#_Toc520786380)6

 10.1 Independent HREC approval……………………………………………………….…………………………….16

 10.2 Registration with ANZCTR………………………………………………………………….……………………..16

 10.3 NHMRC training……………………………………………………………………….……………………………….16

 10.4 Amendments to the protocol………………………………………………………………….………………..16

 10.5 Protocol deviations………………………………………………………….……………………………………….16

 10.6 Participant reimbursement………………………………………………………….……………………………16

 10.7 Financial disclosure and conflicts of interest…………………………………………………………….16

[**11.** **USE OF DATA AND PUBLICATIONS POLICY** 1](#_Toc520786381)6

[**12** **REFERENCES** 16](#_Toc520786382)

PROTOCOL SYNOPSIS

|  |  |
| --- | --- |
| Title | A management strategy for awake bruxism |
| Objectives | Primary: To evaluate the use of a plastic tooth cover in the management of awake bruxism.Secondary: To do a cross sectional study of a group of musicians assessing the incidence of oral and facial symptoms possibly related to awake bruxism. |
| Study Design | 1. Cross sectional survey of staff and students of the Sydney Conservatorium of Music.
2. Single blinded, non- randomised controlled clinical trial
 |
| Planned Sample Size | 1. Available to all staff and students of The Conservatorium
2. 30
 |
| Selection Criteria | Students and staff of the Sydney Conservatorium of Music |
| Study Procedures | Initial questionnaire.Selection of consenting participants for the clinical trialDental impressions and distribution of general advice regarding avoiding awake bruxism.Fabrication of plastic tooth covers for participants in the study group.Distribution of tooth covers together with verbal and printed guidance for their use.Second questionnaire |
| Statistical ProceduresSample Size Calculation:Analysis Plan: | Analysis of results in SPSS or R using t-test, Anova, regression & plotting.N=301. Descriptive analysis of responses to 1st questionnaire
2. Comparisons of:
* Control group (CG) with study group (SG) before trial
* CG with SG after the trial
* For CG 1st questionnaire responses compared to 2nd questionnaire
* For SG 1st questionnaire responses compared to 2nd questionniare
 |
| Duration of the study | 18 months |

# STUDY MANAGEMENT

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* 1. **Sponsor**

 University of Sydney

* 1. **Funding and resources**

Application will be made to the Australian Dental Research Fund (ADRF) for a grant. Failing that the study will be self-funded by Dr Graham.

# INTRODUCTION AND BACKGROUND

 **2.1 Background Information**

Tooth clenching, tapping, grinding, together with other oral habits, are described by the term bruxism. Bruxism is divided into sleep and awake bruxism. Both forms of bruxism can cause tooth damage, facial pain and headaches. One of the biggest challenges in managing bruxism for a patient is their lack of awareness of their problem. This research examines a management strategy for awake bruxism with the intention of generating awareness. If a patient is regularly made aware of the activity, they have a continual reminder not to do it. This should reduce the incidence of the activity and therefore reduce tooth damage and related pain symptoms.

A review of the literature shows that musicians suffer from musculo-skeletal problems with an overall incidence slightly greater than the general population [1]. It is thought that this comes about through long hours of rehearsal and performance. In the dental literature there are many case reports and some scientific studies regarding facial pain suffered by musicians. The most frequently reported is facial pain in violinists.

In the first part of the study the staff and students of the Sydney Conservatorium of Music will be surveyed by a questionnaire designed to identify those musicians experiencing symptoms which could be related to bruxing. From the responses to the questionnaire a group of musicians will be recruited who exhibit signs and symptoms of awake bruxism. This group will be divided into a study group and control group. Both groups will be given advice in managing awake bruxism; in addition, the individuals in the study group will have thin clear plastic tooth covers fabricated and fitted. The participants in the study group will be given advice on the use of these covers. After a 3-month study period, the 2 groups will be assessed by a second questionnaire. The effectiveness, or otherwise, of the plastic tooth covers in generating awareness of awake bruxism and hence reducing tooth damage, pain or soreness will be evaluated.

Bruxism has been described as a repetitive jaw-muscle activity characterized by clenching or grinding of the teeth and/or by bracing or thrusting of the lower jaw. Bruxism has been divided into two entities: if it occurs during sleep it is called sleep bruxism, if it happens during wakefulness it is called awake bruxism. The two types of bruxism are separated because of the different factors that are thought to cause them [2]. There is variation in the literature regarding the prevalence rates in the community of the two types of bruxism, from 10.6% of the population to 31.4% [3].

Awake bruxism includes holding the lower teeth against the upper ones, clenching the teeth hard together or lightly tapping the lower teeth against the upper teeth. It may also involve thrusting the tongue against the backs of the front teeth or sucking in of the cheeks [2]. The factors causing awake bruxism are thought to be psycho-social including stress, anxiety, or social, family, or work-related problems [4]. The person involved is frequently totally unaware of what they are doing; often they are doing it at a time when they are concentrating on something else, such as driving the car, working at a computer or playing a musical instrument [5]. Some people regard having the lower teeth in contact with the upper ones as the “normal” position for the jaw. Awake bruxism can overwork the facial and jaw muscles, which may lead to pain, discomfort, and tooth damage [6] [7]. Some researchers consider that daytime clenching causes more pain than nighttime grinding [4]. Awake bruxism may also create scalloping on the sides of the tongue where the tongue is thrust against the side teeth [8]. Also, a white line can form on the inside of the cheek where the cheek is sucked against the contacting upper and lower teeth [9].

**2.2 Research Question**

If a person, who is an awake bruxer, wears a thin clear plastic tooth cover during the day, will it

generateawareness of bruxism leading to a reduction in the activity and a reduction of any

related harmful consequences?

**2.3 Rationale for Current Study**

The current management of bruxism involves hard or soft acrylic mouth guards that are worn, mainly at night. They can be worn during the day if the patient is alone but need to be removed to speak intelligibly [19, 20]. Other management strategies include education about the problem with the patient, making them aware of their habit, and encouraging them to reduce the frequency of their oral habit. One of the key features of both forms of bruxism is the patient’s lack of awareness that they do it [5]. This lack of awareness then becomes an obstacle to management/treatment and would be a routine part of bruxism management for most patients. Additional strategies involve medication, biofeedback and physiotherapy [21-24]

Creating awareness on an ongoing basis could help the patient manage the condition and thereby reduce symptoms. In 2016 BruxApp was developed [25]. This is a mobile device based app which generates a sound on the device or a vibration on an Apple watch reminding the owner not to have their teeth in contact.

Another method of creating awareness of an oral habit is to have patients wear a thin clear plastic tooth cover (the same material as an “Invisalign” orthodontic aligner). As this can be worn in the mouth all day, is aesthetically pleasing, and does not interfere with speech, this tooth cover should engender awareness of oral habits and of awake bruxism. This may assist the patient to reduce the activity of their oral habits which may result in a reduction of their orofacial pain and soreness.

# STUDY OBJECTIVES

# Primary Objective

To determine whether the use of a clear plastic tooth cover would generate awareness of oral habits (e.g. bruxism) in musicians and lead to a change of those habits and a reduction in the symptoms they can cause.

* 1. **Secondary Objective**

To assess the incidence and quantify the degree of oral behaviour problems, possibly associated with playing a musical instrument, in a group of musicians in Sydney.

# STUDY DESIGN

* 1. **Type of Study**

A cross sectional survey followed by a single blinded partially randomised controlled clinical trial.

* 1. **Study Design**

Initial Questionnaire for Staff & Students at the Conservatorium of Music

Group not wishing to participate in clinical trial

 Group consenting to participate in clinical trial.

Select awake bruxers

Study Group

Given instruction &

Tooth cover

Control Group

Given instruction

After 3 months

Second Questionnaire

After 3 months

Second Questionnaire

Results

The following description refers to the Figure above.

The first phase of this research is being conducted by questionnaire. For the diagnosis of awake bruxism, self- reporting has been shown to be as valid as self-reporting combined with clinical evaluation in oro-facial pain patients [26].

* + 1. A survey of the students and staff of the Sydney Conservatorium of Music will be conducted by means of a questionnaire. The Sydney Conservatorium of Music will be selected because it is a faculty within Sydney University and there is a broad cross section of musicians in age, gender, experience, and instruments played.

 **4.2.2** The questions are intended to discover the presence and extent of the awake bruxing problem among musicians.

 This initial questionnaire is de-identified with no requests for name, address (mail or email) or telephone numbers. Therefore, responses to it remain de- identified for anyone not wishing to participate in the second part of the study.

 From the questionnaire, a group will be formed of participants who have consented to become involved in further research. At the end of the questionnaire the clinical study is explained, and participants are invited to be involved in it. If they respond “yes”, they are asked for contact details.

 For anyone responding “no”, no contact details are requested and that completes the questionnaire.

 The uses of the contact details are explained to consenting participants as follows: -

* Participant contact details enable us to identify their responses to the first questionnaire.
* The invitations to participate in the clinical study will be sent to each participant’s email address.
* The link to the second questionnaire at the end of the clinical study will be emailed to each participant.
* Their responses to a second questionnaire at the end of the study will be compared with their responses to the first one, to evaluate the effects of the general advice and the tooth covers.
* Any contact information provided will be kept completely confidential and will only be used for the purposes of this research project and will not be used for any other purpose.
	+ 1. In the second phase of the project every participant in the research group will be asked to attend a private dental clinic in Sydney CBD. Everyone will have dental impressions taken of their lower teeth by the lead researcher. At this time, they will each be given verbal and written guidance on avoiding daytime tooth contact. Each participant will have a code number derived from the initial questionnaire. The laboratory records (impressions, plaster models, tooth cover) will only be identified by that code.
		2. The senior investigator will allocate participants to either the study group or the control group. The groups will be age and gender matched. The lead researcher will not know who is in which group.

Once the members of the study group are allocated, the lead researcher will make a lower tooth cover for each person in the group. The clinic staff will contact each person, arrange for them to collect their tooth cover and give them written and verbal advice on the suggested use and care of the tooth cover.

* + 1. The study group will wear the tooth cover for a 3-month period.
		2. At the end of 3 months both groups will be given a new questionnaire. The responses to this second questionnaire will be compared to their responses to the baseline first questionnaire.
	1. **Number of Participants**

The initial questionnaire will be available to all students and staff at the Sydney Conservatorium of Music.

For the clinical study we anticipate 30 participants.

* 1. **Study sites**

 **4.4.1 For recruitment**

The Sydney Conservatorium of Music

 1 Conservatorium Road

 Sydney NSW 2000

 **4.4.2 For clinical and laboratory work**

Paramount Dental Sydney

 Suite 601, St. James Trust Building

 185 Elizabeth Street

 Sydney NSW 2000

* 1. **Expected Duration of Study**

Expected start date for the initial questionnaire is April 2019. The link to REDCap will be available until 30st June 2019.

It is planned that recruitment for the second part of the study will take place in July 2019.

The clinical trial part of the study is planned to run for 3 months. It is anticipated that this will run August, September, October 2019 to be followed up with a second questionnaire.

* 1. **Primary and Secondary Outcome Measures**

Primary outcome measures:

* Frequency of headache.
* Frequency of daytime tooth contact or jaw thrusting.
* Frequency of tooth, jaw, head, neck and shoulder symptoms possibly related to daytime tooth contact.

Secondary outcome measures:

* The degree to which symptoms affect a musician’s ability to play their instrument.
* Qualitative questions about the intervention.

# PARTICIPANT ENROLLMENT AND RANDOMISATION

**5.1 Recruitment**

The initial questionnaire will be available to the students and staff of The Sydney Conservatorium of Music through the Conservatorium’s digital platforms.

**5.2 Eligibility Criteria**

**5.2.1 Inclusion Criteria**

Being a student or member of staff at The Sydney Conservatorium of Music.

For the clinical trial, participants will be selected from those who completed the final section of the questionnaire in which they consented to participate in further research and gave their contact details.

**5.2.2** **Exclusion Criteria**

Anyone not in the inclusion criteria.

* 1. **Informed Consent Process**

The preamble to the first questionnaire explains that by completing the questionnaire a participant has consented to participation in the cross sectional survey.

At the end of the first questionnaire participants are asked if they wish to participate in the clinical trial. They are advised that if they respond ‘yes’ and give contact details, that will enable us to identify their responses to questions and create a baseline for comparisons with their responses to a second questionnaire at the end of the clinical trial.

For the clinical trial, each participant will be given a participant information statement and asked to sign a participant consent form.

* 1. **Enrolment and Randomisation Procedures**

Those participants who completed the final section of the questionnaire and who agree to participate in further research will be invited via email to enrol in the clinical study. The participants in the clinical study will be divided into control group and study group. The allocation between the groups will be partially randomised. The groups will be age and gender matched as these two factors are known to influence the incidence of oral, facial, head and neck symptoms in patients suffering Temperomandibular Disorders.

* 1. **Blinding arrangements**

The second part of the research, the clinical study, is single blinded. The lead researcher will not know who is wearing a tooth cover and who is not.

The lead researcher will meet all participants to take dental impressions and give general advice on the avoidance of awake bruxism. Impressions and plaster models will be coded using the code initiated by REDCap in the initial questionnaire. Following that the chief investigator will allocate participants to either study group or control group. The lead researcher will be given a list of codes of members of the study group, for whom he will make tooth covers. Another researcher will distribute the tooth covers and give verbal as well as written advice on their use.

At the end of the clinical study, when the study group participants will have used the plastic tooth covers for 3 months, a second questionnaire will be sent to participants in both groups. A link to the questionnaire in REDCap will be emailed to each participant’s email address. Toward the end of the questionnaire, branching logic enables study group and control group participants to respond to different questions.

* 1. **Participant withdrawal**

Any of the participants may withdraw from the study at any stage without explanation.

There is no foreseeable reason to terminate the study early.

Should the study be terminated, the lead researcher Dr. David Graham would be responsible for informing any participants, correspondence with HREC and compiling a final study report.

* 1. **Trial closure**

The results from the initial questionnaire will be made available to participants through one of the Conservatorium’s digital platforms. In due course they will be published in a professional journal.

The results from the clinical study will be available in the same way.

* 1. **Continuation of therapy**

Study group participants may continue to use the plastic tooth covers if they consider them to be beneficial. They will have access to the clinical advice of the lead clinician.

# STUDY VISITS AND PROCEDURES SCHEDULE

See Figure above in section **4.2**

#

# All participants in the clinical trial (both study group and control group) will attend a private dental clinic in the Sydney CBD, where the lead researcher (Dr Graham) will take an impression of their lower teeth. (See attached letter from Dr. Amrinder Oberoi giving approval for these procedures to be carried out in his clinic). The impressions will be taken using a dental alginate impression material into which plaster is poured to make a model of the teeth. The plastic tooth covers are fabricated on the plaster models using a “suck down” machine which generates heat and suction. The plastic is removed from the model, trimmed and polished.

# ADVERSE EVENT REPORTING

In such an event, the procedure outlined in the flow chart on page 22 of the document: -

<https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf>

will be followed.

This is the updated version of: -

<http://www.nhmrc.gov.au/health_ethics/hrecs/reference/_files/090609_nhmrc_position_statement.pdf>

which is recommended in the protocol but is no longer available.

* 1. **Definitions**

In this clinical trial an adverse event in relation to the tooth covers would be: -

1. An allergic reaction to the material. No instances of allergy to this material are evident in the literature
2. An intolerance of wearing the material. The participant would be withdrawn from the study.
3. The loss of a tooth cover. It can easily be replaced.

# STATISTICAL METHODS

* 1. **Sample Size Estimation**

For the initial questionnaire there are potentially 700 students and 150 members of staff.

For the clinical trial, N=30 since this allows us to invoke the Central Limit Theorem and assume normality, meaning we can use simple t-tests/ANOVA and create Confidence Intervals for the mean.

* 1. **Statistical Analysis Plan**

From the responses to questions in REDCap, the data will be downloaded as a spreadsheet in Microsoft Excel. Basic descriptive statistics would be carried out on: -

* Age distribution of participants
* Age related to symptoms.
* Age related to bruxing.
* Gender distribution of the participants
* Gender related to instrument played.
* Gender related to symptoms.
* Staff/student related to symptoms.
* Analysis of instruments related to symptoms: -
1. Those involving the mouth v non- mouth instruments
2. Brass.
3. Keyboard
4. Percussion
5. String
6. Voice
7. Woodwind
* The prevalence of headache and if it is associated with other symptoms.
* The prevalence of sleep bruxism and if it is associated with other symptoms.
* Determine probable/possible bruxers from responses to four questions: -
1. about teeth and tongue
2. tooth wear
3. about soreness, pain and sounds
4. response to final question
* Prevalence of soreness or pain affecting ability to play an instrument and/or making a musician stop playing.
* The questionnaire contains a trait anxiety question and a state anxiety question. The responses to these questions will be analysed related to the participants’ symptoms.
* Analysis of additional comments including qualitative questions in the second questionnaire.
* Analysis of response to final question. This question is unique. All other questions are anamnestic whereas this is of the moment.

 The following comparisons will be made:

* Control group with study group at the start of the trial.
* Control group with study group at the end of the trial.
* Responses to 1st and 2nd questionnaires for the control group.
* Responses to 1st and 2nd questionnaires for the study group.

The data will be analysed in either of the computer programmes SPSS or R.

Statistical analysis will be done by t-test, Anova or regression, together with plotting.

* 1. **Interim analysis**

There will be no interim analysis

1. **DATA MANAGEMENT**
	1. **Data Collection**

Data from both questionnaires will be collected in the University of Sydney’s REDCap server.

* 1. **Data Storage**

The data stored in REDCap is only accessible by the named researchers. For analysis it will be downloaded to a password protected, University of Sydney computer in the possession of the second associate investigator.

 **9.3 Data Confidentiality**

The initial questionnaire does not request any identifying information. So the data from that questionnaire is de-identified. At the end of the questionnaire there is an explanation of the second part of the research with a request for participants who would be interested to be involved in it, to give contact details.

The uses of the contact details are explained as follows: -

* The individual invitations to participate in the clinical study will be sent to each participant’s email address.
* The link to the second questionnaire at the end of the clinical study will be emailed to each participant.
* The participants responses to a second questionnaire at the end of the study, will be compared with their responses to the first questionnaire, to evaluate the effects of the general advice and the tooth covers.
* Any contact information provided will be kept confidential and will only be used for the purposes of this research project. It will not be available for any other use.

The data would be coded for linking purposes. The coding will be kept by the principle investigator on a University of Sydney computer.

Once the processing of the data from the clinical study is completed, the personal identifying information would be removed.

In any publication or dissemination, the results of both questionnaires and the conclusions would be de-identified.

* 1. **Study Record Retention**

All records will be retained for 15 years.

1. ADMINISTRATIVE ASPECTS
	1. Ethics Application has been made, registration No. pending.
	2. Registration of the trial has been made to ANZCTR. Registration number pending.
	3. The lead researcher (Dr. David A Graham) completed NHMRC eLearning modules: -

 Nos. 1 & 2 on 20-07-2018

 No. 3 on 23-07-2018

* 1. Amendments to the protocol

Any amendments will be submitted to HREC for review prior to implementation as per HREC guidelines.

* 1. Protocol deviations

Any protocol deviations will be submitted to HREC for review.

* 1. Participant reimbursement

There are no reimbursements to participants

* 1. Financial disclosure and conflicts of interest

There are no conflicts of interest

**11. USE OF DATA AND PUBLICATIONS POLICY**

A depersonalised summary of the results from both the first questionnaire and the clinical trial will be made available to participants from The Sydney Conservatorium of Music via the Conservatorium’s electronic media outlets.

The details from the first questionnaire and the results from the clinical study will be published separately in the scientific media.

The lead author of each paper will be: - David A. Graham

Other authors to be acknowledged: - Greg Murray, Iven Klineberg, Chris Howden, Terry Whittle, Amrinder Oberoi.

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