# Photobiomodulation induced dental analgesia in humans: A clinical trial

# Griffith University ethics number [GU2022/668]

**Patient Information Booklet**

We would like to invite you to participate in this research study. Before you decide, please take time to review this booklet for information on the purpose and design of the study, what it would involve for you, the potential risks involved, as well as who to contact for more information regarding this study. This study is being completed as part of Dr Sachin Kulkarni’s Doctor of Philosophy (PhD) program at Griffith University.

**Purpose of the study:**

To determine the efficacy of Photobiomodulation on providing anaesthesia of teeth. Fear of dental aesthetic injection can produce anxiety and contribute to dental phobia. Recently, other methods have been studied for their effectiveness to produce anaesthesia. One such method is known as Photobiomodulation. The purpose of this study is to utilise laser to assess where the sensitivity of the nerve inside the tooth reduces.

**What is Photobiomodulation/Low Level Laser Therapy:**

Lasers, as used in medicine and dentistry, can be classified as ‘hot’ or ‘hard’ surgical lasers and on the other end of spectrum ‘cold’ or ‘soft’ lasers. These soft lasers are diode lasers that have been used clinically in a method known as Photobiomodulation. There is substantial research indicating a range of applications, such as in acceleration of wound healing, enhanced remodelling and repair of bone, restoration of normal neural function following injury, normalization of abnormal hormonal function, pain attenuation, stimulation of endorphin release, and modulation of the immune system.

**Potential risks:**

There are no proven side effects of Photobiomodulation. To ensure your safety, we will take the following precautions:

* All appropriate steps will be taken per AS4173: Guide to Safe Use of Lasers in Health Care,
* Safety glasses when looking at the laser to prevent harmful effect on retina,
* Not providing Photobiomodulation if you’re pregnant,
* Not providing Photobiomodulation in area of potential cancerous lesion,
* Not providing Photobiomodulation in the region of thyroid glands,
* Providing Photobiomodulation with appropriately trained practitioner, and
* Providing Low Level Laser locally to the tooth surface.

**What does it mean for you:**

You will be attending a regular dental appointment for fillings on both sides of my mouth (restorations). Protective eyewear will be provided to protect your eyes from the laser light. Your tooth will be tested for sensitivity using an electric pulp test (EPT). The EPT device (Analytic Endodontics, Sybron Dental Specialties, Orange, CA, USA) is used routinely in dental practice to assess dental nerve. You may expect a mild tingling sensation on activation of this device. Any discomfort is very minimal and is not expected to persist for more than a few seconds. This establishes the baseline score.

Part I:

Laser and Sham probe will be used on either side at a particular setting on the tooth. EPT will be used to assess the dental nerve, and the score will be recorded. You will be asked to report on the discomfort felt during the laser procedure. You will be asked to report anxiety felt before laser therapy, and before dental local anaesthesia on Visual Analog Scale for Anxiety (VAS-A).

Part II:

Dental local anaesthesia will be completed on both sides. You will be asked to report on the discomfort felt during the dental local anaesthesia injection. Restorative procedure will be completed as per usual.

This study may add an additional 10 minutes to your appointment with little to negligible amount of discomfort.

**Why have you been selected to participate in this study:**

You have been selected to participate in this research study as you:

* Require bilateral restoration,
* are above the age of 18,
* are not currently taking medication that may modulate pain,
* are not currently taking medication for nerve disorders.

**Data collection and storage:**

As required by Griffith University, all research data (associated data) will be retained in a locked cabinet and/or a password protected electronic file at Griffith University (GU Research Storage platform) for a period of fifteen years before being destroyed.

A plain language summary of the research results can be requested via email. Please indicate your interest in receiving this in the consent form.

Research results will be reported in an academic thesis and may also be disseminated via journal articles and / or conference presentations.

**Approval:**

This study has been reviewed and approved by the Griffith University Human Research Ethics Committee.

**Voluntary participation:**

This research is completely voluntary and is independent from the dental care you are already receiving from practitioners at Berri Dental. You may choose to withdraw from the study part way, without providing a reason, without any ill effect from the provided therapy.

The conduct of this research involves the collection, access, storage and/or use of your identified personal information. The information collected is confidential and will not be disclosed to third parties without your consent, except to meet government, legal or other regulatory authority requirements. A de-identified copy of this data may be used for other research purposes, including publishing openly (e.g. in an open access repository). However, your anonymity will at all times be safeguarded. For further information consult the University's Privacy Plan at http://www.griffith.edu.au/about-griffith/plans-publications/griffith-university-privacy-plan or telephone (07) 3735 4375.

Griffith University conducts research in accordance with the National Statement on Ethical Conduct in Human Research. If you have any concerns or complaints about the ethical conduct of this research project, you are encouraged to contact the Manager, Research Ethics on 07 3735 4375 or research-ethics@griffith.edu.au.

For further information, please contact the following:

Chief Investigator:

Dr Roy George

Griffith Health-G40

Griffith University

Gold Coast campus, Parklands QLD, Australia 4222

P: 61 7 5678 0751

Email: drroygeorge@gmail.com

Doctor of Philosophy student Researcher:

Dr Sachin Kulkarni

Griffith University

Gold Coast campus, Parklands QLD, Australia 4222

P: 61 430 218 069

Email: Sachin.kulkarni@griffithuni.edu.au

Investigator:

Dr Greg Miller

Principal dentist

Berri Dental

7b Ahern Street

Berri SA 5343

P: 61 8 85821944

E: admin@berridentist.com.au

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CONSENT FORM FOR PARTICIPATION IN RESEARCH

**The purpose of this study is to utilise laser to assess where the sensitivity of the nerve inside the tooth reduces.**

I …............................................................................................................................

being over the age of 18 years hereby consent to participate as requested in the Patient Information Booklet provided to me for the research project on Photobiomodulation induced dental analgesia. I have read the information provided.

1. I understand that I am required to attend my appointment for fillings on both sides of my mouth. My teeth will be tested for sensitivity before and after laser therapy, which may involve mild discomfort.
2. Details of procedures and any risks have been explained to my satisfaction.
3. I agree to recording of my information and participation.
4. I am aware that I should retain a copy of the Information Sheet and Consent Form for future reference.
5. I wish to receive plain language summary of the research results via email …………………………………………………………………

4. I understand that:

* I may not directly benefit from taking part in this research.
* I am free to withdraw from the project at any time and am free to decline to answer questions.
* While the information gained in this study will be published as explained, I will not be identified, and individual information will remain confidential.
* Whether I participate or not, or withdraw after participating, will have no effect on any treatment or service that is being provided to me.
* I may ask that the recording/observation be stopped at any time, and that I may withdraw at any time from the session or the research without disadvantage.

**Participant’s signature……………………………………Date…………………...**

I certify that I have explained the study to the volunteer and consider that she/he understands what is involved and freely consents to participation.

**Researcher’s name………………………………….…………………….................**

**Researcher’s signature…………………………………..Date…………………….**