

Informed Consent Form

Register number in CEP-UNUARARAS: 3055814

Project Title: Effect of low intensity electric current on orthodontic movement acceleration and pain perception.

Dear Mr.,

This Consent Form may contain words you do not understand. Ask the researcher to explain the words or information not completely understood.

1) Introduction

You are being invited to an academic survey that will study the action of low-intensity electric current in tooth movement acceleration and pain intensity control. You were selected because you have complete permanent dentition free of caries and gum disease. Besides that, you have front lower anterior teeth crowded (moderate or severe) in need of orthodontic treatment and are not making use of painkillers or anti-inflammatory at this moment, however, your participation in this survey is not compulsory. The objective of this project is to investigate orthodontic treatment time and discomfort caused by tooth movement pain with the use of microcurrent compared to conventional orthodontic treatment. The justification is that once the low-intensity electric current is used, not only the orthodontic treatment time may be shorter, but also the discomfort and pain caused in the initial moments of the appliance installation can be reduced.

2) Study Procedures

During your participation in this study, I ask a special collaboration in being present at all the scheduled returns. The research will last three months, with weekly returns (one time per week).

You will receive an intraoral clinical examination and the application of the therapy to be researched on all returns.

The low intensity electric current device has two metal electrodes with spherical metal ends and uses a continuous current of 10 microamperes. As it is a non-invasive therapy, this treatment poses no risk to you. It does not harm your physical integrity and does NOT involve instruments that pierce the skin.

The application will be in the gums of the anterior lower teeth ("front teeth") and will last for 5 minutes. Ultimately, I ask for your cooperation in answering a questionnaire assessment of the degree of pain in the first 72h after each orthodontic wire exchange, which will be made once a month.

3) Risks and discomforts

The proposed therapy uses a low-intensity electric current and is considered a non-invasive treatment. The treatment does not pose any risk to the survey participants because it does not harm the physical integrity and does not involve instruments that pierce the skin. All possible precautions will be taken to ensure that if any discomfort occurs, they will be minimal and insignificant.

4) Benefits

You will be receiving quality orthodontic treatment at no cost for satisfactory and permanent oral health.

5) Alternative Treatment

If you decide not to participate in this study, there is another treatment available to you, which is nothing more than conventional orthodontic treatment. This treatment is offered by Hermínio Ometto University Center - UNIARARAS, according to the rules of this institution, when they can solve the problem.

6) Monitoring and Responsibility

Despite all possible care, undesirable effects are likely to occur in any research study and can happen without your own or the researchers' fault. If you experience undesirable effects as a direct result of your participation in this study, the necessary

professional assistance will be provided at Hermínio Ometto University Center-UNIARARAS, with full assistance by a qualified orthodontist to be designated.

7) Clarification Guarantee

You will be accompanied by the researchers throughout the research and will have all your questions answered at any time.

8) Placebo or Control Group

During the research, there is a placebo group (control). You will be able to be included in this group.

The study will feature two distinct groups: Group I (control) and Group II (low-intensity electrical current). Each participant's division into the groups will be by lot. This gives you the same chance to participate in the research in Group I or Group II.

Group I (control), as well as Group II (low-intensity electric current) will be completing the proposed orthodontic treatment in the same way and are of fundamental importance for understanding the results of the proposed research.

9) Participation

Your participation in this study is very important and voluntary. You have the right to not participate or withdraw from this study at any time without penalty or loss of the benefits or care you obtained from this institution. You may also be excluded from the study at any time, without your consent, in the following situations: (a) do not properly follow the study guidelines/treatment; (b) experience unexpected undesirable effects; (c) the conclusion of the study. If you decide to withdraw from the study, please notify the attending professional and/or researcher.

The researchers responsible for the study can provide any clarification needed, as well as ask questions by contacting the following address and/or telephone, email: (required)

Researcher Name: Paula Caroline Barsi Batistelli

Researcher's Address: Rua D09, house 11, Vila dos Oficiais. Postal Code: 13643-216
Pirassununga-SP

Researcher's Phone: 14 (981748116)

Search mail: paulabarsi@hotmail.com

10) Confidentiality of Records

Your identity will be kept confidential. Results will always be presented as a portrait of a group rather than a person. Accordingly, you will not be identified when your registration material is used, whether for scientific or educational publication purposes.

11) Costs and Reimbursement

You will not have any expenses for your participation in the study and will not receive payment for it.

12) Consent Statement

I have read or someone read to me the information contained in this document before signing this consent form. I declare that all the technical language used in the research study description has been satisfactorily explained and that I have received answers to all my questions. I also confirm that I have received a copy of this free and informed consent form. I understand that I am free to withdraw from the study at any time without loss of benefits or any other penalty. I give my free and willing consent to participate in this study.

This study was approved by the Ethics and Scientific Merit Committee of the Hermínio Ometto University Center - UNIARARAS, coordinated by Profa. Dr. Miriam de Magalhães Oliveira Levada, who can be contacted in case of ethical questions, by telephone at 19-3543-1439 or by e-mail: comiteetica@uniararas.br or by the address Av. Dr. Maximiliano Baruto, nº 500 - Jd Universitário –Araras / SP.

STATEMENT OF THE DECLARANT

Informed Consent Form

(Name):

RG: Date of birth: / / Sex: M () F ()

Address: No Apt:

Neighborhood: City: Zip:

Phone:

Signature of Declarant

Legal representative:

Nature of Representation:

ID: Date of birth: / / Sex: M () F ()

Address: No: Apt:

Neighborhood: City: Zip:

Phone:

Signature of Declarant

RESEARCHER STATEMENT

I DECLARE, for research purposes, that I have prepared this Informed Consent Form, complying with all the requirements contained in the paragraphs above and that I have obtained, appropriately and voluntarily, the free and informed consent of the above-qualified declarant to conduct this research.

ARARAS, of of 2019.

Researcher's Signature