

Information for Participation in a Research Study

Study title:

Comparison between two teeth- and gum-cleaning methods for the treatment of periodontitis

Introduction

You are invited to take part in a research study comparing two different methods of cleaning teeth and gums to treat a condition called periodontitis (a disease of the gums and the bone surrounding the teeth). This study will help us understand which of the two methods is more effective at improving gum health and reducing harmful bacteria.

Before deciding whether you want to take part, please read the information below carefully. Your participation is voluntary and you have the right to withdraw from the study at any time, without this affecting your usual dental care.

Purpose of the study

This study aims to compare two methods of cleaning teeth and gums during the treatment of periodontitis:

- Guided Biofilm Therapy (GBT®): a modern method using a series of gentle instruments, including a disclosing agent to reveal bacteria, special air-and-fine-powder devices, and gentle ultrasonic instruments.
- Conventional debridement (SRP): the standard cleaning method, using ultrasonic and manual instruments to remove bacterial plaque and tartar from the tooth surface and below the gums.

Our aim is to see which of these two methods is better at:

- Improving gum health (reducing bleeding).
- Reducing the depth of periodontal pockets (the spaces between teeth and gums).
- Changing the types of bacteria present in the mouth.
- How comfortable the treatment is for you.

Procedures

If you decide to take part:

- You will be randomly assigned (like drawing lots) to one of the two treatment groups (GBT® or SRP). You will not be able to choose which group you are in.
- You will attend several sessions of teeth and gum cleaning, as part of your treatment for periodontitis. These sessions will be carried out by a specialist.
- We will carry out regular examinations of your gums (measuring pocket depth, checking for bleeding) at the start of the study and after 12 and 24 weeks.
- You will be asked to answer a few questions about how comfortable the treatment was for you.
- We will collect small bacterial samples from your mouth at the start of the study and after 12 and 24 weeks, to see how they have changed.
- You will need to continue brushing your teeth and using dental floss at home as you normally do.

Your attendance at all scheduled visits is important so that the study produces accurate results. The study will last approximately 6 months, with visits at the start, after 3 months, and after 6 months.

Potential risks

Both cleaning methods are standard procedures used in the treatment of periodontitis. The risks associated with these procedures are usually minor and temporary, and may include:

- Tooth sensitivity: you may feel increased sensitivity to cold or touch after cleaning. This usually resolves within a few days.
- Discomfort or pain: you may feel mild discomfort or pain during or immediately after the procedure. Mild painkillers may be used if needed.
- Bleeding: your gums may bleed slightly during or after cleaning.
- Gingival recession: in the long term, reduced gum inflammation may lead to slight gum recession.

If you experience any unusual problem or discomfort, please contact us immediately.

Potential benefits

Your participation in this study may bring you the following benefits:

- You will receive modern treatment for periodontitis.
- Your gum health may improve.
- You will be closely monitored by specialists throughout the study.
- Your participation will help improve periodontal treatments for other patients in the future.

Confidentiality

All information about you will be kept confidential and used only for the purposes of this study. Your data will be coded so that your identity is not disclosed in the study's reports or publications.

Right to refuse or withdraw

Your participation in this study is entirely voluntary. You have the right to refuse to take part, or to withdraw from the study at any time, without giving a reason and without this affecting your usual dental care.

Questions

If you have questions about this study, the procedures, or your rights as a participant, please do not hesitate to ask any member of the research team.

Consent

If you have read and understood the information above and agree to take part in this study, please sign and date the separate consent form. You will receive a signed copy of this document to keep.

Patient's name: _____

Signature: _____

Researcher's contact details

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Thank you for your time and consideration.