Information Regarding the Clinical Study

"Efficacy of Guided Biofilm Therapy vs. standard debridement during subgingival re-instrumentation in step 3 of treatment of moderate to advanced severe (stages II-IV) periodontitis: A Randomized Controlled Clinical Trial"

Dear Patient,

We would like to invite you to take part in our research project. It is your right to be informed about the purpose and details of the study, so that you can decide, fully informed, whether you wish to participate. For this reason, we invite you to read the following pages carefully. All researchers involved in the project are available to answer any questions you may have.

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Purpose of the study

The main purpose of this study is to evaluate and compare the clinical efficacy of the Guided Biofilm Therapy (GBT®) protocol compared with conventional methods of repeated subgingival instrumentation, applied in the third step of treatment for stage II to IV periodontitis.

Study procedure

Subjects who have completed the second step of periodontal therapy will be recruited and randomized into two parallel groups. One group will receive treatment with Guided Biofilm Therapy (GBT®), while the other group will be treated with conventional subgingival instrumentation (scaling and root planing – SRP) using ultrasonic and manual instruments.

Both groups will undergo repeated sessions of subgingival instrumentation, as part of the third step of periodontal therapy. Participants will be monitored over a period of six months, with outcome assessments carried out at baseline (T0), at 12 weeks (T1), and at 24 weeks (T2) after the initial repeated subgingival instrumentation and after the 12-week re-instrumentation.

Why are we asking you to take part in this study?

70 adult patients aged 18 to 75 years, diagnosed with moderate to severe periodontitis (stages II–IV per the AAP/EFP 2018 classification), will be included in the study. Participants must have a minimum of 15 teeth with probing depths (PD) between 4 mm (with positive bleeding on probing, BOP) and 6 mm. Only patients who have completed the first and second steps of periodontal therapy, who are in generally good health, and who maintain adequate oral hygiene — defined as a plaque index ≤35% and a sulcus bleeding index ≤25% — will be included. Heavy smokers (more than 10 cigarettes/day), pregnant or breastfeeding women, patients with systemic conditions affecting periodontal healing such as uncontrolled diabetes mellitus, those with a history of allergy to erythritol or chlorhexidine, and patients unable to maintain sufficient oral hygiene will be excluded from the study.

Is participation in the study mandatory?

Your involvement in the study is entirely voluntary; if you refuse to participate there will be no negative consequences for you. Furthermore, if at any point you reconsider your decision and wish to leave the study, you may do so without giving any explanation. In the event of withdrawal, the data collected up to that point will be destroyed, except for data already processed for the research project up to that point.

Stages of your participation in this study

Participation in this study follows a detailed description of its characteristics, risks, and benefits. Once you have received all the information, you may consent to take part in the study by signing the informed consent form. You will only be able to actively participate in the study after giving written consent.

What is required of you?

Patients included in this study will be asked to attend periodic check-up visits over a period of six months. During these visits, clinical periodontal examinations will be carried out, including measurement of probing depth, assessment of bleeding on probing, and clinical attachment level. An assessment of oral hygiene will also be performed using specific indices. Participants will receive sessions of repeated subgingival instrumentation according to their random allocation to the GBT® group or the conventional debridement (SRP) group. They will be asked to complete questionnaires about their treatment experience, including the level of pain and discomfort, using a visual analogue scale (VAS). In addition, microbiological samples will be collected at set intervals. Throughout the study, patients must avoid using other periodontal treatments or systemic antibiotics that are not medically necessary. Attendance at all scheduled visits and cooperation with the assessment procedures are essential to the success of the study.

Processing of your personal data

All information regarding the processing of your personal data, including special-category data, is governed in detail by Article 13 of Regulation (EU) 2016/679 (GDPR) and is included in this consent form.

Potential risks and possible discomfort related to this study

During and after repeated subgingival debridement procedures, patients may experience some degree of discomfort. Although both treatment protocols aim to reduce inflammation and improve periodontal health, minor adverse reactions may occur. Subgingival instrumentation — whether via Guided Biofilm Therapy (GBT®) or conventional methods (SRP) — may cause mild, temporary dental sensitivity, particularly where root cementum is exposed. It should also be noted that, in the long term, resolution of gingival inflammation and reduction of periodontal pockets may lead to modest gingival recession. This recession, while an indicator of healing and of reduced pocket depth, may contribute to dental sensitivity to thermal or tactile stimuli. Throughout the study we will monitor and document any reports of discomfort, including dental sensitivity and any change in gingival level, to assess the impact of each treatment protocol on the patient's experience.

Potential benefit of the study

Taking part in this study gives patients the opportunity to benefit from the latest approaches in periodontal therapy. By comparing GBT® with conventional subgingival instrumentation, the study aims to identify more effective and less invasive methods for treating periodontitis. Potential benefits for participants include possible improvement in gum health, reduced bleeding and inflammation, and a potential slowing of alveolar bone loss. In addition, by assessing patient-reported outcomes, the study will provide valuable information on the impact of each treatment on comfort and acceptability. The results of this study will contribute to a better understanding of the efficacy of different treatment approaches and could inform future periodontal treatment guidelines, benefiting a larger number of patients with this condition. Participants will receive specialized dental care and close monitoring throughout the study.

Potentially important health information collected during the study

If information potentially relevant to your health arises from the study, you will be able to state whether or not you wish to be informed of it, in the Informed Consent section of this document.

Other important information

We inform you that the study has been approved by the Research Ethics Committee of the "Victor Babeș" University of Medicine and Pharmacy Timișoara. The original version of the informed consent form signed by you will be kept by the study coordinator. You are entitled to keep a copy for yourself. During the study, you may contact the study coordinator for further information.

Thank you for your participation.

STUDY COORDINATOR'S DECLARATION

I declare that I have provided the patient with complete information and detailed explanations regarding the nature, purpose, procedures, and duration of this research project. I also declare that I have provided the patient with the document containing information about the study.

SIGNATURE	Date: 15/03/2025
SALVATORE CHINNICI	
STUDY COORDINATOR'S SIGNATURE — UMFVB TIMIȘOARA CENTRE	Date:
ȘTEFAN-IOAN STRATUL	

STUDY PARTICIPANT'S SIGNATURE

I, the undersigned, declare that I have received information that has allowed me to understand the research project, including additional information that I personally requested. I also confirm that I have been given a copy of the document containing information about the study.

SIGNATURE	**Date**

INFORMED CONSENT

I, the undersigned _____

- I declare that I have been given detailed information regarding my participation in this experimental study, and I confirm that I have sufficient information about the risks and benefits involved, as set out in the information document above.
- I declare that I have been given the opportunity to discuss this information, to ask any questions I considered necessary, and that I received adequate answers to them.
- I also declare that I have been informed of my right to withdraw from this study at any time.

Therefore, in light of the information provided to me, I, the undersigned
_____

☐ I agree ☐ I do not agree	To take part in this study.
☐ I agree ☐ I do not agree	To be recorded by audio-video means for research documentation purposes (if applicable).
☐ I agree ☐ I do not agree	To be informed of any health issue concerning me arising from this study.

PLACE AND DATE — PATIENT'S SIGNATURE: _____

PLACE AND DATE — STUDY COORDINATOR'S SIGNATURE: _____