P*ATIENT INFORMED CONSENT FORM*

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| **Project Title/ Article Title** | **Natural Mouthwashes in Reducing Dental Plaque and Gingival Inflammation/**<br><br>**Comparative Clinical Evaluation of Chamomile, Sage, and Ginger Mouthwashes in Reducing Plaque and Gingival Inflammation** |
| **Purpose of the Study** | This research is led by Assoc. Prof. Dr. Ioana Elena Lile from the "Vasile Goldiș" Western University of Arad**.** We invite you to take part in this research project, as your participation will help us evaluate the potential benefits of herbal mouthwashes in reducing dental plaque and gingival inflammation.<br>This study investigates the short-term clinical effectiveness of herbal mouthwashes based on Matricaria chamomilla, Salvia officinalis, and Zingiber officinale in reducing dental plaque accumulation and gingival inflammation, compared with placebo and chlorhexidine controls.<br>The results of the project will be used to publish study articles, online in open access format, (creative commons CC BY 4.0 license, http://creativecommons.org/licenses/by/4.0), meaning that it can be downlo aded, copied, and reused without limitation. The primary audience for the published paper will be healthcare professionals, research academics, and s tudents from across the globe. |
| **Procedures** | If you agree to participate in this study, you will undergo a series of non-invasive clinical examinations and will be asked to follow a standardized oral hygiene protocol for a period of twelve weeks. At the beginning of the study (baseline visit), a clinical oral examination will be performed to assess dental plaque and gingival condition. These evaluations will be conducted using established clinical indices, including the Silness–Löe Plaque Index and the modified Löe–Silness Gingival Index. The examination will be carried out using routine dental instruments under standard clinical conditions.<br><br>Participants will then be randomly assigned to one of the study groups. Each participant will receive a mouthwash corresponding to their assigned group. The study includes herbal mouthwash formulations, a placebo mouthwash, and a chlorhexidine mouthwash used as a control. All mouthwash solutions will be provided in identical containers. Both participants and examiners will be unaware of the group allocation during the study.<br><br>Participants will be instructed to rinse with 10 mL of the assigned |

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| | mouthwash for approximately 30 seconds, three times per day, after meals, for a period of twelve weeks. After rinsing, participants will be asked to avoid eating or drinking for approximately 30 minutes.<br><br>During the study period, participants will be asked to maintain their egular toothbrushing routine and to avoid the use of other mouthwashes or dditional oral hygiene products that could influence the study outcomes.<br><br>Clinical examinations will be repeated at predefined intervals during he study in order to monitor changes in dental plaque and gingival ondition. These follow-up assessments will take place approximately 4 veeks, 8 weeks, and 12 weeks after the start of the study.<br><br>Participation in this research is voluntary. Participants may withdraw rom the study at any time without providing a reason and without any ffect on their current or future dental care.<br><br>All collected data will be recorded confidentially and used only for esearch purposes. |
| **Potential Risks and Possible Discomfort** | Participation in this study involves minimal risk. The procedures included consist of routine clinical oral examinations and the use of mouthwash solutions similar to those commonly used in daily oral hygiene.<br><br>Some participants may experience mild and temporary discomfort associated with the use of mouthwash. This may include temporary changes in taste perception, mild oral irritation or sensitivity, or a sensation of dryness of the oral mucosa. In rare cases, allergic reactions to herbal components such as chamomile, sage, or ginger may occur.<br><br>If any discomfort, irritation, or unusual symptoms appear during the study, participants are encouraged to inform the research team immediately. In such situations, the use of the mouthwash may be discontinued and appropriate recommendations will be provided.<br><br>The clinical examinations performed during the study are non-invasive and are not expected to cause pain or significant discomfort. Participation in the study is voluntary, and participants may withdraw at any time without any consequences.<br><br>If at any time you feel discomfort or wish to stop participating, you are free to withdraw from the study without any consequences or impact on your dental care. |
| **Possible Benefits** | Participants may experience improvements in oral hygiene, including a reduction in dental plaque and gingival inflammation as a result of following a structured oral hygiene protocol and using the assigned mouthwash during the study period. However, individual benefits cannot |

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| | be guaranteed.<br><br>Participation in this study may also contribute to increased awareness of personal oral hygiene practices and gingival health. In addition, the information obtained from this research may help improve scientific understanding of the potential role of herbal mouthwashes in oral health care and may contribute to the development of future preventive strategies in dentistry. |
| **Confidentiality** | Any potential disclosure of confidential data will be minimized by storing all collected information in a secure location, such as a locked office, a locked cabinet, or a password-protected computer, and retaining it only for the period required by applicable legislation. All stored data will be destroyed after the legal archiving period has expired.<br><br>If a report or scientific article is prepared based on this research project, participants' identities will be protected to the greatest extent possible. All data will be coded and stored anonymously for research purposes. No identifying information will appear in any publication resulting from this study.<br><br>Personal information may be disclosed only to authorized representatives of the "Vasile Goldiș" Western University of Arad or to competent authorities, in cases where such disclosure is required by law or if there is a risk that the participant or another person may be in danger. |
| **Medical Treatment** | Participants will not incur any costs related to participation in this study. No financial compensation is provided. |
| **Participant's Right to Withdraw and to Ask Questions** | Your participation in this research is entirely voluntary. You may decide not to take part at all. If you choose to participate, you may withdraw at any time. In either case—whether you decide not to participate or you decide to participate and later withdraw—you will not be penalized in any way, and you will not lose any benefits to which you are otherwise entitled.<br><br>If you decide to stop participating, if you have any questions, concerns, or complaints, or if you wish to report any research-related harm or misconduct, please contact the Principal Investigator:<br><br>***Assoc. Prof. dr. Lile Ioana Elena***<br><br>Department of Dentistry, Faculty of Dentistry, "Vasile Goldiș" Western University of Arad, 94-96 Revolutiei Blvd., 310025 Arad, Romania ***lile.ioana@uvvg.ro.*** |

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| | *Assoc. Prof. dr. Marian Diana*<br><br>Department of Dentistry, Faculty of Dentistry, "Vasile Goldiș" Western University of Arad, 94-96 Revolutiei Blvd., 310025 Arad, Romania ***marian.diana@uvvg.ro.*** | |
| **Participants' Rights** | If you have any questions regarding your rights as a research participant or if you wish to report any research-related harm, please contact:<br><br>"Vasile Goldiș" Western University of Arad<br><br>Scientific Research Ethics Committee<br><br>Address: Arad, Bd. Revoluției No. 94–96<br><br>Phone: +40 257 280 260<br><br>This research has been reviewed in accordance with the procedures of the "Vasile Goldiș" Western University of Arad, which are based on internal standards for research involving human subjects. | |
| **Statement of Consent** | Your signature indicates that you are of legal age (at least 18 years old), that you have read this consent form or have had it read to you, that you have received satisfactory answers to your questions, and that you voluntarily agree to participate in this research study.<br><br>You will receive a copy of this signed consent form.<br><br>If you agree to participate, please sign at the bottom of the page: | |
| **Date and Signature**<br>_____ | **Participant's Name:** | |
| | **Participant's Signature:** | |
| | **Date:** | |