Cover Page

Study Title:
The efficiency of frankincense and other extracts in the treatment of mild to moderate plaque biofilm induced gingivitis: a double blinded randomized controlled trial

Brief Title: Frankincense and Herbal Extracts for Plaque-Induced Gingivitis: A Double-Blind RCT

NCT Number NCT ID not yet assigned

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(Added Coverpage)

INFORMATION SHEET

Study Title:
The efficiency of frankincense and other extracts in the treatment of mild to moderate plaque biofilm induced gingivitis: a double blinded randomized controlled trial

Invitation
You are being invited to consider taking part in the research study titled "**The efficiency of frankincense and other extracts in the treatment of mild to moderate plaque biofilm induced gingivitis: a double blinded randomized controlled trial.**"

This project is being undertaken by Mr Abdulaziz Al-Oraimi, Ms Iman Al-Sukaiti, and Dr Triveni Mohan Nalawade (Research Supervisor).
Before you decide whether or not you wish to take part, it is important for you to understand why this research is being done and what it will involve. Please take time to read this information carefully and discuss it with others if you wish. If there is anything unclear or if you would like more information, please feel free to ask.

Aims of the Research
The aim of this study is to compare the effectiveness of frankincense and other extracts in reducing dental plaque accumulation and gingival inflammation in patients with mild to moderate plaque-induced gingivitis.
The research may help to understand the effect of Frankinscence and other extracts on reducing gum disease and gum bleeding in patients having gum health issues.

Participation
Your participation in this study is entirely voluntary. If you decide to take part, you will be asked to sign an informed consent form.
You are free to ask questions at any stage of the study and you may withdraw at any time without giving any reason. If you withdraw, any data related to you will be systematically destroyed.
Every possible effort will be made to maintain confidentiality and protect the identity of all participants.

Procedures
If you agree to participate, you will undergo an initial dental examination to assess your gum health and plaque levels. You will then be randomly assigned to one of three study groups. Depending on the group allocation, you will use either a coconut oil mouth rinse, a frankincense-based mouth rinse, or a chlorhexidine mouth rinse.
You will be instructed on how to use the assigned product and asked to maintain your regular toothbrushing routine while avoiding any additional oral care products not approved for the study. Follow-up visits will be scheduled to assess plaque levels, gingival

inflammation, and gum bleeding.
Your participation will last approximately 4–6 weeks.

Benefits
You may experience an improvement in your gum health, including reduced gingival inflammation and bleeding. You will also receive professional monitoring of your oral health. Your participation will contribute to scientific research on effective treatments for gingivitis using herbal alternatives. However, individual benefits cannot be guaranteed.

The outcomes will be shared with participants as well as at a conference or in a journal.

Risks Involved
The oral care products used are generally safe. Some participants may experience mild temporary side effects such as oral irritation, sensitivity. Documented reports show the prolonged usage of Chlorhexidine mouthwash more than 4 weeks can cause temporary but reversible staining of teeth and taste changes. In this research we are recommending a period of 4 weeks which is considered acceptable.

If any discomfort occurs, please inform the principal investigator or the Research Supervisor immediately.

Use of Collected Information
All information collected will be kept confidential. Data will be coded so that participants cannot be identified. Results may be published or presented in an anonymous form. Access will be limited to the research team only.

Access to information

Every possible effort will be made to hide the identities of the people during and after study. Data collected and stored in secure password protected disks along with online cloud storage and data will be coded and not identifiable anyway with the participants. Data will be accessed by researcher and supervisor for analysis. After completion of the study the data will be deleted from all sources.

Funding and Organisation
This study is funded by MOHERi under Block funding Cycle 3- Undergraduate Research Grant

Contact Information
For concerns or further information, please contact:
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For complaints regarding the research, contact:

Dr Triveni Mohan Nalawade: tnalawade@staff.odc.edu.om

CONSENT FORM

Title of Project: The efficiency of frankincense and other extracts in the treatment of mild to moderate plaque biofilm induced gingivitis: a double blinded randomized controlled trial

Principal Investigator:
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Co- Principal Investigator:

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Please write your initials within the box if you agree with the statements below:

1. I confirm that I have read and understood the information sheet dated …….. (version no …….) for the above study and have had the opportunity to ask questions ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time.

In the event of withdrawal, and where it is possible, relevant data will also be withdrawn ☐

3. I agree to take part in this study ☐

_____	_____	_____
Name of participant	Date	Signature
_____	_____	_____
Researcher	Date	Signature