

PARTICIPANT INFORMATION SHEET

Study title: **POSTOPERATIVE SEQUELAE AND QUALITY OF LIFE FOLLOWING IMPACTED MANDIBULAR THIRD MOLAR EXTRACTION USING COMPLETE CLOSURE AND SUTURELESS TECHNIQUES**

Location: Dental & Maxillofacial surgery department, UDUTH

Ethics committee ref:

Lead investigator: Dr Chukwuma, Benedict

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You are invited to take part in a study on “Postoperative sequelae and quality of life following impacted mandibular third molar extraction - Complete closure versus sutureless technique’. Whether or not you take part is your choice. If you don’t want to take part, you don’t have to give a reason, and it won’t affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This information sheet will help you decide if you’d like to take part. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. Please make sure you have read and understood all the information herein.

What is the purpose of this study?

The study aims to compare two wound closure techniques following impacted third molar surgery as it relates to the postoperative pain, trismus, swelling and wellbeing. This study, on completion will help dental surgeons around the world to decide what technique their patients having third molar surgery would tolerate better.

Participants will be randomly allocated to any of the two techniques being studied. This is to remove bias in patient selection as much as possible.

Both techniques in this study are acceptable and are currently used techniques for this procedure. This study has been reviewed and approved by the Health research and ethics committee of UDUTH

What will my participation in this study involve?

You have been chosen for this study because you are about to do an impacted third molar surgery. This is a safe and routine procedure in dental clinics around the country.

Under local anaesthesia, a gum flap will be raised to expose your buried tooth, and some bone will be removed to allow the delivery of the tooth. The wound is now closed using any of the two techniques being studied.

You will be required to come for a review on postoperative days 1, 3, 7, 14 and 28

You will be required to fill out questionnaires and rate your experience of pain, swelling and your wellbeing for several days after the procedure.

What are the possible benefits and risk of the study?

Third molar surgery is associated with a few risks and complications. Pain, swelling and trismus are expected outcomes following this procedure. Complications are rare following third molar surgery and may include dry socket, persistent and worrisome numbness in your cheek and tongue, lip and cheek injury, bleeding and infection.

Participating in this study does not increase or decrease your risk of complications significantly. Rather, participating in the study ensures that your dental surgeon is fully aware of what you are going through daily during the postoperative period.

Each review appointment will last about 20minutes and will be fast tracked so that you will not have to wait for long queues to be seen. There will be a designated staff to attend to you promptly.

Who pays for the study?

You will not incur any costs for participating in this study.

What are my rights?

Your participation in this study is voluntary, and you are free to decline to participate, or to withdraw from the research at any time without experiencing any disadvantage. You don't need to give any reasons for your withdrawal.

Every information obtained as part of this study including your identity will be kept confidential. You have the right to access all information about you collected as part of the study

What happens after the study?

After the last review appointment (postoperative Day28), your participation in this study is complete.

Information obtained as part of the study will be available for about 1 year after which it will be used to prepare a dissertation and to publish articles in scientific journals

Outcome of this study will be made available to you through an online platform.

Who do I contact for more information or if I have further concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Taiwo Abdulrazaq, Research supervisor I

08078061517 draotaiwo@gmail.com

Dr Ibikunle Adebayo, Research supervisor II

08029190888 adebayoibikunle@gmail.com

If you want to talk to someone who isn't involved with the study, you can contact an independent dental surgeon:

Dr Mujtaba Bala 08061267162

Proforma of informed written consent

I, _____ hereby Surname

First Name

Middle Name

declare that, I voluntarily accept my participation in the study titled **“POSTOPERATIVE SEQUELAE AND QUALITY OF LIFE FOLLOWING IMPACTED MANDIBULAR THIRD MOLAR EXTRACTION USING COMPLETE CLOSURE AND SUTURELESS TECHNIQUES’**

Information pertaining to the purpose and methods of the study has been well explained to me and I fully understand the benefits and risks associated with my participation in the study. I hereby willingly give my consent to participate in the study.

Signature of participant: _____

Date: _____

Address:

Name of witness: _____

Signature of Witness: _____

Date: _____