INFORMATION SHEET FOR PARTICIPANTS

Ethical Clearance Reference Number: **43439**

YOU WILL BE GIVEN A COPY OF THIS INFORMATION SHEET

Title of project

Assessment Of The Volumetric Occlusal Adjustments Required For Michigan Splints Fabricated Using Various Digital Bite Registrations.

Invitation Paragraph

I would like to invite you to participate in this research project which forms part of my clinical PhD research. Before you decide whether you want to take part, it is important for you to understand why the research is being done and what your participation will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask me if there is anything that is not clear or if you would like more information.

What is the purpose of the project?

Temporomandibular disorder TMD) is a significant public health condition affecting the movement of the lower jaw and is mainly due to teeth grinding during sleep or sometimes by teeth clenching during the day. It can manifest as pain around the ear, clicking sounds when moving your jaw, wear of dental tissues, headaches, difficulty in mouth opening, and sometimes jaw locking. Those symptoms usually get worse when the patients are under stress. It is not usually serious and generally gets better on its own, however in many cases, it requires further consideration. Management of this disordering, soft diet, painkillers, physical joint exercises. Furthermore, or many cases, dentist may decide to fabricate a custom-made dental hard appliance (AKA Michigan splints) that fits in the upper teeth, in order to prevent further damage to the teeth and it may help with pain relief, as it positions the joint in a comfortable position. Efforts to improve understanding, diagnosis, and management of these disorders continue to be a focus of research and clinical practice in dentistry and related fields.

As discussed above, Michigan splint is a type of mouthguard that has been used to help people who suffer from jaw pain, clicking, or discomfort when they chew or open their mouths wide. By participating in this project, you are helping us gather valuable information that could potentially improve the lives of millions of people struggle with jaw problems like TMD; as the overall prevalence of TMD was approximately 31% for adults/elderly and 11% for children/adolescents according to a recent review. Your contribution could lead to better treatments and solutions for this widespread issue. Traditionally, these devices are fabricated by taking impressions in the clinic for both jaws and pouring these impressions in the lab, waxing up then fabricating the occlusal splints. Since digital advances are offering easier and a time-efficient way to fabricate Michigan splints we are focusing within this trial on the digital protocols for the fabrication of these devices.

The purpose of the project is:
1- to evaluate volumetric changes on the biting surface of the occlusal splint following four different fully digital workflow. This will indicate the accuracy of the techniques in capturing the bite.
2- Providing high-quality Michigan devices.
3- Save chairside time for the patient and effort of the clinician.
4- Providing more comfortable records to the patient when fabricating dental devices

Why have I been invited to take part?

You are being invited to participate in this project because you match the inclusion criteria which are, you are between 18-65 years old, fit and well, regular attendee to the dentist, do not have any active dental disease, do not have more than one missing tooth per quadrant, have not been diagnosed by with tempomandibular dysfunction syndrome (TMDS) by your general dental practitioner or GP, and you are not currently under any type of medication related to this condition.

What will happen if I take part?

If you choose to take part in the project, you will be asked to allow us to take digital impressions of your teeth through an intraoral scanner and the digital facebow. Moreover, to record the occlusion we will need to scan your bite when your teeth are fully occluded. Participation will take place at the KCL research clinic at floor 26, tower wing, Guys Hospital As part of participation you will be asked to give us the permission to scan your teeth in the first visit and fabricate an occlusal splint for you after about two weeks you will be called again to try out the 4 occlusal splints fabricated from the same records taken at the first visit and we will fit them and do some modification then we will take them out to scan them in the lab.And simply the procedure is explained by the following steps over two visits:

Visit 1:

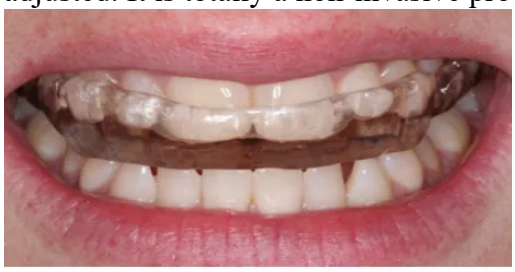
1- Scanning the upper and lower teeth using an intra-oral scanner.

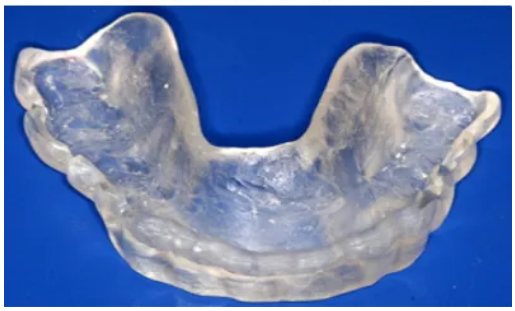
2- We will take another digital record for the upper jaw, where we ask you to bite on the fork as part of the device and then we scan it.

3- Both scans will be used in the lab design of the splint.
4- We will take two records of the bite one when your teeth are fully touching each other and the second one when your teeth are slightly apart.

This visit will be between 60-90 minutes in total. In the very rare occasions, we may ask you to come back to repeat these records if required.

Visit 2:
After two weeks you will be called for another visit to fit the splints on your teeth and will assess how it come together with the bottom teeth and make our modification outside your mouth until it is fully adjusted. It is totally a non-invasive procedure. This visit will require 60-90 minutes.





You will not be provided with any splints at the end of the visit.

Do I have to take part?

Participation is completely voluntary. You should only take part if you want to and choosing not to take part will not disadvantage you in any way. Once you have read the information sheet, please contact us if you have any questions that will help you decide about taking part. If you decide to take part, we will ask you to sign a consent form and you will be given a copy of this consent form to keep.

What are the possible risks of taking part?

No risk to your health or teeth will be applied. Slight discomfort may arise when taking the scans as well as during the fitting of the splint. You can choose to stop the procedure at any time.

What are the possible benefits of taking part?

we will offer a gift which is a 50-pound voucher of amazon.

Data handling and confidentiality

Your data will be processed under the terms of UK data protection law (including the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018). I can confirm that we are not collecting any personal information besides the name on the consent form and the contact details to make it easier to arrange the appointments and to updates you about anything related to your participation.

- We don't intend to identify you or give any personal information about either during or after the study except to what's mentioned above.
- The scans that will be taken of your teeth will be used to design and fabricate the splints.
- The data (the recorded scans) will be archived in a KCL computer, and the file will be secured by a password that will be shared only within the research team for future records as long as the PhD course.
- I Confirm that data will only be shared within the research team and the lab who will fabricate your splint.

King's College London has a responsibility to keep information collected about you safe and secure, and to ensure the integrity of research data. Specialist teams within King's College London continually assess and ensure that data is held in the most appropriate and secure way.

Data Protection Statement

I can confirm that we are not collecting any personal information besides the name on the consent form and your contact details.

What if I change my mind about taking part?

You are free withdraw at any point of the project if you did not make it to the second clinical visit, if the records were taken at the second clinical visit it is hard to withdraw. Withdrawing from the project will not affect you in any way and you do not have to explain your reasons.
If you wish to withdraw, please confirm that by sending an email to one of the contacts below.

How is the project being funded?

This project is being funded by the Hashemite university of Jordan, and the scholarship is covering the tuition fees, bench fees and living expenses.

What will happen to the results of the project?

The results of the project will be summarised in PhD clinical research project, and it will be a base to other upcoming future projects with regards to the use of digital devices and software in patients' treatment.

If there is a potential for incidental findings?

You will be notified directly to explain the finding and you will be advised to This communication will be done promptly and sensitively. You will be provided by a referral letter.

Who should I contact for further information?

If you have any questions or require more information about this project, please contact me using the following contact details:
Arwa Alhusban
Arwa.alhusban@kcl.ac.uk

What if I have further questions, or if something goes wrong?

If this project has harmed, you in any way or if you wish to make a complaint about the conduct of the project you can contact King's College London using the details below for further advice and information:

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Thank you for reading this information sheet and for considering taking part in this research.