Participant Information Sheet

Study title	Jaw opening forces in subjects diagnosed with Temporomandibular disorder	
Principal investigator:	Name: Paul Brunton Department: Faculty of Dentistry Position: Dean	Contact phone number: 03 479 7039

Invitation to take part

Thank you for showing an interest in this project. Please read this information sheet carefully and take time to consider. If you wish, talk with your relatives or friends before deciding whether or not to participate. If you decide to participate, we thank you. If you decide not to take part, there will be no disadvantage to you and we thank you for considering our request.

What is the purpose of the study?

Until now, the assessment of temporomandibular disorders (TMDs) has been based on questionnaires, dental X-rays and CT scans. This project is a proof of concept study to test the feasibility and acceptability of a jaw opening device as a quantitative diagnostic tool to screen temporomandibular disorders.

The TMD specialist will carefully evaluate your medical history and examine your masticatory system. If you are diagnosed with a TMD, you will receive standard treatment during your initial visit to the TMJ clinic. Following the treatment, you will have to attend review appointments at 1, 3 and 6 months where you normally receive further treatment depending on the severity of your TMD.

The main aim of this study is to measure your maximum jaw opening forces using a head device and to see if there is a difference in the maximum jaw opening forces after receiving treatment.

Why have I been chosen?

You have been chosen because you are diagnosed with a temporomandibular disorder. You should take part in this study if you are having myofascial pain, pain in the temporomandibular joint or both.

If you participate, what will you be asked to do?

You will be asked to attend a 15 – 20 min session where you will wear a head device designed to measure the jaw opening forces. You will be asked to open your jaw seven times with a two second interval. Your jaw opening forces will then be recorded. Following your baseline appointment, the maximum jaw opening forces will be measured during your review appointments at 1, 3 and 6 months.

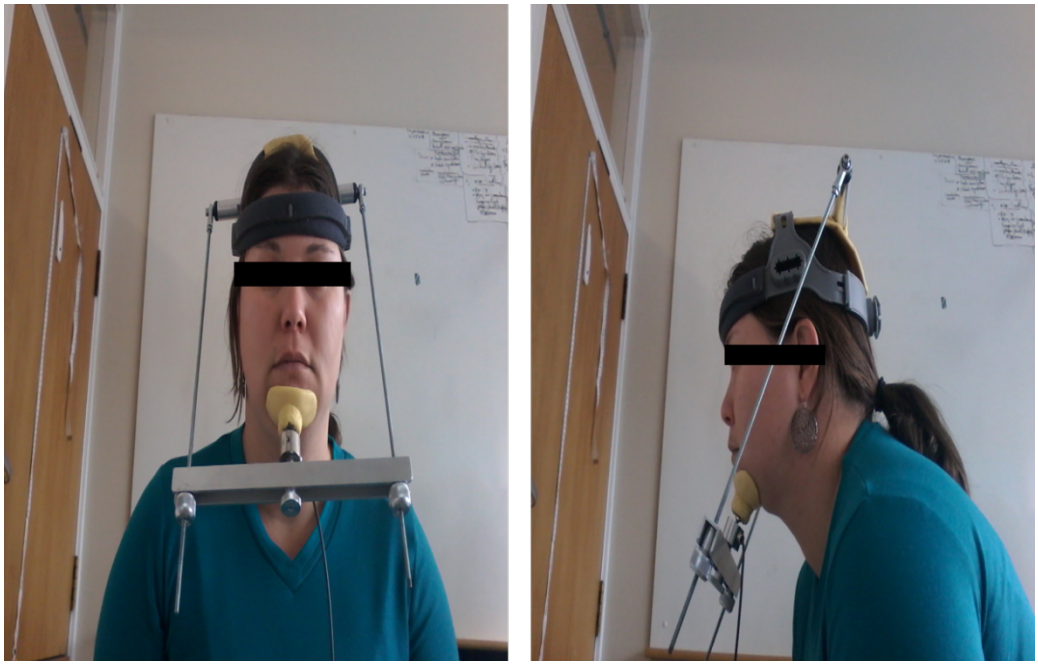

Figure 1: Head device coupled to a loading cell in order to measure jaw-opening forces.

You will also be asked to complete a simple form with your contact information, date of birth, gender, self-reported ethnicity, height and weight.

Your participation in this research is entirely voluntary. We do appreciate this and thank your collaboration.

Is there any risk of discomfort from participation?

There is no discomfort in participating in this research.

What happens if something goes wrong?

In the unlikely event that you are harmed by taking part in this research project, this could be covered under the terms of the accident compensation legislation with its limitations. While a claim may be lodged, it is always up to ACC to accept or decline your claim. If you have any questions about ACC, please feel free to ask the researcher for more information before you agree to take part in this study.

If you have any queries or concerns about your rights as a participant in this study, you may wish to contact the local Health and Disability Services Consumer Advocate:

Telephone: (03) 479 0265 or Freephone 0800 377 766 or
Free fax: 0800 2787 7678 (0800 2 SUPPORT) or
Email: advocacy@hdc.org.nz

If there is a specific Maori issue or concern, please contact
Prof. John Broughton, Assoc. Dean Maori.
Telephone: (03) 479 7639
Email: john.broughton@otago.ac.nz

What specimens, data or information will be collected, and how will they be used?

Measurements of jaw opening force will be collected during your baseline appointment followed by the review appointments at 1, 3 and 6 months. The jaw opening forces will be correlated with subjects without jaw problems. This data will be used in scientific publications and conference presentations.

What about anonymity and confidentiality?

All data collected will be published preserving confidentiality and anonymity. You will be assigned a number code for de-identification purposes and data will be stored in a

password-secured computer. You will receive a copy of a summary of the final report, if you wish. Any publication will be confidential and the details of the individual patients will not be made available to anyone outside the study. You cannot be identified personally from any publication of the study.

If you agree to participate, can you withdraw later?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this *Information Sheet* to keep and be asked to sign a *Consent form*. You are free to withdraw from the study at any stage of the study without having to give any reason. Any previously collected data will be securely stored in a password protected computer. If you decide to withdraw from the study at any time, or decide not to take part in the study, this will not affect you in any way and your normal care will continue.

Who is organising and funding the research

This study is organised by Prof. Paul Brunton, Dean of the Faculty of Dentistry. The study is funded through internal research funds from the Faculty of Dentistry, University of Otago. None of the research team conducting this research will be paid for carrying out the research. You will not be paid for taking part in the study and there are no expenses to be paid for travelling costs to attend for your appointments.

Where can you receive more information?

If you have any questions now or in the future, please feel free to contact either:

Prof. Paul Brunton Position: Dean Department Faculty of Dentistry	Contact phone number: 03 479 7039
Jithendra Ratnayake Position: Assistant Research Fellow Department Sir John Walsh Research Institute	Contact phone number: 0225145892

This study has been approved by the Health and disability ethics committee (HDEC). If you have any concerns about the ethical conduct of the research you may contact the ***Committee through the Human Ethics Committee Administrator (phone +64 3 479 8256 or email gary.witte@otago.ac.nz)****. Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.*

CONSENT FORM FOR PARTICIPANTS

Jaw opening forces in subjects diagnosed with Temporomandibular disorder

Principal Investigator: Professor Paul Brunton (paul.brunton@otago.ac.nz; 03 479 7039)

Please tick to indicate you consent to the following:

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.		
I have been given sufficient time to consider whether or not to participate in this study.		
I know that as a participant I will be required to complete a form with basic personal information and to attend a 20 min session to measure jaw opening forces		
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.		
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.		
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.		
I consent to the research staff collecting and processing my information, including information about my health.		
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.	Yes ☐	No ☐

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	
I understand the compensation provisions in case of injury during the study.	
I know who to contact if I have any questions about the study in general.	
I understand my responsibilities as a study participant.	
I wish to receive a summary of the results from the study.	Yes ☐ No ☐

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:	Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature:	Date: