27 July 2021

Emma Joyce
By email: fyi-request-15926-9b68880a@requests.fyi.org.nz

Dear Emma

I am writing in response to your information request dated 29 June 2021 made under the Official Information Act (Act).

You have asked for:

- Copies of the ethics application and approval for the DentalSlim Diet Control Device; and
- Any correspondence, procedures and policies related to maintaining, monitoring, and sustaining the well-being of persons involved in the trial.

We attach copies of the documents you have requested which include:

- the approved ethics application dated 20 May 2016;
- documents referred to in the ethics application including the Study Protocol;
- approval letter by the Health and Disability Ethics Committee dated 24 July 2016;
- Participant Information Sheet; and
- Consent Form which was provided to each participant.

We note that the following University policies and procedures are relevant:

- Responsible Practice in Research - Code of Conduct (https://www.otago.ac.nz/administration/policies/otago003211.html)
- Research Consultation with Maori Policy (https://www.otago.ac.nz/administration/policies/otago003272.html)
- Guidelines for ethical practices in research and teaching involving human participants (https://www.otago.ac.nz/administration/policies/otago029484.html)

Consistent with section 18(d) of the Act, we have not included a copy of the 7 June 2016 minutes of the Northern B Health and Disability Ethics Committee in which this ethics application was approved. These minutes are publicly available on the Health and Disability Ethics Committee's website - https://ethics.health.govt.nz/about-the-committees/meeting-dates-venues-and-minutes/northern-b-minutes/.

We note that the ethics application was considered in a closed meeting of the Northern B Health and Disability Ethics Committee to protect the intellectual property of the dental device, which included novel and original technology. However, as noted above the minutes of this meeting are now publicly available.

Having given careful attention to public interest considerations in accordance with section 9(1) of the Act, we have redacted some parts of the attached documents where we consider that good reasons exist for withholding information. We consider that these redactions are necessary to protect employees of the University (including employees of organisations working alongside the University in relation to the approved ethics application) from improper pressure or harassment, consistent with section 9(2)(g)(ii) of the Act. These redactions include the names and other identifying details of these individuals that are contained in the attached documents.

We have also redacted the Universal Trial Number as this is confidential. We withhold this information pursuant to section 9(2)(k) of the Act to prevent this information being used for improper gain or advantage.

If you are not satisfied with our response to your information request, section 28(3) of the Act provides you with the right to ask an Ombudsman to investigate and review this response. However, we would welcome the opportunity to discuss any concerns with you first.

Yours sincerely

M. Mendis

Mayhaka Mendis
Manager, Policy and Compliance
Office of the Registrar

Health and disability research

These screening questions will help determine whether HDEC review is required for your study. They are based on the rules contained in section three of the *Standard Operating Procedures for Health and Disability Ethics Committees*.

Don't hesitate to contact us if you'd like help answering these questions, or any others in the HDEC form.

A. Health and disability research

Does your study aim to improve health outcomes, or outcomes for disabled people?

- (•) Yes
- ( ) No

Human reproductive research

B. Will your study involve the creation or use of a human gamete, a human embryo or a hybrid embryo?

- ( ) Yes
- (•) No

Type of study

C. Is your study:

- (•) an intervention study?

In intervention studies, the investigator controls and studies the preventive, diagnostic or therapeutic intervention(s) provided to participants for the purpose of adding to knowledge of the health effects of the intervention(s). Many intervention studies are clinical trials.

- ( ) an observational study?

In observational studies the researcher has no control over study variables, and merely observes outcomes.

Main Criteria

D. Will your study involve **human participants** recruited in their capacity as:

- consumers of health or disability support services, or
- relatives and/or caregivers of consumers of health or disability support services, or
- volunteers in clinical trials (including bioequivalence and bioavailability studies)?

- ( ) Yes
- (•) No

E. Does your study involve the use, collection or storage of **human tissue** (as defined by section 7 of the Human Tissue Act 2008)?

Examples of human tissue include:

- *all or any part of a body*
- *whole human organs or parts of them*
- *human stem cells or other human cells*
- *human blood*
- *human bone marrow*
- *human hair, nails, and skin*
- *human mucus, sputum, or urine.*

◯ Yes

◉ No

G. Will your study involve the use or disclosure of **health information** (as defined by section 4(1) of the Health Information Privacy Code 1996)?

Health information is about identifiable individuals. It includes:

- *information about the health of an individual, including his or her medical history*
- *information about any disabilities that individual has, or has had*
- *information about any health services or disability services that are being provided, or have been provided, to that individual*
- *information in connection with the donation of any body part or any bodily substance of that individual*
- *information derived from the testing or examination of any body part, or any bodily substance of that individual*
- *information about the individual which is collected before or in the course of, and incidental to, the provision of any health service or disability service to that individual.*

◉ Yes

◯ No

H. *You don't need HDEC approval to use health information for research if:*

- *informed consent to this use has already been obtained*
  or
- *the health information won't be disclosed* to researchers in a form that would allow them to identify the individual(s) concerned, or to match the information with other datasets through a non-encrypted identifier (eg, an NHI number).*

Does one of these exceptions to the need to obtain HDEC approval apply to your study?

◯ Yes

◉ No

* See rule 11 of the Health Information Privacy Code 1996.

Exemptions

I. *Exemption for low risk medical devices*

Does your study involve evaluating a low-risk (class I) medical device?

Low-risk (class I) medical devices are defined from page 77 of the Australian Therapeutic Goods Administration's Australian Regulatory Guidelines for Medical Devices.

◉ yes

◯ no

INCLUSIONS

Ma. *Guthrie cards*

Will your study involve the use of human tissue samples (known as Guthrie cards) obtained as part of New Zealand's Newborn Metabolic Screening Programme?

The Newborn Metabolic Screening Programme Policy Framework contains further information on the use of Guthrie cards for research.

◯ yes
◉ no

Mb. *HRC-funded research*

Is your study funded by the Health Research Council of New Zealand (HRC), and unable to be reviewed by an approved institutional ethics committee?

◯ yes
◉ no

Mc. *Tissue banks*

Does your application involve the establishment or maintenance of a tissue bank?

A tissue bank is a collection of human tissue samples stored for potential use in research beyond the life of a specific research project.

◯ yes
◉ no

HDEC REVIEW

O. Your study requires HDEC review

The question below will determine the review pathway appropriate to your study.

Does your study involve any of the following? (select all that apply)

☐ a new medicine
☐ an approved medicine being used for a new indication or through a new mode of administration
☐ a medical device that is or would be classified as a class IIb, class III, or active implantable medical device by the Therapeutic Goods Administration (TGA)
☐ a new surgical intervention
☐ one or more participants who will not have given informed consent to participate
☐ one or more participants who are vulnerable (that is, who have a restricted ability to make independent decisions about their participation)
☐ standard treatment being withheld from one or more participants
☐ the storage, preservation or use of human tissue without consent
☐ Future Unspecified Use of Tissue

☑ none

Exp.

*Your study will be reviewed by the **expedited review** pathway described at section 6 of the Standard Operating Procedures for Health and Disability Ethics Committees.*

a.1 Title and summary

a.1.1.

Short study title: Feasibility study of an oral device to promote weight loss

a.1.2.

Formal study title: Feasibility study of an oral device to promote weight loss

a.1.3. A protocol must be uploaded in the "Documents" tab before submission to an HDEC.

If this protocol has a unique identifier, please enter this below.

Protocol number (if applicable): none

a.1.4. Please provide the dates on which you plan to commence and conclude your study in New Zealand

Planned commencement date: 04/07/2016
Planned conclusion date: 31/05/2017

a.1.5. Please provide a brief, plain English summary of your study.

[< 2000 characters]

The purpose of this study is to test out a new treatment for obesity, which is an increasing health problem in developed countries including New Zealand. People can lose weight if they eat less, but generally people can't stick to a diet for more than a week or two. Increasingly, bariatric surgery interventions are being used to manage obesity in an effort to reduce the risk of other health problems. Bariatric surgery, however, is not suited to all patients and surgical complications are common. This study will test a new way of helping people to eat less and so stick to their diet.
A little device will be fitted to the back teeth of a small number of subjects (n = 10). This device uses magnetic technology to make it difficult to chew. Instead of eating solid food, the subjects will be given a liquid diet. The purpose of the study is test tolerance to the device and to determine what weight loss could be achieved in a four week period. Preliminary trials with removable appliances suggested that weight loss could be of the order of 10% of body weight in 28 days, but the removable nature of the device was problematic. The fixed nature of this new design overcomes this limitation; however, the concept of the device needs clinical validation.

a.1.6. Please provide a brief summary of the main ethical issues that you believe your study may raise.

[< 1200 characters]

There are no real ethical issues here in that treatment to stop patients eating solid food has been provided before in the form of jaw wiring. The treatment being tested here provides for a less interventive, much safer, treatment designed to achieve the same result.

a.2.1. Does your study aim to improve knowledge of:

◯ diagnosis

- ◯ early detection / screening
- ◯ prevention
- ◉ treatment
  - ◯ medicines
  - ◉ devices
  - ◯ surgery
  - ◯ radiotherapy
  - ◯ other:
- ◯ rehabilitation
- ◯ lifestyle/behaviour
- ◯ other:

a.2.1.1. Which of the following best describe your intervention study?

Blinding:	◯ open-label	◯ single-blind	◯ double-blind		
Arms:	◯ two-arm	◯ multi-arm			
Design:	◯ parallel	◯ crossover	◯ dose-ranging	◯ cluster	◯ factorial
Control:	◯ placebo-controlled	◯ active-controlled	◯ uncontrolled		
Randomisation:	◯ randomised	◯ non-randomised			
Aim:	◯ superiority	◯ equivalence	◯ non-inferiority		
	◉ none of the above				

a.2.1.3. Which of the Therapeutic Goods Administration's risk classifications applies to the medical device that you propose to study?

The TGA's risk classifications for medical devices are explained from page 77 of the Australian Regulatory Guidelines for Medical Devices. If you are studying more than one medical device, please select the highest relevant classification

- ◉ low-medium risk (class IIa)
- ◯ medium-high risk (class IIb)
- ◯ high risk (class III)
- ◯ high risk (active implantable medical device)

a.2.2. Please select the ANZSRC field of research that best describes your study from the drop-down menus.

Level 1: 11 Medical and Health Sciences

Level 2: Dentistry

Level 3: Dentistry not elsewhere classified

a.3 Investigators

Co-ordinating Investigator (CI)

The CI has overall responsibility for the conduct of the study, including adherence to established ethical standards.

In student research, the student him- or herself is the CI.

a.3.1. Are you the CI for this study?

- (•) Yes
- ( ) No

a.3.1.1. *The CI must authorise this application (through the "Authorisations" tab) before it can be submitted to an HDEC for review. You should request authorisation once you have completed all questions in the Online Form, or sign this form as the Co-ordinating Investigator in the Authorisations tab.*

Please provide the following information on the study's CI.

Title:	Forename/Initials:	Surname:
Prof.	Paul	Brunton

Mailing Address:	Faculty of Dentistry, University of Otago
Suburb/Town:	Dunedin North
Postcode:	9054
Country:	New Zealand
Organisation:	
Department*:	Sir John Walsh Research Institute
Position:	
E-mail:	paul.brunton@otago.ac.nz
Phone (BH):	[redacted]
Phone (AH)*:	
Mobile*:	
Fax:	

Other Investigator(s)

Other than the Co-ordinating Investigator, Investigators at all localities in a multi-centre intervention study must be listed as Investigators. Supervisors of student research must also be listed as Investigators.

You may list any other Investigators at your discretion.

a.3.2. Will any co-investigators be involved in conducting your study?

- (•) Yes
- ( ) No

a.3.2.1. *You should request authorisation from each Investigator in your study (using the "Authorisations" tab) once you have completed all questions in the Online Form.*

(For each co-investigator:)

Other CI 1

Title: Forename/Initials: Surname:

[redacted]

Mailing Address: Dunedin School of Medicine

Suburb/Town: Dunedin
Postcode: 9054
Country: New Zealand
Organisation: University of Otago
Department*: [redacted]
Position: [redacted]
E-mail: [redacted]
Phone (BH): [redacted]
Phone (AH)*:
Mobile*:
Fax:

Other CI 2

Title: Forename/Initials: Surname:

[redacted]

Mailing Address: [redacted]

Suburb/Town: Dunedin
Postcode: 9054
Country: New Zealand
Organisation: University of Otago
Department*: [redacted]
Position:
E-mail: [redacted]
Phone (BH): [redacted]
Phone (AH)*:
Mobile*:
Fax:

Other CI 3

Title: Forename/Initials: Surname:

[redacted]

Mailing Address: [redacted]

Suburb/Town: Dunedin
Postcode: 9054
Country: New Zealand
Organisation: University of Otago
Department*: [redacted]
Position: [redacted]
E-mail: [redacted]
Phone (BH): [redacted]
Phone (AH)*:

Mobile*:
Fax:

Other CI 4

Title: Forename/Initials: Surname:
[redacted]

Mailing Address: [redacted]

Suburb/Town: [redacted]
Postcode:
Country:
Organisation:
Department*:
Position:
E-mail:
Phone (BH):
Phone (AH)*:
Mobile*:
Fax:

Other CI 5

Title: Forename/Initials: Surname:
[redacted]

Mailing Address: [redacted]

Suburb/Town: [redacted]
Postcode:
Country:
Organisation:
Department*:
Position:
E-mail:
Phone (BH):
Phone (AH)*:
Mobile*:
Fax:

a.4 Primary contact person

a.4.1. Are you the primary contact person for this study?

(•) Yes
( ) No

Title:	Forename/Initials:	Surname:
Prof.	Paul	Brunton

Mailing Address: Faculty of Dentistry, University of Otago

Suburb/Town: Dunedin North
Postcode: 9054

Country:	New Zealand
Organisation:	Faculty of Dentistry, University of Otago
Department*:	Sir John Walsh Research Institute
Position:	Dean
E-mail:	paul.brunton@otago.ac.nz
Phone (BH):	[redacted]
Phone (AH)*:	
Mobile*:	
Fax:	

a.5 Sponsor

The sponsor has overall responsibility for the initiation, management, and financing arrangements of a study.

a.5.1. Which of the following best describe the sponsor(s) of your study?

- ☐ pharmaceutical company
- ☐ medical device company
- ☐ academic institution
- ☐ collaborative research group
- ☐ district health board (DHB)
- ☐ other government agency
- ☐ non-governmental organisation (NGO)
- ☐ other

- ☑ no sponsor

Third party performing sponsor's duties or functions in New Zealand

a.6 Localities and participants

New Zealand

It is a standard condition of HDEC approval that locality authorisation be obtained (through the "Authorisations" tab) ***before a study commences at a locality****. This authorisation confirms that the locality has addressed research governance issues that may arise as a result of the study.*

However, locality authorisation ***does not*** *have to be obtained prior to submission of your application to an HDEC.*

Other organisations involved in studies may prefer or require that their involvement in studies be recorded as an authorisation. You should check with these organisations before proceeding with your study.

Contact details for DHB research offices are available here

a.6.1. At which type(s) of locality do you intend to conduct your study?

- ☐ district health board
- ☐ tertiary education institution
- ☐ primary health care centre

☐ private organisation

☑ other - please specify: University of Otago

a.6.2. Approximately how many participants do you intend to recruit in New Zealand?

10

Other countries

a.6.3. Will your study also involve participants recruited in countries other than New Zealand?

◯ Yes

◉ No

a.7 Prior review

a.7.1. Is this application related to one or more previous applications for HDEC review?

◯ Yes

◉ No

a.7.2. Has an application for this study (or a substantially similar study) previously been declined approval by an HDEC in New Zealand?

◯ Yes

◉ No

a.7.3. Has an application for this study (or a substantially similar study) previously been declined approval by an overseas ethics committee?

◯ Yes

◉ No

a.8 Clinical trials of new medicines

You can apply for HDEC approval and regulatory approval(s) in any order. The PI and study sponsor are responsible for ensuring that all necessary regulatory approvals have been obtained before the study commences.

a.8.1. Is your intervention study a clinical trial of a new medicine (as defined by the Medicines Act 1981)?

◯ Yes

◉ No

a.9 Open/closed meeting

HDECs are public administrative bodies, and their meetings are open to the public. Your study may be reviewed in a closed meeting only if grounds may exist to withhold information about it under the Official Information Act 1982.

a.9.1. Do you want your application to be considered in a closed meeting?

◉ Yes

○ No

a.9.1.1. Please provide reasons, and specify the grounds that you consider may exist under the Official Information Act 1982. to withhold information about your study.

[< 1200 characters]

To protect IP as this is a study testing novel and original technology

a.10 HDEC review preference

b.1 Research should be based around a clear study question that can produce benefits.

b.1.1. Briefly and in plain English, what is the principal study question (hypothesis) that your study will test?
You can refer to page numbers of your study's protocol for further detail if you need to.

[< 2000 characters]

This research aims to test the performance and tolerability of an intra-oral dental device designed to aid in weight loss. The main questions are: 1) Can participants tolerate using the fixed dental appliance for 28 days? 2) What are the main challenges/changes experienced during this period? 3) Can participants achieve a reduction in body weight of 10% or more in 28 days? 4) What is the weight loss achieved in trials longer or shorter than 28 days?

b.1.2. Please briefly describe the scientific basis for your study (including, where appropriate, brief discussion of previous research).
You can refer to page numbers of your study's protocol for further detail if you need to.

[< 2000 characters]

The scientific basis of this study is to prove the concept that the innovative use of magnetic technology can achieve significant weight loss (see protocol).

b.1.3. Please briefly explain how your study will contribute to new knowledge and improve health outcomes.

[< 2000 characters]

This research has the potential to have significant impact on health care delivery in New Zealand by providing a much lower cost, evidence-based, treatment to help effectively manage obesity. It will allow for an adjunctive treatment for obesity available across New Zealand rather than just in specialist centres as it is now. This will have the benefit of reducing health inequalities, particularly amongst disadvantaged groups of the population, and allow for informed changes in national policy around the management of obesity. In addition, significant resources currently being spent on bariatric surgery can be redirected to other priority healthcare areas. Co-morbidities associated with obesity would also potentially be reduced, leading to improved quality of life for obese New Zealanders.

Direct benefits for participants: therapeutic and non-therapeutic studies

b.1.4. *Therapeutic studies are studies that examine interventions or procedures that hold the prospect of direct diagnostic, therapeutic or preventative benefit for individual participants.*

Is your intervention study a therapeutic study?

◉ Yes ○ No

b.1.4.1. Please briefly describe the direct diagnostic, therapeutic or preventative benefits that your intervention study may have for participants.

[< 600 characters]

Increasing bariatric surgery interventions are being used to manage obesity in an effort to reduce the risk of other health problems; however, it is not suited to all patients and with common surgical complications. A new and alternative approach to the management of obesity is needed. The fixed dental device we propose to validate clinically may help promoting significant life-changing weight loss for obese patients.

b.2 Research should be well-designed, so that it can answer the study question.

b.2.1. Please briefly describe and justify the design of your study.

[< 1200 characters]

This is a proof of concept study with up to 10 participants to test the feasibility and applicability of the device prior to more wide scale clinical trials.

b.2.2. Please indicate whether peer review of the scientific and statistical quality of your study has been obtained from one or more of the following.

- ☐ the Standing Committee on Therapeutic Trials (SCOTT)
- ☐ the study's funder (e.g. the Health Research Council)
- ☐ the study's sponsor
- ☑ experts within the research team
- ☑ senior colleague(s) in the field
- ☐ other

b.2.2.1. *Evidence of favourable peer review for this study must be uploaded in the "Documents" tab before submission to an HDEC.*

Please briefly describe the peer review process that has been carried out for your study.

[< 1200 characters]

All members of the research team have reviewed both the study protocol and ethics application.
In addition, two senior researchers were contacted to provide peer review.

b.3 Research should be conducted by an appropriate Principal Investigator, to ensure that the study protocol is respected and followed.

b.3.1. *A CV for the study's Co-ordinating Investigator must be uploaded in the "Documents" tab before submission to an HDEC.*

Please briefly summarise the Co-ordinating Investigator's qualifications and experience relating to conducting studies of this nature.

[< 1200 characters]

Prof. Paul Brunton's qualifications include a PhD at the University of Manchester, MSc in restorative dentistry at the University of Manchester, and BChD from the University of Leeds School of Dentistry. He is also a FDSRCS Rest Dent (Edin), FGDP (UK), RCS (Eng), FDSRCS (Eng).
He is a leading scholar in Restorative Dentistry with research interests in operative dentistry, tooth preparation and

tooth whitening, and the early diagnosis and treatment of tooth wear.

b.4 Where possible, research should generate material that is useful for future research.

Reporting and dissemination of results

b.4.1. How do you intend to report or disseminate the results of your study?

- [x] article(s) in peer-reviewed scientific journals
- [ ] internal reports
- [x] conference presentations
- [ ] publication on website
- [x] other publications
- [ ] submission to regulatory authorities (e.g. Medsafe, TGA, FDA, EMA)
- [ ] other
- [ ] no plans to report or disseminate results

b.4.2. Will any restrictions be placed (for example, by your study's sponsor or funder) on the publication of the results of your study?

○ Yes ◉ No

Future research using data generated in your study

b.4.4.

Might data generated in your study be made available for use in future research?

◉ Yes ○ No

b.4.4.1. *You should explain this clearly to potential participants.*

Which of the following best describes the form in which data generated by your study might be made available to other researchers?

- ○ identified
- ○ potentially identifiable
- ○ partially de-identified
- ◉ de-identified
- ○ anonymous
- ○ other – describe:

b.4.6. ***Intervention studies must be registered prior to commencement.***
Has your intervention study already been registered in a clinical trials registryapproved by the World Health

Organisation?

◯ yes
◉ no

b.4.7. You can obtain HDEC approval prior to registration, as long as you have obtianed a Universal Trial Number (UTN) for your study.

[redacted]

r.1 Risk of physical harm to participants

r.2 Risk of breach of privacy and confidentiality

Before the study

r.2.1. Will your study involve reviewing or screening health information, for example in order to identify potential participants?

The term "health information" is defined in the Health Information Privacy Code
◯ Yes ◉ No

During the study

r.2.2. During your study, who will have access to health information used in your study?

[< 600 characters]

Only the CI and collaborators will have access to health information used in this study.

r.2.3. Please briefly explain how you will ensure the confidentiality of this health information during the study.

[< 600 characters]

Password protection on the computers used in the study coupled with the use of patient identifiers (alpha-numeric codes).

r.2.3.1. Will your study involve the use of surveys or questionnaires?

◯ Yes ◯ No

r.2.3.2. *Copies of these surveys or questionnaires must be uploaded in the "Documents" tab before submission to an HDEC.*

After the study

r.2.4. Which of the following best describes the form in which data generated in your study will be stored after the study has finished?

- ◯ identified
- ◯ potentially identifiable
- ◯ partially de-identified
- ◉ de-identified
- ◯ anonymous
- ◯ other – describe:

r.2.4.1. Please briefly explain your answer above.

[< 600 characters]

All data collected will preserve confidentiality and anonymity. Participants will be assigned a number code for de-identification purposes and data will be stored in a password-secured computer.

r.2.5. *The Health (Retention of Health Information) Regulations 1996 require that **some** health information be retained for a period of ten years.*

For how long will health information generated in your study be stored?
[< 600 characters]

At least 10 years.

Publication of results

r.2.6. Will the results of your study be published in a form that identifies (or could reasonably be expected to identify) individual participants?

◯ Yes ◉ No

r.3 Risks associated with the use of human tissue

r.4 Risk of unexpected clinically significant findings

r.4.1. Might any aspect of your study produce findings that may be both unexpected and clinically significant for participants, donors of existing stored human tissue, or their families?

◯ Yes ◉ No

r.5 Risk of potential conflict of interest

Funding and remuneration

r.5.1. Please briefly describe the main source(s) of funding for your study.

[< 600 characters]

Internal university funding

r.5.2. Does the Co-ordinating Investigator, any Co-Investigator, or any direct member of their families have any commercial interest in the intervention(s) to be studied, or any financial relationship to the study sponsor or funder(s), that may inappropriately influence his or her conduct in the study?

◯ Yes ◉ No

r.5.3. Will the Co-ordinating Investigator or any Co-Investigator be remunerated for their involvement in the study in a way that may inappropriately influence his or her conduct in the study (for instance, bonuses for favourable results or high recruitment rates)?

◯ Yes ◉ No

Health or disability support service providers

r.5.4. Will the Co-ordinating Investigator or any Co-Investigator also be the usual health or disability support service provider for one or more participants in your study?

◯ Yes ◉ No

r.5.5. Will the usual health or disability service provider for one or more participants in your study receive any remuneration (or any other valuable consideration) for referring potential participants to the research team in your study?

◯ Yes ◉ No

Other potential conflicts of interest

r.5.6. Please briefly describe any other potential conflicts of interest that may arise for researchers in your study, and describe how they will be minimised and managed.

[< 600 characters]

None are envisaged

r.6 Risk of stigmatisation

r.6.1. Please briefly indicate whether the results of your study may risk stigmatising individuals or population groups, and if so, how this risk will be minimised and managed.

[< 600 characters]

There are no risks of stigmatisation of individuals or population groups part of this study.

r.7 Risks to researchers and third parties

r.7.1. Please briefly indicate whether your study may pose any significant risks to researchers and/or third parties, and briefly explain how such risks will be minimised and managed.

[< 600 characters]

No significant risks are envisaged

r.8 Summary: the risks of research should be proportional to its expected benefits

r.8.1. Please briefly explain why you consider the risks of your study to be proportional to its expected benefits.

[< 1200 characters]

No significant risks are envisaged and as such, the potential benefits to the study outweigh any risks.
The benefits of the study are in testing the tolerance and comfort of this new treatment method, in addition to

estimating how much weight participants can lose in four weeks. The disadvantages/risks are that participants may feel hungry during the study; and if they attempt to eat solid food there is a risk that they may choke - participants will be shown how to open their mouth in an emergency, if necessary.

Participants should consent to their participation in research.

Consent should be informed by adequate understanding of relevant information.

Consent should be voluntary.

P.4 Population groups, particularly Māori, should be consulted in the design and conduct of research that is of relevance to them.

Consultation with Māori

p.4.1. Please describe whether and how your study may benefit Māori.

[< 1200 characters]

Obesity in New Zealand demonstrates marked social inequalities, with 48% of Māori and 68% of Pacific Islander adults being obese (Ministry of Health 2015). People with less education and lower socio-economic status, especially women, are also more likely to be obese (OECD 2014).Our study will test a much lower cost, evidence-based, treatment to effectively contribute to the overall management obesity. Māori and Pasifika groups will particularly benefit from this approach, as co-morbidities associated with obesity will be reduced, improving quality of life for obese New Zealanders. This can lead to a reduced ongoing need for healthcare in the longer term for the management of chronic conditions associated with obesity such as diabetes and cardiovascular disease, but also to economic benefits as healthier New Zealanders are more productive members of society.

p.4.2. Please identify the main cultural issues that may arise for Māori who may participate in your study, and explain how these issues will be managed.

If Māori will be excluded from participating, please state this. You will be asked to explain your inclusion/exclusion criteria in the next section of the Form.

[< 1200 characters]

Māori participation in this study will follow kaupapa Māori research methodologies, particularly "Te Whare Tapa Wha" model applied to oral health research. [redacted] will help liaise with Māori participants.

p.4.3. According to the Health Research Council's Guidelines for Researchers on Health Research Involving Māori, is formal consultation with Māori required for your study?

◉ Yes ○ No

p.4.3.1. Please either describe your study's consultation process, or explain why you do not consider that formal consultation with Māori is required.

[< 1200 characters]

Consultation was sought and obtained through the University of Otago Ngai Tahu research consultation committee in January 2016.

p.4.4. Does your study involve kaupapa Māori research methodologies?

○ Yes ◉ No

Consultation with other relevant population groups

p.4.5. Will any other population groups be specifically targeted for recruitment into your study?

○ Yes ◉ No

Collection of ethnicity status

p.4.6. Will participants' ethnicity status be collected as part of your study?

◉ Yes ○ No

Community intervention studies

p.4.7. Is your study a community intervention study?

○ Yes ◉ No

f.1 Where possible, research should reduce health inequalities.

f.1.1. Might your intervention study contribute to reducing inequalities in health outcomes between different populations, and particularly between Māori, Pacific peoples and other New Zealanders?

◉ Yes ○ No

f.1.2. Please explain your answer above.

[< 1200 characters]

Obesity in New Zealand demonstrates marked social inequalities, with 48% of Māori and 68% of Pacific Islander adults being obese (Ministry of Health 2015). People with less education and lower socio-economic status, especially women, are also more likely to be obese (OECD 2014).Our study will test a much lower cost, evidence-based, treatment to effectively contribute to the overall management obesity.

f.2 Participants and non-participants should be treated fairly compared to each other.

Impact on health and disability support service provision

f.2.4. Might your study adversely impact on the provision of health and disability services?

○ Yes ◉ No

Best intervention standard

f.2.5. *An intervention study meets the best intervention standard if the intervention(s) in the study are tested against the best proven intervention(s) available outside the study.*
Please explain how your study meets the "best intervention standard".

[< 600 characters]

This is a proof of concept study and an intervention study of the type described will follow in due course.

f.3 Different groups of participants should be treated fairly compared to each other

Post-study access for participants to best-proven intervention

f.3.1. Will all participants have continued access to the best-proven intervention after the end of your intervention study?

◯ Yes ◉ No

You need to explain this clearly to participants.

Equipoise Standard

f.3.2. *An intervention study meets the equipoise standard if the evidence is 'equally poised' as to the overall balance of risks and benefits of each of the interventions offered in the study, so that it cannot be determined in advance which of the groups in a proposed study will be better off.*

Please briefly explain how your intervention study meets the equipoise standard.

[< 600 characters]

This is a proof of concept study. The equipoise standard is relevant to the intervention study that will follow.

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

24 July 2016

Prof. Paul Brunton
Faculty of Dentistry, University of Otago
Dunedin North 9054

Dear Prof. Brunton

Re:	**Ethics ref:**	**16/NTB/89**
	Study title:	Feasibility study of an oral device to promote weight loss

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions:

— Please alter PIS to state that transport costs will be covered, as stated by teleconference during the Ethics committee meeting.
— PIS Page 5, please add extension number (if there is one, for [redacted]
— Consent Form: Please remover superfluous Yes/No boxes.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 23 July 2017.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

[redacted]

[redacted]
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI: Prof. Paul Brunton's CV	1	19 January 2016
CVs for other Investigators: CV for Co-investigator [redacted]	1	19 January 2016
CVs for other Investigators: CV for co-investigator [redacted]	1	19 January 2016
CVs for other Investigators: CV for co-investigator [redacted]	Version 1	14 March 2016
CVs for other Investigators: CV for co-investigator [redacted]	Version 1	14 March 2016
CVs for other Investigators: CV for co-investigator [redacted]	Version 1	15 March 2016
Evidence of scientific review: Peer review 1	Version 1	30 March 2016
Evidence of scientific review: Evidence of peer-review 2	Version 1	26 March 2016
PIS/CF: Information sheet and consent form	Version 2	20 July 2016
Protocol: Study Protocol	Version 4	20 July 2016
Survey/questionnaire: Questionnaire tolerance and acceptability device	Version 2	20 July 2016
Survey/questionnaire: Obesity and quality of life questionnaire	Version 1	20 May 2016
Response to HDEC-Full Review queries	Version 1	20 July 2016

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
[redacted]	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
[redacted]	Lay (the law)	14/12/2015	14/12/2018
[redacted]	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
[redacted]	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
[redacted]	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
[redacted]	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018
[redacted]	Non-lay (intervention studies)	01/07/2015	01/07/2018
[redacted]	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

UNIVERSITY OF OTAGO
INTERIM LOCALITY ASSESSMENT REVIEW TEMPLATE FOR RESEARCH NOT CONDUCTED THROUGH A DHB

*Only use this form for University of Otago applications being sent to Health and Disability Ethics Committees that are **NOT being conducted through a District Health Board**.* If your *research accesses staff, patients or resources of a DHB, contact your campus Health Research Office.*

NOTE: All research proposals using University of Otago controlled or owned localities that are not being carried out in their local DHB must complete this locality assessment template.

PART ONE: UNIVERSITY OF OTAGO PRINCIPAL INVESTIGATOR TO COMPLETE THIS SECTION AND SEND TO CAMPUS HDEC MANAGER/ADVISOR*

**Campus HDEC Managers/Advisors: Dunedin - [redacted] Health Research South, DSM; Christchurch – [redacted] Research Office; Wellington – [redacted] Department of Medicine.*

Full project title	FEASIBILITY STUDY OF AN ORAL DEVICE TO PROMOTE WEIGHT LOSS
University of Otago locality/ies where research will take place	Faculty of Dentistry, University of Otago
Outline of study (Copy and paste research abstract/summary)	This is an open label uncontrolled intervention study of 1200 calorie liquid diet plus an oral magnetic device which is attached to the back 4 teeth to prevent chewing. The aim is to facilitate weight loss of 10% over 4 weeks in participants with BMI >35, aged 20-65 with a healthy mouth and no major contraindication.

Contact Details

Principal Investigator	Title/Name Prof. Paul Brunton Email paul.brunton@otago.ac.nz	Dept Faculty of Dentistry Phone [redacted]
All Associate Investigator/s (copy and paste as required)	Title/Name [redacted] Email [redacted]	Dept [redacted] Phone [redacted]
	Title/Name [redacted] Email [redacted]	Dept [redacted] Phone
	Title/Name [redacted] Email [redacted]	Dept [redacted] Phone [redacted]
	Title/Name [redacted] Email [redacted]	[redacted]
	Title/Name [redacted] Email [redacted]	[redacted]

PRINCIPAL INVESTIGATOR DECLARATION

1. All **regulatory consents** are in place if research involves administration of a new medicine. ☐
2. All **relevant** Departments, Administrators, Health Professionals have been notified about the research ☑
3. Māori Consultation has taken place ☑ (date Feb 2016) **or** is being undertaken. ☐
4. Other requisite cultural requirements have been undertaken. ☑
5. A copy of the full research proposal is attached (incl. budget and funding details). ☑
6. All relevant other documents (eg consent letters) are attached. ☑

P.I.A.R — 8/8/16

PRINCIPAL INVESTIGATOR SIGNATURE — **DATE**

UNIVERSITY OF OTAGO CAMPUS HDEC MANAGER/ADVISOR TO COMPLETE

1. PI/AI details correct	☐	4. Other consultation	☐
2. Regulatory Consents in place	☐	5. Application attached	☐
3. Māori consultation	☐	6. Other documents attached	☐

Name [redacted] *Signature* [redacted] *Date* 31/8/2016

PART TWO: HEAD OF DEPARTMENT TO COMPLETE AND SIGN THIS SECTION

HoD's Declaration

I declare that

- *the Principal Investigator(s) has/have the requisite qualifications and experience to conduct of the study;*
- *the facilities are adequate for the conduct of the study;*
- *the study is supported by the Department.*

Signature:	[redacted]	Date:	12/8/16
Name:	[redacted]	Position:	[redacted]
Comments:	I support this study and facilities are available		

HODs TO SEND HARD COPY TO THE AUTHORISER FOR THEIR CAMPUS

DUNEDIN: [redacted]
CHRISTCHURCH: [redacted] University of Otago, Christchurch
WELLINGTON: [redacted] University of Otago, Wellington

PART THREE: UNIVERSITY OF OTAGO AUTHORISATION

- *I am authorised to complete locality approval on behalf of the University of Otago that the University of Otago location indicated in the proposal is suitable for the purposes of the stated human research.*
- *I understand that I may withdraw locality approval if any significant local concerns arise. I agree to advise the principal investigator and then the relevant ethics committee should this occur.*

Signature:	[redacted]	Date:	31/8/16
Name:	[redacted]	Position:	
Comments:	An interesting & potentially useful study		

NGĀI TAHU RESEARCH CONSULTATION COMMITTEE
TE KOMITI RAKAHAU KI KĀI TAHU

Tuesday, 02 February 2016.

Professor Paul Brunton,
Faculty of Dentistry - Sir John Walsh Research Institute,
DUNEDIN.

Tēnā Koe Professor Paul Brunton,

Dental device alternative to bariatric surgery

The Ngāi Tahu Research Consultation Committee (the committee) met on Tuesday, 02 February 2016 to discuss your research proposition.

By way of introduction, this response from The Committee is provided as part of the Memorandum of Understanding between Te Rūnanga o Ngāi Tahu and the University. In the statement of principles of the memorandum it states "Ngāi Tahu acknowledges that the consultation process outline in this policy provides no power of veto by Ngāi Tahu to research undertaken at the University of Otago". As such, this response is not "approval" or "mandate" for the research, rather it is a mandated response from a Ngāi Tahu appointed committee. This process is part of a number of requirements for researchers to undertake and does not cover other issues relating to ethics, including methodology they are separate requirements with other committees, for example the Human Ethics Committee, etc.

Within the context of the Policy for Research Consultation with Māori, the Committee base consultation on that defined by Justice McGechan:

"Consultation does not mean negotiation or agreement. It means: setting out a proposal not fully decided upon; adequately informing a party about relevant information upon which the proposal is based; listening to what the others have to say with an open mind (in that there is room to be persuaded against the proposal); undertaking that task in a genuine and not cosmetic manner. Reaching a decision that may or may not alter the original proposal."

The Committee notes this is Southern District Health Board research.

The Committee considers the research to be of importance to Māori health.

As this study involves human participants, the Committee strongly encourage that ethnicity data be collected as part of the research project. That is the questions on self-identified ethnicity and descent, these questions are contained in the latest census.

The Committee suggests dissemination of the findings to relevant Māori health organisations, for example the National Māori Organisation for Dental Health, Oranga Niho and to [redacted] and [redacted] who are involved in Māori Dental Health, University of Otago.

We wish you every success in your research and the committee also requests a copy of the research findings.

This letter of suggestion, recommendation and advice is current for an 18 month period from Tuesday, 02 February 2016 to 2 August 2017.

Nāhaku noa, nā

[redacted]

[redacted]
Research Division
Te Whare Wānanga o Otāgo
Ph: [redacted]
Email: [redacted]
Web: www.otago.ac.nz

UNIVERSITY of OTAGO
Te Whare Wānanga o Otāgo
NEW ZEALAND

A FEASABILITY STUDY OF AN ORAL DEVICE TO PROMOTE WEIGHT LOSS

Study Protocol

Research Personnel

Prof. Paul Brunton
[redacted]
Faculty of Dentistry, University of Otago

[redacted] University of Otago

[redacted]

[redacted]

Dunedin, NZ
2016

BACKGROUND

Definition of normal, overweight and obesity

One may define whether a person is underweight, normal weight, overweight or obese, by measuring their height and weight. By dividing the weight in kilograms by the height in metres squared, one may calculate the body mass index (BMI = $\frac{\text{Weight in kg}}{\text{Height in m}^2}$).

People with normal weight have a BMI of 20 to 25, whereas underweight is less than 20. Overweight is defined as a BMI of 25 to 30, whilst obesity is defined when a person present with a BMI of 30 or over. A person with a BMI of over 40 is considered 'morbidly obese'.

Complications of Obesity

Obese people may suffer physical symptoms such as general discomfort, shortness of breath, reduced mobility and pain in the joints. Psychological symptoms may be present, including embarrassment, depression and loss of self-esteem. Obese people may suffer eating disorders, together with stigmatisation and discrimination.

Overweight and obesity are associated with a variety of medical conditions, including diabetes, high blood pressure, elevated blood cholesterol level, risk of stroke and coronary artery disease, osteoarthritis, a disorder of breathing during sleep called 'sleep apnoea syndrome', gallstones, chest disorders and various cancers (Ministry of Health 2015). Both overweight and obese people have a risk of reduced life expectancy. On average, severely obese people die 8-10 years sooner than those of normal weight; every 15 extra kilograms increases risk of early death by approximately 30% (OECD 2014). However, weight reduction may improve life expectancy and also reverse many of the medical conditions that are associated with obesity.

Prevalence

New Zealand and other developed countries are suffering an epidemic of overweight and obesity, with serious health, economic, and social consequences. A 2014 OECD study reported that 31.3% of New Zealanders aged 15 years and over

were obese (OECD 2014), a significant increase from the 17% reported in 2001 (Wilson et al. 2001). New Zealand rates of obesity are only exceeded by Mexico (32.4%) and the USA (35.3%) (OECD 2014). The health care costs of obesity in New Zealand were estimated at around NZ$135 million in the late 1990s (Swinburn et al. 1997). Obesity in New Zealand also demonstrates marked social inequalities, with 48% of Māori and 68% of Pacific Islander adults being obese (Ministry of Health 2015). People with less education and lower socio-economic status, especially women, are also more likely to be obese (OECD 2014).

Treatment Options

Alterations in diet and physical activity are the mainstays of initial treatment. Calorie restriction and increased energy expenditure should be successful, although in many people the effects are either negligible or only successful in the short term, because of poor motivation and brief adherence to lifestyle changes. After successful weight reduction, some people may attempt to prevent weight regain by applying a tight cord around the waist which provides a psychological and physical barrier to this.

A variety of drugs have been tried as adjuncts to diet therapy. Earlier drugs were related to the amphetamine group and had serious side effects, some addictive properties and are not generally used today. More recent derivatives of those drugs have been withdrawn from the market because of potential serious side effects. Drug therapy has only been proven to be helpful in the short or medium, rather than in the long term, and continued drug therapy may not only have side effects, but is also expensive. More recent drug innovations include Orlistat, which blocks fat digestion, and Sibutramine, which promotes a sense of satiety. Both drugs have various contra-indications and side effects. However, once morbid obesity is present, eating habits are firmly established and difficult to change in an environment of plentiful food, exercise is limited by body bulk and drugs and diet will have little effect.

Increasingly, bariatric surgery is being used to treat obesity, with significant cost and a high risk of morbidity. Bariatric surgery, however, is not suited to all patients and surgical complications are common. Although reasonably low, there is a clear mortality risk associated with this surgery. The increasing numbers of bariatric procedures are estimated to reach 200,000 annually in the United States and half a million annually

worldwide (Buchwald et al. 2007). It is estimated that less than 2% of the morbidly obese population are receiving bariatric surgery (Buchwald and Oien 2013). Because there is still reluctance to accept obesity, and even morbid obesity, as a disease entity, the surgery for this problem and its operative mortality are not well accepted by the medical and lay communities. Although metabolic/bariatric surgery plays a major role in the management of the morbidly obese today, it cannot be relied upon to manage the global obesity epidemic. Alternative strategies are required which may obviate surgery, or which reduce weight prior to surgery and so make it easier and safer.

The upper and lower jaws may be approximated by the technique of jaw wiring. Fixing the jaws together prevents the normal intake of food and only liquid is possible. Jaw wiring has been a successful aid to diet therapy, either as a precursor to surgery, or as a true alternative, and studies have shown that it is as effective as surgery in inducing major weight loss (Garrow and Gardiner 1981). Jaw wiring has the advantage that it is non-surgical, no anaesthetic is required and it is relatively non-invasive. Most studies of jaw wiring have only lasted approximately 6 months, and beyond that period success in preventing weight regain has involved the use of a waist cord. Conventional jaw wiring has not been tried in the long term, as it is uncomfortable due to cheek and tongue irritation as well as direct trauma to the gums surrounding the teeth that have been wired. The general discomfort, eating difficulties and bad breath that results from stagnant food debris results in poor long-term tolerance. The wiring severely restricts oral hygiene and the patient's dentition is at increased risk of developing dental decay and periodontal disease. There is also a small risk that patients may choke if they try to eat solid food whilst their jaws were wired, or if they vomit.

Magnetic dental splints

Magnetic dental splints provide a novel approach to the treatment of obesity. They could be used in the short, medium or long term, either continuously or intermittently. The use of magnets and the absence of complete jaw approximation avoid the rare potential hazard of choking on solid food. They make it difficult to chew, but the patient can open the mouth in an emergency with a special tool. These splints allow more effective dental hygiene than can be achieved with wiring. They can be used as an adjunct to other therapy such as dietetic advice, exercise prescription and

drugs, or as a precursor to or an alternative to surgical operations, such as gastric bypass procedures.

Magnetic dental splints could be used to treat many more obese patients than currently done with operative procedures. At present there are long waiting lists in New Zealand for bariatric surgery, and magnetic dental splints provide a realistic, attractive and economic alternative to surgical procedures. They may also be useful for a short period, allowing desired weight loss prior to bariatric surgery. The device could be helpful for short term weight loss with a certain goal, such as in obese patients who require knee or hip replacement surgery, but who will only get their procedure if they lose a defined lower weight.

The Device

Unobtrusive, light in weight and very thin dental bands are fixed to the posterior teeth by a combination of temporary dental cements and a unique locking screw. They are individually made after recording detailed impressions of the patient's jaws and then mounting these on an articulator to study the way the opposing jaws meet. The bands cover the upper and lower back teeth and incorporate titanium magnets and opposing keepers (Figure 1). The magnetic system keeps the teeth tightly opposed making chewing very difficult. However, their configuration maintains the airway, allows speech and feeding using a liquid diet.

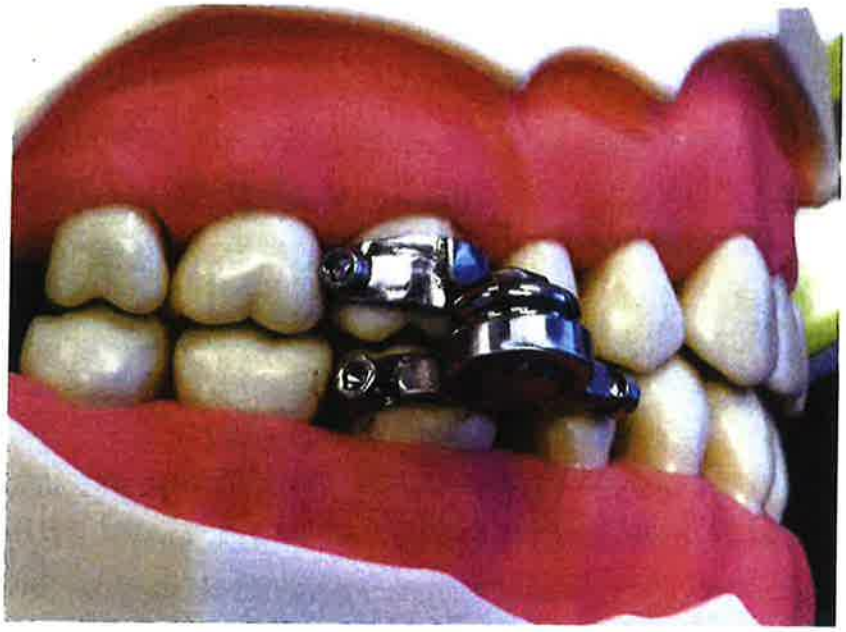

Figure 1: Device composed of metal bands and titanium magnets.

In an emergency, the mouth can be opened by the jaw muscles, aided by a special tool. The splints can be removed by the dentist to allow for dental examinations, maintenance and hygiene treatment.

Aims of the Study

This feasibility study aims to investigate the practicality, comfort, tolerability and safety of an intra-oral device and the magnitude of weight loss achieved during the study period. The expected weight loss over 4 weeks is around 10% of body weight.

Subjects

Ten obese patients will be invited to participate in this study aimed at facilitating weight loss. Patients who require treatment for obesity and are interested in taking part in this project will be recruited from an existing panel of subjects who have participated in research studies previously (*e.g.* The POWER Study, Endocrinology Research Unity, Department of Medicine). These participants represent a relatively balanced potential pool of participants that are representative of the age, gender and ethnicity of those with obesity in the general population in Dunedin. Inclusion criteria include a BMI of over 35, no major co-occurring health conditions that may affect the ability of participating in the study, and a healthy mouth with a sound posterior dentition. Participants using continuous positive airway pressure (CPAP) devices to manage sleep apnoea are not eligible. Males and females aging 20-65 of all ethnicities will be invited to participate. Any patient who is on oral medication that cannot be givein in liquid form; diabetic patients on insulin; and any patient with diabetes on oral hypoglycaemic therapy will be excluded from the study.

Methods

All patients will give informed consent and may withdraw from the study at any time. A dental inspection will confirm each individual's suitability for the study and baseline screening tests will be performed including a medical history, dietary assessment, and measurement of weight and height. Separation elastics, which are commonly used in orthodontics, will be placed to allow for a reversible separation of the teeth. When adequate separation of the teeth is achieved, a dental impression will be

taken to allow for the manufacture of the dental device. The technology consists of a customised device made from components already available commercially but linked by a specifically-designed attachment. This device is cemented to four of the patients' upper and lower teeth. It consists of stainless steel orthodontic-type metal bands wrapped around four posterior teeth. A closed magnet and its keeper are attached to the upper and lower bands, which then restricts mouth opening. A safety-feature allows the disengagement of the device in case of an emergency (e.g. vomiting).

With the device in place, the participant is able to drink and speak normally, but chewing becomes extremely difficult. The magnetic dental splints prevent chewing of food and the patients will be given a liquid diet for 4 weeks. The diet consists of commercially available Fortisip Drinks (Nutricia), a nutritionally complete formula containing essential vitamins and minerals. Fortisip provides 300kcal/200ml bottle. Local dietitians of the Southern District Health Board will supervise and prescribe the liquid diet. Those participants that meet the eligibility criteria will commence a 4 week low calorie diet (LCD) consisting of 1200kcal/day (4 Fortisip bottles per day, plus some extra low calorie liquids such as tea, coffee and diet lemonade). During this 4-week phase participants will see a dietitian on a weekly basis.

During the study, ten participants will receive dental, dietetic and medical supervision before, during and after device placement. Subjects will be reviewed 24 hours and at 3, 7, 14, 21 and 28 days after the device has been placed. The comfort and tolerability of the device will be assessed, together with the resultant weight loss, at each time point. During the feasibility study, qualitative and quantitative data will be collected on: tolerance of the device, effect on oral health, weight loss, and acceptability to patients. These will be assessed using standard and modified Quality of Life (QoL) questionnaires. Data collected will inform further development and modification of the device, if needed. This feasibility study will test the tolerance of the concept of fixed magnetic dental splints as a treatment modality, allowing for further development and application of the technology to a larger study in the future. A 24 hour helpline will be given to all subjects.

Data Analysis

1. Comfort and tolerability of the device will be after four weeks using a visual analogue scale.

2. Dental hygiene assessments will be recorded by the dentist at each visit.

3. Weight will be recorded before and weekly to the end of the study.

4. Body composition will be assessed by electrical impedance.

Data and safety monitoring processes

All data collected will preserve confidentiality and anonymity. Participants will be assigned a number code for de-identification purposes and data will be stored in a password-secured computer. This study will follow standard monitoring practices adopted in similar clinical research at the Faculty of Dentistry of the University of Otago.

References

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Wilson, B. D., Wilson, N. C., Russell, D. G. (2001) Obesity and body fat distribution in the New Zealand population. *The New Zealand Medical Journal*,114(1128): 127-130.

UNIVERSITY of OTAGO
Te Whare Wānanga o Otāgo
NEW ZEALAND

CONSENT FORM

FEASIBILITY STUDY OF AN ORAL DEVICE TO PROMOTE WEIGHT LOSS

Please tick to indicate 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 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.
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.
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.

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: _____

UNIVERSITY of OTAGO
Te Whare Wānanga o Otāgo
NEW ZEALAND

PARTICIPANT INFORMATION SHEET

FEASIBILITY STUDY OF AN ORAL DEVICE TO PROMOTE WEIGHT LOSS

Invitation to take part

You are being invited to take part in a research study. Before you decide to take part, it is important for you to understand why the research is being done and what it will involve.

Please take time to read the following information carefully. Please discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

This study will try out a new treatment for overweight people. People can lose weight if they eat less, but most people can't stick to a diet for more than a week or two. This study tries out a new way of helping people to eat less and so stick to their diet. The idea is to use a very thin, lightweight device which fits over your back teeth. The little device fits over the upper and lower back teeth on both sides of the jaw. Each one contains tiny magnets, so that when you close your mouth, the magnets make it very difficult to chew (Figure 1). Instead of eating solid food, you will be given a liquid diet. This liquid diet is low in calories and so you should lose weight.

With the device in place you will be able to talk, drink, swallow, and breathe easily, but opening and closing your mouth, and so eating solid food, will be quite difficult. You will be able to open your mouth in an emergency and you will be shown how to do this.

A dentist will examine your teeth to see if they are suitable for you to wear the magnetic device. If you are suitable, the dentist will make the device to fit the shape of your teeth.

The main aim of the study is to see how you tolerate wearing the device and how comfortable it is, and how much weight you can lose in four weeks.

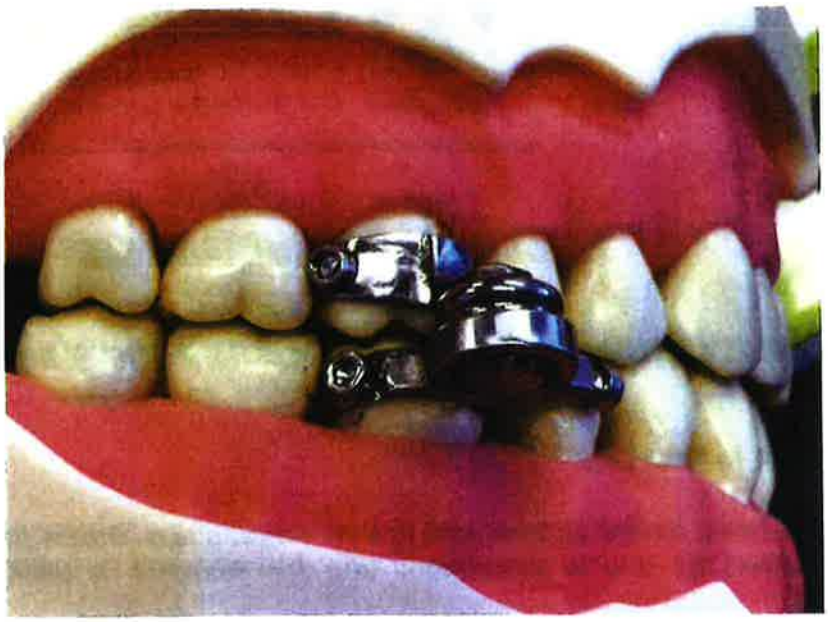

Figure 1: Device composed of metal bands and titanium magnets.

This study lasts four weeks. During that time, we will see if the bands are comfortable and if you find them acceptable as a treatment for losing weight. If you are happy with wearing the splints and you have started to lose weight, then you may be approached to carry on wearing the device for longer periods in future studies.

Why have I been chosen?

You have been chosen because losing weight would be helpful for your overall health. You should take part in this study if you have had difficulty in losing weight with diets in the past.

Do I have to take part?

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. If you decide to take part you are still free to withdraw from the study at any time and without giving your reason. 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.

What will my participation in the study involve?

Your teeth will be examined by a dentist to see if you are suitable to take part in this study. If your teeth are suitable, then the dentist will make the devices to fit your teeth. The devices will be applied so that you will find it difficult to chew and eat solid food. A dietitian will give you advice about a liquid diet, which you will be able to take and swallow easily. This liquid diet will be low in calories and so you should lose weight. The liquid diet will be provided to you for the duration of the study at no cost. The study will last for one month. During this time, you will be monitored by the research team at

24h, 3 days, 7 days, 14 days, 21 days and 28 days after device placement, and will be requested to fill in questionnaires about your experience with the device and the impact of weight on your quality of life. Some of these questions might be personal/sensitive.

At the end of four weeks, you will be weighed and your teeth inspected. You will be monitored for one year by the study multidisciplinary team to assess if the weight loss has continued or not, and if it has had any impact in the your eating habits and lifestyle. This monitoring involves phone calls and a visit to the study team after one year.

If you agree to take part in the study, you must agree to stick to the liquid diet while you are wearing the magnetic devices. If you try to eat and chew solid food, there is a chance that you could choke. If you do choke, you will be able to open your mouth and we will show you how to do this if there is an emergency. You must also agree to attend the clinic when requested for a checkup. Your transport costs will be covered for these visits.

All the participants in this study will try the device and your weight before and after taking part will be compared.

What do I have to do?

You must follow the diet advice that you are given and stick to the liquid diet. You must not take any solid food whilst you take part in the study. If you are on tablet medication, then this needs to be discussed with the doctor supervising the study, so that suitable medication is provided. You may need to crush your tablets or we may need to supply a liquid medication instead of tablets.

Explanation of the procedure that is being tested

This study will try out a magnetic device to make it difficult for people to chew, compared with being on their usual diet for weight reduction. In the past, people have had their jaws wired together to help them stop eating. Jaw wiring is a very effective way of losing weight, but it may be uncomfortable and cleaning your teeth can be difficult. The magnetic device tried in this study should be so comfortable so that you can't notice it is there, and you should be able to clean your teeth.

You also will be given a card stating that you are in a study of a new treatment for weight loss which gives the telephone details of the doctors supervising the trial.

Alternative treatment

Instead of using the magnetic device, you could have tablets to help you lose weight, or have an operation to staple and reduce your stomach, which means that you can only eat smaller meals.

What are the potential disadvantages and risks of taking part?

You may feel hungry on the liquid diet while you lose weight.

The device may feel uncomfortable and if it is, then you will need to have it adjusted by the dentist supervisor of the trial.

If you attempt to eat solid food there is a risk that you may choke. If you are sick, there is a chance that some vomit could go in your windpipe and cause choking. You will be shown how to open your mouth in an emergency, if necessary.

You may withdraw from participation in the study at any time and without any disadvantage to yourself.

How do I open my mouth in an emergency?

You may feel the need to open your mouth in an emergency, for example if you feel sick. You may be able to open your mouth if you try very hard with your jaw muscles. You can help by pulling your mouth open by holding your nose and your chin. You will also be given a metal tool to aid device opening, like a shoe horn, and be shown how to use it.

When the magnets are fitted, the dentist will make sure that you can open your mouth for emergencies.

EMERGENCY TELEPHONE NUMBER:

PROF. PAUL BRUNTON
Office - Faculty of Dentistry, University of Otago
9.00am – 5.00pm Monday - Friday
[redacted]

Mobile: [redacted] **24 hours**

What are the possible benefits of taking part?

We hope that this treatment will help you and that you will lose some weight during the study.

What if new information becomes available?

While you take part in the study new information could become available about your treatment. You will be told if this happens and you will always have the choice of leaving the study at any time. If you leave the study, your normal care will continue. If you continue with the study, you will be asked to sign an updated consent form. If some new information becomes available, your research doctor may advise you to leave the study in your best interests. Any reasons for doing this and arrangements will be explained to you.

What happens when the research study stops?

At this stage, it is not intended for anybody to use the dental device for more than four weeks at a time. If you wish to continue for longer than four weeks, you could be entered in a further follow up study.

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 [redacted]
Telephone: [redacted]
Email: [redacted]

Will taking part in the study be kept confidential?

If you consent to take part in this research study, your medical records will be inspected by the doctors and dentists conducting the study. If you take part, then this is confidential and no one else will know apart from you, the study doctors and dentists, and your GP will be informed. The fact that you are taking part in the study will be in the hospital notes and any other hospital doctor that needs to know this will be able to see this in your notes. The normal rules of Health Service confidentiality apply to this study.

When the project is completed, all personal identifying information will be removed from the paper records and electronic files which represent the data from the project. Paper records will be kept in locked cabinets. Electronic data will be stored on a password secured computer stored at the Faculty of Dentistry. The computers will be contained within locked rooms, in alarm activated area of the respective buildings. Data collected during the duration of this study will be stored for at least 10 years.

What will happen to the results of the research study?

If the research study shows a positive result, then the researchers will hope to publish the results in an appropriate journal within 12 months of the end of the study. All patients who take part in the study will be told the eventual results. Any publication will be confidential and the details of individual patients will not be made available to anyone outside the study. You cannot be identified personally from any publication about the study.

Who is organising and funding the research?

This study is organised by Prof. Paul Brunton, Dean of the Faculty of Dentistry, [redacted] and [redacted]
The work on this study has been financed by the Faculty of Dentistry and other grants. None of the doctors or dentists 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 to you for travelling costs for you to attend for your appointments.

Contact for further information

If you require any further information then please feel free to discuss this with Prof. Paul Brunton at the Faculty of Dentistry, University of Otago, telephone [redacted]

You will be given a 24 hour helpline number in case of problems.