

**Participant Information Sheet**

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| **Study title:** FastFX vs Optifast for Low Energy Meal Replacement with Intragastric Balloon Insertion: A Randomised Doubled Blinded Trial. |  |

**Locality**: Macmurray Gastroenterology and Endoscopy Center. 3 Macmurray Rd, Remuera, Auckland 1050

**Lead investigator**: Dr Alasdair Patrick

**Ethics Ref No: TBA**

You are invited to take part in our study which aims to compare two different types of meal replacement prior to the placement of your weight loss balloon.

The decision to participate in this study is your choice. If you do not want to take part, it will not affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you’d like to take part. It sets out why we are doing the study, what your participation would involve and what the benefits and risks to you might be. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, wh*ā*nau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 4 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

**What is the purpose of the study?**

Diet is an important part of the weight loss journey which you are undertaking. We know that meal replacement items help to improve weight loss by removing choices, controlling portions and providing fullness at lower calorie intakes.

Currently, prior to the placement of the balloon, patients are asked to replace meals for 1 week with Optifast, which is a liquid shake taken 3 times per day as meal replacement. We would usually follow-up with regular meetings with our dietician to see how you are progressing.

At MacMurray, we have developed a new meal replacement containing pea-protein.

We are running a trial to see which meal replacement is most effective, or if they are both the same.

**What will my participation in the study involve?**

You have been chosen to participate in this study because you are receiving a weight loss balloon and meal replacement to try and lose weight.

Usually, prior to our patients having their balloon placed, they will start a meal replacement plan in conjunction with our dietician to assist with weight loss. In this study, we are comparing two different types of ‘shakes’ as meal replacement for 2 weeks prior to balloon insertion.

You will be randomly selected into one of the two groups. As your health professionals, we will not know which group you are in. All other follow-up appointments and measurements we do are exactly the same. Every 3 months we will measure your weight loss to see if there is a difference between the two meal replacements.

At the conclusion of the 2 weeks, you will be asked to fill out a questionnaire as to your thoughts on taste, satiety (how full it made you), mood, cravings.

Any information collected for this study will be strictly anonymous.

**What are the possible risks of this study?**

Risks of participation in this study are very small. Allergy to contents of the meal replacements will be checked prior to participation.

**Who pays for this?**

This study is funded in partnership between the MacMurray Centre and HeathFx. The owners of the MacMurray Centre (including lead study investigator Dr Patrick) also have a financial shareholding in HealthFx.

**What are my rights?**

Participation in this study is entirely voluntary. You are free to decline or withdraw from participation at any time without any disadvantage to your usual healthcare. Any medical information collected will be destroyed after 10 years.

All medical information collected will be strictly anonymous and will be stored electronically on a secure network for approximately 10 years. Access to this information will be limited to study investigators only.

You are entitled to receive a summary of your results if you wish.

If you were injured in this study, which is extremely unlikely, you would be eligible to apply for

compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

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

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

Michelle Ford or your Balloon-inserting Gastroenterologist

Maori health support:

If you require Māori cultural support talk to your whānau in the first instance. Alternatively you may contact Michelle.

If you want to talk to someone who isn’t involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz



**Consent Form**



**Please tick to indicate you consent to the following**

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| --- | --- | --- |
| I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.  | Yes □ | No □ |
| I have been given sufficient time to consider whether or not to participate in this study. | Yes □ | No □ |
| 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. | Yes □ | No □ |
| 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. | 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. | Yes □ | No □ |
| I agree to study investigators accessing my medical records and results for purposes related to this study. | Yes □ | No □ |
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**Declaration by participant:**

I hereby consent to take part in this study.

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| 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.

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| Researcher’s name: |
| Signature: | Date: |