

SCIENTIFIC PEER REVIEW:

Date 12/03/2020

Research Title: FastFx vs Optifast for Low Energy Meal Replacement prior to Intra-gastric Balloon insertion: A Randomised Doubled Blinded Trial


Co-coordinating Investigator: Catherine Patrick, Dr Cameron Schauer, Dr. Alasdair Patrick

Peer Reviewer Name: Dr Anurag Sekra

Peer Reviewer Position: Consultant Gastroenterologist & Interventional endoscopist, Middlemore hospital

Independent from study? Yes

Peer Reviewer signature:



Recommendation: Approve / Revise minor / Revise major / Decline

REVIEW GUIDELINE	GUIDELINE PROMPTS	COMMENTS
Relative merit of the research	<ul style="list-style-type: none"> • Important, worthwhile and justifiable. • Addresses a health issue that is important for health and/or society. • Aims, research questions and hypotheses build on and address gaps in existing knowledge. 	<p>About 65% of NZ adult population are either overweight or obese. It has resulted in a number of adverse outcomes including diabetes, hypertension, Obstructive sleep apnoea etc which strains healthcare system significantly. With increasing prevalence of obesity in our community it is vital that non-invasive interventions to tackle obesity are employed which will reduce both morbidity and mortality associated with obesity.</p> <p>The aim of this study is to compare FastFx low energy meal replacement with Optifast low energy meal. A low energy meal is commenced one week prior to insertion of intra-gastric balloon to optimize weight loss. Currently the group is using Optifast for this purpose. The group has hypothesized that due to presence of a plant based protein in the FastFx it has lower potential for allergies, it has better taste and it induces satiety. This would potentially mean more weight loss in this group as compared to Optifast pre balloon insertion.</p>
Design and methods	<ul style="list-style-type: none"> • Quality of study design • Robustness of the methods used. • Includes a description of sample recruitment and characteristics (including number, gender and 	<p>This is a sponsor initiated, single centre prospective, double blinded 1:1 randomized trial. Patients will receive meal replacement in single serve plain snap lock bags with instruction only. The data will be collected prior to intervention (commencement of meals) and post intervention. A questionnaire will be given to the patients</p>

	<p>ethnicity where relevant) proposed methods of data analysis.</p> <ul style="list-style-type: none"> • Timelines for the research included 	<p>to assess satisfaction with the diet. The study design is sound.</p> <p>The statistical analysis planning is robust and will be using SAS version 9.4 which is a robust programme. It is a non-inferiority study.</p> <p>Minimum of 56 participants (28 in each group) are required.</p> <p>The timeline is one year.</p>
Feasibility of the research	<ul style="list-style-type: none"> • Overall strategy, methodology and analyses are well reasoned and appropriate to achieve the specific aims of the project. • Likely to improve scientific knowledge, concepts, technical capacity or methods in the research field, or of contributing to better treatments, services, health outcomes or preventive interventions. • Achievable within the specified timeframe • Researcher/research team has the appropriate experience and expertise. 	<p>The research is feasible. The methodology and data collection utilise existing data points that are available as part of standard care for patients. The number of team members and various roles means that there should be no issue capturing these data points.</p> <p>The research team has appropriate experience. All the dietitians participating in the trial have a specific interest in obesity management.</p> <p>Macmurray team performs about 100 intragastric balloon procedures per year and the number of participants required should be recruitable in this time period.</p> <p>The outcomes of the research will improve our knowledge of plant based protein tolerability and weight loss results from that.</p>
Reviewer Independence /objectivity	<ul style="list-style-type: none"> • Peer review is considered free of bias, equitable and fair. • Objectivity can be compromised if peer reviewers have conflicts of interest, and so appropriate peer reviewers typically will not be materially connected to the researcher(s) in a way that might undermine objectivity, and be free from either positive or negative inducements. • If the peer reviewer is connected to the study please explain what measures are taken to mitigate conflict of interest. 	<p>I am independent to this study and I have no connection with FastFx group. I will be one of the endoscopists performing the procedure but outcomes of weight loss pre balloon are independent of outcomes post intragastric balloon insertion.</p>
Other comments	<ul style="list-style-type: none"> • Any reviewer observations that are not covered in the points above. 	<p>The data from this study will serve as a platform for future studies.</p>