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A feasibility study to investigate the effectiveness and
safety of an intermittent fasting diet for weight
reduction in adults with Type 2 Diabetes treated with
insulin

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Abstract

Background: Type 2 diabetes (T2DM) is the most common form of diabetes. Obesity is associated with both the development of T2DM and also the development of the complications of diabetes; increasing health care costs and morbidity and mortality. Weight loss and control of blood glucose levels should be managed with a tailored eating plan developed in negotiation between the person with diabetes and their health care team. It is essential that health care professionals are familiar with different strategies that achieve weight reduction, glycaemic and cardiovascular risk reduction goals. One emerging weight reduction strategy is fasting diets. There is currently a gap in the knowledge of whether fasting diets are an effective and safe weight reduction strategy for people with T2DM on insulin.

Aim: To investigate the effectiveness and safety of an intermittent fasting diet (two day per week) as an alternative to standard dietary advice (portion control diet) for weight reduction in obese adults with insulin dependent T2DM attending a 12-week group based intervention at Waitemata District Health Board (DHB).

Methods:

Obese patients with T2DM treated with insulin who were attending Waitemata DHB Diabetes Service were recruited for this two arm open-label design intervention feasibility study. Both dietary strategies were implemented during a 12-week intervention at which participants received monthly dietitian-led group education and support. The intermittent fasting diet (IFD) intervention (n=8) investigated was a two day per week reduced energy intake (550-650kcal / 2300-2700kJ per day) and five days' usual intake making low fat choices. The portion control diet (PCD) was the comparison group (n=7) and focused on daily energy restriction through reduction in portion sizes and low fat food choices in line with current New Zealand dietary recommendations for management of T2DM.

Results: Similar weight loss was achieved in both groups (IFD: 2.7 ± 3.0 kg, PCD: 1.7 ± 2.5 kg). This reduction was not significant between groups. There was a significant difference between groups in reduction in HbA1c. ($P=0.003$) (IFD: -11 mmol/mol, PCD: -3 mmol/mol). This decrease was significant in the IFD group only ($P=0.018$). Reported hypoglycaemic events were low in both groups (8 events in IFD; 21 events in PCD). Non-significant between group reductions in waist circumference ($P=0.402$), waist: height ratio ($P=0.455$), diastolic ($P=0.189$) and systolic blood pressure ($P=0.443$) were observed. Lipid profile remained stable in both groups.

Conclusion: This feasibility study showed that an intermittent fasting diet can achieve similar weight loss to current standard practice dietary advice in people with T2DM. However, it is the significant reductions in HbA1c compared to a daily energy restriction diet over a three-month period seen in this study that warrant further investigation. With education from health care professionals and modification of insulin on pre-fasting and fasting day this diet may be followed safely and hypoglycaemia avoided or managed appropriately.

Acknowledgements

There is a story behind this thesis which may help to put in to context the practical nature of this research. Bear with me. Thirty years ago this year (2016) I was diagnosed with Type 1 Diabetes. Aged 13 and within five days of my diagnosis I had mapped out my career as a Dietitian. This year is also the 22nd anniversary of graduating from Queen Margaret College (now University), Edinburgh with a Bachelor of Science degree in Dietetics. When I was diagnosed with diabetes I was fortunate that neither my parents nor health care team put restrictions on what I could or could not achieve. I feel fortunate that I have travelled the world, had many adventures, run many half-marathons, and have two wonderful daughters, a husband and my health. So, when faced with people who try and tell me that I can't do something just because I have diabetes I don't often believe them. And this is the case with this research. I still have the original Radio Times magazine article about a Horizon documentary that my mother sent me from Scotland. The documentary was about a Doctor, a health journalist, who investigated intermittent fasting because he had been diagnosed with pre-diabetes. Mum wanted to know my opinion. In my investigations I came across many people telling me that people with diabetes on insulin shouldn't fast. Yet I knew that personally I had fasted safely, and professionally I had worked with people who had fasted. Meanwhile, in an office at the hospital I worked at, Dr Catherine McNamara, Consultant Endocrinologist had also heard about intermittent fasting. More than that, she had read the book and the research and was intrigued as to whether it would be of benefit to her patients with Type 2 Diabetes who needed to lose weight. People were asking about this diet in clinics. Together we came up with the research study that is presented here as my MSc thesis. Living and working with diabetes there is one thing that has come up time and time again, and that is there are no set rules when it comes to diabetes. Trying to fit the condition(s) that are labelled as diabetes in to neat boxes does not work, because blood glucose is affected by so many things. People with diabetes tend to have multiple diagnoses and multiple stresses. It was important to keep this research as practical and "real life" as possible, whilst making sure that the results were still meaningful. It seems fitting

that my dietetic career started with a diagnosis of diabetes, and here I am concluding my academic studies with research to help people with diabetes.

I would particularly like to thank the participants of this study. Without you we wouldn't have the knowledge that we now have about this type of dietary intervention. We recognised that diabetes is a condition that takes up a lot of time, effort, brain-power and emotion. Adding a dietary intervention that is slightly out of the box on top of that, I am very grateful for you for spending that extra time and effort to take part in this dietary intervention. Thank you to the staff at the Diabetes Service, Waitemata District Health Board for your support, advice and enthusiasm in helping to recruit and run this study. Especially Eirean Gamble, Diabetes Dietitian Team Leader whose feedback and support was invaluable, and Dr Catherine McNamara, Consultant Endocrinologist who identified the need for this study and provided medical support and input to the study.

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List of Abbreviations

ADF	Alternate day fasting
BP	Blood pressure
DSME	Diabetes self-management education
GP	General Practitioner
IF	Intermittent fasting
IFD	Intermittent fasting diet
OHA	Oral hypoglycaemic agent
PCD	Portion control diet
SMBG	Self-monitored blood glucose
T2DM	Type 2 Diabetes