

Title: Pragmatic management of low energy diets in people with type 2 diabetes in primary care: a decision aid for clinicians.

Short title: Decision aid for pragmatic management of low energy diets for type 2 diabetes

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Word count: 1181

Acknowledgements: We acknowledge the University of Newcastle, University of Glasgow, Oxford University, and Imperial College London, and in particular Prof Roy Taylor and Prof Mike Lean, who have led the advancement of type 2 diabetes remission research.

Main Text:

### ***Application of energy restriction diets for type 2 diabetes remission***

Significant weight loss at a level to achieve remission in the short-term has been achieved through total dietary replacement or a low energy diets (1–3). These aim for an energy restriction between 800-1600kcal/d, and could achieve 15% weight loss in 8-12weeks (4). This is distinct from a very low energy diet of less than 800kcal/d (5). As observed by Astbury et al (2019) combinations of food, meals and meal replacement products are all effective at achieving a significant level of weight loss in this time (2). Analysis of the pragmatic intervention utilised in the Diabetes Remission Clinical Trial (DiRECT) indicates that it is a safe and cost effective strategy and appears to result in sustained weight loss in some cases (6).

Doctors in primary care are at the frontline in obesity and diabetes management, and ideally placed to facilitate a person-centred approach to achieve weight loss (7). Multidisciplinary primary health care teams are increasingly encountering informed individuals embarking upon their own versions of the “remission” diet or commercial programmes, following the success and media attention of remission studies. Health care professionals should be confident to medically manage and support motivated people to achieve weight loss safely. The observed self-determination for people to try to achieve remission and follow a low energy diet can be supported through primary care and fits with the model of person-centred care. To support clinical practice and management there is now a consensus statement defining remission and outlining an approach to monitoring (8). With this in mind we designed a clinical decision aid for clinicians before, during and after a low energy diet.

### ***Clinical decision aid***

This aid was developed by clinicians and researchers at the Leicester Diabetes Centre as part of safety protocol development for people with type 2 diabetes participating in low energy diet studies. It has been piloted and repeatedly modified as a component of the adverse events reporting process of our research work and has been used in local clinical practice. It was originally developed for clinicians as an aid for safe insulin dose adjustment as neither DiRECT (9), or subsequent studies,

such as the primary care Doctor Referral of Overweight People to a Low-Energy Treatment (DROPLET) study (3), had recruited patients on injectable therapies. The tool was subsequently expanded and includes advice on other glucose lowering medications lipid and blood pressure lowering agents. It reflects our clinical opinion and experience and does not claim to be evidence based or superior to other practice.

In counselling a person considering a low energy diet we note that it is most effective as part of a multicomponent approach including behaviour change. We also acknowledge that low energy diet research is not as yet generalizable, and there are gaps in knowledge regarding application and impact in ethnic populations and wider health implications (10). Suggested management may not be suitable for all so clinicians are advised to adopt an individualised approach and seek expert advice where uncertainties arise.

**Steps 1-3 (Fig 1)** should be consulted preceding the diet (confirmation of diagnosis, HbA1c check, and diabetes duration). **Step 4 (Figs 2-3)** adapting current treatment regimen, has recommendations before, during and following the diet.

### ***Step 1: Confirm diagnosis of type 2 diabetes***

Due to misclassification, caution is required to exclude people with type 1 diabetes. In most cases this will be straightforward after review of the clinical history, however if there are doubts we recommend seeking expert advice before proceeding.

### ***Step 2: Glycated haemoglobin (HbA1c) check in the last three months***

The upper glycaemic threshold for inclusion in the DiRECT study was 12% or 108mmol/mol (11). Patients commencing a low energy diet who have very poor glycaemic control will inevitably experience a significant reduction in carbohydrate intake and plasma glucose concentration. Very rapid improvement in diabetes control has been linked to microvascular complications particularly retinopathy, gastrointestinal disturbances and constitutional upset especially in people taking insulin (12). Whilst there is no evidence *per se* that glycaemic improvement associated with short term use of low energy diets can precipitate or worsen pre-existing microvascular disease, we pragmatically suggest attempts are made to improve control as a precursor to joining a programme if the HbA1c is >10% or 86mmol/mol.

### ***Step 3: Diabetes duration***

The DiRECT study used a diabetes duration threshold of 6 years or less as this was calculated to be the period beyond which remission was less likely (11). It is important to manage expectations about the potential benefits weight loss will bring; such as reducing long-term cardiovascular risk, improving mental health and quality of life, as well as day-to-day glycaemic control. Managing expectations will be important, but it is anticipated clinicians will want to encourage people to lose weight and not discourage them from attempting the diet. Therefore we have included some recommendations for people with a longer duration of diabetes within this document. We emphasise that evidence based outcomes are unclear for such people and recommend that this is discussed before embarking upon the diet. These people are likely to need additional support and monitoring through the process.

#### ***Step 4: Adapting current treatment regimen (Figs 2-3)***

Due to the significant impact of an acute energy restriction, such as a low energy diet, response in both blood pressure and blood glucose can be dramatic in the first few days and weeks. Blood lipids will also respond over the duration of the diet, and require timely treatment adaptation.

**Prior** to starting a dietary regimen we recommend referring to the clinical decision aid pathways (Figure 2 and 3) to manage medications for:

1. Oral glucose lowering agents
2. Injectable glucose lowering therapies (with and without oral therapies including insulin and GLP-1 RA)
3. Lipid modification
4. Anti-hypertensive medications

#### ***Monitoring & hypoglycaemia (Fig 4)***

Our observations from practice and previous research have highlighted the need for monitoring throughout the diet, which can be achieved through a combination of reported self-monitoring, and clinical review. Timely management can ameliorate the well documented transient side effects of low energy diets, such as constipation, fatigue and headache (10). Responsive adaptation of the medication plan can help avoid and manage hypoglycaemic events for those prescribed insulin and sulphonylureas, whilst efficient supported reintroduction of treatments can optimise care in the post-diet period. Throughout the process we recommend referring to the ADA/EASD consensus report for treatment intensification for clinical safety and monitoring guidance (13). Capillary glucose self-monitoring should be performed during the dietary and food reintroduction phases, or where available, continuous glucose monitoring.

#### ***Conclusion***

Low energy diets are an increasingly popular weight management option, leading to significant health benefits and reduced medication burden for people with type 2 diabetes. It is therefore likely, and has been observed, that many people will want to attempt this type of diet. Here we present a practical tool for health care professionals in the delivery of a low energy diet for people with type 2 diabetes. It reflects our clinical opinion and experience and does not claim to be evidence based or superior to other practice, and may not be suitable for all .

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Tables: None

Figure Legends:

Figure 1: Pre-diet clinical decision aid.

Figure 2: Treatment modification for oral glucose lowering agents, and injectable glucose lowering therapies (with and without oral therapies including insulin and GLP-1 RA).

Figure 3: Treatment modification for lipid modification, and anti-hypertensive medications.

Figure 4: Hypoglycaemic management.