

LEVEL 6 ASSESSMENT SPECIFICATION

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The effect of Low-Carbohydrate Diet on Glycaemic control in service users with type 2 diabetes.

Abstract

Intermittent fasting and carbohydrate-restricted diets are rapidly gaining popularity among the general public and people who suffer cardiometabolic diseases like obesity, diabetes, and hypertension (Tay *et al.*, 2015). There are, however, few professional advice for these diet plans and their outcomes. The objective of this study was to assess the strength of the scientific data about the advantages and disadvantages of carbohydrate-restricted diets in order to provide sound recommendations.

Aim

To conduct a comprehensive review and meta-analysis to assess the efficacy of carbohydrate restriction on glycemic control in people with Type 2 diabetes.

Introduction

Diabetes is a prevalent, fatal, and costly medical illness (Dyson, 2015). According to estimates, diabetes affects one in every eleven persons worldwide, accounts for 11% of annual fatalities, and has a direct economic impact of £570 billion (Dyson, 2015). Diabetes is a health condition in which elevated levels of glucose are found within the blood stream. There are two types of diabetes; Type 1 diabetes is an autoimmune disease which has a sudden onset, which is not caused by diet or lifestyle choices, whereby the onset of Type 2 Diabetes is gradual and less severe and differently to Type 1, is heavily influenced by diet and lifestyle choices (Bolla *et al.*, 2019).

When Glucose is attained from the diet, it is released into the blood stream, at which stage the glucose is used for energy. Those with diabetes cannot access the glucose of energy; causing the glucose to remain in the blood stream causing high blood glucose levels, also known as hyperglycaemia. Prolonged hyperglycaemia can cause irreversible damage to the kidneys, heart and eyesight (Bolla *et al.*, 2019).

Individuals with Type 1 diabetes are unable to produce any insulin in the pancreas, making it an impossible task for the body to access glucose to use for energy. This is where the concern of Diabetic Ketoacidosis can occur, as the body's reaction to the lack of energy forces the break down of fat; releasing fatty acids called ketones into the bloodstream (Franz *et al.*, 2017). This is a life-threatening consequence of poorly managed, or undiagnosed Type 1 diabetes (Franz *et al.*, 2017).

The opposed version of Diabetes is Type 2, this is characterised by which the pancreas does not work adequately to supply enough insulin, as a result of this, the body's response is to signal the pancreas to release further insulin causing the pancreas to work tirelessly to excrete the insulin, resulting in high levels

in the blood stream causing insulin resistance, causing damage to the pancreas due to the added pressure (Goldenberg et al., 2021).

Type 2 diabetes is the most dominant type of the disease, making up 90–95% of cases. It has been a fast-expanding global issue for decades (Ajala, English and Pinkney, 2013). Type 2 diabetes is often identified by measurements of glycemia such as fasting blood glucose glycated haemoglobin (HbA1c) values (Goldenberg et al., 2021). In context healthy levels of present glucose levels in the blood stream are 42mmol/mol, risk of becoming diabetic would reflect a reading of 42-47mmol/mol, and diagnosed diabetes being 48mmol/mol. In order to correctly diagnose diabetes, levels of glycated haemoglobin (HbA1c) are tested over a 3-month period; unused glucose in the blood stream sticks to the haemoglobin – red blood cells; causing them to become glycated, high HbA1c levels as indicated above are an indication of Diabetes (Strychar *et al.*, 2009; Ajala, English and Pinkney, 2013).

Type 2 diabetes can be developed due to genetic risk factors, for example the child of a parent with Type 2 Diabetes has a 1 in 3 chance of developing the disease (McArdle *et al.*, 2019). Age is a factor, those in the age category over 40 are more at risk, along with obesity, smokers, and those of ethnic background. Some of these risk factors can be controlled whilst others unfortunately cannot (McGuire *et al.*, 2016).

As discussed, Type 1 diabetes is a life-long condition in which insulin is essential, no dietary intervention can prevent or reverse the disease, although it can certainly play a vast role in management. Type 2 diabetes, however, is preventable and reversible (Ahmad *et al.*, 2022). Research has proven that a healthy, balance diet along with exercise can drastically reduce the chances of developing type 2 diabetes and can also reverse the condition if already developed (Bolla *et al.*, 2019).

Patients with diabetes are frequently advised to follow structured dietary therapy, with different suggestions coming from reputable organisations (Goldenberg et al., 2021). Prior to the discovery of insulin, diets that prioritised carbohydrate restriction had been widely employed to manage diabetes, but more recently, their use has declined (Schwingshackl et al., 2017). Lowering dietary intake of carbohydrates, the majority of which are absorbed as glucose or fructose, has been suggested to improve blood glucose control and outcomes of type 2 diabetes because one of the main underlying mechanisms of type 2 diabetes is insulin resistance driven in part by chronic hyperglycaemia (Dyson, 2015).

In the research literature, structured diets with carbohydrate restriction have been described but are frequently divided into three categories: 20–50 g of carbohydrates per day, or less than 10% of the 2000 kcal per day diet, less than 130 g per day, or less than 26% of the 2000 kcal per day diet, and less than 45% of the 2000 kcal per day diet are all generally adequate to cause ketosis (Goldenberg et al., 2021). A low carbohydrate diet (LCD) is one that contains less than 130 grams of carbohydrates per day, or less than 26% of total daily calorie intake based on 2000 kcal (Goldenberg et al., 2021). Despite numerous pharmaceutical advancements and a global focus on glycaemic management, type 2 diabetes continues to be a serious and deteriorating problem on a global scale. Although structured diets are acknowledged as a crucial part in

treating diabetes. However, it is one of the most contentious and challenging parts of type 2 diabetes therapy, therefore there is still some doubt about which diet to follow. (Halton *et al.*, 2008).

This systematic review's objective is to analyse, synthesise, and summarise the most recent research on the impact of a low-carb diet on the treatment of Type 2 Diabetes (Khazrai, Defeudis and Pozzilli, 2014). Determine the calibre of the evidence that is already accessible through reviews inclusive of HbA1c findings and body mass index (BMI) based on a type 2 diabetic following low carbohydrate diet, will be one of the review objectives (Tay *et al.*, 2018). The results of this review may have an impact on therapies to manage diabetes and ultimately encourage remission (Hussain *et al.*, 2012).

Both Men, and women with Type 2 diabetes will make up the population of this review; age categories will not be used due to the lack of particular studies on this (Halton *et al.*, 2008a; de Koning *et al.*, 2011a). Reviewing type 2 diabetics' HbA1c readings and BMI variations after adhering to a low-carbohydrate diet will be the intervention. Due to the existing studies, there can be contrasting evidence (Tay *et al.*, 2015).

The purpose of this review is to gather evidence and critically analyse whether a low carbohydrate diet has a positive effect on those with type 2 diabetes (Hall and Chung, 2018a). There is a vast amount of conflicting evidence on this topic (Tay *et al.*, 2015).

A low carbohydrate dietary approach restricts the amount of carbohydrates that are being consumed (Hall and Chung, 2018b). Low; is classed as less than 130g of carbohydrates a day, very low is less than 50g per day. The guidelines in which can be found in the Nutrition for Health model is for individuals to consume between 0 to 4 portions of carbohydrates per day whilst following this 'low carb' approach (McArdle *et al.*, 2016a). The focus and science behind this method is the less carbohydrates that are being consumed, the most individuals will rely on their fat supply for their source of energy (McArdle *et al.*, 2016a). Thus aiding weight loss, and in turn decreasing the HbA1c level (McArdle *et al.*, 2019). As of 2011, Diabetes UK advocate the low carb diet as an option, along with the British Dietetic Association (Wang *et al.*, 2018). Both type 2 diabetes, and those categorised as pre diabetic are conditions of carbohydrate intolerance (Rivellese, Giacco and Costabile, 2012). The main benefit advocated within this dietary approach is reducing the amount of carbohydrates the body has to deal with; improving blood glucose control, and can too, reduce insulin levels (Dyson, 2015a). There are many studies to support the benefits from this approach, evidencing blood glucose reduction, reduction in body weight, body fats such as triglycerides (Rothberg *et al.*, 2014a). The negatives however can be impactful on day-to-day life such as socialisation; adapting dietary approaches can be isolating and restrictive (Larsen *et al.*, 2011).

Methodology

A systematic review with meta-analysis of randomised controlled trials assessing the efficacy and safety of LCDs in adult patients, namely females with type 2 diabetes will be utilised based on the available protocols

(Schwingshackl *et al.*, 2017a). People with or without cardiovascular disease will be included, regardless of medication use, glucose concentration, or HbA1c level to widen the search of available journals and reviews. Using trustworthy article searches from the British Medical Journal (BMJ), the University of Wales Trinity Saint David (UWTSD) library, Medline via PubMed, and the National Institute for Health and Care Excellence (NICE) will be the first step in the enquiry.

According to availability, the journal search will be limited to the most recent trials; however, it may be required to broaden the search in order to gather a varied overview of evidence relating to this topic. To allow for extensive research, terms such as; type 2 diabetes in females, Low carbohydrate diet in diabetes management, Type 2 diabetes remission, Low Carb Diet, nutritional treatment for Type 2 Diabetes; will be used.

Results

Throughout the literature search in order to complete this study many articles, research papers, reviews and trials were studied. There were however multiple studies that were duplicated – more than 5 in total were of the same study. Many of the studies identified were not specific enough to utilise, for example; not specific to a low carbohydrate diet, they included alternative diet options for type 2 diabetes which made it difficult to identify and summarise the specifics of this study.

One of the studies researched was based on Korean Diabetes Care/practice, which was not specific enough to be used for result purposes as the units/measurements may differ to those in the United Kingdom (Choi *et al.*, 2022).

Several limitations in the evidence base were discovered and considered in the assessment. These are outlined below:

- Because there is no agreed-upon definition of a 'low' carbohydrate diet; and there is overlap in reported mean carbohydrate intakes between lower and higher. carbohydrate categories making the definition within each study difficult to differentiate (de Koning *et al.*, 2011a; Tay *et al.*, 2015).

Table 1. Consensus definition of different levels of dietary carbohydrate (McArdle *et al.*, 2019)

	Carbohydrate: g per day	Carbohydrate: % of energy*
Very low carbohydrate	20–50 g	6–10%
Low carbohydrate	<130 g	<26%
Moderate carbohydrate	130–225 g	26–45%
High carbohydrate	>225 g	>45%

- There seemed to be insufficient information on adherence to advised intakes over the course of the trial, or consideration of how adherence might affect results.
- Most shorter-term studies did not assess outcomes between 6 and 12 months, and few longer-term studies assessed outcomes beyond 12 months;
- There was a clear variation in the type and amount of macronutrient that replaced carbohydrate (fat and/or protein), as well as the duration and intensity of advice given to participants on adhering to their prescribed diets (Dashti, Mathew and Al-Zaid, 2021)

The following section summarises the studies that appropriately met the inclusion criteria for this study;

Figure 1. Summary of Studies.

Author, Year of Publication	Participants	Range of Carbohydrate restriction %	Diet used within the studies	Outcomes
Meng, 2017 (Meng <i>et al.</i> , 2017)	743	less than 130 g carbohydrate/day or 26% of dail	low carbohydrate diet (LCD)	Positive difference on Hba1c

		y energy from carbohydrates		
Yancy, 2010 (Forouhi <i>et al.</i> , 2018)	146 (45 with diabetes)	50–60 g carbohydrates, 50–60 g fat, 50–55 g protein	Low-carbohydrate diet (LCD)	No significant difference in weight lost or glycemic control in entire study population
Haimoto, 2009 (Haimoto <i>et al.</i> , 2009)	127	45% carbohydrates, 33% fat, 18% protein	Low-carbohydrate diet (LCD)	Higher weight loss (−1.2 kg). lower HbA1c (−0.6%)
Sainsbury, 2018 (Sainsbury <i>et al.</i> , 2018)	25	<20g Carbohydrates for every 45% daily energy intake.	Low Glycaemic index, Carbohydrate restriction	No Difference to outcome measures.
Fan, 2017 (Fan <i>et al.</i> , 2017)	10	20g carbohydrates for every 50% daily energy intake.	Low Glycaemic Index, Calorie Restriction	Both Hba1c and Weight results favoured restricted Carbohydrate

The rationale for low-carbohydrate diets in type 2 diabetes patients is that carbohydrate ingestion raises blood glucose levels; thus, a low-carbohydrate diet lowers glycaemic and insulin levels, causing an increase in circulating fatty acids that can be used as energy by the body, with the production of ketone bodies. This results in quick weight loss and improved satiety (Meng *et al.*, 2017). Critics of this sort of diet contend that eating less carbohydrate usually results in an increase in the quantity of saturated fatty acids in the diet, which has a bad impact on cardiovascular disease (Meng *et al.*, 2017). However, researchers have proposed that low-carbohydrate diets lower glycemia, reducing the need for medication and, as a result, lowering the risk

of hypoglycaemia, which is in turn, associated with a high risk of morbidity and therefore favours weight loss (Schwingshackl *et al.*, 2017b).

A critical challenge is standardising what constitutes a low-carbohydrate diet. The definition of a low-carbohydrate diet as fewer than 130 g carbohydrate per day (in context; 26% of a 2000 kcal diet as carbohydrate); they define a moderate carbohydrate diet to contain 45-26% of total energy as carbohydrate. A very low-carbohydrate ketogenic diet has 30 g of carbohydrate per day. According to Wheeler *et al.* a moderate-to-low carbohydrate diet provides 30-40% of calories as carbohydrate, whereas a very low-carbohydrate diet contains 21-70 g of carbohydrate per day (Schwingshackl *et al.*, 2017b).

Studies on the efficacy of low-carbohydrate diets in patients with type 2 diabetes have primarily been short-term and with small population sizes, despite the fact that benefits, particularly weight loss, have been observed (Strychar *et al.*, 2009). Larsen *et al.*, on the other hand, recently evaluated two groups of adults with type 2 diabetes for a year. One group of 53 people was assigned to a diet high in protein (30% of total energy intake) and low glycaemic index carbohydrate (40% of total energy), while another group of 46 people was assigned to a diet high in protein (15% of total energy intake) and low glycaemic index carbohydrate (55% of total energy). There were, however, no significant variations in weight loss between the two groups at the end of the intervention period (Larsen *et al.*, 2011).

Other reviews of evidence from randomised trials on people with type 2 diabetes have reached varying conclusions regarding glycemia (Fan *et al.*, 2017). Some researchers, (Haimoto *et al.*, 2009) concluded that low carbohydrate diets were superior to other diets for glycaemic control, or that there was a dose response relationship, with stricter low carbohydrate restriction resulting in greater glycaemic reductions (Sainsbury *et al.*, 2018). Others expressed concern that the short-term benefits would not be sustained over time, or that there would be no overall advantage over the comparator diet (Goldenberg *et al.*, 2021a). Narrative reviews have often been more emphatic about the benefits of low carbohydrate diets, including enhanced satiety, and have highlighted the benefits for weight loss and metabolic parameters (Choi *et al.*, 2022).

Discussion

A large body of evidence suggests that a low carbohydrate diet is effective for improving type 2 diabetes HbA1c results and weight loss; one study provides evidence for the effectiveness of carbohydrate-restricted diets for short-term, 3–6-month time scale and improvements in glycaemic control in adults with type 2 diabetes. Although both carbohydrate-restricted and high carbohydrate diets produced a clinically meaningful HbA1c reduction of 0.5%, our meta-analyses revealed that carbohydrate-restricted diets produce greater HbA1c reductions of up to 0.19% over six months (Sainsbury *et al.*, 2018).

This impact was driven by low carbohydrate diets 26% of total energy, which provided a 0.47% larger reduction in HbA1c at 3 months and 0.36% at 6 months, with no significant difference detected between moderate 26-45% of total energy and high carbohydrate diets at 3 or 6 months (Forouhi *et al.*, 2018). The favourable effects of carbohydrate restriction were no longer detected after 12 months, with both diets displaying decreased effectiveness over time (Forouhi *et al.*, 2018)

The current comprehensive review and meta-analysis of carbohydrate restriction for glycaemic control in Type 2 diabetes found no significant overall effect on HbA1c or body weight (Sainsbury *et al.*, 2018). Current national dietary guidelines for Type 2 diabetes reflect this and make no particular recommendations about the amount of carbohydrate that should be consumed (Sainsbury *et al.*, 2018).

A minor but clinically meaningful reduction in HbA1c of 5 mmol/mol -0.49% was observed in the subset of studies that used 50-130 g carbohydrate per day (Forouhi *et al.*, 2018) . These trials were either 6 months in length or only reported results at 6 months, which is a significant limitation for clinical implementation of this finding (Forouhi *et al.*, 2018). Previous studies discovered that decreases in HbA1c or weight at 3 or 6 months were not sustained after 12 months (Forouhi *et al.*, 2018). Adherence to the prescribed diets was high in this group, which may have contributed to the positive results seen in the meta-analysis (Forouhi *et al.*, 2018) . However, if this success cannot be replicated in longer trials or with even stricter carbohydrate restrictions, this is a significant limitation with implications for future research and clinical practise.

Table 1. summarises the findings of eight additional meta-analyses published in the last thirteen years that address a similar research issue to that of the most current review. The lack of concordance among these meta-analyses is due in part to differences in technique, such as inclusion criteria or meta-analysis strategy. Several reviews found similar results to the most current review. While most studies found that the greatest improvements in HbA1c were associated with the greatest carbohydrate reductions, there are two contradictory studies that show no significant changes across weight loss and HbA1c results.

The larger drop in HbA1c on reduced carbohydrate diets is most likely due to increased weight loss (Kelly, Unwin and Finucane, 2020a). A previous systematic review and meta-analysis found that carbohydrate-restricted diets resulted in significantly greater short-term weight loss in people with and without diabetes, and our findings back up these findings, with low carbohydrate diets producing approximately 2.5 kg more weight loss than high carbohydrate diets at 3 months (Hussain *et al.*, 2012). Although no significant difference in weight loss was seen at 6 months, this was most likely owing to the omission of Fan *et al.*, 2017., who reported significantly larger weight reduction for the low carbohydrate diet group.

Barriers such as restrictions in the variety of foods available for ingestion on Very-low calorie ketogenic diets may also accidentally reduce energy intake; creating an unreliable result for the reasoning behind weight loss/Hba1c improvement (Bolla *et al.*, 2019). Due to the lack of trials available, it was a difficult task

to use this as viable data (Bolla *et al.*, 2019). Though they may be a viable alternative in the short term for overweight or obese patients with diabetes, promoting weight loss and subsequent improvements in HbA1c (Dashti, Mathew and Al-Zaid, 2021).

Several methodological limitations are present in the randomised controlled trials included in this review, specifically the lack of isocaloric (moderate-carbohydrate, moderate-fat diet) (Jenkins *et al.*, 1981), the varied methods of dietary assessment, differences in study participants' baseline glycemic control, a lack of adherence to the study diet, and differences in study protocols for diabetes medication adjustment (McArdle *et al.*, 2019).

Improvements in HbA1c are reported in the groups that are included within this study and may be due to a reduction in energy intake and subsequent weight loss across the entire study population (McArdle *et al.*, 2016b). With a few exceptions, most studies did not seek to maintain the amount of dietary energy between study arms identical, and hence results may have been confused by differential weight changes as a result of variable energy intakes between study groups (Feinman *et al.*, 2015a). Caution should be used when interpreting these results in the context of dietary modifications, especially given the variability of the methods of dietary measurement used and their inherent inaccuracy (Dyson, 2015a; McGuire *et al.*, 2016).

Many reviews showed overall adherence to the prescribed carbohydrate amount, and in several cases where there was adherence, the amount of carbohydrate consumed was very similar to the pre-study intake (Forouhi *et al.*, 2018). Although there was a small reduction in carbohydrate intake in the intervention group in each case, whether these studies achieved their goals and thus the validity of including them in this meta-analysis could be questioned (Forouhi *et al.*, 2018). The variations between the intervention and control diets were frequently substantially greater than a simple difference in carbohydrate consumption (Meyer *et al.*, 2000). When the absolute amount or proportion of one nutrient is changed, the proportion or absolute number of other macronutrients is automatically changed (Goldenberg and Johnston, 2021).

This was sometimes the study's principal goal. The findings of the review are consistent with the findings, whereby it was concluded that both low-carbohydrate and high-carbohydrate groups have difficulty achieving and adhering to the prescribed level of carbohydrate intake, with a difference between groups as small as 8 g/day (Jenkins *et al.*, 1981). The majority of trials used an intention-to-treat approach to analysis (Dyson, 2015a).

The studies used within this review utilise a wide range of methods of dietary assessment. It is evident that within the randomised controlled trials, dieticians are on board with advising and creating a diet plan to follow; this however is left to the participant to follow, and trust that the advice they are given is adhered to (Meng *et al.*, 2017). This inevitably opens up the study to inaccuracy due to the potential unreliable reports from the participant.

The inclusion criteria for the current review were intended to encompass the breadth of evidence regarding carbohydrate levels in Type 2 diabetes, but the large variation in the duration of included trials, the range of dietary approaches used, and whether included studies achieved the intended dietary changes may also limit the findings (Meng *et al.*, 2017). Subgroup analysis implies that incorporating just studies lasting 12 months would have no meaningful impact on the overall pooled effect, a finding supported by other reviews that have grouped their findings by study duration (Champagne *et al.*, 2011). The elimination of trials that did not disclose participants' carbohydrate intake is recognised as a potential source of bias; nonetheless, this resulted in the exclusion of only one Randomised controlled trial and the majority of Randomised controlled trials (Champagne *et al.*, 2011). Because several of the trials failed to report on medication changes or physical activity, these factors remain possible unobserved confounders (Tay *et al.*, 2015). Weight loss is recognised as a significant predictor of improvements in glycaemic control in Type 2 diabetes, it was also demonstrated a significant relationship between HbA1c reduction and mean differences in weight (Tay *et al.*, 2015).

The current review provides evidence of short-term improvements in glycaemic control achieved by restricting carbohydrate intake to 50-130 g per day; however, it suggests that there is little evidence to support recommending a general carbohydrate restriction for all people with Type 2 diabetes (Goldenberg *et al.*, 2021b). Controversy in the area of dietary carbohydrate is likely to persist, with recent publications calling for dietary guidelines to be reconsidered; however, data from studies of carbohydrate-restricted diets raise important questions about the long-term sustainability of such diets, given the poor overall concordance with the prescribed quantity of carbohydrate, even in a trial setting (Adeva-Andany *et al.*, 2019a). Individuals' glycaemic responses to carbohydrate are expected to differ significantly, which may explain the experiments' inconclusiveness (Adeva-Andany *et al.*, 2019a).

Based on the trials reviewed for this literature review; it is clear to see the gaps within this area are the specifics to the classification of 'low carbohydrate', the carbohydrates in which are being consumed, and the lack of information surrounding physical activity (Bolla *et al.*, 2019). These are all factors that will effect the validity of any trial. For future research; planning trials similar to the ones used should be carefully considered as there are multiple duplication of trials and methodology (Bolla *et al.*, 2019). There is little evidence on trials that are monitored over long term; they are mostly 3-6 month trials (Bolla *et al.*, 2019). This can give a false representation of weight loss, and potentially only two consecutive HbA1c readings as these are based on 3 month periods (Hussain *et al.*, 2012; Sainsbury *et al.*, 2018). The follow up approach of whether this method works as a long term, realistic diet approach to maintaining a 'non diabetic' HbA1c reading (Sainsbury *et al.*, 2018).

Current guidelines recommend low-carbohydrate diets as an alternative to typical low-fat, calorie-counting guidance for obese or type 2 diabetic patients (Rothberg *et al.*, 2014b). Low-carbohydrate diets should be supported by experienced health care professionals and a specialist dietician who can assist optimal nutritional intake in patients who are on several medications and/or insulin, or who have many dietary limitations or other co-morbidities such as renal illness (Kelly, Unwin and Finucane, 2020b). Even if diabetic remission is established, it is advised by clinicians that observation and care of other risk factors

Large multicentred randomised controlled trials with cardiovascular and other hard endpoints, as well as feasibility and cost-effectiveness evaluations, appear needed and deserving of prioritisation (Adeva-Andany *et al.*, 2019b). It should be highlighted that, like with any other dietary intervention, the data for long-term compliance with, and sustainability of, carbohydrate restriction is currently lacking. In the absence of this higher-level evidence, existing data imply that a low-carbohydrate diet is a legitimate and possibly extremely successful therapy option for patients with diabetes and obesity (Kelly, Unwin and Finucane, 2020b)

Overall, the evidence supports that lower carbohydrate diets have a favourable effect on HbA1c, fasting plasma glucose, and serum triacylglycerol in the short run (de Koning *et al.*, 2011b). Although there was no consistent evidence of weight loss with lower carbohydrate diets, the evidence considered makes it impossible to separate the effects of weight change from the effects of carbohydrate intake change. Lower carbohydrate diets may allow for medication reductions in diabetics, however interpretation is hampered by variations in reporting and monitoring of medication use changes (Dyson, 2015b).

In the short or long term, no variations in blood total cholesterol or LDL cholesterol were seen between higher and lower carbohydrate diets (Feinman *et al.*, 2015b). In the majority of primary randomised controlled trials, there was no difference in the occurrence of adverse outcomes between lower and higher carbohydrate diets in the short term, but there was in the longer term (Feinman *et al.*, 2015b). A variety of ambiguities and restrictions in the data hampered the overall quality of the evidence foundation (Dyson, 2015b). It is unknown whether the stated effects of lower carbohydrate diets apply to people of different ethnicities because the bulk of primary randomised controlled trials did not mention ethnicity of participants and were conducted in predominantly white British populations (Halton *et al.*, 2008b).

The evidence on the effect of lower carbohydrate diets in the general population without type 2 diabetes was not evaluated in this paper. It is unknown if the reported effects of low-carbohydrate diets in individuals with type 2 diabetes generalise to the entire adult population who does not have type 2 diabetes (Halton *et al.*, 2008b). Given the hypoglycemic effect of carbohydrate restriction, people with diabetes who follow low carbohydrate diets and their providers must learn how to avoid hypoglycemia by correctly reducing glucose-

lowering drugs. Finally, low carbohydrate diets can limit whole grain intake, and while some low carbohydrate meals can deliver the fibre and minerals found in grains, incorporating such foods may require more effort (Dyson, 2015b)

In conclusion, the trials with type 2 diabetic patients yielded inconclusive results. There are very few meta-analysis to assess the efficacy of a reduced carbohydrate diet for type 2 diabetes therapy meaning the overall review was based on a small volume of unique literature. The low carbohydrate diet intervention improved HbA1c, triglycerides, and HDL cholesterol levels. A reduced carbohydrate diet proved successful for weight loss in a short period of time; therefore as mentioned above the need for longer term research reviews would be beneficial. Reducing dietary carbohydrate may result in clinical improvements in the management of type 2 diabetes. More research is needed to understand the true effect of dietary carbohydrate restriction on HbA1c independent of medication reduction and to address known issues with adherence to this dietary intervention. Clarity is required regarding the appropriate classification of a low-carbohydrate diet.

Reference List

- Adeva-Andany, M. M. *et al.* (2019a) 'Dietary habits contribute to define the risk of type 2 diabetes in humans', *Clinical Nutrition ESPEN*, 34, pp. 8–17. doi: 10.1016/j.clnesp.2019.08.002.
- Adeva-Andany, M. M. *et al.* (2019b) 'Dietary habits contribute to define the risk of type 2 diabetes in humans', *Clinical Nutrition ESPEN*, 34, pp. 8–17. doi: 10.1016/j.clnesp.2019.08.002.
- Ahmad, E. *et al.* (2022) 'Type 2 diabetes', *The Lancet*, 400(10365), pp. 1803–1820. doi: 10.1016/S0140-6736(22)01655-5.
- Ajala, O., English, P. and Pinkney, J. (2013) 'Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes', *The American Journal of Clinical Nutrition*, 97(3), pp. 505–516. doi: 10.3945/ajcn.112.042457.
- Bolla *et al.* (2019) 'Low-Carb and Ketogenic Diets in Type 1 and Type 2 Diabetes', *Nutrients*, 11(5), p. 962. doi: 10.3390/nu11050962.
- Champagne, C. M. *et al.* (2011) 'Dietary Intakes Associated with Successful Weight Loss and Maintenance during the Weight Loss Maintenance Trial', *Journal of the American Dietetic Association*, 111(12), pp. 1826–1835. doi: 10.1016/j.jada.2011.09.014.
- Choi, J. H. *et al.* (2022) 'Effect of Carbohydrate-Restricted Diets and Intermittent Fasting on Obesity, Type 2 Diabetes Mellitus, and Hypertension Management: Consensus Statement of the Korean Society for the Study of Obesity, Korean Diabetes Association, and Korean Society of Hypertension', *Diabetes & Metabolism Journal*, 46(3), pp. 355–376. doi: 10.4093/dmj.2022.0038.
- Dashti, H. M., Mathew, T. C. and Al-Zaid, N. S. (2021) 'Efficacy of Low-Carbohydrate Ketogenic Diet in the Treatment of Type 2 Diabetes', *Medical Principles and Practice*, 30(3), pp. 223–235. doi: 10.1159/000512142.
- Dyson, P. (2015a) 'Low Carbohydrate Diets and Type 2 Diabetes: What is the Latest Evidence?', *Diabetes Therapy*, 6(4), pp. 411–424. doi: 10.1007/s13300-015-0136-9.
- Dyson, P. (2015b) 'Low Carbohydrate Diets and Type 2 Diabetes: What is the Latest Evidence?', *Diabetes Therapy*, 6(4), pp. 411–424. doi: 10.1007/s13300-015-0136-9.
- Fan, M.-H. *et al.* (2017) 'Effect of individualized diabetes education for type 2 diabetes mellitus: a single-center randomized clinical trial', *African Health Sciences*, 16(4), p. 1157. doi: 10.4314/ahs.v16i4.34.
- Feinman, R. D. *et al.* (2015a) 'Dietary carbohydrate restriction as the first approach in diabetes management: Critical review and evidence base', *Nutrition*, 31(1), pp. 1–13. doi: 10.1016/j.nut.2014.06.011.
- Feinman, R. D. *et al.* (2015b) 'Dietary carbohydrate restriction as the first approach in diabetes management: Critical review and evidence base', *Nutrition*, 31(1), pp. 1–13. doi: 10.1016/j.nut.2014.06.011.
- Forouhi, N. G. *et al.* (2018) 'Dietary and nutritional approaches for prevention and management of type 2 diabetes', *BMJ*, p. k2234. doi: 10.1136/bmj.k2234.

- Franz, M. J. *et al.* (2017) 'Academy of Nutrition and Dietetics Nutrition Practice Guideline for Type 1 and Type 2 Diabetes in Adults: Systematic Review of Evidence for Medical Nutrition Therapy Effectiveness and Recommendations for Integration into the Nutrition Care Process', *Journal of the Academy of Nutrition and Dietetics*, 117(10), pp. 1659–1679. doi: 10.1016/j.jand.2017.03.022.
- Goldenberg, J. Z. *et al.* (2021a) 'Efficacy and safety of low and very low carbohydrate diets for type 2 diabetes remission: systematic review and meta-analysis of published and unpublished randomized trial data', *BMJ*, p. m4743. doi: 10.1136/bmj.m4743.
- Goldenberg, J. Z. *et al.* (2021b) 'Efficacy and safety of low and very low carbohydrate diets for type 2 diabetes remission: systematic review and meta-analysis of published and unpublished randomized trial data', *BMJ*, p. m4743. doi: 10.1136/bmj.m4743.
- Goldenberg, J. Z. and Johnston, B. C. (2021) 'Low and very low carbohydrate diets for diabetes remission', *BMJ*, p. n262. doi: 10.1136/bmj.n262.
- Haimoto, H. *et al.* (2009) 'Effects of a low-carbohydrate diet on glycemic control in outpatients with severe type 2 diabetes', *Nutrition & Metabolism*, 6(1), p. 21. doi: 10.1186/1743-7075-6-21.
- Hall, K. D. and Chung, S. T. (2018a) 'Low-carbohydrate diets for the treatment of obesity and type 2 diabetes', *Current Opinion in Clinical Nutrition & Metabolic Care*, 21(4), pp. 308–312. doi: 10.1097/MCO.0000000000000470.
- Hall, K. D. and Chung, S. T. (2018b) 'Low-carbohydrate diets for the treatment of obesity and type 2 diabetes', *Current Opinion in Clinical Nutrition & Metabolic Care*, 21(4), pp. 308–312. doi: 10.1097/MCO.0000000000000470.
- Halton, T. L. *et al.* (2008a) 'Low-carbohydrate-diet score and risk of type 2 diabetes in women', *The American Journal of Clinical Nutrition*, 87(2), pp. 339–346. doi: 10.1093/ajcn/87.2.339.
- Halton, T. L. *et al.* (2008b) 'Low-carbohydrate-diet score and risk of type 2 diabetes in women', *The American Journal of Clinical Nutrition*, 87(2), pp. 339–346. doi: 10.1093/ajcn/87.2.339.
- Hussain, T. A. *et al.* (2012) 'Effect of low-calorie versus low-carbohydrate ketogenic diet in type 2 diabetes.', *Nutrition (Burbank, Los Angeles County, Calif.)*, 28(10), pp. 1016–21. doi: 10.1016/j.nut.2012.01.016.
- Jenkins, D. J. *et al.* (1981) 'Glycemic index of foods: a physiological basis for carbohydrate exchange', *The American Journal of Clinical Nutrition*, 34(3), pp. 362–366. doi: 10.1093/ajcn/34.3.362.
- Kelly, T., Unwin, D. and Finucane, F. (2020a) 'Low-Carbohydrate Diets in the Management of Obesity and Type 2 Diabetes: A Review from Clinicians Using the Approach in Practice', *International Journal of Environmental Research and Public Health*, 17(7), p. 2557. doi: 10.3390/ijerph17072557.
- Kelly, T., Unwin, D. and Finucane, F. (2020b) 'Low-Carbohydrate Diets in the Management of Obesity and Type 2 Diabetes: A Review from Clinicians Using the Approach in Practice', *International Journal of Environmental Research and Public Health*, 17(7), p. 2557. doi: 10.3390/ijerph17072557.

- Khazrai, Y. M., Defeudis, G. and Pozzilli, P. (2014) 'Effect of diet on type 2 diabetes mellitus: a review', *Diabetes/Metabolism Research and Reviews*, 30(S1), pp. 24–33. doi: 10.1002/dmrr.2515.
- de Koning, L. et al. (2011a) 'Low-carbohydrate diet scores and risk of type 2 diabetes in men', *The American Journal of Clinical Nutrition*, 93(4), pp. 844–850. doi: 10.3945/ajcn.110.004333.
- de Koning, L. et al. (2011b) 'Low-carbohydrate diet scores and risk of type 2 diabetes in men', *The American Journal of Clinical Nutrition*, 93(4), pp. 844–850. doi: 10.3945/ajcn.110.004333.
- Larsen, R. N. et al. (2011) 'The effect of high-protein, low-carbohydrate diets in the treatment of type 2 diabetes: a 12 month randomised controlled trial', *Diabetologia*, 54(4), pp. 731–740. doi: 10.1007/s00125-010-2027-y.
- McArdle, P. D. et al. (2016a) 'The role of carbohydrate in diabetes management', *Practical Diabetes*, 33(7), pp. 237–242. doi: 10.1002/pdi.2048.
- McArdle, P. D. et al. (2016b) 'The role of carbohydrate in diabetes management', *Practical Diabetes*, 33(7), pp. 237–242. doi: 10.1002/pdi.2048.
- McArdle, P. D. et al. (2019) 'Carbohydrate restriction for glycaemic control in Type 2 diabetes: a systematic review and meta-analysis', *Diabetic Medicine*, 36(3), pp. 335–348. doi: 10.1111/dme.13862.
- McGuire, H. et al. (2016) 'Management of type 2 diabetes in adults: summary of updated NICE guidance', *BMJ*, p. i1575. doi: 10.1136/bmj.i1575.
- Meng, Y. et al. (2017) 'Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials', *Diabetes Research and Clinical Practice*, 131, pp. 124–131. doi: 10.1016/j.diabres.2017.07.006.
- Meyer, K. A. et al. (2000) 'Carbohydrates, dietary fiber, and incident type 2 diabetes in older women', *The American Journal of Clinical Nutrition*, 71(4), pp. 921–930. doi: 10.1093/ajcn/71.4.921.
- Rivellese, A. A., Giacco, R. and Costabile, G. (2012) 'Dietary Carbohydrates for Diabetics', *Current Atherosclerosis Reports*, 14(6), pp. 563–569. doi: 10.1007/s11883-012-0278-4.
- Rothberg, A. E. et al. (2014a) 'Very-low-energy diet for type 2 diabetes: An underutilized therapy?', *Journal of Diabetes and its Complications*, 28(4), pp. 506–510. doi: 10.1016/j.jdiacomp.2014.03.014.
- Rothberg, A. E. et al. (2014b) 'Very-low-energy diet for type 2 diabetes: An underutilized therapy?', *Journal of Diabetes and its Complications*, 28(4), pp. 506–510. doi: 10.1016/j.jdiacomp.2014.03.014.
- Sainsbury, E. et al. (2018) 'Effect of dietary carbohydrate restriction on glycemic control in adults with diabetes: A systematic review and meta-analysis', *Diabetes Research and Clinical Practice*, 139, pp. 239–252. doi: 10.1016/j.diabres.2018.02.026.
- Schwingshackl, L. et al. (2017a) 'Food groups and risk of type 2 diabetes mellitus: a systematic review and meta-analysis of prospective studies', *European Journal of Epidemiology*, 32(5), pp. 363–375. doi: 10.1007/s10654-017-0246-y.

Schwingshackl, L. *et al.* (2017b) 'Food groups and risk of type 2 diabetes mellitus: a systematic review and meta-analysis of prospective studies', *European Journal of Epidemiology*, 32(5), pp. 363–375. doi: 10.1007/s10654-017-0246-y.

Strychar, I. *et al.* (2009) 'Effects of a Diet Higher in Carbohydrate/Lower in Fat Versus Lower in Carbohydrate/Higher in Monounsaturated Fat on Postmeal Triglyceride Concentrations and Other Cardiovascular Risk Factors in Type 1 Diabetes', *Diabetes Care*, 32(9), pp. 1597–1599. doi: 10.2337/dc08-2322.

Tay, J. *et al.* (2015) 'Comparison of low- and high-carbohydrate diets for type 2 diabetes management: a randomized trial', *The American Journal of Clinical Nutrition*, 102(4), pp. 780–790. doi: 10.3945/ajcn.115.112581.

Tay, J. *et al.* (2018) 'Effects of an energy-restricted low-carbohydrate, high unsaturated fat/low saturated fat diet versus a high-carbohydrate, low-fat diet in type 2 diabetes: A 2-year randomized clinical trial', *Diabetes, Obesity and Metabolism*, 20(4), pp. 858–871. doi: 10.1111/dom.13164.

Wang, L.-L. *et al.* (2018) 'The Effect of Low-Carbohydrate Diet on Glycemic Control in Patients with Type 2 Diabetes Mellitus', *Nutrients*, 10(6), p. 661. doi: 10.3390/nu10060661.

STUDENT FEEDBACK FORM

This section details the *extent* to which the assessment criteria are demonstrated by you, which in turn determines your mark. The marks available for each category of skill are shown. Lecturers will use the space provided to comment on the achievement of the task(s), including those areas in which you have performed well and areas that would benefit from development/improvement.

Generic Assessment Criteria	Marks available	Marks awarded
1. Engagement with Literature Skills		
	25	
2. Knowledge and Understanding Skills		
	25	
3. Cognitive and Intellectual Skills		
	30	
4. Practical Application Skills		
	10	
5. Transferable Skills for Life and Professional Practice		
	10	

Assessment Mark (Assessment marks are subject to ratification at the Exam Board. These comments and marks are to give feedback on module work and are for guidance only until they are confirmed.)	Late Submission Penalties (tick if appropriate)		%
	Up to 1 week late (40% Max)		
	Over 1 week late (0%)		

