Monitoring Carbohydrate Intake in the First Year Following a Diagnosis of Type 2 Diabetes

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Monitoring Carbohydrate Intake in the First Year Following a Diagnosis of Type 2 Diabetes

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Statement of Originality

This work has not previously been submitted for a degree or diploma in any university. To the best of my knowledge and belief, the thesis contains no material previously published or written by another person except where due reference is made in the thesis itself.

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Tracy L'Allier Ebacher 24/6/2022

Abstract

Background

Type 2 diabetes (T2D) is a prevalent chronic disease that can result in serious complications including retinopathy, nephropathy and neuropathy. The health problem incurs significant personal and social costs related to treatment and loss of healthy life. Glycaemic control is important in reducing the complications and burden of T2D. It is estimated that in 10 years' time, one in 10 adults will be living with T2D. Carbohydrate is one of four macronutrients and its intake directly influences glycaemia. Although studies have assessed the impact of various dietary interventions on the management of T2D, there is no specific amount of carbohydrate intake recommended for adults living with T2D. Instead, it is advised that carbohydrate intake, along with the other macronutrients, be assessed based on the current diet, preferences and metabolic goals. Knowing more about the carbohydrate intake of people recently diagnosed with T2D over time in a real-world setting could inform effective and tailored interventions and trials as well as to reduce the costs and impact of T2D.

Aim

This study aimed to assess dietary intake in the first year following a diagnosis of T2D without dietary intervention and to explore the relationships between carbohydrate intake and outcomes using two different classifications systems of low-carbohydrate diet (LCD; absolute grams and percentage of total energy intake; TEI).

Method

This study was a secondary analysis of data from the 3D case series study (How does Diet change after a Diagnosis of Diabetes?) in which dietary intake was observed without prescription of a specific dietary intervention at five time points over 12 months. The 3D study was conducted in Australia between May 2018 and October 2019. Trained interviewers with expertise in dietetics collected the data by telephone. Weight, waist circumference and special diet followed were self-reported. Other data collected included socio-demographic information, medication use and physical activity. Dietary intake was collected from 24-hour recall at each interview and analysed using FoodWorks nutritional software. Completer analysis was used to compare difference in dietary intake over time. Intention-to-treat (ITT) analysis was used to identify differences in participant characteristics according to the level of carbohydrate intake, with an LCD either below 130 g per day or below 26% of TEI. The average dietary intake was calculated with

available food recalls and last observation carried forward was used for the anthropometric measures. Chi-square test for homogeneity, Mann–Whitney *U* test, non-parametric Friedman test, analysis of covariance and Spearman's rho correlation test were performed with IBM SPSS Statistics for Windows. Median and IQR were used as the Shapiro–Wilk test revealed not normally distributed data.

Results

A total of 225 participants (54% men, median age 60 years and interquartile range, IQR 16) were recruited. At baseline, most participants were classified as obese, had a waist circumference above the sex-specific guideline (median 107.3 cm, IQR 21), were using anti-diabetes medication and were not smoking. At 12 months, 153 participants remained (retention rate of 68%). The participants who did not complete data collection at 12 months were more likely to be obese according to their BMI and less likely to live with a partner. There was no significant difference in the average energy, macronutrient or food groups intake of completers and non-completers.

Median carbohydrate intake was significantly higher at 12 months than at baseline for male participants only, (157 g vs 187 g, p=0.019, completer analysis). Most participants had a carbohydrate intake below the minimum 45% of total energy intake recommended for people without T2D. When compared with the general Australian population, male and female participants in the 3D study reported a lower mean energy, carbohydrate and alcohol intake, and higher fat and protein intake.

A total of 35% of participants had a carbohydrate intake below 130 g (LCD) but only 13% were also classified as consuming an LCD according to the TEI classification (<26% of TEI from carbohydrate). The socio-demographic characteristics of participants did not differ between the LCD and other groups. For both classification systems, participants in the LCD group had a higher TEI from fats and proteins compared with the other groups. The median intakes of fruits, vegetables and dairy were below the recommendation of the Australian Guide to Healthy Eating. The recommended serves of grains were only attained by those on the HCD for both classification systems. The participants in the LCD groups (both classifications) had a lower intake of grains, fruits and dairy. The median dietary approaches to stop hypertension (DASH) score of participants was suboptimal. Women following an LCD had a smaller waist circumference at the end of the study compared with those who had an intake above 130 g carbohydrate. More than half the participants reporting following an LCD (n=21, 50% for grams classification, and n=31, 71% for TEI percentage classification) reported a mean carbohydrate intake that was higher than established classifications for LCD.

Conclusion

This sub-analysis of the 3D study data described the longitudinal macronutrient intake, with focus on carbohydrate, in men and women who were newly diagnosed with T2D. This study highlights the need for universal usage of one of the two classification systems for carbohydrate-restricted diet, either absolute grams of carbohydrate or percentage of TEI form carbohydrate, to improve the research for people with T2D. The diet quality of participants was inadequate, with low DASH score and intake below the recommendations for several food groups. Future research should be developed using innovative dietary data collection method such as photographic food journal and should encompass measures of carbohydrate quality as well as details of the time when carbohydrate are consumed to explore new areas for the population with T2D.

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List of Abbreviations and Acronyms

ABS	Australian Bureau of Statistics
ADA	American Diabetes Association
AMDR	Acceptable Macronutrient Distribution Range
ANCOVA	Analysis of covariance
ASA-24	Automated Self-Administered 24-hour Dietary Assessment
BMI	Body mass index
CQI	Carbohydrate Quality Index
DASH	Dietary Approaches to Stop Hypertension
FBG	Fasting blood glucose
FFQ	Food frequency questionnaire
GP	General practitioner
HbA1c	Glycated haemoglobin
HCD	High-carbohydrate diet
HDL	High-density lipoprotein cholesterol
ITT	Intention-to-treat
LCD	Low-carbohydrate diet
LCHF	Low-carbohydrate, high-fat diet
LDL	Low-density lipoprotein cholesterol
LFD	Low-fat diet
LOCF	Last observation carried forward
MCD	Moderate-carbohydrate diet
NDSS	National Diabetes Services Scheme
RCT	Randomised controlled trial
T2D	Type 2 diabetes
TEI	Total energy intake
VLCD	Very low-carbohydrate diet
WHO	World Health Organization

Chapter 1. Introduction

1.1 Overview

Type 2 diabetes (T2D) is a chronic disease of great concern to society, particularly given its increasing prevalence and possible serious complications. This chronic metabolic disease is characterised by impaired glucose metabolism that results in higher-than-normal blood glucose levels, or hyperglycaemia, caused by reduced production of insulin by the pancreas, often paired with insulin resistance (1). Glycaemic control is affected by carbohydrate intake, the only macronutrient metabolised directly into glucose. Inadequate control of glycaemia can impose considerable, and potential macro- and microvascular complications, and co-morbidities can affect people with T2D (2).

T2D is a non-communicable disease caused by the interaction of multiple genetic, environmental and lifestyle factors over several years. Ageing populations, unhealthy eating habits, sedentary lifestyles and urbanisation of developing nations are among the most frequent causes or contributors to T2D (3). To prevent T2D, healthy lifestyle behaviours are recommended, such as maintaining a body weight in the healthy range, eating a nutritious diet, being physically active, not smoking and consuming alcohol only in moderation (4-6). Early weight loss was find to be a predictor of T2D remission (7).

Globally, about 422 million people were living with diabetes in 2014, and 90% of these people are diagnosed with T2D (2). It was estimated that 463 million people worldwide had diabetes in 2019 (8). The prevalence of diabetes nearly doubled in 34 years, from 4.7% in 1980 to 8.5% in 2014 worldwide. At this rate, it is predicted that one adult in 10 will develop diabetes by 2030. This chronic disease previously affected mainly middle-age and older people but is now diagnosed in younger age groups, including children (2). According to the Global Burden of Disease Study, diabetes was the 28th leading cause of death in 1990 and increased to the 15th leading cause in 2017, when it accounted for 1.23 million deaths that year (9).

In Australia in 2017–18, it was estimated that one million people were living with T2D (10) and about 500,000 might be living with T2D that has not been detected (11). In 2017–18, 34,500 hospitalisations in Australia were attributable primarily to T2D, as well as 9,500 associated deaths (12). According to the most recent detailed economic figures stratified by health condition from the Australian Institute of Health and Welfare (2008–09), the annual diabetes expenditure was $1,507 million, and more than 60% of those funds were for T2D (13). Eligible people with T2D in Australia can access subsidised medication under the Pharmaceutical Benefits Scheme (14), primary care allied health services through the Medicare Benefits Schedule (15) and testing strips, insulin syringes and pen needles through the National Diabetes Services Scheme (16). Given increasing prevalence, high financial and human cost, effective management of this condition is a health priority in Australia.

To address this international problem, the International Diabetes Foundation has developed a Global Diabetes Action Plan (2011–21) with strategies to prevent the development of T2D and improve health outcomes of those living with the chronic condition given that prevention and treatment are effective and cost effective (17). Lifestyle changes, including weight loss for overweight or obese people, are the first-line recommendations for T2D management (18, 19). Receiving a diagnosis of T2D can prompt lifestyle behaviour changes but can also bring on negative emotions regarding dietary restrictions (20). The motivation to maintain healthy dietary behaviours is complex (21). Improving dietary habits along with medication and self-monitoring of blood glucose level can help to improve glycaemic control (22). Dietary interventions after a diagnosis of T2D can include dietary behaviour change (23), although these changes appear to be challenging to maintain over time (24, 25). A 2017 systematic review of 11 cross-sectional studies found that people with T2D did not comply with food group recommendations, consuming less fruits, vegetables, dairy and grains than recommended (26). Clearly, there is a need to improve the dietary intake of people with T2D.

Adequate glycaemic control is the key to reducing healthcare costs and short- and long-term consequences of T2D, and can be improved soon after the diagnosis with an intensive dietary intervention (27). In 2008, only 53% of Australians with T2D achieved the target of adequate glycaemic control (i.e., glycated haemoglobin, HbA1c <7%) (11). Different rates of HbA1c target achievement were found recently in cross-sectional studies conducted in Norway (50% achieved HbA1c <7%) (28) and in the Netherlands (34% achieved HbA1c <7%).

The postprandial glycaemic response and glycaemic control are directly affected by carbohydrate (29). Despite the central role of carbohydrates in glycaemic control, there is no single carbohydrate recommendation for people with T2D, with studies in this area to date being inconclusive (18). A consensus by the American Diabetes Association reports (30):

> “[…] there is not an ideal percentage of calories from carbohydrate, protein, and fat for all people with or at risk for diabetes; therefore, macronutrient distribution should be based on individualized assessment of current eating patterns, preferences, and metabolic goals.”

The Royal Australian College of General Practitioners and Diabetes Australia both recommend that all people with T2D consider the amount and quality of carbohydrate they consume, for example by choosing foods with a low glycaemic load rather than high glycaemic load, but without specifying an ideal amount (31). These professional associations recommend that people with T2D should seek advice from an Accredited Practising Dietitian and to follow the Australian Dietary Guidelines (32) as a sensible, balanced eating pattern.

Without specific guidelines about the ideal amount of carbohydrate for people with T2D and with an increasing body of evidence showing some positive outcomes for carbohydrate-restricted diets, a low-carbohydrate diet (LCD) is attracting increasing attention across health professionals and the general population. A recent systematic review and meta-analysis showed that an LCD can lead to T2D remission, greater weight loss, triglycerides reduction, and improved insulin sensitivity at six months(33). However, some long-term outcomes diminished and therefore remain unclear, with variable adherence to restrictive diets. A comprehensive synthesis of evidence on the topic of LCD and T2D is presented in Chapter 2.

Long-term observational data about the dietary intake of people recently diagnosed with T2D in Australia is limited and justifies further research (26). Furthermore, little is known about the carbohydrate intake of people with T2D who try to follow an LCD. Greater knowledge of the carbohydrate intake of people who have received a diagnosis of T2D may be useful for designing future research, formulating relevant messages for public health and improving dietary support for this population.

1.2 Thesis outline

A literature review on carbohydrate intake of people with T2D as well as summary of research on carbohydrate-restricted diets are presented in Chapter 2, along with the aims and research question. The methods, including research design, recruitment of participants, survey design, data collected, variables and statistical tests are detailed in Chapter 3. The results of the research are presented in Chapter 4 and the results are discussed in the context of the research questions and literature in Chapter 5.

Chapter 2. Literature Review

2.1 Preface

This literature review explores the relationship between carbohydrates and type 2 diabetes (T2D) by focusing on the purported benefits of carbohydrate-restricted diets. This chapter is divided into three sections. First, the biochemical characteristics of carbohydrates are described, along with recommendations for their dietary intake to support optimal health. Second, the aetiology, prevalence and burden of T2D, as well as the associations between carbohydrate intake and management of T2D are examined, highlighting the lack of details regarding the quality of carbohydrate. Third, carbohydrate-restricted diets are described and reviewed in detail, particularly in terms of the outcomes for people with T2D. A synthesis of meta-analyses on low-carbohydrate diets (LCDs) and T2D as well as a review of randomised controlled trials (RCTs) on very low-carbohydrate diets (VLCDs) are presented in sections 2.3.1 and 2.3.2, respectively.

Between July 2019 and March 2022, databases such as Medline, Wiley Online Library, NCBI, Scopus and Griffith Library were searched for peer-reviewed journal articles, systematic reviews and meta-analyses. The key search terms used were type 2 diabetes, carbohydrate, low-carbohydrate diet, ketogenic diet, recommendations, dietary intake, systematic review, meta-analysis, randomised controlled trial, observational study, longitudinal study, new diagnosis, glycaemic control, weight and waist circumference. Reference lists from relevant studies were consulted to identify additional sources of information. International and national organisational reports, guidelines and other publications were also used where appropriate.

2.2 Type 2 diabetes, diet and carbohydrates

2.2.1 Carbohydrates: Composition, classification and metabolism

Carbohydrates are one of the four macronutrients that, along with proteins, fats and alcohol, provide energy to the body (34). Carbohydrates are macromolecules composed of carbon (carbo-) and hydrogen with oxygen (-hydrate). In the human diet, only plant-based foods and mammalian milk contain carbohydrates (35). As shown in Figure 2.1, carbohydrates can be classified as simple (one or two molecules of sugars; monosaccharides or disaccharides) or complex (longer chains of molecules, also called polysaccharides, such as starches and dietary fibre) (36).

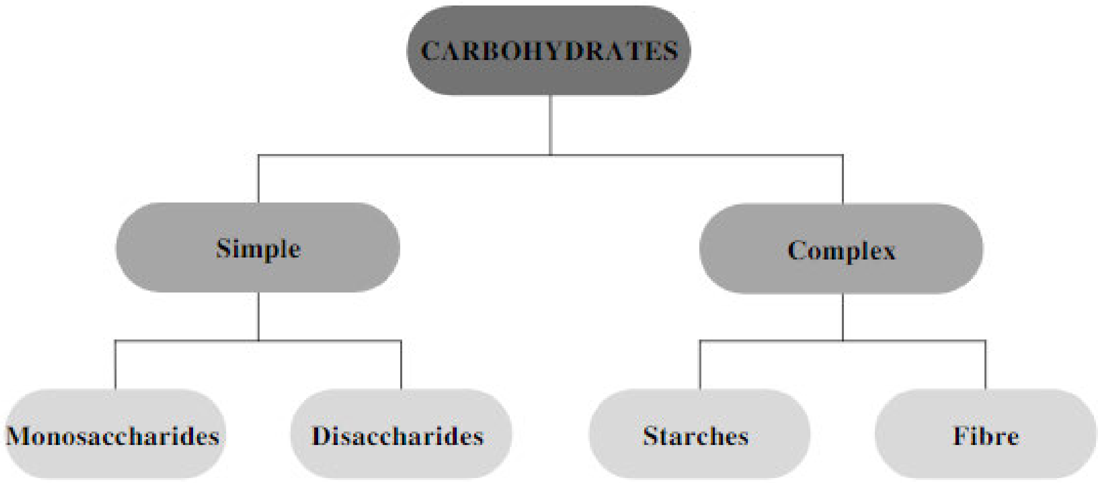


Figure 2.1 Carbohydrates classification
Adapted from (36)

Complex carbohydrates are digested into smaller monosaccharides by amylase in the small intestine, where absorption also occurs. Once in the bloodstream, the liver converts different monosaccharides into glucose, which is the end product of carbohydrate metabolism. Glucose is a source of energy and enters the cells through the action of insulin, a pancreatic hormone secreted when blood glucose increases (36).

For people with T2D, the insulin production and its efficacy at lowering blood glucose level are compromised. The impaired insulin action fails to suppress the hepatic glucose production (37). Therefore, blood glucose concentration may remain elevated in the bloodstream and glucose cannot enter the cells to be used a source of energy, creating a toxic hyperglycaemia (38). Hyperglycaemia is associated with clinical complications, especially microvascular and will be presented in the next section (39).

2.2.2 Associations between carbohydrate intake, glycaemic control and health outcomes

Carbohydrate intake does not appear to be related to the development of T2D and, paradoxically, a higher intake may be associated with lower risk. The Australian Longitudinal Study on Women's Health (n=8,370) used validated food frequency questionnaires to track macronutrient intake and risk of T2D for 6 years and found no significant association with carbohydrate intake after adjustment for confounding variables (40). The United Kingdom National Diet and Nutrition Survey investigated the dietary intake of 3,234 participants for 8 years using a 4-day food diary and found that every 5% decrease in total energy intake (TEI) from carbohydrate was associated with 12% increased risk of developing T2D (41). In its 2018 recommendations for prevention of T2D, Diabetes UK listed "moderate carbohydrate restriction" as a very low-strength recommendation based on very low-quality evidence (42).

High carbohydrate ingestion might not cause T2D but may have a direct and immediate influence on post-prandial glycaemia (43). The effect of carbohydrate on glycaemia is greater than that of other macronutrients. However, while fat intake has a modest influence on glycaemia it indirectly influences insulin sensitivity and resistance (44). Protein intake impacts glycaemia through stimulating insulin production (44). Because of possible complications associated with poorly managed glycaemia and the direct impact of carbohydrate intake on the glycaemia, carbohydrate is the nutrient of interest in this research.

Glycaemic control can be assessed by measuring glycated haemoglobin (HbA1c) in the bloodstream (45). This is the concentration of haemoglobin that has reacted with sugar and reflects glycaemic control over approximately 106 days (45). Prospective observational study has shown that a reduction in HbA1c leads to a reduction of the rate of complications such as myocardial infarction, stroke, microvascular disease, heart failure, amputation or cataracts (39). Most of the literature examining the effect of carbohydrate on glycaemic control and other health outcomes has focused on interventions testing carbohydrate-restricted diets, although two studies reporting on carbohydrate intake not modified by an intervention are also presented here. Vital and colleagues performed a secondary data analysis of the TOSCA.IT study, an Italian RCT involving 1,785 people with suboptimal glycaemic control of their T2D managed by metformin only who were randomised to add a sulfonylurea or pioglitazone. Data from food frequency questionnaires were collected before randomisation and showed a decrease in HbA1c, triglycerides and C-reactive protein in participants with a carbohydrate intake ≥60% of TEI compared with participants with an intake <45% of TEI (46). However, a Japanese prospective study of one month (n=3,032) found a carbohydrate intake >60% of TEI to be associated with an elevated HbA1c level when compared to intake <45% (47). Participants with an HbA1c level >8% had a higher body mass index (BMI), higher mean TEI from carbohydrate intake, lower mean TEI from protein and lower mean fibre intake compared to participants with an HbA1c level <7% (47). It is difficult to draw conclusions about a non-prescribed carbohydrate intake with divergent results from those two studies, warranting future research.

2.2.3 *Quality of carbohydrates: Fibres and sugars*

A limitation of the data presented in the previous section is the lack of detail about the type or quality of carbohydrate consumed. Indicators of the carbohydrate quality, such as glycaemic index, sugar intake, proportions of wholegrain and total grain or processed food intake have not been examined comprehensively. Carbohydrate components, such as dietary fibre or sugars, may influence glycaemic control and health outcomes in people with T2D. In studies that included people with T2D, higher dietary fibre intake has been associated with lower HbA1c level (48-50), lower fasting blood glucose (FBG) level (49), higher high-density lipoprotein cholesterol (HDL), lower body weight and waist circumference (50), lower BMI (51) and lower triglyceride and C-reactive protein levels (46). A recent meta-analysis of 44 studies found evidence of an association between positive health outcomes and higher fibre intake in people with T2D (52).

The World Health Organization (WHO) published a recommendation in 2015 to lower free sugar intake to 10% or less of TEI because of the association between free sugar intake and increased risk of chronic disease (53). Free sugars represent the sum of added sugars and the "sugars naturally present in honey, syrups, fruit juices and fruit juice concentrates" (53). In the secondary analysis of the TOSCA.IT study mentioned above, Vital and colleagues found that higher intake of added sugars was associated with increased levels of triglycerides, HbA1c and C-reactive protein (46). In a systematic review and meta-analyses of 30 RCTs and 39 prospective cohort studies, Te Morenga and colleagues found that in ad libitum diets, an increase or decrease in free sugars were associated with a parallel change in body weight (54). Contrarily to dietary fibre which seems to have a positive impact (48-50), added and free sugars appear to be detrimental risk factors for T2D and glycaemic control.

2.2.4 *Total carbohydrate intake recommendations for people with T2D*

Carbohydrate recommendations for people with T2D are contentious. For people without diabetes, the Nutrient Reference Values for Australia and New Zealand recommend an acceptable macronutrient distribution range (AMDR) from carbohydrates to represent 45% to 65% of TEI (55). This range has been set by the American Institute of Medicine by taking into consideration an increased risk of obesity when the intake is below the lower limit and an increased risk of coronary heart disease when the intake is higher than the higher limit (34). However, for people with diabetes, the ideal amount of carbohydrate is still widely debated, as it was at the beginning of the 20th century (56). In the 1930s, physicians prescribed strict carbohydrate restriction to as low as 10 g per day with a gradual daily increase until optimal glycaemic control was attained (57). With the emergence of non-insulin oral anti-diabetes medication such as the sulfonylurea and biguanides (58), carbohydrate recommendations were liberalised in 1971 by the American Diabetes Association (ADA) to between 50% and 60% of TEI (59).

Between 2007 and 2008, the Standards of Medical Care in Diabetes from the ADA changed its recommendations regarding carbohydrate intake considerably. In 2007, 45% to 65% of TEI from carbohydrate was recommended and LCDs (<130 g per day) were not recommended because of a lack of long-term data regarding the outcomes and safety (60). In 2008, the percentage of TEI from carbohydrates was no longer mentioned in the guideline, and LCDs were recommended for short-term weight loss, with a suggestion to monitor lipid profile and renal function (61). The most recent release of the Standards of Medical Care in Diabetes by the ADA did not recommend an ideal percentage of TEI from carbohydrates or other macronutrients (18). Rather, it recommends that people with diabetes be selective about the food source of carbohydrates and to eat more foods rich in fibre (such as in wholegrains, fruits, and non-starchy vegetables) and less foods with processed carbohydrate and added sugars. An overall reduction in carbohydrate intake seems to be positive for glycaemic control (18).

2.2.5 Measuring carbohydrate intake

Dietary intake can be measured using various methods, the most common being the diet record, 24-hour recall, and food frequency questionnaires (62). Each method has their own benefit and inconvenient, but all requires honesty and memory from participants. Generally, dietary intake measurements are subject to energy underreporting systematic error but 24-hour recalls have been found to be the least biased (62).

The mean carbohydrate intake of adult Australians does not exceed the AMDR recommendations (55, 63). The Australian Health Survey conducted in 2011–13 included a 24-hour dietary recall by 12,000 adults (>18years), including people with and without health conditions (63). The mean daily reported carbohydrate intake was higher for men than women (259 vs 194 g) but the proportion of TEI from carbohydrate was similar (44 vs 43%). Sixty per cent of respondents aged 19 years and older reported a carbohydrate intake below the minimum AMDR of 45% of TEI, and none had an intake above the maximum AMDR of 65% of TEI.

Similarly, observational studies in other Western countries reports carbohydrate intake towards the lower end of the AMDR (45% of TEI) for people with T2D, as shown in Table 2.1. Three studies compared participants intake to the recommendations and approximately half of the participants had a carbohydrate intake below recommendations (45% to 60% or 65% of TEI) (51, 64, 65). Participants with diabetes reported a lower energy (65-67), carbohydrate (67) and simple carbohydrate or sugar intake(66, 68) than those without diabetes or than the general population.

Food intake is influenced by cultural norms (69). Cross-sectional studies in non-Western countries with people with T2D have reported carbohydrate intake higher than Western countries. In Saudi Arabia, 404 patients reported a mean carbohydrate intake was 67% of TEI through food frequency questionnaires. White basmati rice was the main contributor to carbohydrate intake (43% of total carbohydrate intake) (70). In Sri Lanka, the mean TEI from carbohydrate was 68% in the 123 people who reported their intake in 24-hour recall. Half of the participants had a carbohydrate intake >65% of TEI (71). In Thailand, patients (n=304) reported an average carbohydrate intake of 52% of TEI in a 3-day food record (72).

Table 2.1 Studies without interventions that reported energy and carbohydrate intake of people with type 2 diabetes

First author (year) Country Participants with T2D Nutritional assessment	Characteristics of participants Mean (SD) age (years) Mean (SD) BMI (kg/m^2)	Daily mean intake Energy (SD) Carbohydrate (SD)	Findings
Avedzi (64) (2018) Canada n=170 (46.5% F) 3-day food records	65.8 (9.6) 31.3 (7.0) Diabetes duration: mean 13.4 years (SD 8.6)	M: 2218.6 kcal/day (635.4) 59.3% (<45% TEI) 6.6% (>65% TEI) F: 1941.6 kcal/day (666.8) 36.7% (<45% TEI) 15.2% (>65% TEI)	One third (M) and about half (F) had carbohydrate intake within the AMDR (45-65% TEI)
Castetbon (66) (2014) France n=101 Three 24-hour recalls	61.6 (SE 1.1) 30.8 (SE 0.6)	1,790 kcal/day (SE 58) 41.3% TEI (SE 0.9)	No significant difference between TEI from carbohydrates for participant with and without diabetes, lower energy and sugar intake for those with diabetes
Ewers (65) (2019) Denmark n=348 (29% F) FFQ	Median 66 (IQR 13) Median 29.2 (IQR 6.8)	Median 7.4 MJ/day (IQR 3.5) or 1,770 kcal/day (IQR 837)* Median 46.1% TEI (IQR 8.8)	About half did not meet the carbohydrate recommendations (45–60% TEI), energy intake lower for those with diabetes compared to general population
Mannucci (67) (2008) Italy n=109 (51.4% F) FFQ InCHIANTI study	73.4 (8.8)	1,793 kcal/day (481) 223 g/day (70.1) or 49.7%**TEI	Participants with T2D had significantly lower energy and carbohydrate intake than those without diabetes
Marques-Vidal (68) (2017) Switzerland n=299 FFQ	Diabetes not on diet 63.3 (9.4) 29 (5.3) Diabetes on diet 64.2 (9.1) 30.1 (5.5)	Diabetes not on diet 1,963 kcal/day (695) 47.0% TEI (9.0) Diabetes on diet 1,909 kcal/day (658) 47.4% TEI (8.1)	No significant difference in energy and carbohydrate intake between participant with diabetes not on a diet and with diabetes on a diet Participants with diabetes had a lower intake of simple sugar than those without diabetes
Vitale (51) (2016) Italy n=2573 (40.3% F) FFQ	62.1 (6.5) 30.3 (4.5) Diabetes duration: 8.5 years (SD 5.7)	M: 1934 kcal/day (674) 45.3% TEI (7.1) F: 1680 kcal/day (593) 44.8% TEI (7.3)	Nonadherence to 45–60% TEI from carbohydrate for 51.2% (M) 53.8% (F) Nonadherence to <10% TEI from carbohydrate for 2.7% (M) 2.8% (F)
Vitolins (73) (2009) USA n=2,757 (59% F) FFQ Look AHEAD trial	Age category: 45–55 years 43%, 56–65 year 43%, 68–75 14% BMI category 25 to <30 14%, 30 to <35 35%, 35 to <40 27%, ≥40 24%	M: 2,000 kcal/day F: 1,744 kcal/day 44% TEI	Overall lower TEI from carbohydrates and higher TEI from fats

Abbreviations: *T2D* type 2 diabetes, *SD* standard deviation *BMI* body mass index, , *M* males, *F* females, *AMDR* acceptable macronutrient distribution range, *TEI* total energy intake, SE standard error, *IQR* interquartile range
Calculated by the author using *1 MJ=239 kcal and ** 4 kcal/g

Changes to carbohydrate intake have been investigated in some countries. In the United States, the cross-sectional National Health and Nutrition Examination Surveys (NHANES) conducted between 1988 and 2012 used 24-hour recall to analyse the dietary intake of 4,885 Americans with diabetes. The TEI from carbohydrate remained constant over the five data collection points: 47–49% of TEI (74). A prospective cohort study of French women (n=57,304) found that those who developed T2D between 1993 and 2005 (n=1,249) reduced their carbohydrate intake only if they were living within a family or were more highly educated (75).

2.2.6 Carbohydrate intake following a diagnosis of type 2 diabetes

Intervention studies have tested the efficacy of various dietary interventions among patients newly diagnosed with T2D. Using a secondary analysis of data from the UK Early ACTID trial, England and colleagues described the change in food group intake of 262 people aged between 30 and 80 years newly diagnosed (5 to 8 months) with T2D during a 6-month nonprescriptive dietary intervention comprising 11 individual appointments based around goal setting and motivational interview (23). Participants reported a reduced intake of energy-dense food, low-fibre food and alcoholic drinks at the end of the intervention period. They found that, to reduce energy intake, men tended to reduce alcoholic drinks and savoury and sweet treats, whereas women mainly reduced the volume of mixed main meals (23). Esposito and colleagues followed 215 participants over 4 years in Italy and found that those randomised to a low-carbohydrate Mediterranean diet (<50% of TEI from carbohydrate) postponed the use anti-diabetes medication by about 2 years compared with the low-fat diet (LFD) group, independent of weight loss (76). In China, Liu and colleagues randomised 122 participants to four diets and found a greater reduction in HbA1c and FBG levels after 12 weeks in the group assigned to the low-carbohydrate high-protein diet with omega-3 fatty acid supplementation (compared with the other three groups (control with high carbohydrate, low protein and low omega-3; low-carbohydrate high-protein diet only, omega-3 supplementation only) (77). The restriction at different level of carbohydrate intake in people newly diagnosed with T2D has been sparsely studied in people with recent T2D.

Qualitative research has explored dietary modification in people with a recent diagnosis of T2D or those living with the condition for a longer period. Ten people living in Australia who had received a T2D diagnosis within the previous 4 months participated in a series of semi-structured phone interviews (20) in which they shared their perceptions of how a diagnosis of T2D changed their eating habits over time. Most participants reported difficulty adapting to the diagnosis and the restrictions required to achieve a healthy diet, which generated negative emotions toward their eating habits. Interestingly, participants reported feeling overwhelmed by receiving contradicting nutrition information received after their diagnosis (20). This contradiction could be explained in part by the ambiguous recommendations for carbohydrate intake, as noted in Section 2.2.4. Negative emotions were also reported by people who had been living with T2D for longer (78). Mexican study used semi-structured interviews of 45 people (average duration of T2D=13 years) in an area of Mexico with a relatively high prevalence of diabetes (78). The authors found that strict adherence to a prescribed diet was only short term after the diagnosis of T2D. An important finding is that patients experienced discomfort as a result of the change in their diet and found it difficult to modify or reduce their food intake. All participants reported displeasure caused by changes in their diet (78). These two qualitative studies illustrate the negative emotions commonly experienced by people changing dietary habits in the pursuit of health.

Researchers at Griffith University undertook the 3D study (How does Diet change after a Diagnosis of Diabetes?), a case series study involving five phone interviews over 12 months. The literature reviewed for the broader 3D study showed that various factors can influence the dietary intake of people with T2D (79). Being younger or being a woman seemed to be a predictor of a change in diet, and a better quality of diet was associated with higher education level and BMI classified as normal or overweight. The results of the 3D study have shown that short-term improvements in the Dietary Approaches to Stop Hypertension (DASH) score (from baseline to 3 months) correlated with smoking status, physical activity and BMI (80). Over the long term, the mean DASH score remained stable during the 12 months of the study. Many participants (43%) did not improve their DASH score between baseline and 3 months or between 3 and 12 months, and only 7% improve at both time points (81). Assessing the carbohydrate intake of this sample will add to the body of literature.

2.3 Carbohydrate-restricted diets

Modifying carbohydrate quantity is a controversial strategy to lose weight or manage glycaemic control for people with T2D as LCDs are often higher in proteins or fats, possibly increasing the risk of negative outcomes. A cohort study with a median follow-up of 25 years (1987-2017) of Americans aged 45–64 years at enrolment (12% of participants with diabetes of all form), found that both low (<40% TEI) and high (>70% TEI) intakes of carbohydrate were associated with an increased risk of mortality (82). However, greater risk was observed when carbohydrates were replaced with animalbased food and lower risk with plant-based food. The lowest mortality risk was associated with a carbohydrate intake between 50% and 55% of TEI from carbohydrates (82)

The LCDs are often high in protein in terms of absolute gram intake as well as percentage of TEI from protein. However, this increased protein intake may affect kidney function and glomerular filtration, which are already at higher risk of dysfunction for people with T2D (83). A meta-analysis of 12 controlled trials explored the effects of an LCD on renal function in people with T2D. No significant difference was found after following an LCD when compared to control group in several markers of renal function (estimated glomerular filtration rate and levels of creatinine, urinary albumin, serum creatinine and serum uric acid) (84). A small retrospective cohort study of 143 patients advised by their general practitioner or practice nurse to follow an LCD found a significant improvement in renal and cardiovascular risk factors (85). However, dietary intake was not assessed in that study, and adherence to LCD could not be verified.

The level of carbohydrate restriction in LCD also varies in the literature. Based on publications of previous experimental studies, Feinman and colleagues suggested in 2015 the classification presented in Table 2.2 (86).

Table 2.2 Classification of carbohydrate-restricted diets

VLCD	20–50 g/day or <10% of TEI from carbohydrate of the 8,350 kJ diet
LCD	<130 g/day or <26% of TEI from carbohydrate
MCD	26–45% of TEI from carbohydrate
HCD	>45% TEI from carbohydrate

VLCD very low-carbohydrate diet, *LCD* low-carbohydrate diet, *MCD* moderate-carbohydrate diet, *HCD* high-carbohydrate diet, *g* grams, *TEI* total energy intake, *kJ* kilojoules
Source: adapted from (86)

Even with a definition based on absolute grams per day or percentage of TEI, the classification of LCDs can differ as identified by Wylie-Rosett and colleagues (87). They use the example of a diet of 130 g of carbohydrate being equal to 26% of TEI from carbohydrate and which would be considered LCD when the diet contains a total daily intake of 8,350 kJ (2,000 kcal). With a lower energy intake of 4,900 kJ (1,200 kcal), common among people attempting weight loss (88), 130 g of carbohydrate becomes a high-carbohydrate diet according to the established classification (>45% of TEI) (86).

Considering that males usually have higher energy intake than females due to larger body weight, classification of carbohydrate-restricted diets based on absolute grams differs by sex where %TEI carbohydrate does not. The debate around the definition and classification of LCD continues.

In the Australian Health Survey (2011–2013), of the respondents reporting being on a current diet (15%), the most frequently reported diet was a weight loss/low-calorie diet (44% of respondents). About 15% of respondents reported being on an LCD, 13% on a sugar-free or low-sugar diet and 9% on a diabetic diet.

2.3.1 Low-carbohydrate diets: Evidence from meta-analyses of RCTs

Several RCTs and meta-analyses have explored the outcomes of LCDs for people with T2D, particularly on weight management and glycaemic control, but there is still no obvious consensus. Ten meta-analyses of RCTs relevant to LCDs and T2D were conducted between 2009 and 2021. The details and outcomes of these meta-analyses are presented in Table 2.3 with the objective of clearly summarising the evidence and identifying gaps. The limitations frequently reported in those meta-analyses are listed in Table 2.4.

The number of studies included in the meta-analyses ranged between nine and 37, and the total number of participants between 306 and 3301. A total of 78 different studies were analysed across the 10 meta-analyses, and 51 studies of these were included in only one or two meta-analyses. Three of the RCTs were included in eight (89, 90) or nine (91) of the 10 meta-analyses. One of the core studies by Westman and colleagues, was funded by the Robert C. Atkins Foundation and did not declare whether the funding source played a role in the design or interpretation of the results (89). This may have increased the risk of bias given that Dr Atkin has been an advocate for VLCD since the 1970s (92).

Most of the meta-analyses comprised studies with a carbohydrate restriction threshold between 20 g per day and 45% of TEI. One meta-analysis included studies with a higher range of carbohydrate intake of 30–50% of TEI (93). Only one meta-analysis included studies with dietary intervention of 10 days (93). Intervention duration of the studies included in the other meta-analyses varied between 12 weeks and 4 years.

Table 2.3 Summary of meta-analyses of RCTs of type 2 diabetes and low-carbohydrate diet with reported outcomes and conclusions

First author Year Studies Participants	CHO restriction Intervention duration	Outcomes**			Dietary adherence Authors' conclusion
		Weight loss	Glycaemic control	Lipid levels	
Ajala (94) 2013 20* RCTs n=3073	20–25 g/day with 5 g increments/week to 50% of TEI 6 months to 4 years	No difference between groups	Favoured LCD (HbA1c)	Favoured LCD (HDL) No difference between groups (LDL and TG)	- LCD (along with other diet such as low-GI, Mediterranean, and high-protein) improved some cardiovascular risk markers and could be part the overall strategy of diabetes management.
Goldenberg (33) 2021 23 RCTs n=1357	20 to 130 g/day 3 months to 12 months	Favoured LCD at 6 months No difference between groups at 12 months	Favoured LCD (HbA1c) Favoured LCD at 6 months (FBG)	Favoured control at 12 months (LDL)	15/16 reported adequate adherence (7 not stated) Compared to other diets (such as LFD), LCD may have better rates of diabetes remission without adverse consequences at 6 months, but the benefits diminished at 12 months.
Huntriss (95) 2017 18 RCTs n=2204	<20 g/day to 45% of TEI 12 weeks to 2 years	No difference between groups at 12 months	Favoured LCD at 12 months (HbA1c)	Favoured LCD 12 months (HDL and TG) No difference between groups (TC, LDL)	6/12 with adherence within 5% of TEI prescribed^ Reducing CHO intake in a healthy diet might lead to favourable outcomes in for of diabetes management.
Kodama (93) 2009 19 RCTs n=306	30 to 50% TEI 10 days to 12 weeks	-	No difference between groups (HbA1c) Favoured LCD (fasting insulin)	Favoured LCD (TG, HDL) No difference between groups (TC, LDL)	- In the context of consistent energy intake, substituting fat with CHO significantly increased postprandial glucose and fasting insulin levels
Korsmo-Haugen (96) 2019 23 RCTs n=2178	5% to 40% TEI 3 months to 3 years	No difference between groups in short and long term	Favoured LCD mainly for the short term (HbA1c), ≤6 months	Favoured LCD (TG) No difference between groups (HDL, LDL, TC)	9/18 with adherence within 5% of TEI prescribed (7/9 low-compliance were prescribed 5-22% TEI) In longer-term trials, TEI from CHO intake is not an important determinant for the outcomes of diabetes management.
McArdle (97) 2019 23 RCTs n=2132	20 to 232 g/day 12 weeks to 4 years	No difference between groups	No difference overall (HbA1c) Favoured of LCD 50-130 g at 6 months or less (HbA1c)	Favoured LCD (HDL)	13/23 with adherence within 10% g of CHO prescribed In shorter-term trials, LCD (50–130 g/day) improved glycaemic control but little evidence that this recommendation should be generalised for all people with T2D.
Meng (98) 2017 9 RCTs n=734	20 to 130 g/day 12 weeks to 24 months	Favoured LCD over the short term No difference over the long term between groups	Favoured LCD (HbA1c) No difference between groups (FBG)	Favoured LCD (TG, HDL) No difference between groups (TC, LDL)	- LCD showed beneficial effect on glucose control, TG and HDL concentrations but without a significant effect in long-term weight loss.

First author Year Studies Participants	CHO restriction Intervention duration	Outcomes**			Dietary adherence Authors' conclusion
		Weight loss	Glycaemic control	Lipid levels	
Sainsbury (99) 2018 25 RCTs n=2412	<20 g/day to 45% of TEI 3 months to 24 months	Favoured LCD at 3 months No difference between groups at 6 and 12 months Favours MDC over HCD at 12 months	Favoured LCD at 3 and 6 months (HbA1c) No difference between groups at 3 and 6 months when omitting studies with greater weight loss No difference between groups at 12 and 24 months	No difference at 3-6 months between groups (TC, LCD)	4 studies reported declining adherence overtime LCD (mostly <26% of TEI) had greater improvement in HbA1c in short term than HCD, possibly due to greater weight loss. LCD showed no negative impact on cardiovascular risk markers. LCD could be part of individual diabetes management plan.
Silverii (83) 2020 37 RCTs n=3301	20 g/day to 45% of TEI 3 months to 48 months	Favoured VLCD at 3 months No difference between groups for LCD	Favoured LCD at 3 months and VLCD at 3 and 6 months (HbA1c) No difference between groups at 6 and 12 months for LCD (HbA1c) Favours control at 24 months (HbA1c)	Favoured LCD at 12 months (HDL) No difference between groups (LDL) Favours control at 6 and 24 months (TC)	16/31 with adherence within 5% of TEI prescribed^ LCD might improve HbA1c level and weight in the short term but not on the long term. Insufficient data on renal safety.
Snorgaard (100) 2017 10 RCTs n=1376	14% to 45% of TEI 3 months to 24 months	No difference between groups in short and long term	Favoured LCD at 3 and 6 months (HbA1c) No difference between groups at 12 months (HbA1c)	No difference between groups (LDL)	2/5 with adherence within 5% of TEI prescribed^ LCD (<45% TEI) produced greater improvement in glycaemic control than HCD in the short term, the effect was similar in the long term.

* Nine studies with an LCD intervention** Outcomes of LCD compared with the control or comparative diets ^ Dietary adherence gathered from information available in the publish meta-analysis or supplementary material

Abbreviations: *CHO* carbohydrates, *RCT* randomised controlled trial, *g* grams, *TEI* total energy intake, *LCD* low-carbohydrate diet, *HbA1*c glycated haemoglobin, *HDL* high-density lipoprotein cholesterol, *LDL* low-density lipoprotein cholesterol, *TG* triglycerides, *Low-GI* low glycaemic index, *FBG* fasting blood glucose, *LFD* low-fat diet, *TC* total cholesterol, , *T2D* type 2 diabetes, *LFHC* low-fat, high carbohydrates, *HFLC* high-fat, low-carbohydrate, *MDC* moderate-carbohydrate diet, *HCD* high-carbohydrate diet, *VLCD* very low-carbohydrate diet

Not all studies included in the meta-analyses reported carbohydrate intake and seven out of the 10 meta-analyses discussed dietary adherence. Different criteria were used to define adherence, either carbohydrate intake within the LCD categories defined by the authors of the meta-analyses (33), or within a percentage of the prescribed intake in grams (97) or from TEI (96). For three meta-analyses, dietary adherence was gathered from data from the paper or available in the supplementary material (83, 95, 100). In most meta-analyses, dietary adherence was adequate for approximately half of the studies reporting carbohydrate intake.

The most frequently reported outcomes were weight, blood glucose measures and lipids. Most meta-analyses (9/10) included body weight as an outcome measure. Four of these meta-analyses reported significantly greater weight loss for participants following an LCD (33, 98, 99) or VLCD (83) compared with the control groups in the short term but no differences between the groups in the long term. All but one meta-analysis (93) reported an improvement in HbA1c level after the LCD intervention, but more than half (7/10) reported that this effect was only observed for a part of the studies, i.e. the first 3 months (83), 6 months (33, 96, 97, 99, 100) or 12 months (95). Goldenberg and colleagues reported that an LCD induced a greater reduction in HbA1c at 6 months (17 studies, mean reduction of –0.47%) but that this effect was halved at 12 months (eight studies, mean difference of –0.23%). This study also reported an increase of diabetes remission at 6 months (HbA1c level <6.5%) by an additional 32 per 100 participants for those on an LCD diet (33).

Of the five meta-analyses reporting the total cholesterol level, only one study observed improved lipid levels for the LCD diet compared to the control at 6 and 24 months (83). Seven meta-analyses examined HDL and LDL levels. Only one meta-analysis (33) found that an LCD intervention led to an improvement in LDL, and the other six reported no significant differences between diets. Three of the four meta-analyses reporting on triglyceride levels identified a beneficial effect of the LCD diet compared with the control, and one found no significant difference.

Outcomes less frequently reported included anti-diabetes medication use, blood pressure and quality of life. Four meta-analyses found that LCD interventions promoted a reduced use of anti-diabetes medication (33, 95, 99, 100). Three meta-analyses reported no differences in blood pressure between diets (83, 96, 97) and one found that systolic pressure reduced in the LCD group (95). No meta-analyses have reported on waist circumference. Only two meta-analyses reported on quality of life and observed higher scores for control groups (33) or found no difference between groups (83).

Table 2.4 Summary of key limitations of meta-analyses of studies of type 2 diabetes and low-carbohydrate diet

Generalisation limited by the frequent comparisons with a low-fat diets
Heterogeneous studies of various durations and
Lack of standardisation of carbohydrate prescription for the LCD intervention
Larger dropout rates sometimes higher for the low-carbohydrate diet
Participants could not be blinded because of the nature of the intervention
Lack of information about the quality of carbohydrates
Outcomes affected by anti-diabetic medications, which were generally adjusted during the studies
Adherence to diet sometimes poor, especially for very strict carbohydrate restriction
Some trials with small numbers of participants
Difficulty in differentiating the effect of carbohydrate restriction from that of caloric restriction or weight loss on outcomes.

Source: summarised from (33, 83, 93-100)

From this evidence-based synthesis of meta-analyses, LCDs appear to lead to weight reduction, improvement in glycaemic control, reduction in triglyceride level and increased HDL level, at least in the short term, while being safe for renal function. However, those studies are of variable quality and have used various definitions of LCD. Future studies would benefit from using dietary adherence as a selection criterion and use a narrower definition of LCD with specific range of carbohydrate intake. Silverii and colleagues discussed the absence of differences between groups in some parameters over the long term may be explained by a decreasing gap in actual carbohydrate intake between groups over time (83).

2.3.2 Very low-carbohydrate diets

No systematic quantitative reviews of VLCD or ketogenic diet in T2D could be found in the published literature. Therefore, evidence from available RCTs was synthesised. The lack of well-defined carbohydrate categories in the meta-analyses presented in section 2.3.1 was addresses by targeting the VLCD. As discussed earlier, the definition of LCD varies greatly and stricter diets fall in the category of VLCD if they contain <50 g of carbohydrate per day or <10% of TEI. A VLCD that induces ketogenesis or ‘fat burning’ may positively impact glycaemia on two levels: by reducing the total intake of carbohydrate, which affects post-prandial glycaemia, and by inducing weight loss (18). It is important to note that the ADA do not recommend the use of VLCDs by pregnant or lactating women, people with or at risk of eating disorder, people with renal disease or people with T2D taking sodium–glucose cotransporter 2 inhibitors (sold in Australia as dapagliflozin and empagliflozin) because of the potential risk of ketoacidosis (18), a severe condition that can occur when the blood glucose level is too low and free fatty acids are metabolised into ketone bodies by gluconeogenesis (37).

Description of the studies

Table 2.5 presents a summary of RCTs with interventions of at least 12 weeks and a prescribed VLCD for one of the groups. Only studies that included outpatient or ambulatory participants and reported dietary intake were considered, and studies that included tube feeding or liquid meal replacements were excluded. Seven studies were included. Most studies (4/7) were conducted in the USA (89, 91, 101, 102), and the others in Australia (103), Sweden (104) and Israel (105). The intervention duration was between 24 weeks and 24 months. The number of participants per study varied from 34 to 115, which yielded a total of 500 people who began and 360 who completed the studies. The average baseline glycated haemoglobin level was 6.6% to 9.0% and BMI 32 to 41 kg/m^2.

Most interventions included individual (91, 103-105) or group sessions with a dietitian (89) or led by another health professional (102). Exercise was included as an intervention for three of seven studies (89, 102, 103). The prescribed carbohydrate intake at baseline was set to 20–25 g per day for the VLCD group in five of the studies (89, 91, 101, 105), three of which increased carbohydrate content gradually (91, 101, 105). For the other studies, the carbohydrate intake prescribed for the VLDC group was 20–50 g per day (102), 14% of TEI from carbohydrate (or <50 g) (103) or 20% of TEI (104). The comparison diet comprised mainly a low-fat diet with various levels of carbohydrate intake. One study included the use of orlistat in the comparison group along with a low-fat diet (101). A low-glycaemic index diet was prescribed for the comparison group in two studies (89, 103).

Table 2.5 Summary of randomised controlled trials with type 2 diabetes participants following a very low-carbohydrate diets

First author Year Country n (retention%) Design Duration	Aim	Diet groups Adherence to CHO restriction for VLCD group	Mean carbohydrate intake (SD)		Outcomes			
			First time point after baseline	Last time point	Weight loss	HbA1c	Lipids	Anti-diabetes medication
Davis (91) 2009 USA n=105 (81%) RCT 12 months	To compare weight loss and glycaemic control between VLCD and LFD for people with T2D	**VLCD**: Modified Atkin diet 2-week phase of CHO restriction of 20–25 g increasing by 5 g/week Decreased adherence at 6 and 12 months	77 g (44) or 24% (3 months)	137 g* or 33% (13) (12 months)	Significantly greater loss for VLCD at 3 and 12 months	No significant difference between groups at all time points	Significant increase in HDL for VLCD No significant differences in LDL and TG between groups	Insulin reduction of 10 ± 14 units
		LFD: Diabetes Prevention Program Fat 25% TEI based on baseline weight	199 g (69) or 53% (3 months)	227 g* or 50% (10) (12 months)				Insulin reduction of 4 ± 19 units
Goldstein (105) 2011 Israel n= 55 (51%) Concurrent RCT 12 months	To compare an Atkins-like diet with a conventional ADA-recommended diet over 1 year	**VLCD**: 25 g of CHO for the first 6 weeks after randomisation, thereafter, increasing to a ceiling of 40 g/day. No energy restriction Low adherence (intake double the goal at 3, 6 and 12 months) Ketogenic effect at 12 months in 7% of participants	60 g (33) or 16%* (6 weeks)	85 g (53) or 20% (12 months)	No significant difference in weight loss between groups at any point. VLCD lost weight only in first 6 months; ADA weight loss continued.	Significant decrease in both groups at 6 weeks and 3, 6 and 12 months. No significant between-group differences	Significant decrease in LDL and TG and increase in HDL in both groups.	Reduction by 3 months in many patients (17/26 VLCD and 11/26 ADA).
		ADA: 10%-20% of TEI from protein and the other 80% divided between fats and CHO and 35 g of fibre Energy intake up to 1500/1200 (males/females) kcal/day	164 g (74) or 37% (6 weeks)	208 g (61) or 43% (12 months)				

First author Year Country n (retention%) Design Duration	Aim	Diet groups Adherence to CHO restriction for VLCD group	Mean carbohydrate intake (SD)		Outcomes			
			First time point after baseline	Last time point	Weight loss	HbA1c	Lipids	Anti-diabetes medication
Guldbrand(104) 2012 Sweden n=61 (NR) RCT 24 months	To compare the effects of a VLCD or LFD with 4 group-meetings	**VLCD**: CHO 20% TEI Fat 50% TEI Protein 30% TEI Adherence was better at 6 months CHO intake increased over time	87 g* or 25% (8) (6 months)	97 g* or 31% (6) (24 months) 10 participants did not provide food records	Significant weight loss of~4 kg at 6 months for both groups but no significant difference between groups at all time points	No significant differences between groups at all time points VLCD: Significant reduction at 6 months but not at 24 months	Significant decrease in LDL and increase in HDL at 24 months for both groups but no differences between groups.	Significant reduction in insulin dose at 6 months for VLCD
		LFD: CHO 55–60% TEI Fat 30% TEI Protein 10–15% TEI	191 g* or 49% (6) (6 months)	171 g* or 47% (7) (24 months) 4 participants did not provide food records		LFD: No significant change at all time points		
Mayer (101) 2014 USA n=46 (NR) RCT 48 weeks	To compare two weight loss diets in terms of HbA1c, weight and intensity of anti-diabetic medication use	**VLCD**: Initial CHO intake of 20 g/day, slowly liberalised as approached weight goal No energy restriction Adherence not discussed	NR	76 g (77) or 18% * (48 weeks) 11 participants did not provide food records	Significant loss for both groups but no significant difference between groups	Greater reduction for VLCD group at 48 weeks	No significant differences between groups for LDL and HDL	More participants in VLCD achieved a 50% decrease in medication effect score
		LFD + O: Fat <30% TEI Daily 500–1000 kcal restriction Orlistat 120 mg three times per day	NR	156 g (79) or 44% * (48 weeks) 13 participants did not provide food records				

First author Year Country n (retention%) Design Duration	Aim	Diet groups Adherence to CHO restriction for VLCD group	Mean carbohydrate intake (SD)		Outcomes			
			First time point after baseline	Last time point	Weight loss	HbA1c	Lipids	Anti-diabetes medication
Saslow (102) 2017 USA n=34 (85%) Parallel-group RCT 12 months	To compare the effects of 2 diets on glycaemic control	**VLCD**: 20–50 g of CHO per day (excluding fibre), high fat No energy restriction Less CHO for VLCD than MCCR at 12 months	EMM 44 g (27, 61) or 11%* (6 months)	EMM 74 g (52, 96) or 19%* (12 months)	Significantly greater weight loss in VLCD (8.3%) than MMCR (3.8%) at 12 months	Significant reduction for VLCD Twice the percentage of participants had HbA1c <6.5% in the VLCD group (significant difference at 6 months only)	Significant increase in LDL for VLCD at 6 months but not significant at 12 months	6/6 stopped sulfonylureas or DPP IV inhibitors 3/10 stopped metformin
		MCCR: CHO 45–50% TEI, CHO counting, low fat Daily 500 kcal reduction	EMM 160 g (131, 190) or 43%* (6 months)	EMM 150 g (120, 180) or 36%* (12 months)				0/4 stopped sulfonylureas or DPP IV inhibitors 0/12 stopped metformin
Tay (103) 2018 Australia n=115 (53%) Single-centre, parallel-groups RCT 24 months	To compare VLCD and LFD high-CHO, LGI for the improvement of glycaemic control and CVD risk factors in overweight and obese patients with T2D	**VLCD**: CHO 14% TEI (<50 g/day) then additional 20 g CHO after week 24 Fat 58% TEI Protein 28% TEI Over time CHO intake increased and ketone body decreased	EMM 55 g (50, 60) or 14% (13, 14) (3 months)	EMM 83 g (73, 94) or 19% (17, 20) (24 months)	Significant weight loss but no difference between groups	Significant reduction for both groups but no significant difference between groups	Significant greater reduction in TG but HDL maintained in VLCD group	Over twice participants in VLCD group had a ≥20% reduction in diabetes medication effect score compared with LFD
		LFD LGI: CHO 53% TEI (processed CHO and high-GI foods discouraged) Protein 17% TEI fat <30% TEI Addition of a food exchange after week 24 for the remainder of the study	EMM 202 g (197, 207) or 51% (50, 51) (3 months)	EMM 216 g (206, 227) or 48% (46, 49) (24 months)				
Westman (89) 2008 USA n=84 (58%) RCT 24 weeks	To test the improvement in glycaemic control of a diet lower in CHO with patients with obesity and T2D	**VLCD**: <20 g CHO/day No explicit energy restriction Adequate adherence	NR	49 g (33) or 13% (24 weeks)	Significantly reduced for both groups but greater reduction for VLCD	Significantly greater reduction at 24 months for the VLCD group, independent of the change in weight	HDL increase in VLCD group only	20/21 stopped or reduced medication 4/8 stopped insulin
		LGI: CHO 55% TEI Daily 500 kcal reduction	NR	149 g (46) or 44% (24 weeks)				18/29 eliminated or reduced medication 1/3 stopped insulin

Abbreviations: *CHO* carbohydrate, *VLCD* very low-carbohydrate diet, *TEI* total energy intake, *SD* standard deviation, *HbA1c* glycated haemoglobin, *RCT* randomised controlled trial, *LFD* low-fat diet, *HDL* high-density lipoprotein cholesterol, *T2D* type 2 diabetes, *g* grams, *LDL* low-density lipoprotein cholesterol, *TG* triglycerides, *ADA* American Diabetes Association, *NR* not reported, *LFD + O* low-fat diet and orlistat, *kcal* kilocalories, *EMM* estimated marginal mean (95% confidence intervals), *MCCR* moderate-carbohydrate, calorie-restricted low-fat, *DPP IV* dipeptidyl peptidase-4 inhibitors, *LGI* low glycaemic index
* Calculated by the author using 4 kcal/g

Carbohydrate intake and adherence

Adherence to dietary restriction appears to be problematic for diets with <50 g of carbohydrate. For the VLCD groups, carbohydrate intake tends to be adequate and meet the target at the beginning of the studies but increase over time. Only one study reported a mean carbohydrate intake <50 g per day for the VLCD group at the end of the intervention, which was also the study with the shortest duration (24 weeks) (89). For the other six studies, the carbohydrate intakes at the first time point after baseline up varied between 44 g (102) and 87 g (104) while at the last time point it varied between 74 g (102) and 137 g per day (91). In the comparison groups, the carbohydrate intake was generally more stable with three studies reporting a variation within 20 g between the time point after baseline and last data collection (102-104). Three studies measured the ketone bodies in urine (89, 105) or plasma (103), but only one reported results for this measure (105).

Outcomes

Three studies reported no difference in weight loss between VLCD and LFD group (101, 103, 104), and three found a greater weight loss for the VLCD group than low-glycaemic index (89), LFD (91) and moderate-carbohydrate, calorie-restricted low-fat group (102). Two of the three studies reporting a greater weight loss for the VLCD group also reported a greater reduction in HbA1c level than their control groups (89, 102). All studies reported a greater reduction in the dosage or use of anti-diabetes medication or insulin in the VLCD groups compared to their control groups. This indicates that, even if glycaemic control was not improved for all VLCD groups, it was similar to the comparison groups while the use of anti-diabetes medication was reduced.

Improvement in the serum lipid profile in the VLCD group was reported in three studies, two that reported an increase in HDL cholesterol level (89, 91) and another a decrease in triglyceride levels (103). Three studies reported improvement in the serum lipid profile but without difference between VLCD and control groups (101, 104, 105). Waist circumference was measured in three of seven studies, and all found a significant reduction but without difference between VLCD and their control group (89, 103, 104). The outcomes for blood pressure were conflicting: three studies reported no improvement for any of the groups (91, 102, 103), three studies reported improvement but no significant difference between the groups (89, 104, 105), and one study found a significant improvement in the VLCD group only (101).

Limitations

The ability to generalise these results is limited because some of the studies were conducted on uniform populations such as Black or Hispanic Americans (91), Caucasian male veterans (101) or women (89). In most of dietary interventions, there is a high risk of performance bias given that it is nearly impossible to hide the diet content from participants. Between 4 and 5 days of food records are required to estimate the true carbohydrate average intake of a group (106). Only three studies used an adequate length of food records of 4 (101), 5 (89) or 7 days (103).Two of the studies were funded by the Robert C. Atkins Foundation (89, 107), but only one of them declared that the funding source did not play a role in the design and interpretation of the results (107), meaning it is possible that the funder had some role to play in the conclusion for the other one (89). Two members of the Atkins Scientific Advisory Board were co-authors of another study (102). Dr Atkin was actively promoting VLCD in his career (92).

Future research

Future studies on VLCDs would benefit from a control of possible confounding variables such as physical activity and use of anti-diabetes medication. For interventional research, measures of carbohydrate should use a minimum of 4-day food records and ketone bodies should be measured in plasma or urine to classify participants based on their ketosis state. Prepared meals could be supplied to participants to ensure that a maximum of 50 g of carbohydrate is consumed daily.

Summary of evidence

There is no clear consensus about weight loss, waist circumference and improvement in HbA1c level for people with T2D on a VLCD. However, reduction or elimination of anti-diabetic medication is observed more frequently. Even with individual or group support, participants of studies of VLCD struggle to keep their carbohydrate intake below the goal of 20–50 g per day for longer than 24 weeks. With a generally low dietary adherence to carbohydrate-restricted diet, it is relevant to look at the carbohydrate intake of people with T2D in a real-world setting as the natural intake could greatly differ from the prescribed intervention.

2.3.3 Real-world studies of carbohydrate- restricted intake

A few studies with small sample sizes have observed people with T2D who choose freely to follow an LDC or VLCD, without a dietary intervention. Webster and colleagues followed 28 adults in Cape Town, South Africa, who chose to avoid high-carbohydrate food but did not restrict their fat intake (low-carbohydrate, high-fat diet, LCHF) over 15 months (108). Participants were motivated to follow a LCHF diet to reduce their medication intake in most cases and followed this diet for 6 months to 6 years (median 14 months, interquartile range IQR 29); seven of the participants (25%) started this diet soon after their diagnosis. The reported median daily carbohydrate intake was 61 g (IQR 30), which corresponds to a median TEI from carbohydrate of 12% (IQR 5). Participants reported reduced hunger and craving for sweet food with the LCHF, and felt it was easy to sustain because they did not have to measure portions or count calories. In the first 6 months after starting the LCHF diet, eight of 24 participants discontinued metformin, the others reported a dose reduction, and eight of the 11 participants taking insulin had discontinued it. Statins were used by 14 participants before the start of the LCHF diet, and eight of them discontinued that medication after stating the diet. One important limitation to this study is the selection of highly motivated participants.

In Canada, Wong and colleagues conducted qualitative research involving 14 adults with T1D and T2D (79% of participants) who were following a ketogenic diet for a median duration of 5 months (109). Adherence to the ketogenic diet was assessed during screening with a 24-hour phone recall. Most participants were measuring their ketones bodies daily and had an average carbohydrate target of 22 ± 12 g per day. The motivators and benefits of following the diet included improvement of glycaemic control, weight loss, reduction or cessation use of anti-diabetes medication and reversal of diabetes. Participants reported an increase satiety and overall described a positive experience, despite the perceived lack of support from health professionals for this diet.

Outside of the studies involving prescribed carbohydrate restriction and the studies cited above, there is limited information in the literature about the dietary intake on a longer period of time of people following an LCD in the real-world setting (110), especially after a diagnosis of T2D, which confirms the need for further research. Historically, research on nutrition and diseases has focused on specific nutrients. However, the use of food-based or dietary pattern recommendations is a current trend (111). This research focused on carbohydrate as a specific component of the diet for people with T2D but it also analysed a trending diet among people with T2D and research community, namely carbohydrate-restricted diets.

2.4 Conclusion and study aims

T2D is a chronic disease with an increasing prevalence, considerable burden for society and individuals. Carbohydrate has been a nutrient of interest over the last century for people with or without T2D pursuing health goals. Despite numerous studies on the topic, there is still no consensus about the ideal amount of carbohydrate people with T2D should eat. People with T2D in Western countries tend to eat less carbohydrate than the lower range recommended for the general population. Carbohydrate-restricted diets are sparking a special interest among the population and the scientific community with some outcomes improved on short term, but the different levels of restriction are not always well defined and there are discrepancies between the use of daily grams and percentage of TEI from carbohydrate. Adherence to those diets in intervention studies is most often reported as low.

Despite a multitude of carbohydrate-restricted dietary interventions, little is known about the intake of people with T2D deciding to follow an LCD or VLCD in a real-world setting. No published observational longitudinal quantitative data could be found on the carbohydrate intake of people newly diagnosed with T2D and this warrants further research. The aims of this project were to assess dietary intake in the first year following a diagnosis of T2D without dietary intervention and to use two different classifications of LCD (absolute grams and percentage of TEI) to explore the relationships between carbohydrate intake, characteristics of participants and health outcomes in people newly diagnosed with T2D.

Chapter 3. Methods

This chapter first describes the hypotheses, study design, recruitment of participants, eligibility criteria and survey design, and then describes the procedures for the data collection and data handling, variables and statistical tests used in the analyses.

3.1 Hypotheses

The following hypotheses were developed based on the review of the literature.

1. The classification of participants based on their carbohydrate intake will be different when considering the absolute grams of carbohydrate or the percentage of TEI from carbohydrates (87).
2. Carbohydrate intake in terms of absolute grams and total energy intake (TEI) of males and females recently diagnosed with type 2 diabetes (T2D) will:
    a. Increase over 12 months (91, 102, 105);
    b. Be lower than the general population (66-68).
3. When comparing to those with a higher carbohydrate intake, people reporting intake consistent with a low-carbohydrate diet (LCD, <130 g or < 26% TEI from carbohydrate) will:
    a. Experience a similar weight loss (33, 83, 95-100) and similar reduction of waist circumference in the 12 months following the diagnosis of T2D
    b. Have an average higher intake of TEI from fats as well as proteins (102, 103, 105) and a lower intake of grains, fruits and dairy food (26).
4. People newly diagnosed with T2D will not accurately describe their carbohydrate intake in terms of whether or not they are following an LCD (89, 102, 104, 105).

3.2 Study design

The hypotheses stated above are best tested using longitudinal design, hence the appropriateness to use data from the 3D study (How does Diet change after a Diagnosis of Diabetes?). As the research candidate, I did not participate in the conceptualisation of the 3D study but took an active role in the data collection, data cleaning and data entry. I collected data for the last time point in August and September 2019. Prior participation in the data collection was not possible because I was admitted to Griffith University in July 2019. I performed some of the data coding and cleaning from the 3-month time point onwards. I was responsible for the food intake data entry into FoodWorks for three of the five time points. I codified the participants' medications from baseline, edited the medication data dictionary accordingly. I investigated and verified excessively high and low nutritional intake from all time points and re-entered the data when required.

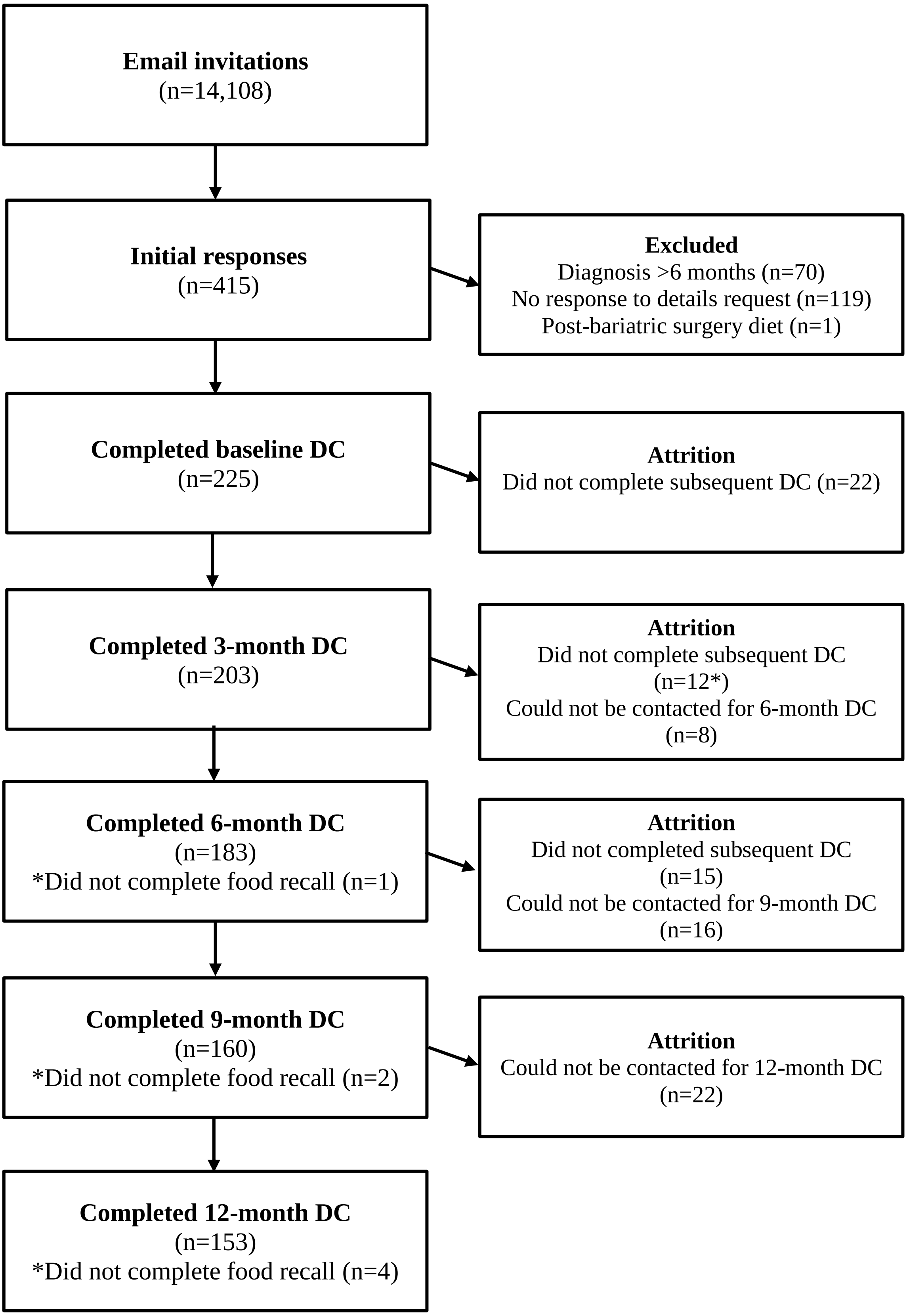
The 3D study was a case-series study aimed at examining the dietary changes that occur following a diagnosis T2D, without an intervention, in Australian adults. Case-series designs are appropriate when following people with common characteristics (112), in this case adults recently diagnosed with T2D. This descriptive study provided an opportunity to examine the carbohydrate intake of participants at five time points over 12 months in relation to a range of variables.

The 3D study was registered with the Australian New Zealand Clinical Trials Registry (ref: ACTRN12618000375257) and was approved by the Griffith University Human Research Ethics Committee (ref: 2017/951) (79). The study protocol was conceptualised (79) with guidance from the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) checklist for cohort studies (113).

3.3 Participants

Participants in the 3D study were recruited through the National Diabetes Services Scheme (NDSS), an initiative of the Australian Government (16). Eligible people living in Australia diagnosed with any type of diabetes can register with the NDSS. Registering with NDSS is not compulsory but is routinely made by a general practitioner (GP), nurse practitioner or diabetes educator for people with T2D, giving the best possible representation of the target population for this study (16). The registration with NDSS provides access to support services, health and diabetes information as well as subsidies for products such as blood glucose and urine testing strips, insulin syringes and pen needles (16). This scheme was created in 1987 and is administered by Diabetes Australia (16). In 2020, about 1.2 million people with T2D were registered with the NDSS (16).

The eligibility criteria for the 3D study included age 18 years or older, diagnosed with T2D <6 months before recruitment and being able to communicate in English. Participants were excluded if they were diagnosed with another type of diabetes (type 1 or gestational diabetes, latent autoimmune diabetes in adults, pre-diabetes) or were following a special diet because of co-morbidity (79).



DC: data collection

Figure 3.1 Completed data collection and attrition at each time point

Recruitment and participation are shown in Figure 3.1. Diabetes Australia sent an email invitation letter and lay summary of the study on behalf of the research team to 14,108 people registered with the NDSS who agreed to be contacted for research purposes. Four hundred and fifteen potential participants contacted the research team by email or telephone to be screened for eligibility. Of the 190 excluded, 70 were because their T2D was diagnosed >6 months before the study, 119 did not respond to a request for details and one was following a specialised diet after bariatric surgery. A total of 225 participants provided informed consent and completed baseline data collection. Participants were informed that withdrawal from the study was possible at any stage (79). A total of 149 participants completed the data collection involving a 24-hour food recall at 12 months, an attrition rate of 32%. A few participants did not complete the 24-hour recall because they did not have time or did not wish to discuss their food intake.

3.4 Survey design and data collection

Data collection for the 3D study began in May 2018 and concluded in October 2019. Telephone surveys were conducted at five time points over 12 months (baseline, 3, 6, 9 and 12 months). The survey took about 30 minutes and was administered by trained interviewers with expertise in dietetics (Accredited Practising Dietitian and senior dietetics students) (79). Information from the interviews was entered in a Lime Survey, an online survey management system (114). The data collected are summarised in Table 3.1.

3.4.1 Socio-demographic data

The socio-demographic data included in this analysis were age, sex, highest education level, household income, living arrangement, living environment and smoking status. Four of the socio-demographic data were categorised. Highest education level was reported as four categories and collapsed into three: high school diploma or below, diploma or certificate and university or post-graduate degree. Income was classified into three categories:<$50,000, $50,001–100,000 and >$100,001. Living environment based on post code was classified into five categories and collapsed into three: major city, inner regional outer regional and remote (79).

Table 3.1 Data collected during the 3D study and measures used in the subanalysis

Data category	Measures	Baseline only
Socio-demographic	Age *	✓
	Sex *	✓
	Highest education level *	✓
	Self-selected social class	✓
	Household income *	✓
	Ability to manage on income	✓
	Living arrangement *	✓
	Living environment *	✓
	Smoking status *	✓
	Aboriginal or Torres Strait Islander origin	✓
	Languages spoken at home	✓
Anthropometrics	Self-reported weight *	
	Self-reported height *	✓
	Self-reported waist circumference *	
	BMI (calculated with weight and height) and BMI class *	
Dietary intake	24-hour recall *	
	DASH Score (calculated from recall)	
	Self-reported special diet	(From 6 months)
	Quality of diet since the last 3 months	(From 6 months)
Medication	Diabetes medication *	
	Other prescribed medicine	
	Over-the counter	
	Supplements	
Psychosocial	K10 (mental health questionnaire)	
	Healthful Eating Beliefs Scale	
Health professional	Number of visits to GP and satisfaction	
	Number of visits to dietitian * and satisfaction	
	Number of visits to other health professionals and satisfaction	
	Discussion about diet with any health professionals	
Others	Pathology results (HbA1c, FBG, HDL, LDL, TG, CRP levels)	
	Physical activity *	
	Pre-diabetes	

Abbreviations: *BMI* body mass index, DASH dietary approaches to stop hypertension, *HbA1c* glycated haemoglobin, *FBG* fasting blood glucose, *HDL* high-density lipoprotein cholesterol, *LDL* low-density lipoprotein cholesterol, *TG* triglycerides, *CRP* c-reactive protein
* measures used for the subanalysis analysis

3.4.2 Anthropometrics measures

Participants reported their height in centimetres at baseline only and their weight in kilograms, measured on an analogue or digital scale at home, doctors or elsewhere, at all time points. Self-reported anthropometric measures have been considered sufficiently accurate in previous studies despite the fact that weight was under-reported, height over-reported and consequently body mass index (BMI) under-reported (115). BMI was calculated using reported body weight and height squared (weight/height^2). BMI is a useful measure of obesity, and participants were classified based on the World Health

Organization (WHO) classification (116). BMI is classified as underweight (<18.50 kg/m^2), normal weight (18.50–24.99 kg/m^2), overweight (25.00- 29.99 kg/m^2) or obese (≥30.00 kg/m^2, class I 30.00–34.99 kg/m^2, class II 18.50–24.99 kg/m^2, class III ≥40.00 kg/m^2).

A measuring tape was mailed to participants before the first round of data collection along with a written explanation on how to measure waist circumference in centimetres (79). Using a measuring tape and pictorial instructions to self-report waist circumference has been found to give very similar results to measurement by a health professional (117). Waist circumference gives a better indication of abdominal obesity than BMI, and participants were classified as meeting or not meeting the sex-specific WHO guideline, which is <94 cm for men and <80 cm for women (Caucasian) (118).

3.4.3 Nutrient intake

Interviewers collected dietary intake with a 24-hour recall at each time point. Participants were asked to list and quantify all foods and beverages consumed the day before the interview. From the 6-month time point, participants were also asked an open question about whether they followed a specific diet, for example ketogenic, low carbohydrate, vegetarian, intermittent fasting, etc (79).

The reported food intake was entered in the Australian version of the Automated Self-Administered 24-hour Dietary Assessment tool (ASA-24), which is usually self-administered online and automated. It was decided that ASA-24 would be used by the interviewers instead of participants themselves to reduce the strain on participants and bias related to technology use. The ASA-24 is based on the validated Automated Multiple-Pass Method which contains several probes to reduce bias in the estimation of dietary intake by asking questions about forgotten food, cooking methods and quantity eaten (119). This is an optimal method to gather dietary intake information and it aligns with the most recent National Nutrition Survey (63).

Food, beverages and associated quantities were then manually entered into FoodWorks (version 9), a dietary analysis software program. FoodWorks uses the Australian Food Composition Database 2011–13 to calculate the nutritional intake and to generate a detailed report in terms of nutrients, vitamins, minerals and food groups (120). For this substudy, the following data on intake were used from FoodWorks: total energy (kJ), total carbohydrates (g and % total energy intake, TEI), proteins (% TEI), fats (% TEI), alcohol (%TEI) and food groups (serves). The dietary approaches to stop hypertension (DASH) score was calculated to investigate diet quality as part of the main 3D study and those results have been published (80).

A feasibility study was conducted in 2016–17 to test the recruitment method and survey questions. An invitation email was sent to 1,000 potential participants, 22 of whom were recruited, 17 completed baseline data collection and 11 were retained over 12 months. The survey questions were tested to confirm they were comprehensible, relevant and appropriate to the participants and to ensure the length was appropriate. Participants in the feasibility study were not included in the 3D study (79).

3.4.4 Medication

At baseline, participants reported their medication, name and dosage for prescription and over-the-counter medication and vitamin and mineral supplements. They were then asked to record any modifications between each time point. The use or not anti-diabetes medication was and analysed as part of health and diabetes characteristics.

3.4.5 Physical activity

The intensity (vigorous, moderate, walking), frequency (days per week) and duration (minutes per day) of physical activity were reported at each time point. These data were used to score each participant based on the International Physical Activity Questionnaire (121). The criteria for each physical activity level classification are presented in Table 3.2. The metabolic equivalent task (MET)-minutes/week were calculated by multiplying minutes, days and the associated coefficient for each type of activity (coefficient for walking=3.3, moderate-intensity activity=4.0, vigorous-intensity activity=8.0) (121).

Table 3.2 Criteria for classification of physical activity level

Level	Criteria				
High	≥3 days of vigorous activity and ≥1500 MET-minutes/week	or	≥7 days of any combination of activities and ≥3000 MET-minutes/week		
Moderate	≥3 days of vigorous activity and ≥20 minutes per day	or	≥5 days of moderate activity or walking ≥30 minutes per day	or	≥5 days of any combination of activities and ≥600 MET-min/week
Low	Individuals not meeting the criteria for high or moderate activity are considered low/inactive				

Table adapted from (121)

3.4.6 Other data

Participants were asked whether they had seen a GP or other health professional, including a dietitian and whether they discussed nutrition, how satisfied they were with that service on a 5-point Likert. Participants were asked at baseline to self-report whether or not they had been told by a health professional that they had pre-diabetes prior to being diagnosed with T2D and another subanalysis was completed on this topic (122). The collection of pathology results was added to the study protocol afterward. Unfortunately, information such as HbA1c and other biomarkers were not collected with enough participants to be analysed.

3.5 Data handling and outliers

An unrealistic variation in weight was noted for eight participants between the 9- and 12-month data collection time points as shown by a weight loss or gain of >20% in a 3-month period. After verification of the raw data, the incorrect information was adjusted.

Total energy intake and the following nutrients were inspected: carbohydrates, proteins, fats, alcohol, fibre and sugars. Food recalls were re-entered into FoodWorks when errors were detected. Based on previous methodology, 24-hour recalls of male and female participant with <2,500/2,100 kJ or >17,500/15,000 kJ were considered as outliers and removed (82).

When detected, extreme outliers were modified to the closest plausible value. Extreme outliers of the change in weight and waist circumference between the last and first observations were changed to their previous or following observation. For the number of visits to a dietitian, extreme outliers (9, 24 and 36 visits in 1 year) were changed to seven visits, the closest value among the participants.

3.6 Variables and statistical tests

IBM SPSS Statistics for Windows (version 27.0) was used for all statistical analyses. For this subanalysis, the independent variables were the carbohydrate intake level (LCD or HCD) and sex. Risk factors such as body weight (kg), waist circumference (cm) and BMI (weight/height^2) were the dependent continuous ratio variables. Socio-demographic data were also analysed as dependant variables. Normality of the distribution of continuous variables was checked using the Shapiro–Wilk test. Continuous data were reported using median and interquartile range (IQR) when they were not normally distributed.

3.6.1 Baseline characteristics of the participants

Differences in the baseline characteristics between sex were identified using chi-square test for homogeneity for the categorical variables (Fisher's exact test for BMI) and Mann–Whitney *U* test for the continuous variables.

The characteristics of participants with data at baseline and 12 months ("completers", n=153) were compared with those without data at 12 months ("non-completers", n=72) using the chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables. Post hoc analysis with three z-tests of two proportions with a Bonferroni correction were performed for physical activity level, living situation and household income. The retention rate between baseline and 12 months was similar for males (67%) and female participants (65%, *p*=0.729).

3.6.2 Nutrient intake

Nutrient intake was reported at each time point as median and IQR. The non-parametric Friedman test was used to compare the intake of participants between all the five time points. Pairwise comparisons were performed with the Bonferroni correction for factors that showed significant associations. Difference in intake between men and women were identified using the non-parametric Mann–Whitney *U* test. Analysis of covariance (ANCOVA) was used to investigate if the changes in weight and waist circumference were associated with energy and carbohydrate intake.

3.6.3 Comparison with the general Australian population

One sample *t* tests were performed to identify differences in mean intake between the 3D participants and general adult population. While the intake of the 3D study participants was not normally distributed, it was the most accessible test to compare with population data. The mean intake for men and women aged 51–70 years from the Australian Bureau of Statistics' 2011–13 Australian Health Survey (63), the most recent survey that included a 24-hour recall, was used. This age category was used because majority of the 3D study participants (68%) were in this age group.

3.6.4 Correlational analysis

Spearman's rho correlation test was performed for each sex. The variables tested were age, average intake of carbohydrate (g), energy (kJ), alcohol (%TEI), average METs, BMI (last observation carried forward, LOCF), weight and waist change between the LOCF and baseline. LOCF was used to minimise the attrition bias (123). A correlation around 0.3 (or –0.3) was considered weak, between 0.3 and 0.5 (or –0.3 and –0.5) moderate and around 0.7 (or –0.7) strong (124).

3.6.5 Carbohydrate-restricted diets

LCDs are described in the literature as a daily intake <130 g (86), as discussed in Section 2.3. The limits defined in Table 2.2 were used to classify participants according to the mean for all food recalls available. Intention-to-treat analysis was used with a total of 225 entries to increase the number of days available to evaluate the carbohydrate intake and reduce the risk of bias of missing participants at the last observation of the study (125). The comparison between the characteristics of participants in each group was performed on the data collected at baseline for remoteness, living situation, education, smoking status and diagnosis of pre-diabetes; at 12 months for weight, BMI, waist circumference and physical activity (LOCF); and for the overall study for the use of diabetes medication, dietitian visits and self-reported diet.

Difference between categories of carbohydrate-restricted diets were identified using the chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables. Differences between men and women were tested using the Mann–Whitney *U* test. Multivariate repeated measures models were used to test if the changes in weight and waist circumference were associated with energy intake. The intake by food group was based on the Australian Guide for Healthy eating (32) and included grains (with subclasses of wholegrains and refined grains), protein foods, fruits (with a subclass of fruits juices), vegetables (with a subclass of starchy vegetables) and dairy.

Chapter 4. Results

This chapter presents the results of the 3D study subanalysis focused on carbohydrate intake and carbohydrate-restricted diets. To address the hypotheses, the characteristics of participants at baseline are reported, followed by dietary intakes, including macronutrients and food groups serves, listed for men and women. The average macronutrient intake is compared with that of the general Australian population, and the outcomes are contrasted based on two classification systems for carbohydrate intake.

4.1 Baseline characteristics of participants

A total of 225 adults with a median age of 60 years, commenced the 3D study, and 153 participants remained at 12 months, resulting in a retention rate of 68%. The baseline characteristics of the sample has previously been reported and compared with other populations (80). Table 4.1 shows the baseline characteristics of male and female participants. There were more men (n=125, 56%) than women in the sample at baseline. Men were more likely than women to live with a partner or spouse and women were more likely than men to live alone ($p<0.001$). This difference is also reflected in the reported household income, which was higher for men than women ($p=0.016$).

The median self-reported weight and height was significantly higher for men than women ($p<0.001$) but median body mass index (BMI) did not differ ($p=0.339$). Self-reported waist circumference did not differ between men and women ($p=0.468$), and the median was 107.3 cm (IQR 21). Given the guidelines are sex specific this meant that significantly more women (97% above 80 cm) than men (86% above 94 cm, $p=0.008$) had a waist circumference above their respective guidelines (118).

Table 4.1 Baseline characteristics of participants according to sex

	All participants n=225[1] (100%)	Males (M) n=125 (56%)	Females (F) n=100 (44%)	p^2
Age (years) *median (IQR)*	60.0 (16)	59.0 (16)	61.0 (15)	0.311
Remoteness *n (%)*				
Major city	151 (67)	82 (66)	69 (70)	0.855
Inner regional	47 (21)	27 (22)	20 (20)	
Outer regional/remote	27 (12)	16 (13)	11 (10)	
Living situation *n (%)*				**<0.001[a]**
Partner/spouse	148 (66)	94 (76)	54 (54)	**<0.001**
Alone	44 (20)	14 (11)	30 (30)	**<0.001**
Other	31 (14)	15 (12)	16 (16)	NS
Highest education *n (%)*				
Year 12 or below	61 (27)	36 (29)	25 (25)	0.262
Diploma or certificate	81 (36)	39 (32)	42 (42)	
University	82 (37)	49 (40)	33 (33)	
Household gross income *n (%)*				**0.011[b]**
<$50,000	70 (36)	31 (28)	39 (48)	0.005
$50,001–100,000	60 (31)	36 (32)	24 (29)	NS
>$100,001	63 (33)	44 (40)	19 (23)	0.016
Weight (kg) *median (IQR)*	90.0 (27)	94.0 (26)	86.0 (27)	**<0.001**
Height (cm) *median (IQR)*	171.0 (15)	176.0 (9)	163.0 (10)	**<0.001**
BMI (kg/m^2) *median (IQR)*	30.9 (9)	30.2 (8)	31.7 (10)	0.102
BMI category *n (%)*				
Underweight	1 (0)	-	1 (1)	0.339
Normal	30 (13)	18 (15)	12 (12)	
Overweight	62 (28)	40 (32)	22 (22)	
Obesity				
Obesity class I	63 (28)	32 (26)	31 (31)	
Obesity class II	47 (21)	25 (20)	22 (22)	
Obesity class III	21 (9)	9 (7)	12 (12)	
Waist circumference *(cm) median (IQR)*	107.3 (21)	107.0 (19)	108.0 (22)	0.468
Waist circumference above guidelines for sex *n (%)*	185 (91)	97 (86)	88 (97)	**0.008**
Physical activity *n (%)*				0.043[c]
Low	76 (34)	35 (28)	41 (41)	NS
Moderate	120 (53)	69 (55)	51 (51)	NS
High	29 (13)	21 (17)	8 (8)	NS
Using diabetes medication *n (%)*				
Yes	150 (67)	84 (67)	66 (66)	0.850
No	75 (33)	41 (33)	34 (34)	
Seen dietitian before baseline *n (%)*				
Yes	121 (54)	65 (52)	56 (56)	0.550
No	104 (46)	60 (48)	44 (44)	
Smoking status *n (%)*				
Yes	26 (12)	16 (13)	10 (10)	0.514
No	199 (88)	109 (87)	90 (90)	
Pre-diabetes diagnosis *n (%)*				
Yes	101 (46)	57 (47)	44 (44)	0.693
No	119 (54)	64 (53)	55 (56)	

IQR interquartile range, *NS* not significant, *BMI* body mass index

[1] Waist: n=204 (M 113, F 91), BMI and Education n=224 (M 124, F 100), Living situation n=223 (M 123, F 100), Income n=193 (M 111, F 82), Pre-diabetes n=220 (M 121, F 99)

[2] Statistical tests used to compare men and women: chi-square test for homogeneity for categorical variables (Fisher's exact test for BMI) and Mann–Whitney *U* test for continuous variables.

[a] Post hoc analysis with three z-tests of two proportions with a Bonferroni correction. Significance was accepted at $p<0.017$. Pairwise comparisons for "Partner/spouse" and "Alone" were significant (p<0.001).

[b] Post hoc analysis with three z-tests of two proportions with a Bonferroni correction. Significance was accepted at $p<0.017$. Pairwise comparisons for "<$50,000" (p=0.005) and ">$100,001" (p=0.016) were significant.

[c] Post hoc analysis with three z-tests of two proportions with a Bonferroni correction. Significance was accepted at $p<0.017$. All pairwise comparisons were not significant.

Some of the baseline characteristics differed between people who completed the study (n=153, ‘completers’) and people who did not complete the study (n=72, ‘non-completers’). Table 4.2 compares the baseline demographic and health data for those who remained in the study to 12 months compared to those who did not. The non-completers were more likely than the completers to have been classified as obese at baseline (p=0.013). The non-completers were less likely than the completers to live with a partner or a spouse (p<0.001) and more likely to live in other situations (p<0.001), such as living with parents, other adults or own or other children, but there were no other demographic differences. The dietary intake at baseline was compared between completers and non-completers (data not shown). No differences were found for energy, macronutrient, alcohol or food groups intake (all p>0.05). There was no difference when comparing the categorisation of completers and non-completers based on their carbohydrate-restricted diet for both classification systems (77 participants without food recall at 12 months). Using the absolute grams of carbohydrate classification, 47% of the non-completer were on the low-carbohydrate diet (LCD) and 53% on the high carbohydrate diet (HCD, 53%, p=0.268) at baseline. When looking at the percentage of TEI from carbohydrate, there was 20% of non-completers on an LCD, 68% on a moderate carbohydrate diet (MCD) and 12% on an HCD at baseline (p=0.428).

Table 4.2 Baseline characteristics of completers and non-completers

	Completers n=153[1] (68%)	**Non-completers n=72[1] (32%)**	***p*[2]**
Sex *n (%)*			
Males	85 (56)	40 (56)	1.000
Females	69 (44)	32 (44)	
Age (years) *median (IQR)*	60.0 (15)	57.5 (15)	0.283
Remoteness *n (%)*			
Major city	104 (68)	47 (65)	0.123
Inner regional	35 (23)	12 (17)	
Outer regional/remote	14 (9)	13 (18)	
Living situation *n (%)*			**0.026[a]**
Partner/spouse	108 (71)	40 (56)	**<0.001**
Alone	29 (19)	15 (21)	NS
Other	15 (10)	31 (23)	**<0.001**
Highest education *n (%)*			
Year 12 or below	43 (28)	18 (25)	0.383
Diploma or certificate	58 (38)	23 (32)	
University	51 (34)	31 (43)	
Household gross income *n (%)*			
<$50,000	48 (36)	22 (36)	0.923
$50,001–100,000	42 (32)	18 (30)	
>$100,001	42 (32)	21 (34)	
Weight (kg) *median (IQR)*	90.0 (27)	91.2 (25)	0.316
Height (cm) *median (IQR)*	171.0 (15)	170.0 (15)	0.679
BMI (kg/m^2) *median (IQR)*	30.2 (10)	31.9 (7)	0.087
BMI category *n (%)*			**0.030[b]**
Normal	26 (17)	5 (7)	NS
Overweight	46 (30)	16 (23)	NS
Obesity	81 (53)	50 (70)	**0.013**
Waist circumference (cm) *median (IQR)*	107.0 (21)	108.0 (19)	0.601
Waist circumference above guidelines for sex *n (%)*	128 (91)	57 (91)	0.945
Physical activity *n (%)*			
Low	50 (33)	26 (36)	0.582
Moderate	85 (56)	35 (49)	
High	18 (12)	11 (15)	
Using diabetes medication *n (%)*			
Yes	57 (37)	18 (25)	0.069
No	96 (63)	54 (75)	
Seen dietitian pre-baseline *n (%)*			
Yes	83 (54)	38 (53)	0.836
No	70 (46)	34 (47)	
Smoking status *n (%)*			
Yes	18 (12)	8 (11)	0.886
No	135 (88)	64 (89)	
Pre-diabetes diagnosis *n (%)*			
Yes	72 (48)	29 (41)	0.362
No	78 (52)	41 (59)	

Completers participants with data collected at baseline and 12 months, *Non-completers* participants with data collected at baseline but not at 12 months

IQR interquartile range, *BMI* body mass index

[1] Waist: n=204 (completers 141, non-completers 63), BMI and Education n=224 (completers 152, non-completers 72), Living situation n=223 (completers 152, non-completers 71), Income n=193 (completers 132, non-completers 61), Pre-diabetes n=220 (completers 150, non-completers 70)

[2] Statistical analysis between completers and non-completers: chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables

[a] Post hoc analysis with three z-tests of two proportions with a Bonferroni correction. Significance was accepted at $p<0.017$. Pairwise comparisons for “Partner/spouse” and “Other” were significant ($p<0.001$).

[b] For this analysis, the participant with a BMI classified as underweight was included in the normal BMI. Post hoc analysis with three z-tests of two proportions with a Bonferroni correction. Significance was accepted at $p<0.017$. Pairwise comparisons for “Obese” BMI ($p=0.013$) were significant.

4.2 Nutrient intake at all time points

Table 4.3 shows the energy and macronutrient intake for participants at each of the five data collection points. Total carbohydrate intake of the cohort varied over time with the difference due to men whose median daily total carbohydrate intake had significantly increased from baseline compared to 12 months (157 vs 187 g, p=0.028). The mean total energy intake (TEI) from carbohydrates was below the minimum acceptable macronutrient distribution range (AMDR) of 45% of TEI and this did not vary across all five time points. The median TEI and carbohydrate intake were significantly higher for men than women but there was no difference in median TEI from carbohydrate (percentage) at any time point (p>0.05).

The median TEI from fats was significantly higher for women than men at 3 months (median TEI 41.4 vs 35.6%, respectively, p=0.002) and 6 months (median TEI 39.4 vs 35.6%, respectively, p=0.041). However, when analysing fat in grams, this difference was not significant. The median fat intake for men and women was respectively of 69 g (IQR 45) and 67 g (IQR 37, p=0.835) at 3 months and 75 g (IQR 47) and 62 g (IQR 39) at 6 months (p=0.186). The median TEI from alcohol was significantly lower in women at all time points (p<0.05) except at 3 months. Although the median TEI from alcohol was zero at all time points and the IQR was small, some participants reported consuming alcohol. For example, at baseline 50 participants reported drinking alcohol (175 participants reported no alcohol intake) in the 24-hour recall. The mean alcohol intake for the cohort was 2.1% of TEI (SD 5.2) or 7 g of alcohol (SD 16). The average daily median fibre intake was significantly higher in men than women (23 vs 20 g, respectively, p<0.0010 with the intake for both below the recommendations (30 g for men and 25 g for women per day) (55).

Table 4.3 Median energy and macronutrient intake for participants at each of five time points

	Baseline (n=222)	3 months (n=197)	6 months (n=180)	9 months (n=155)	12 months (n=147)	Average (n=225)		
	Median (IQR)	*Median (IQR)*	*Median (IQR)*	*Median (IQR)*	*Median (IQR)*	*Median (IQR)*	***p*[1]**	***p*[2]**
ALL PARTICIPANTS								
Energy (MJ/day)	6.8 (3.5)	6.6 (3.3)	6.6 (4.0)	6.9 (3.3)	7.1 (3.9)	6.8 (2.6)	0.548	*
Carbohydrates (g/day)	145 (94)	145 (94)	141 (98)	146 (94)	157 (93)	151 (77)	**0.040[a]**	*
Carbohydrates (% TEI)	33.5 (16)	35.3 (14)	35.0 (14)	35.4 (16)	36.8 (15)	36.0 (11)	0.172	NS
Proteins (% TEI)	20.3 (8)	20.4 (8)	20.6 (7)	19.7 (7)	20.8 (8)	20.7 (6)	0.114	NS
Fats (% TEI)	38.6 (11)	38.4 (14)	37.0 (11)	37.2 (14)	34.5 (13)	36.8 (8)	**0.026[a]**	*
Alcohol (% TEI)	0 (0)	0 (0)	0 (3)	0 (0)	0 (0)	0 (2.5)	0.983	*
MALES	n=122	n=110	n=103	n=86	n=83	n=125		
Energy (MJ/day)	7.5 (3.4)	7.0 (3.8)	7.5 (4.6)	7.6 (2.9)	8.3 (4.0)	7.6 (2.9)	0.201	
Carbohydrates (g/day)	157 (97)	158 (97)	165 (101)	159 (100)	187 (110)	157 (94)	**0.028[b]**	
Carbohydrates (% TEI)	35.3 (15)	35.9 (14)	36.0 (13)	35.0 (16)	35.9 (14)	35.3 (11)	0.284	
Proteins (% TEI)	19.9 (8)	20.3 (8)	20.3 (7)	20.1 (8)	20.1 (8)	20.3 (5)	0.958	
Fats (% TEI)	39.0 (11)	35.6 (15)	35.6 (11)	35.2 (16)	35.5 (13)	36.1 (8)	0.085	
Alcohol (% TEI)	0 (4)	0 (0)	0 (5)	0 (5)	0 (4)	0 (4)	0.958	
FEMALES	n=100	n=87	n=77	n=69	n=64	n=100		
Energy (MJ/day)	6.0 (2.8)	6.2 (2.6)	5.9 (3.1)	6.0 (2.6)	6.1 (2.3)	6.1 (2.1)	0.889	
Carbohydrates (g/day)	123 (75)	124 (92)	119 (89)	129 (80)	133 (60)	136 (76)	0.732	
Carbohydrates (% TEI)	35.6 (17)	34.2 (14)	33.8 (15)	35.6 (16)	37.0 (17)	36.6 (10)	0.402	
Proteins (% TEI)	20.7 (8)	20.6 (7)	20.7 (8)	19.2 (6)	21.8 (9)	21.7 (5)	**0.026[c]**	
Fats (% TEI)	38.5 (12)	41.4 (13)	39.4 (13)	35.7 (15)	33.9 (15)	38.0 (8)	**0.019[d]**	
Alcohol (% TEI)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (2)	0.947	

MJ megajoules, *IQR* interquartile range, *TEI* total energy intake, *NS* not significant (p>0.05) [1] Difference between time points tested using the Friedman test (baseline and 3, 6, 9 and 12 months). [2] Difference between males and females tested using the Mann–Whitney *U* test. [a] Pairwise comparison showed significant differences between baseline and 12 months (p=0.019 for carbohydrate grams and p=0.32 for fat, adjusted for Bonferroni correction). [b] Pairwise comparison showed significant difference between baseline and 12 months (p=0.011, adjusted for Bonferroni correction). [c] Pairwise comparison showed significant difference between 9 and 12 months (p=0.017, adjusted for Bonferroni correction). [d] Pairwise comparison showed significant difference between 3 and 12 months (p=0.014, adjusted for Bonferroni correction).* Significant difference between males and females for Energy (p<0.001 at baseline and 9 and 12 months, and average, p=0.016 at 3 months, p=0.002 at 6 months), Carbohydrate (grams) (p=0.002 at baseline, p=0.014 at 3 months, p<0.001 at 6 and 12 months and average, p=0.016 at 9 months), Fats (p=0.002 at 3 months, p=0.041 at 6 months), Alcohol (p=0.004 at baseline, p=0.023 at 6 months, p=0.026 at 9 months, p=0.014 at 12 months, p=0.002 average)

Weight and key aspects of nutrient intake were compared between the 3D participants (median age 60 years, ranged between 30 and 81 years old) and the Australian population between 51 and 70 years (Table 4.4). Male and female participants in the 3D study reported significantly higher weight but lower intake of energy and carbohydrates as well as TEI from alcohol, and a higher TEI from proteins and fats compared with the Australian population of a similar age. Fibre intake for male participants was similar to the general population and female participants had a lower intake than the general population.

Table 4.4 Energy and macronutrient intake of 3D participants compared with the general Australian population

	Men			Women		
	ABS n=2,370 *Mean (SE)*	3D study n=125 *Mean (SD)*	*P*[1]	ABS n=2,438 *Mean (SE)*	3D study n=100 *Mean (SD)*	*p*[1]
Weight (kg)	81.2 (0.64)	94.0 (26)	**<0.001**	79.9 (0.67)	86.0 (27)	**0.026**
Energy (MJ/day)	9.4 (2.3)	7.7 (2.1)	**<0.001**	7.3 (1.2)	6.4 (1.5)	**<0.001**
Carbohydrate intake (g)	234 (1.6)	163 (61)	**<0.001**	184 (1.6)	135 (51)	**<0.001**
Carbohydrates (% TEI)	42 (2.8)	34.6 (8.6)	**<0.001**	42 (0.6)	34.5 (9.0)	**<0.001**
Fibre (g)	25 (1.9)	25 (9.9)	0.615	22 (2.6)	20 (6.9)	**0.008**
Proteins (% TEI)	19 (1.7)	21.1 (5.2)	**<0.001**	19 (1.6)	21.8 (4.3)	**<0.001**
Fats (% TEI)	30 (2.6)	37.3 (7.7)	**<0.001**	31 (1.6)	38.5 (6.9)	**<0.001**
Alcohol (% TEI)	7 (8.9)	3.1 (5.8)	**<0.001**	5 (7.3)	1.4 (3.4)	**<0.001**

MJ megajoules, *TEI* total energy intake, *ABS* Australian Bureau of Statistics, *SE* Relative Standard Error of estimate (%)
ABS Australian Health Survey 2011–13, men and women aged 51–70 years
3D study participants' median age 60 (IQR 16, minimum 30, maximum 81)
[1] Difference between ABS and 3D study participants using one-sample *t* test

4.3 Classification according to carbohydrate intake

Table 4.5 presents the number and proportion of participants classified in each level of carbohydrate restriction (described in Table 2.2) according to both absolute grams of carbohydrates and percentage of TEI from carbohydrate using the average of all available 24-hour food recalls. Few participants had an average intake of carbohydrates at the very low-carbohydrate diet level for either classification (four participants <50 g and one participant <10% TEI). These participants were added to the low-carbohydrate diet (LCD) group for the analysis. Using absolute grams of carbohydrate, 37% of participants had an intake classifying them as being on an LCD (<130 g) and 63% were classified on being on an HCD (≥130 g). Most participants (73%) were classified into moderate carbohydrate intake (26 to 45% of TEI). Only 9% of participants had an intake >45% of TEI from carbohydrate (HCD). More participants were classified in the LCD based on absolute grams than with the percentage of TEI from carbohydrate classification system.

Table 4.5 Carbohydrate-restricted diet classification of 3D study participants based on absolute grams of carbohydrate and on percentage of TEI from carbohydrate

		Average of all food recalls (n=225)	
		Absolute grams *n* **(%)**	**Percentage of TEI** *n* **(%)**
VLCD	**Criteria**	**<50 g**	**<10% TEI**
	Total	4 (2)	1 (0)
	Males	2 (2)	1 (1)
	Females	2 (2)	0 (0)
LCD	**Criteria**	**<130 g**	**<26% TEI**
	Total	79 (35)	39 (17)
	Males	35 (28)	20 (16)
	Females	44 (44)	19 (19)
MCD	**Criteria**	-	**26–45% TEI**
	Total		165 (73)
	Males		93 (74)
	Females		72 (72)
HCD	**Criteria**	**>130 g**	**>45% TEI**
	Total	142 (63)	20 (9)
	Males	88 (70)	11 (9)
	Females	54 (54)	9 (9)

TEI total energy intake, *VLCD* very low-carbohydrate diet, *LCD* low-carbohydrate diet, *MCD* moderate-carbohydrate diet, *HCD* high-carbohydrate diet
n (%): for the total line, the percentage based on the total number of participants, for males and females the percentage is based on the total number of males and females.

Table 4.6 presents the distribution of participants using the two classification systems based on carbohydrate intake. Only 22% of participants were classified in the same groups based on both classification systems (13% in the LCD and 9% in the high-carbohydrate diet (HCD) groups). The lack of definition for the moderate-carbohydrate diet (MCD) based on absolute grams (126) increased the disparity between the two classification systems because 165 participants (74%) were classified into the MCD group based on the TEI from carbohydrates. Alcohol intake changed the proportion of other macronutrients and therefore impacted on the classification of participants. Of the nine participants reporting an alcohol intake ≥ 15% TEI, two were classified in different level of carbohydrate-restricted diet based on absolute grams or TEI from carbohydrate.

Table 4.6 Distribution of participants according to two classification systems for carbohydrate-restricted diets based on the average of all food recalls for the 3D study participants

	Absolute grams classification (n=225)		
TEI from carbohydrate classification	**VLCD (<50 g)** **n (%)**	**LCD (<130 g)** **n (%)**	**HCD (≥130 g)** **n (%)**
VLCD (<10% TEI)	–	1 (0)	–
LCD (<26% TEI)	4 (2)	30 (13)	5 (2)
MCD (26–45% TEI)	–	47 (21)	118 (53)
HCD (>45% TEI)	–	1 (0)	19 (9)

TEI total energy intake, *VLCD* very low-carbohydrate diet, *LCD* low-carbohydrate diet, *MCD* moderate-carbohydrate diet, *HCD* high-carbohydrate diet
Intention-to-treat analysis
Shaded numbers represent the number of participants classified in the same category according to the two classification systems.

Most participants (70%) were classified into the same category at baseline and 12 months based on the absolute carbohydrate gram classification; 24% of participants were classified into the LCD and 46% into the HCD at the beginning and end of the study. However, using the TEI percentage classification, only 47% were in the same category and most of these (72%) were in the MCD group at baseline and 12 months (data not shown).

4.3.1 Demographic characteristics

Demographic characteristics are presented in Table 4.7 and were similar between groups using both classification systems. The only significant difference was a greater proportion of women than men in the LCD group based on the absolute grams of carbohydrate (55% women vs 45% men, p=0.011).

4.3.2 Anthropometric characteristics

Anthropometric characteristics of participants are presented in Table 4.8 and the following paragraphs describe the results for each classification systems.

Absolute grams of carbohydrate classification

The median waist circumference at 12 months (last observation carried forward, LOCF) was lower in the LCD than in the HCD group (absolute grams of carbohydrate classification, 101.5 vs 106.0 cm, respectively, p=0.038). When adjusted for energy intake, the difference in waist circumference based on grams of carbohydrate intake was significant only for women (analysis of covariance (ANCOVA), p=0.047). The last waist circumference observed was also explained by the last weight observed (ANCOVA, $p<0.001$).

Between baseline and 12 months (LOCF), waist circumference decreased significantly more in female participants on an LCD than in those on an HCD (absolute grams classification, 5.6% reduction for LCD vs 2.6% for HCD, p=0.007). When adjusted for the energy intake, the difference between the two groups was no longer significant (p=0.165).

Percentage of TEI from carbohydrate classification

No difference was observed between the anthropometric characteristics of the three groups of LCD, MCD and HCD based on the percentage of TEI from carbohydrate classification. However, there were some differences when analysing the LCD and HCD groups only. The median BMI and waist circumference were higher in women in the HCD group than in the LCD group (40.0 vs 29.8 kg/m^2, p=0.037 and 113 vs 102 cm, p=0.030, respectively). When adjusted for average TEI, the difference was significant for waist circumference (ANCOVA, p=0.016) but not for BMI (ANCOVA, p=0.085). The waist circumference decreased significantly more from baseline to 12 months in the LCD group than the HCD group (3.6 vs 0.9%, respectively, p=0.018). However, when adjusted for average TEI, the decrease in waist circumference did not remain significant (ANCOVA, p=0.107).

4.3.3 Health and diabetes characteristics

No difference in health (diet quality score, physical activity, dietitian visit, smoking status) and diabetes characteristics (using diabetes medication, pre-diabetes diagnosis) were observed for both classification systems as shown in Table 4.9.

Table 4.7 Demographic characteristics according to the absolute grams of carbohydrate and total energy intake from carbohydrate diet classification based on average of all food recalls for the 3D study participants

	Average of all food recalls (n=225[1])							
	LCD* <130 g	**HCD ≥130 g**	***p*[2]**	**LCD** <26% TEI**	**MCD 26–45% TEI**	**HCD >45% TEI**	***p*[3]**	***p*[4]**
	n=83 (37%)	**n=142 (63%)**		**n=40 (18%)**	**n=165 (73%)**	**n=20 (9%)**		
Sex *n (%)*								
Male	37 (45)	88 (62)	**0.011**	21 (53)	93 (56)	11 (55)	0.906	0.855
Female	46 (55)	54 (38)		19 (48)	72 (43)	9 (45)		
Age (years) *median (IQR)*	58.0 (19)	60.5 (14)	0.305	55.0 (16)	60.0 (15)	62 (17)	0.153	0.195
Remoteness *n (%)*								
Major city	63 (76)	88 (62)	0.070	27 (68)	111 (67)	13 (68)	0.995	0.991
Inner regional	11 (13)	36 (25)		9 (22)	34 (21)	4 (21)		
Outer regional/remote	9 (11)	18 (13)		4 (10)	20 (12)	2 (11)		
Living situation *n (%)*								
Partner/spouse	54 (66)	94 (67)	0.741	27 (70)	111 (68)	10 (50)	0.544	0.311
Alone	18 (22)	26 (18)		6 (15)	32 (19)	6 (30)		
Other	10 (12)	21 (15)		6 (15)	21 (13)	4 (20)		
Education *n (%)*								
Year 12 or below	18 (22)	43 (30)	0.097	10 (26)	43 (26)	8 (40)	0.759	0.523
Diploma or certificate	37 (45)	44 (31)		15 (38)	60 (36)	6 (30)		
University	27 (33)	55 (39)		14 (36)	62 (38)	6 (30)		
Household gross income *n (%)*								
<$50,000	20 (28)	50 (41)	0.238	8 (24)	52 (37)	10 (53)	0.080	0.061
$50,001–100,000	25 (36)	35 (29)		8 (24)	47 (33)	5 (26)		
>$100,001	25 (36)	38 (31)		17 (52)	42 (30)	4 (21)		

LCD low-carbohydrate diet, *HCD* high-carbohydrate diet, *TEI* total energy intake, *MCD* moderate-carbohydrate diet, *IQR* interquartile range * Very low-carbohydrate diet n=4 included in this category ** Very low-carbohydrate diet n=1 included in this category. Intention-to-treat analysis [1] Living situation n=223, Education n=224 and Income n=193 [2] Difference between LCD and HCD based on absolute grams classification tested using chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables. [3] Difference between LCD, MCD and HCD based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables and Kruskal–Wallis *H* test for continuous variables. [4] Difference between LCD and HCD only based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables.

Table 4.8 Anthropometric characteristics according to the absolute grams of carbohydrate and total energy intake from carbohydrate diet classification based on average of all food recalls for the 3D study participants

	Average of all food recalls (n=225[1])							
	LCD* < 130 g	**HCD ≥ 130 g**	p[2]	**LCD** <26% TEI**	**MCD 26–45% TEI**	**HCD >45% TEI**	*p*[3]	*p*[4]
	n=83 (37%)	**n=142 (63%)**		**n=40 (18%)**	**n=165 (73%)**	**n=20 (9%)**		
Weight (kg) *median (IQR)*	85.0 (24)	91.0 (32)	0.169	86.0 (24)	89.0 (31)	99.0 (37)	0 537	0.312
Males	92.0 (19)	94.7 (33)	0.797	94.6 (29)	93.0 (27)	102.0 (41)	0.805	0.755
Females	78.5 (24)	84.3 (26)	0.333	79.2 (24)	81.0 (26)	90.7 (29)	0 360	0.188
Weight change baseline to 12 months (%) *median (IQR)*	–1.5 (6)	–1.4 (7)	0.317	0.0 (6)	–1.6 (7)	0.0 (6)	0.491	0.515
Males	0.0 (5)	1.1 (8)	0.651	0.0 (4)	–1.5 (8)	0.0 (5.2)	0 594	0.876
Females	–2.4 (7)	–1.6 (6)	0.099	–2.1 (8)	–2.1 (6)	–1.6 (9)	0.716	0.530
BMI (kg/m^2) *median (IQR)*	29.4 (7)	31.3 (9)	0.118	29.7 (8)	30.6 (9)	31.7 (13)	0 274	0.113
Males	29.0 (6)	31.1 (9)	0.115	29.5 (8)	30.4 (8)	31.5 (10)	0 954	0.815
Females	30.4 (9)	32.3 (11)	0.356	29.8 (7)	30.7 (10)	40.0 (11)	0 143	**0.037**
BMI category *n (%)*								
Underweight	0 (0)	1 (1)	0.071	–	1 (1)	–	0 327	0.167
Normal	7 (13)	19 (19)		3 (7)	27 (16)	2 (10)		
Overweight	26 (50)	27 (28)		18 (45)	50 (31)	4 (20)		
Obesity	19 (37)	51 (52)		19 (48)	86 (52)	14 (70)		
Waist circumference (cm) *median (IQR)*	101.5 (22)	106.0 (22)	**0.038**	102.0 (25)	104.0 (20)	113.0 (28)	0 244	0.100
Males	102.0 (21)	106.0 (23)	0.251	105.5 (25)	105.0 (21)	102.0 (26)	0 960	0.761
Females	99.0 (21)	105.5 (20)	0.131	98.0 (20)	102.0 (20)	115.5 (28)	0.075	**0.030**
Waist circumference change baseline to 12 months (%) *median (IQR)*	–4.5 (8)	–2.2 (5)	**0.017**	–3.6 (7)	–2.6 (7)	–0.9 (5)	0 102	**0.018**
Males	–2.2 (7)	–2.0 (5)	0.709	–2.5 (6)	–2.1 (6)	–1.6 (4)	0.419	0.145
Females	–5.6 (11)	–2.6 (6)	**0.007**	–5.0 (8)	–3.4 (7)	–0.4 (5)	0 268	0.062
Waist circumference above guidelines for sex *n (%)*	69 (88)	122 (87)	0.777	32 (84)	143 (89)	16 (84)	0.662	1.000
Males	27 (77)	74 (84)	0.364	15 (75)	77 (84)	9 (82)	0.665	0.664
Females	42 (98)	48 (92)	0.244	17 (94)	66 (96)	7 (88)	0.619	0.540

LCD low-carbohydrate diet, *HCD* high-carbohydrate diet, *TEI* total energy intake, *MCD* moderate-carbohydrate diet, *kg* kilogram, *IQR* interquartile range, *BMI* body mass index
Intention-to-treat analysis. Using last observation carried forward for weight/weight change, BMI, waist circumference, waist circumference change. Waist above guideline >80 cm (women), >94 cm (men) * Very low-carbohydrate diet n=4 included in this category ** Very low-carbohydrate diet n=1 included in this category. [1] BMI n=224, Waist circumference and guideline n=218. [2] Difference between LCD and HCD based on absolute grams classification tested using chi-square test for homogeneity for categorical variables (Fisher's exact test for BMI) and Mann–Whitney *U* test for continuous variables. [3] Difference between LCD, MCD and HCD based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables (Fisher's exact test for BMI) and Kruskal–Wallis *H* test for continuous variables. [4] Difference between LCD and HCD only based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables.

Table 4.9 Health and diabetes characteristics according to the absolute grams of carbohydrate and total energy intake from carbohydrate diet classification based on average of all food recalls for the 3D study participants

	Average of all food recalls (n=225[1])							
	LCD* < 130 g	**HCD ≥ 130 g**	p[2]	**LCD** <26% TEI**	**MCD 26–45% TEI**	**HCD >45% TEI**	*p*[3]	*p*[4]
	n=83 (37%)	**n=142 (63%)**		**n=40 (18%)**	**n=165 (73%)**	**n=20 (9%)**		
DASH score average *median (IQR)*	24 (5)	24 (6)	0.786	24 (4)	24 (4)	22 (5)	0.091	0.876
Physical activity (MET-min/week) *median (IQR)*	1370 (1328)	1431 (1682)	0.799	1380 (1550)	1401 (1493)	1837 (3065)	0.681	0.576
Using diabetes medication *n (%)*	49 (59)	98 (69)	0.129	24 (60)	107 (65)	16 (80)	0.298	0.121
Seen dietitian *n (%)*	48 (58)	86 (61)	0.987	22 (50)	100 (60)	12 (60)	0.810	0.713
Number of visits *median (IQR)*	1 (2)	1 (2)	0.536	1.0 (2)	1 (2)	1 (2)	0.327	0.167
Current smoker *n (%)*	14 (17)	12 (9)	0.057	3 (8)	22 (13)	1 (5)	0.369	0.714
Pre-diabetes diagnosis *n (%)*	37 (45)	64 (46)	0.857	20 (51)	71 (44)	10 (50)	0.670	0.926

LCD low-carbohydrate diet, *HCD* high-carbohydrate diet, *TEI* total energy intake, *MCD* moderate-carbohydrate diet, *IQR* interquartile range, *DASH* Dietary Approaches to Stop Hypertension
* Very low-carbohydrate diet n=4 included in this category ** Very low-carbohydrate diet n=1 included in this category. Intention-to-treat analysis
Using last observation carried forward for physical activity and use of diabetes medication. Total dietitian visits during study. Using if participants has seen a dietitian at some point during the study and number total of visits.
[1] Pre-diabetes n=220
[2] Difference between LCD and HCD based on absolute grams classification tested using chi-square test for homogeneity for categorical variables (Fisher's exact test for BMI) and Mann–Whitney *U* test for continuous variables
[3] Difference between LCD, MCD and HCD based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables (Fisher's exact test for BMI) and Kruskal–Wallis *H* test for continuous variables
[4] Difference between LCD (n=40) and HCD (n=40) only based on TEI from carbohydrate tested using chi-square test for homogeneity for categorical variables and Mann–Whitney *U* test for continuous variables.

4.3.4 *Energy and macronutrient intake*

The median nutritional intake of all food recalls are displayed in Table 4.10 by absolute grams and TEI from carbohydrate classifications. The analysis by absolute grams showed that the median intake of energy, carbohydrates and fibre were significantly lower for male and female participants on LCD compared with those on an HCD (p<0.001). The median intakes of proteins and fats were significantly higher for those on an LCD compared with those on an HCD (p<0.001). Energy intake was significantly lower in female than in male participants in both groups (p<0.05). Men in the HCD group had a significantly higher intake of carbohydrate, fibre and alcohol than women (p<0.05).

When using the percentage of TEI classification, carbohydrate intake (grams and TEI from carbohydrate) differed significantly between groups as expected. Intakes of fat and proteins also differed significantly between the groups, with percentages higher in the LCD than the HCD group (p<0.001). Energy and alcohol intake were similar across the three groups for both sexes. In men, fibre intake was lower in the LCD group than in the MCD and HCD groups (p=0.008). In the LCD group, total energy intake did not differ significantly between men and women (p>0.05) Intakes in the MCD and HCD groups were greater for men than women in term of energy (p<0.05), carbohydrate in grams (p<0.05), fibre (p<0.001) and proteins (MCD only, p<0.05).

Table 4.10 Energy intake and macronutrient distribution in men and women according to the absolute grams of carbohydrate and total energy intake from carbohydrate diet classification the average of all food recalls for the 3D study participants

				Average of all food recalls (n=225)				
	LCD* <130 g *Median (IQR)*	**HCD ≥130 g** *Median (IQR)*	***p***[1]	**LCD** <26% TEI** *Median (IQR)*	**MCD 26–45% TEI** *Median (IQR)*	**HCD >45% TEI** *Median (IQR)*	*p*[2]	*p*[3]
MALES n (%)	**n=37 (31%)**	**n=88 (69%)**		**n=21 (17%)**	**n=93 (74%)**	**n=11 (9%)**		
Energy (MJ)	5.8 (1.3)[a]	8.2 (2.2)[b]	**<0.001**	6.5 (3.7)	7.7 (2.7)[b]	7.7 (4.5)[a]	0.232	0.104
Carbohydrate (g)	99 (38)	184 (50)[a]	**<0.001**	92 (58)	170 (67)[b]	216 (133)[a]	**<0.001**	**<0.001**
Carbohydrate (% TEI)	27.2 (11)	38.7 (9)	**<0.001**	22.5 (6)	36.1 (7)	48.0 (4)	**<0.001**	**<0.001**
Fibre (g)	19 (12)	25 (12)[a]	**<0.001**	20 (14)	24 (11)[a]	34 (19)[a]	**0.008***	**0.016**
Proteins (% TEI)	24.2 (8)	19.6 (4)	**<0.001**	24.9 (13)	20.3 (4)[a]	17.3 (3)	**<0.001**	**0.003**
Fats (% TEI)	40.4 (13)	35.2 (7)	**<0.001**	47.5 (16)	35.9 (6)	27.8 (7)	**<0.001**	**<0.001**
Alcohol (% TEI)	0 (3)	0.8 (6)[b]	0.083	1.6 (5)	0.6 (4)[a]	0 (0)	0.103	0.133
FEMALES n (%)	**n=46 (46%)**	**n=54 (54%)**		**n=19 (19%)**	**n=72 (72%)**	**n=9 (9%)**		
Energy (MJ)	5.5 (1.2)[a]	7.1 (1.6)[b]	**<0.001**	5.8 (1.2)	6.6 (2.1)[b]	5.5 (2.4)[a]	0.158	0699
Carbohydrate (g)	89 (34)	167 (38)[a]	**<0.001**	78 (30)	143 (61)[b]	170 (55)[a]	**<0.001^**	**<0.001**
Carbohydrate (% TEI)	29.6 (13)	38.8 (5)	**<0.001**	21.9 (6)	36.8 (6)	51.1 (5)	**<0.001**	**<0.001**
Fibre (g)	17 (9)	23 (9)[a]	**<0.001**	17 (9)	21.0 (9)[a]	17.5 (12)[a]	0.080	0.847
Proteins (% TEI)	23.2 (5)	20.3 (4)	**<0.001**	23.3 (5)	21.6 (5)[a]	16.0 (6)	**<0.001**	**<0.001**
Fats (% TEI)	40.6 (10)	35.9 (6)	**<0.001**	46.6 (11)	37.0 (5)	31.2 (6)	**<0.001**	**<0.001**
Alcohol (% TEI)	0 (2)	0 (1)[b]	0.426	0 (4)	0 (1)	0 (0)	0.447	0.357

LCD low-carbohydrate diet, *HCD* high-carbohydrate diet, *TEI* total energy intake, *MCD* moderate-carbohydrate diet, *MJ* megajoules, *IQR* interquartile range. *Very low-carbohydrate diet n=4 included in this category **Very low-carbohydrate diet n=1 included in this category. Intention-to-treat analysis. [1] Difference between LCD and HCD based on absolute grams classification tested using Mann–Whitney *U* test. [2] Difference between LCD, MCD and HCD based on TEI from carbohydrate tested using Kruskal–Wallis *H* test. [3] Difference between LCD and HCD only based on TEI from carbohydrate tested using Mann–Whitney *U* test.
Difference between males and females, Mann–Whitney *U* test [a] p<0.05, [b] p<0.001 ^Significant difference for LCD–MCD and LCD–HCD pairs (not significant for MCD–HCD pair)

4.3.5 *Intake by food groups*

The median intake of food groups according to the average of all food recalls are detailed in Table 4.11 (absolute grams classification) and in Table 4.12 (total energy intake classification). For both classifications, the median intake of fruits, vegetables and dairy for all groups of participants was below the Australian Guide to Healthy Eating recommended serves (32). In males and females, the median grains intake was below the recommendation for the LCD (absolute grams classification) and LCD and MCD groups (percentage of TEI classification) while it was above for both HCD groups. According to the absolute grams classification, in both groups males had an intake of protein foods similar to the recommendation whereas all females had an intake above the recommendation. When using the percentage of TEI from carbohydrate, the males and females in the LCD and MCD groups had an intake similar or below the recommendation of grains while those in HCD had an intake above the recommendation. The opposite was observed for the protein foods with participants in the LCD and MCD having an intake similar or above the recommendation and those in HCD having an intake below the recommendation.

For the absolute grams classification, reported food group intake for the whole sample (men and women) was significantly lower for participants on an LCD compared to those on a HCD (p<0.05) except for the proteins foods group(p=0.695). In men, for grains, fruits and dairy, the intake was lower for the LCD group compared to the HCD group (p<0.001). In women, the intakes of total grains, fruits, fruit juices and dairy intake were lower for the LCD group compared to the HCD group (p<0.05). In the HCD group, the intake of grains was higher in men than in women (5.4 vs 4.5 serves, p=0.002). For participants on an LCD, male participants had a greater intake of starchy vegetables compared to females (0.6 serves for males vs 0.3 serves for females, p= 0.024).

For the comparison of intake by food groups based on the TEI from carbohydrate, grain intake was significantly lower for the LCD than the MCD group and for the MCD group than the HCD group (p<0.001). The protein foods group intake was higher for the LCD group than the MCD group and for the MCD group than the HCD group (p<0.001). The intakes of wholegrains, refined grains, fruits and fruit juices, starchy vegetables and dairy were lower for the LCD group than the MCH and HCD groups (p<0.05) but did not differ significantly between the MCD and HCD groups. There was a generally higher intake of protein food and smaller intake of grains, fruits and dairy in the LCD group.

Table 4.11 Average food groups intake according to the absolute grams of carbohydrate diet classification based on the average of all food recalls for the 3D study participants

	All participants (n=225)			Males (n=125)			Females (n=100)		
Food groups (recommended number of serves males/females 51-70 years)	**LCD<130 g n=83 (37%)** *Median (IQR)*	**HCD ≥ 130 g n=142 (63%)** *Median (IQR)*	*p*[1]	**LCD<130 g n=37 (30%)** *Median (IQR)*	**HCD ≥130 g n=88 (70%)** *Median (IQR)*	*p*[1]	**LCD<130 g n=46 (46%)** *Median (IQR)*	**HCD ≥130 g n=54 (54%)** *Median (IQR)*	*p*[1]
Grains (6/4 serves)									
Total	2.5 (2)	4.9 (2)	**0.001**	2.5 (2)	5.4 (2)[a]	**<0.001**	2.5 (2)	4.5 (1)[a]	**<0.001**
Wholegrains	1.2 (1)	1.9 (2)	**<0.001**	1.4 (1)	2.4 (2)[a]	**<0.001**	1.2 (1)	1.5 (2)[a]	0.100
Refined	1.1 (1)	2.8 (2)	**<0.001**	1.3 (1)	2.8 (2)	**<0.001**	1.1 (1)	2.8 (2)	**<0.001**
Protein foods (2.5/2 serves)	2.5 (2)	2.5 (1)	0.695	2.7 (2)	2.5 (2)	0.417	2.3 (2)	2.5 (1)	0.782
Fruits (2 serves)									
Total	0.6 (1)	1 (1)	**<0.001**	0.7 (1)	1.0 (1)	**<0.001**	0.6 (1)	1.1 (1)	**<0.001**
Fruit juices	0 (0)	0 (0)	**0.001**	0 (0)	0 (0)	0.066	0 (0)	0 (0)	**0.004**
Vegetables (5.5/5 serves)									
Total	3.0 (2)	3.7 (3)	**0.046**	3.2 (3)	3.6 (3)	0.472	3.0 (2)	3.7 (3)	0.057
Starchy vegetables	0.5 (1)	0.9 (1)	**<0.001**	0.6 (1)[a]	0.9 (1)	0.095	0.3 (1)[a]	0.8 (1)	**<0.001**
Dairy (2.5/4 serves)	1.0 (1)	1.5 (1)	**<0.001**	0.8 (1)	1.5 (1)	**<0.001**	1.0 (1)	1.6 (1)	**<0.001**

LCD low-carbohydrate diet, *HCD* high-carbohydrate diet, *IQR* interquartile range, *NS* not significant
Intention-to-treat analysis
[1] Difference between LCD and HCD tested using Mann–Whitney *U* test
Difference between males and females tested using Mann–Whitney *U* test [a] $p<0.05$ Significant difference between males and females in HCD for total serves of grains ($p=0.002$) and for serves of wholegrains ($p=0.002$) and in LCD for serves of starchy vegetables ($p=0.024$)
Example of serves: grains (1 slice of bread, ½ cup cooked rice), protein foods (65 g cooked red meat, 2 eggs), fruits (1 medium fruit or ½ cup fruit juice), vegetables (½ cup vegetables), dairy (1 cup of milk or plant based alternative, 40 g cheese) (32)

Table 4.12 Average food groups intake according to percentage of total energy intake from carbohydrate diet classification of the average of all food recalls for the 3D study participants

	All participants (n=225)				**Males (n=125)**				**Females (n=100)**			
Food groups (recommended number of serves males/females 51-70 years)	**LCD <26% TEI n=40 (18%)** *Median (IQR)*	**MCD 26–45% TEI n=165(73%)** *Median (IQR)*	**HCD >45% TEI n=20 (9%)** *Median (IQR)*	*p*[1]	**LCD <26% TEI n=21 (17%)** *Median (IQR)*	**MCD 26–45% TEI n=93 (74%)** *Median (IQR)*	**HCD >45% TEI n=11 (9%)** *Median (IQR)*	*p*[1]	**LCD <26% TEI n=19 (19%)** *Median (IQR)*	**MCD 26–45% TEI n=72 (72%)** *Median (IQR)*	**HCD >45% TEI n=9 (9%)** *Median (IQR)*	*p*[1]
Grains (6/4 serves)												
Total	2.1 (2)	4.4 (2)	6.0 (3)	**<0.001**	2.2 (2)	4.9 (2)[b]	6.9 (3)[a]	**<0.001**	1.5 (1)	4.1 (2)[b]	4.8 (3)[a]	**<0.001***
Wholegrains	1.0 (1)	1.7 (2)	2.7 (4)	**<0.001***	1.4 (1)	2.1 (2)[a]	3.6 (3)[a]	**<0.001**	0.5 (1)	1.5 (2)[a]	1.3 (3)[a]	**0.003^**
Refined	1.0 (1)	2.5 (2)	3.2 (3)	**<0.001***	1.0 (2)	2.5 (2)	3.4 (3)	**<0.001***	0.9 (1)	2.5 (2)	2.5 (3)	**<0.001***
Protein foods (2.5/2 serves)	3.6 (2)	2.5 (1)	1.5 (2)	**<0.001**	3.8 (2)	2.5 (1)[a]	1.7 (1)	**<0.001**	3.5 (2)	2.3 (1)[a]	1.3 (2)	**<0.001***
Fruits (2 serves)												
Total	0.2 (1)	1.0 (1)	1 (1)	**<0.001***	0.8 (1)	1.0 (1)	1.4 (2)	**<0.001***	0.3 (1)	0.8 (1)	0.9 (1)	**0.006***
Fruit juices	0 (0)	0 (0)	0 (1)	**0.003***	0 (0)	0 (0)	0 (1)	0.059	0 (0)	0 (0)	0 (1)	**0.042[NS]**
Vegetables (5.5/5 serves)												
Total	3.2 (3)	3.5 (2)	2.6 (3)	0. 216	3.2 (3)	3.6 (2)	4.2 (4)[a]	0.758	3.3 (2)	3.4 (2)	2.5 (2)[a]	0.074
Starchy vegetables	0.3 (1)	0.7 (1)	0.9 (2)	**0.003***	0.5 (1)	0.8 (1)	1.2 (2)	0.073	0.1 (1)	0.6 (1)	0.8 (2)	**0.024^**
Dairy (2.5/4 serves)	1.0 (1)	1.3 (1)	1.6 (2)	**0.001***	1.0 (1)	1.4 (1)	2.1 (2)	**0.017[O]**	1.0 (1)	1.3 (1)	1.3 (1)	**0.049^**

LCD low-carbohydrate diet, *MCD* moderate-carbohydrate diet, *HCD* high-carbohydrate diet, *IQR* interquartile range
Intention-to-treat analysis
[1] Difference between carbohydrate diets (LCD, MCD HCD) tested using Kruskal–Wallis *H* test
* Significant difference for LCD–MCD and LCD–HCD pairs (not significant for MCD–HCD pair)
^ Significant difference for LCD–MCD pair only (not significant for and LCD–HCD and MCD–HCD pairs)
[O] Significant difference for LCD–HCD pair only (not significant for and LCD–MCD and MCD–HCD pairs)
Difference between males and females with Mann–Whitney *U* test [a] $p<0.05$ [b] $p<0.001$
Examples of serves: grains (1 slice of bread, ½ cup cooked rice), protein foods (65 g cooked red meat, 2 eggs), fruits (1 medium fruit or ½ cup fruit juice), vegetables (½ cup vegetables), dairy (1 cup of milk or plant based alternative, 40 g cheese) (32)

4.3.6 Correlations between carbohydrate intake and other health factors

Correlations between nutritional intake, physical activity and anthropometric measures are presented in Table 4.13. Carbohydrate intake was significantly strongly positively correlated with energy intake in men and women (r_s=0.724 and 0.719, respectively). In women, BMI was significantly moderately negatively correlated with age, which indicated that BMI decreases with increasing age (r_s=–0.430). In women only, ITT analyses of weight change and waist circumference change between baseline and 12 months were significantly moderately positively correlated with average energy intake (r_s=0.299 for weight and 0.288 for waist). The change in waist circumference was also moderately positively correlated with carbohydrate intake (r_s=0.288). As expected, changes in weight and waist circumference were significantly moderately positively correlated for both sex (r_s=0.508 and 0.569 for men and women, respectively). Carbohydrate intake did not correlate significantly with the level of physical activity (METs) or last BMI observed.

Table 4.13 Spearman's correlation matrix based on average of all food recalls for the 3D study participants

		Age	**Carbohydrate average (g)**	**Energy average (kJ)**	**Alcohol average (%TEI)**	**METs average**	**BMI**	**Weight change**
Males	Carbohydrate	0.063						
n=125	Energy	0.060	**0.724*****					
	Alcohol	**0.239****	0.045	**0.254***				
	METs	–0.158	0.101	0.109	0.005			
	BMI	–0.112	0.079	0.006	–0.065	0.082		
	Weight change	0.007	0.002	0.025	–0.006	–0.078	**0.189***	
	Waist change	0.046	0.088	–0.022	–0.153	–0.098	0.154	**0.508*****
Females	Carbohydrate	0.076						
n=100	Energy	0.042	**0.719*****					
	Alcohol	0.027	–0.109	0.083				
	METs	–0.006	–0.193	–0.127	0.189			
	BMI	**–0.430*****	0.157	0.022	–0.147	0.005		
	Weight change	0.144	0.181	**0.299****	**0.243***	0.111	**0.225***	
	Waist change	0.105	**0.288****	**0.288****	0.139	**0.242***	0.018	**0.569*****

$^{*}p<0.05$, $^{**}p<0.01$, $^{***}p<0.001$

kJ kilojoules, *TEI* total energy intake, *MET* metabolic equivalent of task, *BMI* body mass index

BMI using last observation carried forward

Weight and waist change: baseline to 12 months using last observation carried forward

4.3.7 Alignment of self-reported diet type with dietary intake

Table 4.14 shows the average measured carbohydrate intake according to self-reported diet type. Of the 234 occasions specialised diet were reported at 6, 9 and 12 months, diets likely to involve a carbohydrate restriction were reported on 99 occasions. These were comprised of 10 reports of ketogenic diet, 42 of LCD, 24 of low-sugar diet and 23 modified-carbohydrate diet (involving avoidance of specific carbohydrate rich foods such as potatoes, bread or pasta). However, only one of the 10 participants who reported following a ketogenic diet during the study had an average measured carbohydrate intake that met the ketogenic criteria of <50 g per day. One other participant had a TEI from carbohydrates <10% but did not report following a ketogenic diet. Half of the 42 participants who reported following an LCD had an average measured intake <130 g, which indicates alignment between their reported diet and measured intake but the other half exceeded this cut-off. For the TEI from carbohydrate, only one-third of the participants who reported following an LCD had a corresponding measured intake (<26% TEI), with the measured intake at 26–45% of TEI for most of these participants which would be classified as MCD.

Similar patterns were found for other types of reported carbohydrate-restricted diets, such as low-sugar and modified carbohydrate diets. The majority of participants who reported following a low-sugar diet or a modified carbohydrate diet had a measured carbohydrate intake ≥130 g or between 26 and 45% of TEI.

Table 4.14 Comparison between self-reported and measured low-carbohydrate diets (average of all food recalls) for the 3D study participants

	Reported diet n (% of participants reporting the diet)			
Measured diet	**Ketogenic n=10**	**Low-carbohydrate n=42**	**Low-sugar n=24**	**Modified-carb. n=23**
Classification based on absolute grams				
VLDC<50 g n=4	1 (10)	0 (0)	0 (0)	0 (0)
LCD<130 g n=76	6 (60)	21 (50)	7 (29)	8 (35)
HCD ≥130 g n=145	3 (30)	21 (50)	17 (71)	13 (65)
Classification based on percentage of TEI				
VLCD<10% n=1	0 (0)	0 (0)	0 (0)	0 (0)
LCD<26% TEI n=40	6 (60)	12 (29)	4 (17)	2 (9)
MCD 26–45% TEI n=165	4 (40)	29 (69)	17 (71)	19 (82)
HCD ≥45% TEI n=20	0 (0)	1 (2)	3 (2)	2 (9)

VLCD very low-carbohydrate diet, *LCD* low-carbohydrate diet, *MCD* moderate-carbohydrate diet, *HCD* high-carbohydrate diet, *TEI* total energy intake, *Modified carb.* reported restriction of specific carbohydrate-rich food such as potatoes, bread and pasta
Shaded numbers represent the number of participants for whom the self-reported diet type aligns with their measured intake

Chapter 5. Discussion

This research described the carbohydrate intake of men and women recently diagnosed with type 2 diabetes (T2D) in Australia using five 24-hour food recalls over 12 months. To my knowledge, this subanalysis of the 3D study is the first study to examine dietary intake over time in a real-world setting in people recently diagnosed with T2D and compare two approaches to classify low-carbohydrate diet (LCD). This research can inform future work by tailoring effective interventions along with a reduction in impact of T2D.

5.1 Main findings

A summary of hypotheses and results are presented in Table 5.1.

Table 5.1 Summary of hypotheses and results

Hypothesis Statement	Result
1. The classification of participants based on their carbohydrate intake will be different when considering the absolute grams of carbohydrate or the percentage TEI from carbohydrates.	Accepted
2. Carbohydrate intake in terms of absolute grams and TEI of people recently diagnosed with T2D will:	
a. Increase over 12 months;	Accepted (men only)
c. Be lower than the general population	Accepted
3. When comparing to those with a higher carbohydrate intake, people reporting intake consistent with LCD, will	
a. Experience a similar weight loss and similar reduction of waist circumference in the 12 months following the diagnosis of T2D	Accepted
b. Have an average higher intake of TEI from fats and proteins and a lower intake of grains, fruits and dairy food	Accepted
4. People newly diagnosed with T2D will not accurately describe their carbohydrate intake in terms of whether or not they are following an LCD	Accepted

TEI total energy intake, *T2D* type 2 diabetes, *LCD* low-carbohydrate diet (<130 g or < 26% TEI from carbohydrate)

5.1.1 Classification systems of carbohydrate-restricted diets

Discrepancies were found between the classification based on absolute grams of carbohydrate intake and percentage of total energy intake (TEI) from carbohydrate; that is, more participants were classified as being on an LCD according to the absolute grams classification than with the percentage of TEI from carbohydrate classification.

The different levels of carbohydrate-restricted diet were clarified by Feinman and colleagues in 2015 (86) but the classification is still widely discussed. The studies reported in the meta-analyses reviewed in Chapter 2 used the two classification systems for LCD, namely below 130 g of carbohydrate per day or below 26% of TEI, interchangeably. Some studies even use level that would be classified as very low-carbohydrate diet such as <20 g or <50 g(VLCD). However, Wylie-Rosett have shown that these two classifications are equivalent only for a TEI of 8,350 kJ (2,000 kcal) (87). The measured average carbohydrate intake of food recalls over 12 months showed that only 13% of the 3D study participants were classified as being on an LCD according to both classification systems. This supports the idea that the two methods for classification may not be interchangeable and this could greatly impact the research on LCDs.

Few participants self-reported following a very low-carbohydrate diet (VLCD) or ketogenic diet but almost all of those did not achieve a level of carbohydrate intake low enough to be classified this way (<50 g per day or <10% of TEI). More participants of the 3D study self-reported following an LCD, but it was congruent with their measured intake for half of them when using the absolute grams classification and for only 29% when using the percentage of TEI classification, showing that people with T2D might be more accurate at judging their carbohydrate intake in term of absolute grams. The analysis of the measured intake in the real-world setting of this project showed that the terms LCD and VLCD are used inaccurately and that a VLCD is not commonly followed by people newly diagnosed with T2D. This inaccuracy may be explained by the difficulty in estimating the intake of specific nutrients among the general population (127).

In a clinical practice setting, dietitians might be more inclined to use the absolute grams of carbohydrate for people with T2D. Education materials more often use absolute grams of carbohydrate (for example 10 or 15 grams of per serves) (128). The percentage of TEI from carbohydrate offer the advantage of adjusting the level of carbohydrate based on individual energy requirements. However, in this study, favourable outcomes were observed only for the absolute grams classification system, that is waist circumference at 12 months being significantly lower for the LCD group.

5.1.2 Nutrient intake and nutritional quality

The results highlighted differences in carbohydrate intake between men and women with higher measured intake for men than women. The carbohydrate intake increased for men over the 12 months of the study. The carbohydrate intake was lower in the 3D participants than their counterparts in the general population. For both classification systems, participants on an LCD had a higher proportion of TEI from fats as well as proteins.

Most participants (80%) reported an average carbohydrate intake below the minimum acceptable macronutrient distribution range (AMDR; 45% of TEI) recommended for people without T2D (55). Carbohydrate intake <45% TEI is also observed in more than half (60%) of the general Australian population (63). To my knowledge, carbohydrate intake of people newly diagnosed with T2D has not been reported in a longitudinal study. However, for people who have been living T2D for a longer period, carbohydrate intake has also been reported at the lower end of the AMDR in previous studies conducted in Western countries (51, 64-66, 73). Only two of those studies reported the intake for males and females independently (51, 64). This subanalysis of the 3D study data set adds to the body of literature suggesting that carbohydrate intake for people with a new-onset of T2D is lower than the recommended intake for the general population.

The carbohydrate and energy intakes of 3D participants were lower than those observed in the Australian general population (63). Similar results were found in prospective studies in France and Japan. A prospective cohort study of French women (n=37,304) showed that the participants reduced their carbohydrate intake after the diagnosis of T2 but only for those with a family or with an education level between high school and 2-year university diploma (75). Yamakawa and colleagues found in a prospective study (n=3,032) that Japanese with T2D had a TEI lower than that of the general population (47). A reduction in energy intake is relevant because weight loss is part of the recommendation to manage T2D when BMI is above recommendations (4).

The reported average alcohol intake in the 3D participants was lower than in the general Australian population (63). The English Longitudinal Study of Ageing also found a lower alcohol intake for participants who developed T2D compared with those who did not (129). The lower alcohol intake may be explained by the change in behaviours that occurs following a T2D diagnosis. Another possible explanation is that, because the data collection days for the 3D study were during the working week, this decreased the probability of 24-hour recall during the weekend, when alcohol intake is more likely to be higher (130).

The food groups intake differed between participants on different levels of carbohydrate-restricted diets but differently for the two classification systems. Based on the absolute grams classification, LCD participants had a lower intake of all food groups than those on a high-carbohydrate diet (HCD) except for protein food (no significant difference). However, based on the TEI classification, the LCD group had an intake lower than other participants for all food groups except for protein food (higher intake for LCD) and vegetables (no significant difference).

The comparison with the Australian Guide to Healthy Eating recommended serves showed that participants intake of fruits, vegetables and dairy were below the recommendations for both classification systems, similarly to results of a recent systematic review (26). Also, the median dietary approaches to stop hypertension (DASH) score was suboptimal and did not differ between the classification systems. The average score ranged between 22 and 24 for the different groups while the maximum score is 40 for optimal DASH pattern (80). Those findings highlight the inadequate nutritional quality of people with T2D and this should be addressed with appropriate education and health promotion campaign for this clientele.

5.1.3 Anthropometric and health outcomes of low-carbohydrate diets

The characteristics and outcomes of participants on an LCD were generally similar to those with a higher carbohydrate intake. Only the waist circumference at 12 months was lower in women in the LCD group (absolute grams) after adjustment for TEI. The meta-analyses of LCD and T2D described in Chapter 2 did not report on waist circumference. Three of the randomised controlled trials (RCTs) on VLCDs found a significantly waist circumference reduction among participants but the change was not significant between the VLCD and control groups (89, 103, 104). However, these results were not presented for men and women separately. By analysing the waist circumference for men and women independently, the 3D study added to the body of evidence by showing sex differences in the outcomes of LCDs.

The lack of significant difference between median waist circumference at baseline reported by men (107.3 cm) and women (107.0 cm) was unexpected considering the differences in the recommended value between sex (118). However, a meta-analysis of 70 studies showed an increase of 4.63 cm (SE 0.37 cm) in waist circumference for women after menopause (131), which is coherent with the age of the women in this study (median age of 61 years, IQR 15). Increased waist circumference is associated with increased risk of T2D (132), and this may indicate that the participants were more likely to have a higher waist circumference because they had developed T2D. A prospective study on 256 Australian women aged 46 to 57 years found a significant greater increase in waist circumference over 5 years in those with impaired fasting glucose (IFG; increase of 4.5 cm compared to 2.5 for those without IFG, p=0.008) (133). The waist circumference in the general Australian population aged 51 to 70 years is different for men and women and lower than the participants of the 3D study (102.4 cm and 91.4 cm, respectively) (10).

The change in weight and waist circumference over 12 months did not correlate with the TEI in men but did correlate moderately in women. In men, the changes in weight and waist circumference did not correlate with physical activity either (average METs). The lack of correlation between these variables for male participants may be explained by incorrect self-reporting of anthropometric measures or dietary intake. It is known that people tend to under-report their weight (115), waist circumference (134) and energy intake (135).

5.2 Strengths and limitations

This subanalysis of the 3D study data is the first to gather longitudinal data about the carbohydrate intake of people recently diagnosed with T2D. The findings add to the limited information available about dietary intake in real-world settings for this population. The data were collected by a team of trained researchers, which should have reduced the risk of researcher bias.

However, other forms of bias may have been present. There was a possible selection bias because the participants voluntarily enrolled in the 3D study. They might have had a higher level of motivation and ability for self-management and different dietary intake than non-participants. In addition, 44% of the 3D study participants were previously diagnosed with pre-diabetes. Those participants might have modified their dietary intake or lifestyle prior to their participation in the 3D study compared to those who have not received a pre-diabetes diagnosis (122). To further homogenise the sample of the 3D study participants, a selection criterion could have been considered to only recruit people without a pre-diabetes diagnosis. Misreporting bias may also have occurred because of under-reporting of anthropometric measures taken by the participants themselves (115).

Recall bias and social desirability may have impacted the dietary intake. A retrospective bias analysis comparing dietary recall and three-day food records showed that participants tended to underestimate their energy, fat and alcohol intake with the diet recall and those consuming larger quantities of carbohydrate underreported their carbohydrate intake (136). A study focusing on social desirability showed that participants underreported their fat intake and over reported their fruits and vegetables intake when using 24-hour recalls compared to administered screeners in the context of dietary intervention aiming to reduce fat intake and increase fruits and vegetable intake (137). Participants to the 3D study might have felt the social desirability for a lower intake of carbohydrate for people with T2D.

Although a validated tool, the 24-hour recall may not be representative of the usual intake depending on the day of collection, for example, if it occurred after a weekend or on a day when the participant was unwell. It has been estimated that 4–5 days of food records are necessary to obtain a true carbohydrate average intake (106). This limitation was partially overcome by using all 24-hour recalls available for each participant. An average of 4 days was used for the 225 participants, but 27% (n=60) of participants reported their intake on <4 occasions.

Some data could not be analysed. Glycated haemoglobin (HbA1c) and other pathology results were requested in the methodology of the 3D study, however only 48 participants provided their biochemistry results. It was not valid to use those results to assess the effect of carbohydrate-restricted diet in the management of T2D.

Although anthropometric measures were collected for each data collection point, no information was gathered on the participants' ethnicity. Waist circumference guidelines differ between ethnic groups, and the recommended value is lower for Asian men than Caucasian (118). Recent evidence also suggests a lower BMI cut-off in Asian populations (138). According to the 2016 Australian Census, 12.9% of the population identified with Asian ancestry (139), hence the importance of knowing the ethnicity of participants to assess their compliance with waist circumference guidelines. Without the ethnicity information, the analysis of some participants' BMI and waist circumference may not have been completely accurate.

5.3 Recommendations for future research

1. Develop a universal carbohydrate-restricted diet classification system. The small proportion of participants being classified in the same category for the two classification systems emphasises the necessity to adopt one approach to standardise the use of LCD in research. The classification system based on the absolute grams has often been used interchangeably with the percentage of TEI from carbohydrate method. Different aspects should be considered in the decision to implement the use of one system over the other. For example, the health outcome of LCD in a context of prescribed carbohydrate intake should be analysed comparing two groups of participants, one for each classification system. Also, the practicality and ease of the absolute gram classification system for the education of people with T2D should not be overlook.

2. Measure diet and carbohydrate quality of LCD. More research is needed to investigate the impact of carbohydrate-restricted diets on health outcomes. This research has showed that general diet quality of participants was suboptimal but carbohydrate quality was not assessed in the scope of this subanalysis. The quality of the carbohydrate intake most likely plays an important role in the management of T2D. In a review of LCDs and VLCDs, Bolla and colleagues concluded that fibre-rich food should be preferred (140). The positive impact of a high-fibre diet for people with T2D was also reported in a cross-sectional study (48), RCT (51) and meta-analysis (52).

Future research on LCDs could use other scoring systems for evaluating the dietary intake of participants and classifying them into levels of carbohydrate intake in a real-world setting. A combination of the LCD score and the Carbohydrate Quality Index (CQI) could be created. The LCD score was developed by Halton and colleagues using a strata and points system for each of the macronutrients contributing to the percentage of TEI (141). This LCD score classifies participants from the highest to lowest carbohydrate intake and also considers fat and protein intakes. The CQI was developed by a research team in Spain to classify the quality of carbohydrate intake using a validated semi-quantitative food frequency questionnaire and considers the fibre intake, glycaemic index, ratio of whole grains to total grains ratio and ratio of solid carbohydrate to total carbohydrate (142). Considering the quality of carbohydrate might contribute to strengthening the evidence on LCD research.

3. Use comprehensive dietary data collection method. To improve the accuracy of measures of carbohydrate intake, different method could be used. A photographic 4–5-day food journal could be considered instead of the 24-hour recall. A study compared the measured intake from 24-hour recall completed by a dietitian using the Automated Multiple-Pass Method and before-and-after photographs of the participants' meals for the same day (143). Carbohydrate was the only macronutrient with significantly different estimations; that is, ~35 g of carbohydrate more for the 24-hour recall compared with the estimation from the photos. Improving accuracy in the measured carbohydrate would also improve the classification of participants in LCD group.

Additional information regarding the time of carbohydrate intake and meal of the day could also be collected in future longitudinal studies on LCDs. Chang and colleagues found in a randomized crossover (n=23) that a prescribed breakfast low in carbohydrate (10% TEI) and high in fat (85% TEI) improves the 24-hour glycaemic control and variability compared to a breakfast with 55% TEI from carbohydrate, and this without modifying the other meals (144). However, this study included only two 24-hour trials.

By adding details about timing of the carbohydrate intake in a longitudinal study, new evidence could be found about carbohydrate intake pattern and management of T2D.

4. Exclude participants with lifestyle or health condition impacting dietary intake. The exclusion criteria for future research could be modified to control for alcohol intake and other diagnoses. When alcohol contributes to TEI, it reduces the percentage of TEI from carbohydrate and, therefore, can lead to false classification of people on an LCD. Systemic anti-cancer therapy can cause weight loss ≥2.5%, as shown in 24% of patients of a recent cross-sectional study using England's Cancer Analysis System database (145). During the 3D study, seven participants underwent cancer treatments, and three of the seven lost ≥2.5% of body weight during the 12 months of the study. This weight loss may result from the cancer or its treatment instead of dietary intake directly. It would be relevant for future research to exclude participant with diseases that can significantly impact weight, such as cancer, to isolate the effect of dietary intake on outcomes.

5.4 Conclusion

This subanalysis of the 3D study is unique in describing the carbohydrate intake of people newly diagnosed with T2D over 12 months in a real-world setting. Every three months, dietary intake and other health characteristics were collected over the phone by trained interviewers with expertise in dietetics. The carbohydrate intake of the participants was at the lower end of the AMDR and was lower than in the general population. Just over one-third of the participants had a low carbohydrate intake (<130 g per day), but very few had a very low-carbohydrate intake (<50 g per day). A minority of participants were classified as following an LCD according to two classification systems presented, the absolute grams and percentage of TEI systems, supporting the need for a consensus on a universally adopted classification method used in research. Self-reported LCD and measured intake of carbohydrate did not align for most of the participants. Women with a low carbohydrate intake in a natural setting had a lower waist circumference at the end of the study compared with those with a higher carbohydrate intake. Carbohydrate quality should be considered when studying the outcomes of LCDs for people with T2D. Different data collection methods, such as the photographic 4-day food journal, could be considered to improve the accuracy of carbohydrate intake measurement.

References

1. American Diabetes Association. 2. Classification and diagnosis of diabetes: Standards of medical care in diabetes-2021. Diabetes Care. 2021;44(1):S15-33.
2. World Health Organization (WHO). Global Report on Diabetes. Geneva, Switzerland: WHO; 2016.
3. Zheng Y, Ley SH, Hu FB. Global aetiology and epidemiology of type 2 diabetes mellitus and its complications. Nat Rev Endocrinol. 2018;14(2):88-98.
4. Sumamo Schellenberg E, Dryden DM, Vandermeer B, Ha C, Korownyk C. Lifestyle interventions for patients with and at risk for type 2 diabetes: A systematic review and meta-analysis. Ann Intern Med. 2013;159(8):543-51.
5. Uusitupa M, Khan TA, Viguiliouk E, Kahleova H, Rivellese AA, Hermansen K, et al. Prevention of type 2 diabetes by lifestyle changes: A systematic review and meta-analysis. Nutrients. 2019;11(11):2611-32.
6. Dunkley AJ, Bodicoat DH, Greaves CJ, Russell C, Yates T, Davies MJ, et al. Diabetes prevention in the real world: Effectiveness of pragmatic lifestyle interventions for the prevention of type 2 diabetes and of the impact of adherence to guideline recommendations - A systematic review and meta-analysis. Diabetes Care. 2014;37(4):922-33.
7. Thom G, Messow CM, Leslie WS, Barnes AC, Brosnahan N, McCombie L, et al. Predictors of type 2 diabetes remission in the Diabetes Remission Clinical Trial (DiRECT). Diabet Med. 2021;38(8):14395-406.
8. Saeedi P, Petersohn I, Salpea P, Malanda B, Karuranga S, Unwin N, et al. Global and regional diabetes prevalence estimates for 2019 and projections for 2030 and 2045: Results from the International Diabetes Federation Diabetes Atlas, 9 th edition. Diabetes Res Clin Pract. 2019;157:107843-52.
9. GBD 2017 Causes of Death Collaborators. Global, regional, and national age-sex- specific mortality for 282 causes of death in 195 countries and territories, 1980-2017: A systematic analysis for the Global Burden of Disease Study 2017. Lancet. 2019;392:1736-88.
10. Australian Bureau of Statistics (ABS). National Health Survey 2017-18 Canberra: ABS; 2018 [cited 2021 August 9]. Available from: https://www.abs.gov.au/statistics/health/health-conditions-and-risks/national-health-survey-first-results/latest-release.
11. Diabetes Australia. Diabetes: The silent pandemic and its impact on Australia. Canberra: Diabetes Australia; 2012.
12. Australian Institute of Health and Welfare (AIHW). Diabetes. Canberra: AIHW; 2020.
13. Australian Institute of Health and Welfare (AIHW). Diabetes expenditure in Australia 2008–09. Canberra: AIHW; 2013.
14. Australian Department of Health. The Pharmaceutical Benefits Scheme [cited 2021 August 9]. Available from: https://www.pbs.gov.au/pbs/home.
15. Australian Department of Health. Medicare Benefits Schedule [cited 2021 August 9]. Available from: http://www.mbsonline.gov.au/internet/mbsonline/publishing.nsf/Content/Home.
16. National Diabetes Services Scheme (NDSS). [cited 2021 August 9]. Available from: https://www.ndss.com.au/.
17. International Diabetes Foundation (IDF). Global Diabetes Plan 2011-2021. Belgium: IDF; 2011.

18. American Diabetes Association. 5. Facilitating behavior change and well-being to improve health outcomes: Standards of medical care in diabetes−2021. Diabetes Care. 2021;44(1):S53-72.
19. Ley SHP, Hamdy OMD, Mohan VMD, Hu FBP. Prevention and management of type 2 diabetes: Dietary components and nutritional strategies. Lancet. 2014;383(9933):1999-2007.
20. Ball L, Davmor R, Leveritt M, Desbrow B, Ehrlich C, Chaboyer W. Understanding the nutrition care needs of patients newly diagnosed with type 2 diabetes: A need for open communication and patient-focussed consultations. Aust J Prim Health. 2016;22(5):416-22.
21. Sebire SJ, Toumpakari Z, Turner KM, Cooper AR, Page AS, Malpass A, et al. I've made this my lifestyle now: A prospective qualitative study of motivation for lifestyle change among people with newly diagnosed type two diabetes mellitus. BMC Public Health. 2018;18(1):204-13.
22. Houle J, Beaulieu MD, Chiasson JL, Lespérance F, Côté J, Strychar I, et al. Glycaemic control and self-management behaviours in type 2 diabetes: Results from a 1-year longitudinal cohort study. Diabet Med. 2015;32(9):1247-54.
23. England CY, Andrews R, Jago R, Thompson JL. Changes in reported food intake in adults with type 2 diabetes in response to a nonprescriptive dietary intervention. J Hum Nutr Diet. 2014;27(4):311-21.
24. Chong S, Ding D, Byun R, Comino E, Bauman A, Jalaludin B. Lifestyle changes after a diagnosis of type 2 diabetes. Diabetes Spectr. 2017;30(1):43-50.
25. Khunti K, Gray LJ, Skinner T, Carey ME, Realf K, Dallosso H, et al. Effectiveness of a diabetes education and self management programme (DESMOND) for people with newly diagnosed type 2 diabetes mellitus: Three year follow-up of a cluster randomised controlled trial in primary care. Br Med J. 2012;344(7860):e2333-44.
26. Burch E, Ball L, Somerville M, Williams LT. Dietary intake by food group of individuals with type 2 diabetes mellitus: A systematic review. Diabetes Res Clin Pract. 2018;137:160-72.
27. Andrews RCD, Cooper ARP, Montgomery AAP, Norcross AJM, Peters TJP, Sharp DJP, et al. Diet or diet plus physical activity versus usual care in patients with newly diagnosed type 2 diabetes: The Early ACTID randomised controlled trial. Lancet. 2011;378(9786):129-39.
28. Bakke Å, Dalen I, Thue G, Cooper J, Skeie S, Berg TJ, et al. Variation in the achievement of HbA1c, blood pressure and LDL cholesterol targets in type 2 diabetes in general practice and characteristics associated with risk factor control. Diabet Med. 2020;37(9):1471-81.
29. Samkani A, Skytte MJ, Thomsen MN, Astrup A, Deacon CF, Holst JJ, et al. Acute effects of dietary carbohydrate restriction on glycemia, lipemia and appetite regulating hormones in normal-weight to obese subjects. Nutrients. 2018;10(9):1285.
30. Evert AB, Dennison M, Gardner CD, Garvey WT, Lau KHK, MacLeod J, et al. Nutrition Therapy for Adults With Diabetes or Prediabetes: A Consensus Report. Diabetes Care. 2019;42(5):731-54.
31. The Royal Australian College of General Practitioners (RACGP). General practice management of type 2 diabetes: A handbook for general practice. East Melbourne, Vic: RACGP; 2020.
32. National Health and Medical Research Council (NHMRC). Australian Dietary Guidelines Canberra: National Health and Medical Research Council; 2013 [cited 2021 August 9]. Available from: https://www.nhmrc.gov.au/about-us/publications/australian-dietary-guidelines.

33. Goldenberg JZ, Day A, Brinkworth GD, Sato J, Yamada S, Jönsson T, et al. 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. Br Med J (Clin Res Ed). 2021;372:m4743-55.
34. Food and Nutrition Board of the Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids. Washington, D.C: National Academies Press; 2005.
35. Pereira MA, CRC Press LLC. Nutrition and type 2 diabetes: Etiology and prevention. Boca Raton: CRC Press,Taylor & Francis; 2014.
36. Whitney EN. Understanding nutrition. Australian and New Zealand, 1st ed. South Melbourne, Vic: Cengage Learning; 2011.
37. Fried R, Carlton RM, ProQuest E, LLC CRCP. Type 2 diabetes: cardiovascular and related complications and evidence-based complementary treatments. 1 ed. Boca Raton: CRC Press, Taylor & Francis Group; 2019.
38. Yki-Järvinen H. Toxicity of hyperglycaemia in type 2 diabetes. Diabetes Metab Res Rev. 1998;14(1):S45-50.
39. Stratton IM, Adler AI, Neil HAW, Matthews DR, Manley SE, Cull CA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. BMJ. 2000;321(7258):405-12.
40. Alhazmi A, Stojanovski E, McEvoy M, Garg ML. Macronutrient intake and type 2 diabetes risk in middle-aged Australian women. Results from the Australian Longitudinal Study on Women's Health. Public Health Nutr. 2013;17(7):1587-94.
41. Churuangsuk C, Lean MEJ, Combet E. Lower carbohydrate and higher fat intakes are associated with higher hemoglobin A1c: Findings from the UK National Diet and Nutrition Survey 2008-2016. Eur J Nutr. 2020;59(6):2771-82.
42. Dyson PA, Twenefour D, Breen C, Duncan A, Elvin E, Goff L, et al. Diabetes UK evidence-based nutrition guidelines for the prevention and management of diabetes. Diabet Med. 2018;35(5):541-7.
43. Wheeler ML, Pi-Sunyer FX. Carbohydrate issues: Type and amount. J Am Diet Assoc. 2008;108(4):S34-9.
44. Dyson P, McArdle P, Mellor D, Guess N. James Lind Alliance research priorities: What role do carbohydrates, fats and proteins have in the management of type 2 diabetes, and are there risks and benefits associated with particular approaches? Diabet Med. 2019;36(3):287-96.
45. English E, Lenters-Westra E. HbA1c method performance: The great success story of global standardization. Crit Rev Clin Lab Sci. 2018;55(6):408-19.
46. Vitale M, Masulli M, Rivellese AA, Babini AC, Boemi M, Bonora E, et al. Influence of dietary fat and carbohydrates proportions on plasma lipids, glucose control and low-grade inflammation in patients with type 2 diabetes-The TOSCA.IT Study. Eur J Nutr. 2015;55(4):1645-51.
47. Yamakawa T, Sakamoto R, Takahashi K, Suzuki J, Matuura-Shinoda M, Takahashi M, et al. Dietary survey in Japanese patients with type 2 diabetes and the influence of dietary carbohydrate on glycated hemoglobin: The Sleep and Food Registry in Kanagawa study. J Diabetes Investig. 2019;10(2):309-17.
48. AlEssa HB, Ley SH, Rosner B, Malik VS, Willett WC, Campos H, et al. High fiber and low atarch intakes are associated with circulating intermediate biomarkers of type 2 diabetes among women. J Nutr. 2016;146(2):306-17.
49. Chikowore T, Pisa PT, van Zyl T, Feskens EJM, Wentzel-Viljoen E, Conradie KR. Nutrient patterns associated with fasting glucose and glycated haemoglobin levels in a Black South African population. Nutrients. 2017;9(1):9-22.

50. Velázquez-López L, Muñoz-Torres AV, García-Peña C, López-Alarcón M, Islas-Andrade S, Escobedo-de la Peña J. Fiber in diet is associated with improvement of glycated hemoglobin and lipid profile in Mexican patients with type 2 diabetes. J Diabetes Res. 2016;2016:2980406-14.
51. Vitale M, Masulli M, Cocozza S, Anichini R, Babini AC, Boemi M, et al. Sex differences in food choices, adherence to dietary recommendations and plasma lipid profile in type 2 diabetes - The TOSCA.IT study. Nutr Metab Cardiovasc Dis. 2016;26(10):879-85.
52. Reynolds AN, Akerman AP, Mann J. Dietary fibre and whole grains in diabetes management: Systematic review and meta-analyses. PLoS Med. 2020;17(3):e1003053-74.
53. World Health Organization (WHO). Guideline: Sugars intake for adults and children. Geneva: WHO; 2015.
54. Te Morenga L, Mallard S, Mann J. Dietary sugars and body weight: Systematic review and meta-analyses of randomised controlled trials and cohort studies. BMJ. 2013;346(7891):1262-86.
55. National Health and Medical Research Council (NHMRC), Australian Government Department of Health and Ageing, New Zealand Ministry of Health. Nutrient Reference Values for Australia and New Zealand. Canberra: NHMRC; 2006 [cited 2021 November 19]. Available from: https://www.nrv.gov.au/.
56. Harris S. A simplified high carbohydrate diet in diabetes mellitus. South Med J. 1939;32(5):467-71.
57. Cruickshank JN. Carbohydrates in the treatment of diabetes mellitus. Glasgow Med J. 1935;123(5):293-303.
58. White JR. A brief history of the development of diabetes medications. Diabetes Spectr. 2014;27(2):82-6.
59. Ensinck JW, Bierman EL. Dietary management of diabetes mellitus. Annu Rev Med. 1979;30(1):155-70.
60. American Diabetes Association. Standards of medical care in diabetes - 2007. Diabetes Care. 2007;30(suppl 1):S4-41.
61. American Diabetes Association. Standards of medical care in diabetes - 2008. Diabetes Care. 2008;31(suppl 1):S12-54.
62. Bailey RL. Overview of dietary assessment methods for measuring intakes of foods, beverages, and dietary supplements in research studies. Curr Opin Biotechnol. 2021;70:91-6.
63. Australian Bureau of Statistics (ABS). Australian Health Survey 2011-13 Canberra: ABS; 2016 [cited 2021 August 25]. Available from: https://www.abs.gov.au/statistics/health/health-conditions-and-risks/australian-health-survey-nutrition-first-results-foods-and-nutrients/latest-release.
64. Avedzi HM, Mathe N, Storey K, Johnson JA, Johnson ST. Examining sex differences in glycemic index knowledge and intake among individuals with type 2 diabetes. Prim Care Diabetes. 2017;12(1):71-9.
65. Ewers B, Trolle E, Jacobsen SS, Vististen D, Almdal TP, Vilsbøll T, et al. Dietary habits and adherence to dietary recommendations in patients with type 1 and type 2 diabetes compared with the general population in Denmark. Nutrition. 2018;61:49-55.
66. Castetbon K, Bonaldi C, Deschamps V, Vernay M, Malon A, Salanave B, et al. Diet in 45- to 74-year-old individuals with diagnosed diabetes: Comparison to counterparts without diabetes in a nationally representative survey (Etude Nationale Nutrition Santé 2006-2007). J Acad Nutr Diet. 2014;114(6):918-25.

67. Mannucci E, Bartali B, Molino Lova R, Papucci M, Lauretani F, Luisi ML, et al. Eating habits in elderly diabetic subjects: Assessment in the InCHIANTI Study. Nutr Metab Cardiovasc Dis. 2008;18(4):278-82.
68. Marques-Vidal P, Vollenweider P, Grange M, Guessous I, Waeber G. Dietary intake of subjects with diabetes is inadequate in Switzerland: The CoLaus study. Eur J Nutr. 2017;56(3):981-9.
69. Haghighian Roudsari A, Vedadhir A, Amiri P, Kalantari N, Omidvar N, Eini-Zinab H, et al. Psycho-Socio-Cultural Determinants of Food Choice: A Qualitative Study on Adults in Social and Cultural Context of Iran. Iran J Psychiatry. 2017;12(4):241-50.
70. Al-Mssallem MQ, Al-Qarni AA, Al-Jamaan M. Dietary carbohydrate intake in patients with type 2 diabetes mellitus and diabetes control: A cross-sectional study. Food Nutr Res. 2020;64:1-7.
71. Medagama A, Fernando D, Widanapathirana H. Energy and nutrient intakes of Sri Lankan patients with type 2 diabetes mellitus: A cross-sectional survey. BMC Res Notes. 2015;8(1):753-9.
72. Thewjitcharoen Y, Chotwanvirat P, Jantawan A, Siwasaranond N, Saetung S, Nimitphong H, et al. Evaluation of dietary intakes and nutritional knowledge in Thai patients with type 2 diabetes mellitus. J Diabetes Res. 2018;2018:1-11.
73. Vitolins MZ, Anderson A, Delahanty L, Raynor H, Miller GD, Mobley C, et al. Action for Health in Diabetes (Look AHEAD) Trial: Baseline evaluation of selected nutrients and food group intake. J Am Diet Assoc. 2009;109(8):1367-75.
74. Casagrande SS, Cowie CC. Trends in dietary intake among adults with type 2 diabetes: NHANES 1988-2012. J Hum Nutr Diet. 2017;30(4):479-89.
75. Mancini FR, Affret A, Dow C, Balkau B, Bihan H, Clavel-Chapelon F, et al. Educational level and family structure influence the dietary changes after the diagnosis of type 2 diabetes: Evidence from the E3N study. Nutr Res. 2017;44:9-17.
76. Esposito K, Maiorino MI, Petrizzo M, Bellastella G, Giugliano D. The effects of a Mediterranean diet on the need for diabetes drugs and remission of newly diagnosed type 2 diabetes: Follow-up of a randomized trial. Diabetes Care. 2014;37(7):1824-30.
77. Liu K, Wang B, Zhou R, Lang HD, Ran L, Wang J, et al. Effect of combined use of a low-carbohydrate, high-protein diet with omega-3 polyunsaturated fatty acid supplementation on glycemic control in newly diagnosed type 2 diabetes: A randomized, double-blind, parallel-controlled trial. Am J Clin Nutr. 2018;108(2):256-65.
78. Castro-Sánchez AE, Ávila-Ortíz MN. Changing dietary habits in persons living with type 2 diabetes. J Nutr Educ Behav. 2013;45(6):761-6.
79. Burch E, Williams LT, Makepeace H, Alston-Knox C, Ball L. How does diet change with a diagnosis of diabetes? Protocol of the 3D longitudinal study. Nutrients. 2019;11(1):158-72.
80. Burch E, Williams LT, Thalib L, Ball L. Short-term improvements in diet quality in people newly diagnosed with type 2 diabetes are associated with smoking status, physical activity and body mass index: The 3D case series study. Nutr Diabetes. 2020;10(1):25-34.
81. Burch E, Williams LT, Thalib L, Ball L. What happens to diet quality in people newly diagnosed with type 2 diabetes? The 3D case-series study. J Hum Nutr Diet. 2021:1-11.
82. Seidelmann SB, Claggett B, Cheng S, Henglin M, Shah A, Steffen LM, et al. Dietary carbohydrate intake and mortality: A prospective cohort study and meta-analysis. Lancet Public Health. 2018;3(9):e419-28.

83. Silverii GA, Botarelli L, Dicembrini I, Girolamo V, Santagiuliana F, Monami M, et al. Low-carbohydrate diets and type 2 diabetes treatment: A meta-analysis of randomized controlled trials. Acta Diabetol. 2020;57(11):1375-82.
84. Suyoto PST. Effect of low-carbohydrate diet on markers of renal function in patients with type 2 diabetes: A meta-analysis. Diabetes Metab Res Rev. 2018;34(7):e3032-40.
85. Unwin D, Unwin J, Crocombe D, Delon C, Guess N, Wong C. Renal function in patients following a low carbohydrate diet for type 2 diabetes: A review of the literature and analysis of routine clinical data from a primary care service over 7 years. Curr Opin Endocrinol Diabetes Obes. 2021;28(5):469-79.
86. Feinman RD, Pogozelski WK, Astrup A, Bernstein RK, Fine EJ, Westman EC, et al. Dietary carbohydrate restriction as the first approach in diabetes management: Critical review and evidence base. Nutrition. 2015;31(1):1-13.
87. Wylie-Rosett J, Aebersold K, Conlon B, Isasi CR, Ostrovsky NW. Health effects of low-carbohydrate diets: Where should new research go? Curr Diab Rep. 2013;13(2):271-8.
88. Kloecker DE, Zaccardi F, Baldry E, Davies MJ, Khunti K, Webb DR. Efficacy of low‐ and very‐low‐energy diets in people with type 2 diabetes mellitus: A systematic review and meta‐analysis of interventional studies. Diabetes Obes Metab. 2019;21(7):1695-705.
89. Westman EC, Yancy WS, Jr., Mavropoulos JC, Marquart M, McDuffie JR. The effect of a low-carbohydrate, ketogenic diet versus a low-glycemic index diet on glycemic control in type 2 diabetes mellitus. Nutr Metab (Lond). 2008;5:36-44.
90. Yamada Y, Uchida J, Izumi H, Tsukamoto Y, Inoue G, Watanabe Y, et al. A non-calorie-restricted low-carbohydrate diet is effective as an alternative therapy for patients with type 2 diabetes. Intern Med. 2014;53(1):13-9.
91. Davis NJ, Tomuta N, Schechter C, Isasi CR, Segal-Isaacson CJ, Stein D, et al. Comparative study of the effects of a 1-year dietary intervention of a low-carbohydrate diet versus a low-fat diet on weight and glycemic control in type 2 diabetes. Diabetes Care. 2009;32(7):1147-52.
92. Atkins RC. Dr. Atkins' New Diet Revolution. US: M. Evans; 2002.
93. Kodama S, Saito K, Tanaka S, Maki M, Yachi Y, Sato M, et al. Influence of fat and carbohydrate proportions on the metabolic profile in patients with type 2 diabetes: A meta-analysis. Diabetes Care. 2009;32(5):959-65.
94. Ajala O, English P, Pinkney J. Systematic review and meta-analysis of different dietary approaches to the management of type 2 diabetes. Am J Clin Nutr. 2013;97(3):505-16.
95. Huntriss R, Campbell M, Bedwell C. The interpretation and effect of a low-carbohydrate diet in the management of type 2 diabetes: A systematic review and meta-analysis of randomised controlled trials. Eur J Clin Nutr. 2017;72(3):311-25.
96. Korsmo-Haugen HK, Brurberg KG, Mann J, Aas AM. Carbohydrate quantity in the dietary management of type 2 diabetes: A systematic review and meta-analysis. Diabetes Obes Metab. 2019;21(1):15-27.
97. McArdle PD, Greenfield SM, Rilstone SK, Narendran P, Haque MS, Gill PS. Carbohydrate restriction for glycaemic control in type 2 diabetes: A systematic review and meta-analysis. Diabet Med. 2019;36(3):335-48.
98. Meng Y, Bai H, Wang S, Li Z, Wang Q, Chen L. Efficacy of low carbohydrate diet for type 2 diabetes mellitus management: A systematic review and meta-analysis of randomized controlled trials. Diabetes Res Clin Pract. 2017;131:124-31.

99. Sainsbury E, Kizirian NV, Partridge SR, Gill T, Colagiuri S, Gibson AA. Effect of dietary carbohydrate restriction on glycemic control in adults with diabetes: A systematic review and meta-analysis. Diabetes Res Clin Pract. 2018;139:239-52.
100. Snorgaard O, Poulsen GM, Andersen HK, Astrup A. Systematic review and meta-analysis of dietary carbohydrate restriction in patients with type 2 diabetes. BMJ Open Diabetes Res Care. 2017;5(1):e000354-63.
101. Mayer SB, Jeffreys AS, Olsen MK, McDuffie JR, Feinglos MN, Yancy WS. Two diets with different haemoglobin A1c and antiglycaemic medication effects despite similar weight loss in type 2 diabetes. Diabetes Obes Metab. 2014;16(1):90-3.
102. Saslow LR, Daubenmier JJ, Moskowitz JT, Kim S, Murphy EJ, Phinney SD, et al. Twelve-month outcomes of a randomized trial of a moderate-carbohydrate versus very low-carbohydrate diet in overweight adults with type 2 diabetes mellitus or prediabetes. Nutr Diabetes. 2017;7(12):304-9.
103. Tay J, Thompson CH, Luscombe-Marsh ND, Wycherley TP, Noakes M, Buckley JD, et al. 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 Obes Metab. 2018;20(4):858-71.
104. Guldbrand H, Dizdar B, Bunjaku B, Lindström T, Bachrach-Lindström M, Fredrikson M, et al. In type 2 diabetes, randomisation to advice to follow a low-carbohydrate diet transiently improves glycaemic control compared with advice to follow a low-fat diet producing a similar weight loss. Diabetologia. 2012;55(8):2118-27.
105. Goldstein T, Kark JD, Berry EM, Adler B, Ziv E, Raz I. The effect of a low carbohydrate energy-unrestricted diet on weight loss in obese type 2 diabetes patients - A randomized controlled trial. E Spen Eur E J Clin Nutr Metab. 2011;6(4):e178-86.
106. Basiotis PP, Welsh SO, Cronin FJ, Kelsay JL, Mertz W. Number of days of food intake records required to estimate individual and group nutrient intakes with defined confidence. J Nutr. 1987;117(9):1638-41.
107. Davis NJ, Tomuta N, Schechter C, Isasi CR, Segal-Isaacson CJ, Stein D, et al. Comparative study of the effects of a 1-year dietary intervention of a low-carbohydrate diet versus a low-fat diet on weight and glycemic control in type 2 diabetes. Diabetes Care. 2009;32(7):1147-52.
108. Webster CC, Murphy TE, Larmuth KM, Noakes TD, Smith JA. Diet, diabetes status, and personal experiences of individuals with type 2 diabetes who self-selected and followed a low carbohydrate high fat diet. Diabetes Metab Syndr Obes. 2019;12:2567-82.
109. Wong K, Raffray M, Roy-Fleming A, Blunden S, Brazeau A-S. Ketogenic diet as a normal way of eating in adults with type 1 and type 2 diabetes: A qualitative study. Can J Diabetes. 2021;45(2):e137-43.
110. Churuangsuk C, Lean MEJ, Combet E. Low and reduced carbohydrate diets: Challenges and opportunities for type 2 diabetes management and prevention. Proc Nutr Soc. 2020;79(4):498-513.
111. Food and Agricultural Organization (FAO)/World Health Organization (WHO). Technical consultation on national food-based dietary guidelines. FAO/WHO; 2006.
112. Porta MS, International Epidemiological Association, Oxford University Press. A Dictionary of Epidemiology. Sixth ed. New York: Oxford University Press; 2014.
113. Elm Ev, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP, et al. The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) Statement: guidelines for reporting observational studies. Epidemiology. 2007;18(6):800-4.

114. LimeSurvey Organisation. [cited 2021 August 25]. Available from: https://www.limesurvey.org/.
115. Taylor AW, Grande ED, Gill TK, Chittleborough CR, Wilson DH, Adams RJ, et al. How valid are self-reported height and weight? A comparison between CATI self-report and clinic measurements using a large cohort study. Aust N Z J Public Health. 2006;30(3):238-46.
116. World Health Organization (WHO). Obesity - Preventing and Managing the Global Epidemic: Report on a WHO Consultation. London: World Health Organization; 2000.
117. Khunti K, Taub N, Webb D, Srinivasan B, Stockman J, Griffin SJ, et al. Validity of self-assessed waist circumference in a multi-ethnic UK population. Diabet Med. 2012;29(3):404-9.
118. World Health Organization (WHO). Waist circumference and waist-hip ratio: Report of a WHO expert consultation. Geneva: WHO; 2008.
119. Moshfegh AJ, Rhodes DG, Baer DJ, Murayi T, Clemens JC, Rumpler WV, et al. The US Department of Agriculture Automated Multiple-Pass Method reduces bias in the collection of energy intakes. Am J Clin Nutr. 2008;88(2):324-32.
120. Xyris Software. FoodWorks 9 Professional [cited 2021 August 25]. Available from: https://xyris.com.au/products/foodworks-9-professional/.
121. International Physical Activity Questionnaire (IPAQ). [cited 2021 August 25]. Available from: https://sites.google.com/site/theipaq/home.
122. Somerville M, Burch E, Ball L, Williams LT. ‘I could have made those changes years earlier’: Experiences and characteristics associated with receiving a prediabetes diagnosis among individuals recently diagnosed with type 2 diabetes. Fam Pract. 2021;37(3):382-9.
123. SAGE Publications. Encyclopedia of Research Design. USA: SAGE Publications; 2010.
124. SAGE Publications. Learn about Spearman's rank-order correlation coefficient in SPSS with data from the Global Health Observatory Data. London: SAGE Publications; 2015.
125. Johnston BC, Guyatt GH. Best (but oft-forgotten) practices: intention-to-treat, treatment adherence, and missing participant outcome data in the nutrition literature. Am J Clin Nutr. 2016;104(5):1197-201.
126. Feinman RD, Volek JS. Carbohydrate restriction as the default treatment for type 2 diabetes and metabolic syndrome. Scand Cardiovasc J. 2008;42(4):256-63.
127. Mozaffarian D, Ludwig DS. Dietary guidelines in the 21st century-a time for food. J Am Med Assoc. 2010;304(6):681-2.
128. Dietitians of Canada/Les diététistes du Canada. Pen: Practice-based Evidence in Nutrition 2022 [cited 2022 March 18]. Available from: https://www.pennutrition.com/.
129. Hackett RA, Moore C, Steptoe A, Lassale C. Health behaviour changes after type 2 diabetes diagnosis: Findings from the English Longitudinal Study of Ageing. Sci Rep. 2018;8(1):16938-45.
130. Yang PHW, Black JL, Barr SI, Vatanparast H. Examining differences in nutrient intake and dietary quality on weekdays versus weekend days in Canada. Appl Physiol Nutr Metab. 2014;39(12):1413-7.
131. Ambikairajah A, Walsh E, Tabatabaei-Jafari H, Cherbuin N. Fat mass changes during menopause: a metaanalysis. Am J Obstet Gynecol. 2019;221(5):393-409.
132. Kodama S, Horikawa C, Fujihara K, Heianza Y, Hirasawa R, Yachi Y, et al. Comparisons of the strength of associations with future type 2 diabetes risk among anthropometric obesity indicators, including waist-to-height ratio: A meta-analysis. Am J Epidemiol. 2012;176(11):959-69.

133. Guthrie JR, Ball M, Dudley EC, Garamszegi CV, Wahlqvist ML, Dennerstein L, et al. Impaired fasting glycaemia in middle-aged women: a prospective study. International Journal of Obesity. 2001;25(5):646-51.
134. Spencer EA, Roddam AW, Key TJ. Accuracy of self-reported waist and hip measurements in 4492 EPIC–Oxford participants. Public Health Nutr. 2004;7(6):723-7.
135. Poslusna K, Ruprich J, de Vries JHM, Jakubikova M, van't Veer P. Misreporting of energy and micronutrient intake estimated by food records and 24 hour recalls, control and adjustment methods in practice. Br J Nutr. 2009;101(S2):S73-85.
136. Martin GS, Tapsell LC, Batterham MJ, Russell KG. Relative bias in diet history measurements: a quality control technique for dietary intervention trials. Public Health Nutr. 2002;5(4):537-45.
137. Hebert JR, Hurley TG, Peterson KE, Resnicow K, Thompson FE, Yaroch AL, et al. Social desirability trait influences on self-reported dietary measures among diverse participants in a multicenter multiple risk factor trial. J Nutr. 2008;138(1):226S-34S.
138. Caleyachetty R, Barber TM, Mohammed NI, Cappuccio FP, Hardy R, Mathur R, et al. Ethnicity-specific BMI cutoffs for obesity based on type 2 diabetes risk in England: A population-based cohort study. Lancet Diabetes Endocrinol. 2021;9(7):419-26.
139. Australian Bureau of Statistics (ABS). 2016 Census of Population and Housing Canberra: ABS; 2016 [cited 2021 November 19]. Available from: https://www.abs.gov.au/statistics/microdata-tablebuilder/tablebuilder.
140. Bolla AM, Caretto A, Laurenzi A, Scavini M, Piemonti L. Low-carb and ketogenic diets in type 1 and type 2 diabetes. Nutrients. 2019;11(5):962-75.
141. Halton TL, Willett WC, Liu S, Manson JE, Albert CM, Rexrode K, et al. Low-carbohydrate-diet score and the risk of coronary heart disease in women. N Engl J Med. 2006;355(19):1991-2002.
142. Zazpe I, Sánchez-Taínta A, Santiago S, de la Fuente-Arrillaga C, Bes-Rastrollo M, Martínez JA, et al. Association between dietary carbohydrate intake quality and micronutrient intake adequacy in a Mediterranean cohort: The SUN (Seguimiento Universidad de Navarra) Project. Br J Nutr. 2014;111(11):2000-9.
143. Al-Ozairi E, AlAwadhi MM, Al Kandari J, Taghadom E, Abdullah M, Le Roux CW. Photo-assisted dietary method improves estimates of dietary intake among people with sleeve gastrectomy. Obes Surg. 2019;29(5):1602-6.
144. Chang CR, Francois ME, Little JP. Restricting carbohydrates at breakfast is sufficient to reduce 24-hour exposure to postprandial hyperglycemia and improve glycemic variability. Am J Clin Nutr. 2019;109(5):1302-9.
145. Shaw C, Starling N, Reich A, Wilkes E, White R, Shepelev J, et al. Modification of systemic anti-cancer therapies and weight loss, a population-level real-world evidence study. Ther Adv Med Oncol. 2020;12:1-64.