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Clinical Application of Reduced-Carbohydrate Diets for Type 1 Diabetes Management: A Retrospective Case Series

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Abstract

Background: The aim of this study was to explore the clinical application of reduced-carbohydrate (RC) diets for type 1 diabetes (T1D) management at a community-based diabetes centre.

Methods: To be included in this retrospective case series, adults with T1D must have attended at least two appointments with a Credentialled Diabetes Educator and Accredited Practising Dietitian (CDE/APD) for advice regarding: (a) advanced carbohydrate counting, (b) carbohydrate reduction, and/or (b) low-carbohydrate diet support. Data regarding specific dietary recommendations and clinical outcomes was extracted from patient records stored at the center. A semi-structured interview with the CDE/APD was conducted to collect additional information about the design and delivery of the RC diets. Thematic analysis was used to identify core components of the RC diets, and descriptive statistics were used to assess pre-post changes in clinical T1D outcomes.

Results: 26 adults with T1D were eligible and included (77% female). The RC diets represented a patient-led approach involving adjustments to energy and macronutrient intakes, glucose self-monitoring, and insulin management. 22/26 participants attended the center seeking low-carbohydrate diet support, and the average carbohydrate prescription was 63g/day (22-253g/day) which translated to a 37% reduction from baseline. HbA1c reduced from 9.0% (75mmol/mol) to 7.0% (53mmol/mol) (-5.7 to -0.1%), with an average follow-up of 55weeks (n=8). Estimated A1c reduced from 7.1% (54mmol/mol) to 6.3% (45mmol/mol) (-2.9 to+0.6%) over 21 weeks (n=19). Mean total daily insulin reduced from 44 to 31 U/day (-46 to+6 U/day), with an average follow-up of 17 weeks (n=15).

Conclusions: This study provides real-world insights into the clinical application of RC diets in the management of adults with T1D at a community-based diabetes centre. Prospective clinical trials are needed to conclusively determine the effects of RC diets on clinical T1D outcomes.

Keywords: Type 1 diabetes; Glycaemic control; Reduced carbohydrate diets; Retrospective case series.

Abbreviations: RC: Reduced Carbohydrate; HbA1c: Hemoglobin A1c; TEI: Total Energy Intake; LC: Low-Carbohydrate; CDE: Credentialed Diabetes Educator; APD: Accredited Practicing Dietitian; EA1c: Estimated A1c; CGM: Continuous Blood Glucose Monitoring; FGM: Flash Blood Glucose Monitoring; TDI: Total Daily Insulin; BMI: Body Mass Index; ISF: Insulin Sensitivity Factor(s); VLCKD: Very Low-Carbohydrate Ketogenic; LCD: Low-Carbohydrate Diet; MCD: Moderate-Carbohydrate Diet; kcal: Kilocalories; Kilojoules

Introduction

Type 1 Diabetes (T1D) is an autoimmune condition characterized by the destruction of pancreatic beta cells and absolute insulin deficiency. Glycemic control is the strongest predictor of diabetes-related complications with a hemoglobin A1c (HbA1c) level ≤7.0% (53mmol/mol) considered the primary target in diabetes management [1-3]. Standard treatment methods include insulin therapy, blood glucose monitoring and carbohydrate counting [4]. However, dietary advice for people with T1D remains consistent with national recommendations for the general population, which is a high-carbohydrate diet (45-65% total energy intake [TEI]) [4,5]. Data from T1D registries (2010-2013) across nineteen countries in Australasia, Europe, and North America (n=324,501) reported that 84% of patients' HbA1c was >7.0% (53 mmol/mol) [6]. Further, data from the 2006 Australian National Diabetes

Audit-Australian Quality Self-Management Audit (n=3,930) reported a mean HbA1c of 8.4% (68 mmol/mol) amongst T1D patients [7]. It appears that current T1D management strategies are lacking in effect and dietary approaches specifically aimed at improving glycaemic control in T1D should be explored.

It is well established that dietary carbohydrates impose the greatest impact on post-prandial blood glucose levels. Low-carbohydrate (LC) diets providing <130 grams of carbohydrate per day (g/day) or <26% TEI have recently been acknowledged by governing health bodies as an effective approach for type 2 diabetes management and a research priority area for T1D [8-10]. Despite very LC diets being the original method to treat diabetes prior to the discovery of insulin in the early 1900's [11] a 2018 systematic review of diet interventions containing <45% TEI from carbohydrates highlighted a sheer lack of both observational and interventional studies investigating the feasibility and effect(s) of lower-carbohydrate diets in adults with T1D [12]. Nine studies were identified of which two were randomized controlled trials with small sample sizes (n=10), four were pre-post intervention studies, two were retrospective case series, and one was a case report [12]. Nevertheless, the collective evidence demonstrated promising results, including improvements in HbA1c, total daily insulin and frequency of severe hypoglycaemia in T1D adults [12]. A recent observational study of individuals with T1D (n=316) showed that exceptional HbA1c levels of ~5.7% (39mmol/mol) can be obtained with adherence to a very LC diet (~35g/day) [13]. Until prospective clinical trials with sufficient sample sizes are conducted to conclusively determine the effect(s) of RC diets in adults with T1D, small-scale studies exploring the use and feasibility of RC diets in real-world clinical practice settings are useful to help practitioners better understand the role of RC diets for T1D management [9,12].

Therefore, a retrospective case series of adults with T1D who have been actively managed with a RC diet delivered by a Credentialed Diabetes Educator (CDE) and Accredited Practising Dietitian (APD) (hereon referred to as CDE/APD) at a community-based diabetes centre was conducted. The objectives of this study were to 1) describe the core components of RC diets used in real-world T1D management; and 2) determine (pre-post) change(s) in clinical T1D management outcomes for patients choosing to follow a RC diet, including HbA1c, glycaemic variability, total daily insulin use, and fasting blood glucose levels. This is a hypothesis-generating study sought to explore the feasibility and effects of prescribing a RC diet for the management of T1D.

Materials and Methods

Study design

This case series was a retrospective chart review of adults previously diagnosed with T1D who had chosen to follow a RC diet delivered by the CDE/APD between January 2017 and November 2019 at a community-based diabetes centre in Stirling, Western Australia. The study protocol was registered and included in the Australian New Zealand Clinical Trials Registry and allocated a registration number of ACTRN12619001538134 (http://www.ANZCTR.org.au/ ACTRN12619001538134.aspx). Ethical approval was obtained from the University of Sydney's Human Research Ethics Committee (project no.: 2019/668).

Participants

An email was sent out to existing patients at the centre inviting them to complete an online survey and provide informed consent to share their data with researchers and be assessed for eligibility to participate in this retrospective analysis. Ethical approval was obtained for a single email invitation, and no further attempts were made to contact non-responders for consent to share their data. One researcher (JT) assessed the consenting patient records for study eligibility and to collect relevant data for analysis during a 1-week period in November2019. To be included, patients must have attended at least two appointments (≥2 weeks apart) with the CDE/APD for advice regarding a RC diet for the management of T1D and been between 18-60 years of age at the time of their first appointment. A RC diet was defined as any approach that involved; (a) advanced carbohydrate counting, (b) carbohydrate reduction, and/or (b) LC diet support. It was assumed that advanced carbohydrate counting led to a natural reduction in carbohydrate intake irrespective of any specific prescription due to greater participant awareness of the carbohydrate content in various foods. Participants must have also had at least one clinical T1D outcome measured on at least two time-points (≥2 weeks apart) that was recorded in their patient record by the CDE/APD. As the diabetes centre is a private billing allied health clinic, all participants were responsible for scheduling consultations with the CDE/APD on an as-needed basis. Researchers did not contact participants for any missing data, and only data in patient records stored at the diabetes centre or provided by participants in the online survey was assessed. All eligible participants were included in the analysis.

Study outcomes

Core components of the RC diet: Content analysis was performed on the core dietary and delivery components of the RC diets, including the prescribed amounts and types of dietary carbohydrates, proteins, and fats, in addition to total energy. Reported details on the dietary delivery method(s) and any adjustment(s) made to glucose self-monitoring or insulin management were also analysed.

Clinical outcomes: The primary clinical T1D management outcomes were HbA1c and estimated A1c (EA1c), calculated as (mean glucose mmol/L + 2.59)/1.59 using the data recorded by a continuous [CGM] or flash [FGM] blood glucose monitoring device across 7-14 days [14]. EA1c has been used to assess glycaemic control in previous studies [15,16] rather than actual HbA1c, likely due to reduced need for blood collections and clinic visits [14]. Secondary clinical outcomes were time spent in blood glucose target ranges and low glucose events (<3.9mmol/L) recorded

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by a CGM or FGM device across 7-14 days. Additional clinical outcomes were total daily insulin (TDI) and fasting glucose levels, as measured by participants using their own devices. For each outcome, the earliest and last recorded value reported in patient records was considered the 'pre' and 'post' value, respectively.

Data collection

Patient records: Data were collected from patient records stored at the centre. Patient records included clinical notes and medical correspondence written by the CDE/APD. Specialist letters, pathology reports, and blood glucose monitoring reports were also assessed, if available. Patient records were assessed by one researcher (JT) to extract the following data for each participant: Body Mass Index (BMI) as assessed by the CDE/APD; use of CGM/FGM device; use of Insulin Sensitivity Factors (ISF) or insulin pump; use of carbohydrate counting; dietary intake at baseline as assessed by the CDE/APD (including macronutrient and energy intakes); details on the prescribed LC dietary approach; details on any specific delivery techniques used; details on any insulin and blood glucose monitoring adjustments; length of follow-up (i.e., time from first appointment to last appointment); and, all recorded clinical T1D outcome values. Due to the retrospective nature of this study, it was anticipated that not all participants would have complete data available in their patient records. Data analysis was completed on available data with no imputations made for missing data.

Participant survey: Participants completed a short online questionnaire at the time of consent to provide demographic data and general health information that may not have been available from their patient records. This data included: date of birth (for age calculation); ethnicity; religion; gender; highest level of education completed; height; body weight; year of type 1 diabetes diagnosis; and co-morbidities.

Practitioner interview: One researcher (JT) interviewed the centre's CDE/APD and Chief Executive Officer (C.E.O.) to collect and clarify information on the RC diets delivered, in addition to information about the non-clinical social, community and educational services offered at the centre. The interview was semi-structured, and questions are included in the supplementary files (Supplementary Table 8). Answers were recorded verbatim.

Data synthesis & analysis: Thematic analysis was used to assess the dietary prescription details extracted from patient records and the semi-structured interview to identify core components of the RC diets. All investigators reviewed the initial themes identified in the collaborative data until consensus was reached on the core components and general methodologies used amongst included participants. Clinical T1D management outcome values were presented in tabular format for each participant (case-by-case) and pre-post means and mean differences were calculated using descriptive statistics. Mean changes in HbA1c, EA1c, time in target range, low glucose events, TDI and fasting glucose levels were compared using the first recorded value (pre) and the last recorded value (post) available for each participant.

Results

Participants and characteristics

Table 1: Baseline Characteristics of Included Participants (n=26).

Participant ID	Sex	Age (y)	BMI (kg/m^2)	Ethnicity[§]	Religion	Education[‡]	Duration of T1D(y)	Co-Morbidities	CGM / FGM	ISF / Pump	Carb Counting
1	F	18	34.9[†]	White	None	5	1	None disclosed	N	N	S
2	F	23	17.0[†]	White	Christianity	1	13	None	Y(Dexcom)	Y	Y (g)
3	F	19	25.2	Mixed	Christianity	1	8	None	Y (Libre)	Y	Y (g)
4	F	20	24.8	White	Christianity	2	6	Depression/anxiety	Y (Libre)	N	S
6	M	39	27.7	Mixed	None	2	<1 (4 m)	Depression/anxiety	Y (Libre)	N	Y (g)
8	F	36	23.1[†]	White	None	2	<1 (5 m)	None	Y (Libre)	N	Y (g)
9	F	32	26.1	White	None	2	<1 (2 m)	PCOS, depression/anxiety	Y (Libre)	N	Y (g)
11	F	23	34	White	Christianity	2	22	PCOS, Coeliac, depression/anxiety, other	NR	N	Y (g)
13	M	35	35.8	White	None	1	15	None	NR	Y	Y (g)
14	M	37	22.9	White	None	4	20	Hypothyroidism, Coeliac	Y(Dexcom)	NR	NR
15	F	49	26.0[†]	White	None	2	19	Hypertension	N	N	S

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17	F	52	29.0†	White	Christianity	2	<1 (4 m)	Hypothyroidism	Y (Libre)	Y	Y (g)
18	F	45	26.6	White	None	3	35	None	Y(Dexcom)	Y	Y (g)
19	M	34	25.1†	White	None	2	13	None	Y (Libre)	NR	Y (g)
20	M	23	22.0†	White	None	1	7	None	Y(Dexcom)	Y	NR
22	F	30	37.6	Blacks	None	1	<1 (3 m)	Depression/anxiety	Y (Libre)	N	N
23	F	39	31.8	White	Christianity	3	14	Hypothyroidism	N	Y	Y (g)
24	F	39	31.9	White	None	2	29	Hypothyroidism	Y(Dexcom)	Y	Y (g)
26	F	44	22.8	White	None	2	42	None	Y (Libre)	N	Y (g)
27	M	25	23.5†	White	None	3	11	Coeliac	Y (Libre)	Y	Y (g)
28	F	36	22.9	White	None	1	3	Hypothyroidism	Y	Y	N
30	F	32	25.6†	White	None	2	2	None disclosed	N	N	Y (g)
31	F	49	20.9	White	Christianity	2	7	None	N	N	Y
34	F	23	29.0†	White	None	1	12	None	Y	Y	Y (g)
35	F	58	26.0†	White	None	2	27	Hypertension	N	N	N
37	F	45	30	White	None	5	14	None	Y (Libre)	Y	Y

† Survey data was used for these participants and may not reflect true baseline BMI at time of initial appointment.

§ Refers to category: Black / African / Caribbean / Black British.

‡ 1, University or college degree (related to health, medical or nutritional sciences); 2, University or college degree (unrelated to health, medical or nutritional sciences); 3, University or college credit (no degree); 4, Trade/technical or vocational training; 5, High school (or equivalent secondary level).

NR: Not Reported; y: Years; m: Months; Coeliac: Coeliac disease; CGM: Continuous Blood Glucose Monitoring Device; FGM: Flash Blood Glucose Monitoring Device; ISF: Insulin Sensitivity Factor(s); Pump: Insulin Pump; Carb: Carbohydrate; S: Sometimes; G: Grams

Email invitations were sent out to all existing patients at the centre (n=240). Of these, n=38 completed the online survey and provided informed consent to share their patient records with the researchers for assessment. Twenty-six participants were eligible and included in the study, while n=12 were not eligible with reasons provided (Supplementary Table 10). Baseline participant characteristics of included participants (n=26) are presented in Table 1. 77% (20/26) of participants were female with a mean age of 35 years (18-58years). The average duration of T1D was 12.4 years (2 months to 42 years), with 54% (14/26) of participants having lived with T1D for 10 years or longer. 65% (17/26) of participants were overweight or obese and 31% (8/26) were of normal weight according to BMI [17].

Baseline dietary intake

Baseline energy and macronutrient intake data is presented in Supplementary Table 1. Of the 16 participants (16/26) who reported to be following a particular diet at baseline; 75% reported to be following a LC diet, of which one was a vegetarian LC diet; and 19% were following a vegan diet. Nineteen participants (19/26) had baseline carbohydrate intake data in g/day available, with a mean of 100g/day, ranging from 20-283 g/day. According to the suggested definitions by Feinman et al. [18], 37% of participants were following a very LC ketogenic diet (VLCKD) (20-50g/day), 26% were following a LC diet (LCD) (<130g/day), and 32% were following a moderate-carbohydrate diet (MCD) (130-225g/day). Thirteen participants (13/26) had baseline energy intake data, with a mean TEI of 1,662 kcal/day 250 (6,848kJ/day), ranging from 728-2,546kcal/day (3,000-10,489kJ/day).

Core components of RC diets

Participants received personalised advice and support regarding a RC diet by the centre's CDE/APD at various timepoints between January 2017 and November 2019, and the average follow-up duration was 41 weeks (2-127 weeks) (Table 2). The RC diet represented a patient-led approach that included advice and education on the topics of dietary carbohydrates, proteins, and fats; glucose self-monitoring; and insulin management (Table 2 & Supplementary Table 9). The CDE/APD reported that the majority of patients who attend the diabetes centre are actively seeking LC diet support. Actual data from patient records indicated that 85% of participants (22/26) were seeking LC diet support. Prior to implementing any carbohydrate reduction, participants were first educated on how to dose insulin for their absolute carbohydrate intake, including proper use of insulin to carbohydrate ratios and correction factors. If participants were not properly counting carbohydrates in all foods and fluids, then advanced carbohydrate counting education was provided to

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ensure all digestible carbohydrates were accounted for including carbohydrates in non-starchy vegetables, low-sugar fruits, nuts, and seeds. The CDE/APD typically referred patients to an online nutrient database (Calorie King (19)), and the centre offered a carbohydrate counting course. Data extracted from patient records indicated that 65% of participants (17/26) required advanced carbohydrate counting education (Table 2).

Table 2: Diet prescription details of included participants (n=26).

Partici-pant ID	Sex	Appts / FU (w)	TEI (kcal/ day)	Carb (g/ day)	Diet	Carb (%TEI)	Fibre (g/day)	Proteins (g/day)	Proteins (%TEI)	Fats (g/day)	Fats (%TEI)	SFA (g/day)	LCS	ACC
1	F	3/24	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y
2	F	3/6	NR	253	HCD	NR	NR	NR	NR	NR	NR	NR	NR	Y
3	F	10/58	1912	50	VL-CKD	11	30	95	20	160	74	NR	Y	NR
4	F	7 /117	2032	130	MCD	26	30	70	14	103	45	NR	NR	Y
6	M	2/11	2868	50	VL-CKD	7	30	175	25	220	68	NR	Y	Y
8	F	3/6	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y	Y
9	F	5/33	NR	46	VL-CKD	NR	NR	80	NR	NR	NR	NR	Y	Y
11	F	12/97	2103	80	MCD	15	30	100	19	158	66	NR	Y	NR
13	M	12/65	2199	50	VL-CKD	9	30	130	24	160	64	NR	Y	NR
14	M	2/13	3058	40	VL-CKD	5	30	158	21	250	72	NR	Y	NR
15	F	8/45	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y	Y
17	F	4/16	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y	Y
18	F	6/36	1769	40	VL-CKD	9	30	100	23	130	65	NR	Y	NR
19	M	2/4	NR	22	VL-CKD	NR	NR	NR	NR	NR	NR	NR	Y	Y
20	M	4/12	1984	30	VL-CKD	6	25	120	25	150	67	NR	Y	Y
22	F	3/3	1769	50	VL-CKD	11	30	90	21	150	75	NR	Y	Y
23	F	5/28	1697	45	VL-CKD	11	NR	85	20	NR	NR	NR	Y	Y
24	F	10/55	1912	60	LCD	13	30	150	32	112	52	NR	Y	NR
26	F	4/10	2257	31	NR	6	NR	107	19	174	68	NR	Y	Y
27	M	9/54	NR	90	LCD	NR	NR	NR	NR	NR	NR	NR	Y	NR
28	F	3/18	1912	40	VL-CKD	9	25	95	20	155	72	NR	Y	Y
30	F	4/15	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y	NR
31	F	16 /124	1912	30	VL-CKD	6	NR	118	25	150	69	NR	Y	Y
34	F	9/91	1386	50	VL-CKD	15	NR	110	32	80	51	NR	Y	NR
35	F	2/3	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y
37	F	12 /127	2079	64	LCD	13	25	137	27	138	59	50	Y	Y

F: Female; M: Male; Appts: Appointments; FU: Follow Up Duration; w: Weeks; TEI: Total Energy Intake; kcal: Kilocalories; NR: Not Reported; Carb; Total Digestible Carbohydrates; g: Grams; VLCKD: Very Low-Carbohydrate Ketogenic Diet; LCD: Low-Carbohydrate Diet; MCD: Moderate-Carbohydrate Diet; HCD: High-Carbohydrate Diet; SFA: Saturated Fatty Acids; LCS: Low-Carbohydrate Diet Support; ACC: Advanced Carbohydrate Counting; Y: Yes

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The CDE/APD reported that the initial recommended change in carbohydrates was generally a reduction of ~50% from baseline intake, except for those already following a VLCKD. Actual prescriptions were reported in g/day and/or TEI for 77% of participants (20/26) (Table 2). The average carbohydrate prescription of the RC diets was 63g/day (or 11% TEI) ranging from 22-253g/day (or 5-26% TEI), which translated to a 37% reduction from baseline (Table 2 & Supplementary Table 1). 68% of prescriptions were VLCKD (20-50g/day), 16% were LCD (<130g/day), and 11% were MCD (130-225g/day) [18] (Table 2). Participants were routinely provided with a CGM or FGM (if they were not already using one) to use over the initial 1-2 weeks. This was to assist them in identifying the required insulin adjustments to prevent hypoglycaemia in expectation that rapid acting insulin requirements would immediately reduce with carbohydrate reduction. Participants were advised to return for a follow-up within 2-4weeks of the initial appointment to receive further support on titrating insulin dosages in expectation that background/basal insulin requirements would also reduce with continued adherence to the RC diet. The carbohydrate prescription may have continued to be adjusted depending on participants' goals, preferences, motivations, and outcome progress. Total energy prescriptions were calculated using the Schofield equation to help participants meet their energy demands on a RC diet [20]. Sixteen participants (16/26) had total energy prescriptions recorded in their patient records (Table 2). Of these, the average prescription was 2,085 kcal/day (8,590 kJ/day), ranging from 1,408-3,106kcal (5,800-12,795kJ/day), which reflected a 25% increase from baseline (Table 2 & Supplementary Table 1). Dietary protein prescriptions were based on 20-25% of participants' total energy prescription, and protein options and portion sizes were discussed with participants in terms of real food quantities (e.g., 100g cooked meat). Seventeen participants (17/26) had actual protein prescriptions recorded and of these, the average was 113g/day (or 23% TEI), ranging from 70-175g/day (or 14-32% TEI) (Table 2). Participants were recommended to meet their remaining energy requirements with a variety of dietary fats, and fat options and portion sizes were discussed. The types of foods recommended included minimally processed meat, fish, eggs, full-fat dairy, non-starchy vegetables, low-sugar fruits, nuts, seeds, avocado, olive oil, butter, and nut butters. Fifteen participants (15/26) had actual fat prescriptions recorded, with an average prescription of 153 g/day (or 64% TEI), ranging from 80-250g/day (or 45-75% TEI) (Table 2). Participants were given practical advice on structuring meals according to their macronutrient and energy requirements. The CDE/APD provided education to facilitate adherence to the RC diets. Topics included: effect(s) of carbohydrates on blood glucose levels and insulin requirements, role(s) of dietary fats as an energy source and in weight management/general health, effect(s) of increasing dietary fats on cholesterol levels and risk of cardiovascular disease, hypoglycaemia treatment, and ketone monitoring. The CDE/APD reported that participants following the RC diets eventually required education and advice on how to factor in protein when calculating mealtime insulin dosages (known as 'protein bolusing'). Courses, meet-up events, and peer support/learning opportunities were also offered to participants by the community-based diabetes centre to complement the clinical services with the CDE/APD. For example, the centre has a Facebook group with 700 members and 3000 engagements per month.

Clinical outcomes

HbA1c: Eight participants had pre-post values for HbA1c that were either self-reported usual care measurements recorded by the CDE/APD (n=4), usual care measurements taken from pathology reports or specialist correspondence (n=1), a combination of both (n=2), or measured at the diabetes centre (n=1) (Supplementary Table 2). Mean HbA1c reduced from 9.0% (75mmol/mol) to 7.0% (53mmol/mol) (-2.2%; -5.7 to -0.1%), with an average follow-up duration of 55 weeks (10-114 weeks). Four (4/8) participants had a post HbA1c value within the T1D management target range of ≤7.0% (53mmol/mol), while only one (1/8) participant had a pre-value within this target. Two participants with the highest starting HbA1c values experienced the greatest reductions at follow-up (13.4 to 7.7%; -5.7% and 10.6 to 5.3%; -5.3%). No participants had an increase in HbA1c reported.

Estimated A1c: Nineteen participants had pre- and post-values for EA1c measured using an FGM (n=14, FreeStyle Libre™), a CGM (n=1, Dexcom) or both (n=1, Libre + Dexcom; n=3, Libre + Medtronic) (Figure 1 & Supplementary Table 3). Of these participants, eight (8/19) had pre-post values over a duration of 2-10 weeks, of which five experienced a reduction, two experienced no changes, and one experienced an increase, with an average absolute change in EA1c of -0.3% (-1.6 to +0.6%). Six participants (6/19) had pre-postvalues over a duration of 10-25weeks, of which five experienced a reduction and one no change, with an average absolute change of -1.1% (-2.9 to 0.0%); and five participants (5/19) had pre-post values for durations greater than 25weeks of which all experienced a reduction and average absolute change of -1.0% (-2.4 to -0.2%). Across all 19 participants, the average follow-up for measuring changes in EA1c was 21 weeks (2-55weeks), with an overall mean pre-post change of -0.7% (-2.9 to+0.6%), with mean EA1c values reducing from 7.1% (54mmol/mol) (4.6 to 11.4%) to 6.3% (45mmol/mol) (4.6 to 9.0%).

Time in target range: Twelve participants had pre-post values for time in target range that were measured using a FGM (n=7), CGM (n=2) or both (n=3) (Supplementary Table 4). Three participants (3/12) used non-standard blood glucose target ranges within 3.9-8.5mmol/L. Of these, all participants (3/3) experienced an increase in time in target, from an average of 58% to 65% (+7%; +3 to +13%). Nine participants (9/12) used the standard target range of 3.9-10.0 mmol/L and their overall mean time in target increased from 58% to 76% (+18%; -8 to +46%), with an average follow-up duration of 19 weeks (4-52weeks).

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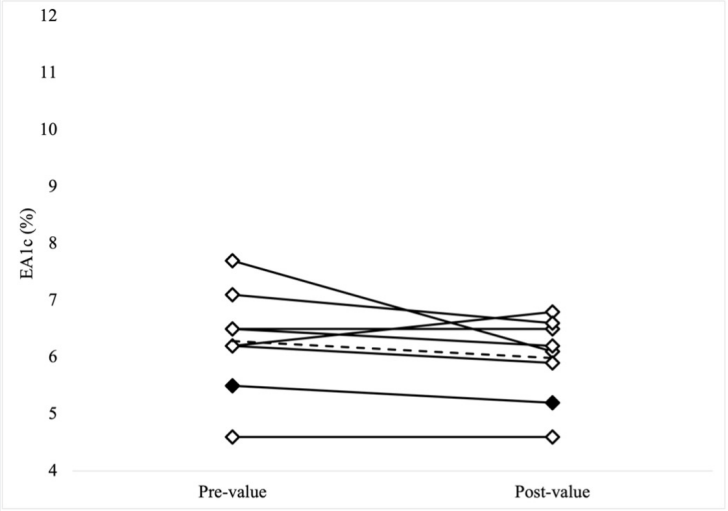
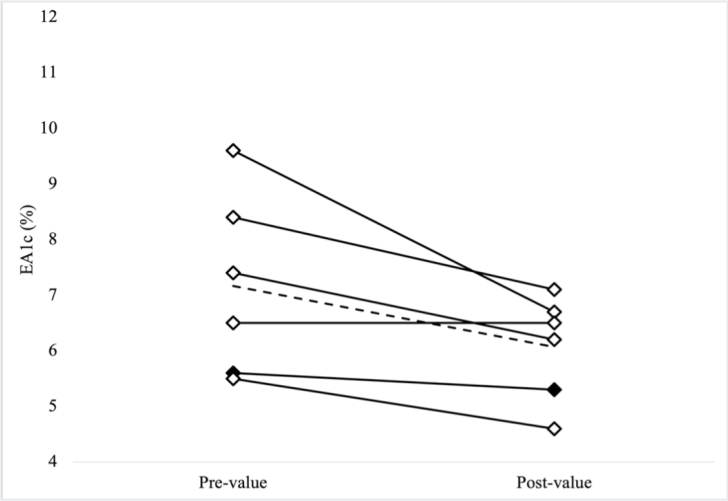
DOI: 10.19080/CRDOJ.2022.15.555919

A)



B)



C)

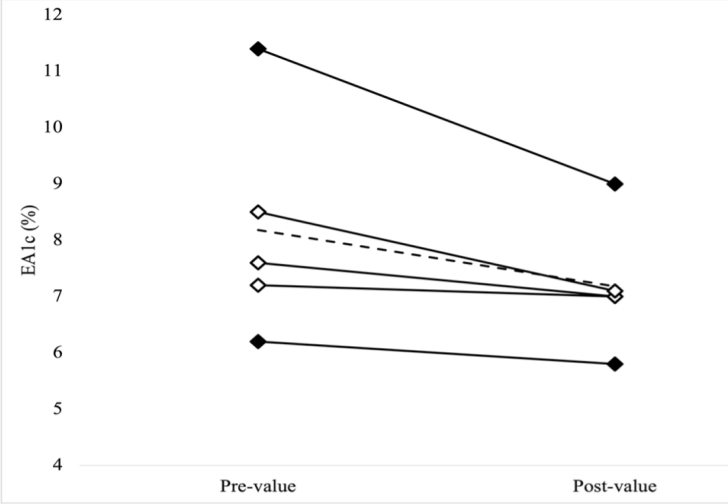


Figure 1 (A-C): Estimated A1c (EA1c) values of adults with type 1 diabetes (n=19) following a reduced carbohydrate diet.

A) Participants with pre-post data for 2-10 weeks duration (n=8); B) Participants with pre-post data for 10-25 weeks duration (n=6); C) Participants with pre-post data for >25 weeks duration (n=5). ◆Male; ◇Female; - - - - mean; EA1c: Estimated A1c

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Low glucose events: Fourteen participants had pre-post values for low glucose events (<3.9 mmol/L) measured over a 2-week period using an FGM (n=10), CGM (n=1) or both (n=3) (Supplementary Table 5). The mean frequency increased by one event following an average duration of 17 weeks, with 50% (7/14) experiencing a decrease in low glucose events ranging from -1 to -13 events over a 2-week period. Ten participants (10/14) had pre-post minute data available (Supplementary Table 5). Of these, the mean minutes spent in the low glucose range (<3.9 mmol/L) for each event reduced from 120 to 94 over a 2-week period.

Total daily insulin: Fifteen participants had pre-post values for TDI that were either self-reported measurements recorded by the CDE/APD (n=6), taken from CGM or FGM reports (n=4), a combination of both (n=4), or taken from a combination of an insulin pump summary report and a CGM report (n=1) (Supplementary Table 6). Mean TDI reduced by 30% from 44 U/day to 31 U/day (-13 U/day; -46 to +6 U/day), with an average follow-up duration of 17 weeks (2-65weeks). Five participants (5/15) reported reductions in TDI of >20 U/day, ranging from -24 to -46 U/day. The participant who experienced the greatest reduction in TDI (-46 U/day) had the highest reported pre-value (91 U/day), with a follow-up duration of 55weeks.

Fasting blood glucose: Five participants self-reported pre-post fasting blood glucose values at least two weeks apart (Supplementary Table 7). All five reported lower post-values with a mean reduction from 12.5mmol/L to 9.3mmol/L (-8.5 to -0.2mmol/L) following an average duration of 29weeks.

Discussion

This retrospective case series explored the practical application and effect(s) of RC diets for T1D patients at a community-based diabetes centre. Professionally supported RC diets appear to be a feasible management option for adults with T1D and may lead to maintenance or improvements in clinical outcomes in some patients. The RC diets described in this analysis were predominantly patient-led approaches involving individuals with an a priori interest in LCD who were actively seeking professional support. In addition to dietary adjustments, the RC diets involved delivery of diet-related education and changes to blood glucose self-monitoring and insulin management practices. The main clinical findings were that RC diets led to reductions in HbA1c and EA1c, increased time spent in target ranges, reduced time spent in the hypoglycaemic range, and less insulin being required overall. However, prospective clinical trials are needed to confirm these findings and conclusively determine the effects of RC diets on clinical outcomes in T1D management.

This study provides real-world insights into the use of professionally supported RC diets, including VLCKD and LCD [18] in the management of adults with T1D. It has been previously reported that individuals with T1D following RC diets experience difficulties in seeking professional support. An online survey of 316 people with T1D self-engaging in a VLCKD reported high levels of overall health and satisfaction with their diabetes management but not with their professional diabetes care team, with only 49% of respondents agreeing or strongly agreeing that their diabetes care providers were supportive of their dietary choices [13]. In the current study, 85% of participants presented to the community-based diabetes centre specifically seeking support with a LC dietary approach for T1D management. Given the sheer dearth of available evidence investigating lower-carbohydrate diets in T1D, the present analysis is a useful contribution to the evidence base on this topic and may assist healthcare professionals in better supporting T1D patients who choose to follow a RC dietary approach.

This study highlights a patient population that is particularly interested in LCD for the management of their T1D. Although the RC diet involved a reduction in total carbohydrates, the mean carbohydrate intake at baseline was already low (100g/day or 24%TEI) relative to the estimated population average. Data from a previous study which analysed the macronutrient profiles of adults with T1D from the Australian Health Survey 2011-13 reported that the average carbohydrate intake was 213g/day (45%E) [21]. Nevertheless, the RC diets involved additional reductions in dietary carbohydrates alongside other dietary manipulations which may have been uniquely beneficial. The CDE/APD recommended that dietary fats make up 'remaining energy requirements' after carbohydrates and proteins were accounted for. The mean dietary fat prescription was 153g/day (or 64%TEI) which was a clinically significant increase of 94% from a baseline fat intake of 79g/day (or 41%TEI). This is consistent with dietary fat prescriptions identified in previous LCD intervention studies of type 2 diabetes patients which were 'unrestricted' in fat (n=9 studies) or 'high fat' diets (>35%E) (n=9 studies) [22]. Dietary fat provides an important source of energy and fat-soluble nutrients for individuals on a RC diet, and substitution of carbohydrates with fats results in a lower glycaemic load [23,24]. With that said, minimally processed fats from meat, fish, eggs, full-fat dairy, nuts, seeds, avocado, olive oil, and butter tended to be the recommended sources of fat in the collective studies [22]. These whole foods contain a natural balance of monounsaturated, polyunsaturated, and saturated fatty acids [24]. On the other hand, ultra-processed oils containing excessively high amounts of omega-6 polyunsaturated fatty acids have been identified as drivers for obesity and cardiovascular disease (CVD) [25, 26]. Although HbA1c is a primary determinant of CVD risk in diabetes, future prospective studies investigating RC diets for T1D should measure an array of CVD risk factors, including lipid changes, to help us better understand the long-term efficacy of higher-fat LCDs in T1D.

In the present analysis, more participants had reliable data for EA1c than HbA1c given that CGM and FGM devices were recommended by the CDE/APD, and reports were available to validate the results. The 0.7% absolute reduction in EA1c shown in this study (7.1% to 6.3%) is consistent with findings

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from previous research in T1D. Nielsen et al. 2012 [27] showed in a 4-year intervention study (n=48) that a LCD (≤75g/ day) significantly reduced HbA1c by 0.7% (7.6% to 6.9%) in adults with T1D. Additionally, a 12-week randomised controlled trial (n=10) showed that a LCD (~100g/day) decreased HbA1c by 0.7% (7.9% to 7.2%) compared to no change with a diet higher in carbohydrates (~200g/day) [28]. A 0.7% HbA1c reduction is considered clinically relevant for patients with T1D [29], particularly if HbA1c is maintained below the recommended target of 7.0%. A large Swedish study (n=10,000) showed that T1D patients with an HbA1c between 6.5% and 6.9% had a lower risk of developing retinopathy and early kidney disease compared to patients with an HbA1c ≥7.0% [30].

RC diets may be a useful option in T1D for improving or maintaining glycaemic control with less use of insulin overall. The present analysis demonstrated a clinically significant reduction in TDI of -14 U/ day from 44 U/day to 31 U/day across 2-65weeks. Similarly, a previous case-series of 10 adults with T1D reported a reduction in TDI of -17 U/day (47 to 30U/day) across 8-61 months with a VLCKD (30g/day) [31]. Excessive long-term reliance on high doses of insulin may lead to additional complications related to hyperinsulinemia, such as obesity, type 2 diabetes [32] and hypertension [32-34]. In addition, requiring less insulin is also expected to result in significant cost-savings for people affected by T1D and the health system [35]. On the other hand, previous dietary modelling showed that comparedto a traditional high-carbohydrate, low-fat diet, a low-carbohydrate, high-fat diet may be associated with negligible, marginally higher costs ($2.06 per person per week) [36]. Hence, potential insulin cost savings, marginally higher dietary intake costs, and costs associated with changes in health outcomes should be considered collectively in determining the value of a RC diet approach for individuals with T1D.

A commonly cited concern of the use of LC diets in T1D is an increased risk of severe hypoglycaemia. However, the present data showed that the overall time spent within the target blood glucose range of 3.9-10 mmol/L increased by 18% with a RC diet, and minutes per low glucose event (<3.9mmol/L) decreased by 25%. Similarly, a 12-month study of 46 adults who self-reduced carbohydrates to ~162 g/day in combination with flexible insulin therapy reported a reduction of severe hypoglycaemia from 3.7 to 0.2 episodes per year. Nevertheless, it must be acknowledged that any diet or lifestyle change in individuals with T1D may increase the risk of hypoglycaemia in the short-term due to the consequent changes in blood glucose self-monitoring and insulin titrations that are often required. Participants in the current study were encouraged to re-appoint within two weeks of commencing dietary change to review their insulin management with the CDE/APD. Unfortunately, evidence-based guidelines for adjusting pharmaceuticals for patients with T1D wishing to follow RC diets are scant, but referring to practical guides used in type 2 diabetes may be a useful approach for practitioners [37].

This study has several limitations. The retrospective nature of this study meant there were major inconsistencies in the outcomes reported for included participants. To some extent, the available data was limited because the CDE/APD did not write clinical notes intending for them to be assessed by external researchers, and researchers did not contact participants to collect missing data. In addition, limitations in the reporting of the data meant that we were unable to assess adherence to the RC diets prescribed or determine pre-post changes in patient wellbeing, or whether any associations exist between the level of dietary carbohydrate prescribed and changes in T1D management outcomes. However, to our knowledge, the diabetes centre selected for this study is the only T1D centre in Australia actively promoting RC diets as an option for T1D management and considering the major lack of available research on this topic, the present analysis is useful and clinically relevant work. The high risk of selection bias must also be emphasised because most patients attending the centre were actively seeking LCD support, with the majority already following some form of LCD (albeit unsupported). For ethical reasons that only permitted a one-off invitation request, data from non-responders could not be examined and therefore any differences between responders and non-responders could not be determined. Finally, the lack of a control group or control period and the multi-modal nature of our exploratory study design precludes the ability to draw causality between the RC diet or other specific aspects of the approach imposed and the observed changes in clinical T1D outcomes. The authors acknowledge the need for high-quality prospective interventional studies investigating this important research area to better inform clinical practice guidelines.

Conclusion

In summary, this hypothesis-generating study provides real-world insights into the practical application of RC diets in the management of adults living with T1D. Professionally supported RC diets appear to be a feasible option for motivated T1D patients and may lead to maintenance or improvements in clinical outcomes. Prospective clinical trials are needed to conclusively determine the effects of RC diets, including LCD and VLCKD, on clinical outcomes in T1D management.

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Author Contributions

Jessica Turton: Conceptualization, Methodology, Formal

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Analysis, Investigation, Writing – Original Draft, Writing – Editing & Review, Visualization, Project Administration. Grant Brinkworth: Conceptualization, Methodology, Writing – Editing & Review, Visualization. Helen Parker: Conceptualization, Methodology, Writing – Editing & Review, Visualization.

Amy Rush: Conceptualization, Methodology, Writing – Editing & Review, Resources. Rebecca Johnson: Conceptualization, Methodology, Writing – Editing & Review, Resources. Kieron Rooney: Conceptualization, Methodology, Writing – Editing & Review, Visualization.

Competing Interests

Ms Rush and Ms Johnson have financial involvements with the community-based diabetes centre where the research was undertaken as an employee and as the C.E.O., respectively. The centre could obtain indirect benefit from this research by receiving information on the effectiveness of their services not normally obtained if not participating in this study. However, no direct financial benefit is expected to be obtained. No other authors have any competing interests to declare.

Supplementary Table 1. Baseline diets of included participants (n=26).

Partici-pant ID	Sex	TEI (kcal/ Day)	Diet Class.	Carb(g/ Day)	Car-b(%TEI)	Fi-bre(g/ Day)	Pro-teins(g/ Day)	Pro-teins	Fats(g/ Day)	Fats(%TEI)	SFA(g/ Day)	Particu-larDiet
1	F	NR	MCD	138	NR	NR	NR	NR	NR	NR	NR	N
2	F	NR	HCD	283	NR	NR	NR	NR	NR	NR	NR	Y - vegan
3	F	717	VLCKD	20	11	10	73	41	35	43	11	Y - LC
4	F	1397	MCD	170	49	50	70	20	40	25	NR	Y- vegan
6	M	1724	VLCKD	37	9	37	161	38	77	39	27	Y- LC
8	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y- LC
9	F	NR	VLCKD	46	NR	NR	60	NR	NR	NR	NR	Y - LC,vege-tarian
11	F	1673	MCD	180	44	20	80	19	65	34	30	N
13	M	1434	LCD	120	34	17	112	32	50	31	20	Y - LC
14	M	2507	VLCKD	34	6	20	133	22	203	72	NR	Y - LC
15	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
17	F	NR	VLCKD	32	NR	NR	NR	NR	NR	NR	NR	Y - LC
18	F	1160	LCD	60	21	20	98	34	55	42	22	NR
19	M	2032	VLCKD	22	4	24	160	32	140	61	60	Y - LC
20	M	NR	LCD	115	NR	NR	NR	NR	NR	NR	NR	NR
22	F	NR	LCD	100	NR	NR	NR	NR	NR	NR	NR	Y-vegetar-ian
23	F	1346	MCD	132	40	9	50	15	54	35	25	NR
24	F	2414	MCD	186	31	19	132	22	121	44	47	NR
26	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR
27	M	2199	MCD	90	17	28	260	48	82	33	17	Y - LC
28	F	1554	VLCKD	33	9	17	156	41	83	47	NR	Y - LC
30	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y- LC
31	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y - LC
34	F	1123	LCD	95	34	20	110	40	27	21	6	NR
35	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	Y - vegan
37	F	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR	NR

ID: Participant ID; F: Female; M: Male; TEI: Total Energy Intake; kcal: Kilocalories; NR: Not Reported; Carb: Total Digestible Carbohydrates; g: Grams; class: Classification; VLCKD: Very Low-Carbohydrate Ketogenic Diet; LCD: Low-Carbohydrate Diet; MCD: Moderate- Carbohydrate Diet; HCD: High Carbohydrate Diet; SFA: Saturated Fatty Acids.

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Supplementary Table 2: Haemoglobin A1c (HbA1c) values of adults with type 1 diabetes (n=8) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up (Weeks)	Pre-Value (%) [mmol/mol]	Post-Value (%) [mmol/mol]	MD (%)	Method (n Measurements)
3	F	44	9.5 [80]	8.6 [70]	-0.9	self-report (2)
9	F	33	10.6 [92]	5.3 [34]	-5.3	pathology report (1), self-report (2)
15	F	45	7.4 [57]	5.8 [40]	-1.6	pathology report (2)
24	F	55	7.0 [53]	6.9 [52]	-0.1	self-report (2)
26	F	10	9.0 [75]	7.0 [53]	-2	self-report (2)
31	F	98	13.4 [123]	7.7 [61]	-5.7	self-report (4)
34	F	40	6.7 [50]	6.1 [43]	-0.6	Measured in clinic (2)
37	F	114	8.4 [68]	8.3 [67]	-0.1	self-report (1), specialist letter (1), pathology report (1)
Mean (n=8)	-	55	9.0 [75]	7.0 [53]	-2.2	-

F: Female; M: Male; MD: Mean Difference.

Supplementary Table 3: Estimated A1c (EA1c) values of adults with type 1 diabetes (n=19) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up(w)	Follow-up Category (w)	Pre-Value (%) [mmol/mol]	Post-Value (%) [mmol/mol]	MD (%)	Method (n Measurements)
2	F	6	2-10	4.6 [27]	4.6 [27]	0	DEXCOM (3)
3	F	16	10-25	9.6 [81]	6.7 [50]	-2.9	Libre (2)
6	M	11	10-25	5.6 [38]	5.3 [34]	-0.3	Libre (2)
8	F	6	2-10	6.5 [48]	6.5 [48]	0	Libre (2), DEXCOM (1)
9	F	16	10-25	5.5 [37]	4.6 [27]	-0.9	Libre (2)
11	F	23	10-25	8.4 [68]	7.1 [54]	-1.3	Libre (2), Medtronic (1)
13	M	55	>25	6.2 [44]	5.8 [40]	-0.4	Libre (7)
15	F	37	>25	7.2 [55]	7.0 [53]	-0.2	Libre (4)
17	F	9	2-10	7.7 [61]	6.1 [43]	-1.6	Libre (2)
18	F	5	2-10	6.2 [44]	6.8 [51]	0.6	Libre (3)
19	M	4	2-10	5.5 [37]	5.2 [33]	-0.3	Libre (2)
22	F	3	2-10	7.1 [54]	6.6 [49]	-0.5	Libre (3)
24	F	23	10-25	6.5 [48]	6.5 [48]	0	Libre (4)
26	F	9	2-10	6.2 [44]	5.9 [41]	-0.3	Libre (3)
27	M	54	>25	11.4 [101]	9.0 [75]	-2.4	Libre (6), Medtronic (1)
30	F	11	10-25	7.4 [57]	6.2 [44]	-1.2	Libre (2)
34	F	49	>25	7.6 [60]	7.0 [53]	-0.6	Medtronic (1), Libre (2)
35	F	2	2-10	6.5 [48]	6.2 [44]	-0.3	Libre (2)
37	F	52	>25	8.5 [69]	7.1 [54]	-1.4	Libre (8)
Mean (n=19)	-	21	-	7.1 [54]	6.3 [45]	-0.7	-

F: Female; M: Male; W: Weeks; MD: Mean Difference.

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Supplementary Table 4: Time in target range (% in target) values of adults with type 1 diabetes (n=12) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up(w)	Target Range(m-mol/L)	Pre-Value (%in Target)	Post-Value (%in Target)	MD (% in Target)	Method (n Measurements)
2	F	6	3.9-10.0	64	72	8	DEXCOM
8	F	6	3.9-10.0	88	80	-8	Libre (2), DEXCOM (1)
11	F	23	3.9-10.0	38	70	32	Libre (2), Medtronic (1)
17	F	9	3.9-10.0	55	95	40	Libre (2)
19	M	4	3.9-10.0	88	88	0	Libre (2)
26	F	10	3.9-10.0	65	78	13	Libre (3)
30	F	11	3.9-10.0	69	80	11	Libre (2)
34	F	49	3.9-10.0	17	63	46	Medtronic (1), Libre (2)
37	F	52	3.9-10.0	42	59	17	Libre (4)
Mean (n=9)	-	19	-	58	76	18	-
13	M	65	3.9-7.0	55	58	3	Libre (7)
20	M	4	3.9-8.5	75	80	5	Medtronic (2)
22	F	3	4.0-8.0	45	58	13	Libre (3)
Mean (n=3)	-	24	-	58	65	7	-

F: Female; M: Male; W: Weeks; MD: Mean Difference.

Supplementary Table 5: Low glucose event (<3.9 mmol/L) values of adults with type 1 diabetes (n=14) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up (w)	Pre-Val-ue (n Events	Pre-Value (Min/Event)	Post-Value (n Events)	Post-Val-ue (Min/ Event)	MD (n Events)	MD (Min/ Event)	Method (n Measure-ments)
8	F	2	3	185	0	0	-3	-185	Libre (2)
11	F	23	10	160	0	0	-10	-160	Libre (2), Medtronic (1)
15	F	37	5	NA	4	NA	-1	NA	Libre (3)
18	F	8	4	NA	13	142	9	NA	Medtronic (2), Libre (3)
19	M	4	20	116	14	197	-6	81	Libre (2)
20	M	4	3	NA	5	NA	2	NA	Medtronic (2)
22	F	3	18	87	5	66	-13	-21	Libre (3)
24	F	23	11	130	7	126	-4	-4	Libre (4)
26	F	10	3	285	23	113	20	-172	Libre (3)
27	M	54	0	NA	4	NA	4	NA	Libre (7), Medtronic (1)
30	F	11	1	87	9	122	8	35	Libre (2)
34	F	8	30	60	18	77	-12	17	Libre (2)
35	F	2	12	91	17	92	5	1	Libre (2)
37	F	52	0	0	12	104	12	104	Libre (6)
Mean (n=14)	-	17	9	120	9	94	1	-30.4	-

F: Female; M: Male; W: Weeks; Min: Minutes; NA: Not Available; MD: Mean Difference.

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Supplementary Table 6: Total Daily Insulin (TDI) values of adults with type 1 diabetes (n=15) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up (w)	Pre-Value(u/Day)	Post-value(u/Day)	MD (U/Day)	Method (n Measurements)
3	F	13	60	35	-25	self-report (2)
11	F	4	38	43	5	self-report (1), Medtronic (1)
13	M	65	60	42	-18	self-report (8)
14	M	13	22	19	-3	self-report (2)
15	F	45	80	50	-31	self-report (1), Libre (2)
17	F	9	40	6	-35	self-report (1), Libre (1)
18	F	2	45	38	-7	Medtronic (2)
19	M	4	32	29	-3	Libre (2)
20	M	4	35	25	-10	Medtronic (2)
22	F	3	40	16	-24	self-report (1), Libre (2)
23	F	25	32	38	6	pump summary (1), Medtronic (1)
24	F	55	91	46	-46	self-report (2)
26	F	10	18	6	-12	Libre (3)
28	F	3	26	22	-4	self-report (2)
37	F	5	45	45	0	self-report (2)
Mean (n=15)	-	17	44	31	-14	-

F: Female; M: Male; W: Weeks; U: Units; MD: Mean Difference.

Supplementary Table 7: Fasting blood glucose values of adults with type 1 diabetes (n=5) following a reduced-carbohydrate diet.

Participant ID	Sex	Follow-Up (w)	Pre-Value(mmol/L)	Post-Value(mmol/L)	MD (mmol/L)	Method
1	F	24	22	16.5	-5.5	self-report
4	F	64	10	9.5	-0.5	self-report
11	F	8	7.5	6	-1.5	self-report
23	F	25	7	6.9	-0.2	self-report
27	M	26	16	7.5	-8.5	self-report
Mean (n=5)	-	29	12.5	9.3	-3.2	-

F: Female; M: Male; W: Weeks; MD: Mean Difference.

Supplementary Table 8: Questions for semi-structured interview about details of RC diets delivered at a community-based diabetes centre.

n	Question
1	How would you describe the reduced-carbohydrate (RC) dietary interventions that you develop for your patients?
2	Are there any indicators that you look for to assess whether a patient should /shouldn't undergo a RC dietary intervention? If there are, what are they and are there any that you consider to be more important than others?
3	How do you determine the energy and macronutrient prescriptions for your RC dietary interventions? How do you communicate these prescriptions to your patients?
4	Are there specific foods that you recommend including in your RC dietary interventions?
5	Are there specific foods that you recommend restricting in your RC dietary interventions?
6	Do you give your patients education relating to the RC dietary interventions? If so, what topics do you commonly cover?
7	What resources or tools, if any, do you provide to help your patients understand and follow your RC dietary interventions?
8	Do you monitor compliance to your RC dietary interventions? If so, how do you go about doing this?

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Supplementary Table 9: Transcript from semi-structured interview about details of RC diets delivered at a community-based diabetes centre.

Question	Speaker	Transcript (verbatim)
1	JT	How would you describe the reduced-carbohydrate (RC) dietary interventions that you develop for your patients? Do you have any definitions, labels, names that you refer to when communicating these interventions to other health professionals, such as in GP letters?
	AR	Not really. I would say more of a personalised approach to lowering carbohydrate intake. If I was writing to a doctor: something about - a personalised approach to lowering carbohydrate in attempt to improve blood glucose management regarding type 1 diabetes (T1D). Sorry. I do always flesh that out.
	JT	So, it's goal focused?
	AR	Yep.
2	JT	Are there any indicators that you look for to assess whether or not a patient should / shouldn't undergo a RC dietary intervention?
	AR	First of all, their willingness. So, them most of, I can't even say most of the time, all of the time, coming to me with this [a low-carbohydrate diet] already in mind. This is already the focus of their session. I'll obviously assess their ability to carb count. If they don't know where carbs are, we've got a lot of ground to work on. Their current insulin and blood glucose management. I mean if it's all over the place and they are not accurately dosing as it is at the moment, there is a lot we need to work on. Their current carbohydrate intake is super important – to see then where we can go from there. What other things are going on – because if there's a lot of other things going on, even just personally or whatever – lowering your carbohydrate, looking at insulin titration, sometimes it's all too much at that point and we need to have that discussion – maybe this is not what we need to do right now, maybe there is something else we need to do right now. Quite often there's a process if they haven't been on continuous glucose monitors (CGM) before or in a very long time. Getting them to actually just wear one and see what's going on before we make the change.
	JT	Would you say then that all participants that go on this type of intervention need to use a CGM?
	AR	No, I wouldn't say 100% but it's beneficial for me to get the data to then help them, but it's also very beneficial if they haven't used one before or in a very long time for them how important it is to be able to accurately bolus their insulin. And the insulin changes that need to be made.
	JT	Going back to what you said about their blood glucose and insulin management – if it is all over the place – would you say addressing that before addressing the diet is important, or do you do it simultaneously?
	AR	Both. It depends on how all over the place and how / what their understanding of it is. If they are coming to me with just set dosages at breakfast, lunch and dinner / they've never carb counted / they don't understand the idea of insulin titration, then they need to understand that a bit more and need to know how to use carbohydrate ratios / correction factors before we can start dropping the carbs back.
	JT	With the current carb intake, you said that it depends on their current carb intake as to whether they would be suitable for this type of intervention, so what would that look like?
	AR	Whatever their current carb intake is, that would depict where we go from there, it wouldn't exclude them or not. You could eat 400-500g carbs per day, I don't care, we will just reduce them to 300g/day at the start.
3	JT	What helps you understand what level of protein, fat, or carbs a person should be prescribed?
	AR	Whether or not they want weight maintenance or weight loss factored in, activity levels are factored in. And then when it comes to first making that decision of what kind of carb intake we are going to aim for, I base that on current carb intake, the patient's wants – quite often they'll come in and be like "I want to do 50 g carbs/day – that's what I am aiming for". But also, if they are not that way inclined, I'll assess how motivated they are, I guess, like if someone's truly motivated, I think well maybe we can drop it a little bit lower than someone who is like "I think I can do this I think this will be fine I want to make the changes", then we might go for something in a little bit of a higher range at the start, where they start to see a change in blood glucose levels, and that's the motivation, so then they get that next step.
	JT	So, it seems like for the carb prescription, it's very much tied into what their goals are and whether they are achieving progress, as to whether or not you're adjusting it?
	AR	Yep.
3	JT	For protein then, how would you work out those requirements?
	AR	Generally, for protein I will go somewhere between 20-25% TEI because the upper level for the Nutrient Reference Value is 25% TEI and I find that if patients – sorry – they need to go up into that range to not have to eat mass amounts of fat – but also – anything much higher than that because a really big issue quite immediately in terms of blood glucose levels because protein's impacting blood glucose levels. We need to find that sweet spot. It also will depend on the person too, if I've got a guy in here who's training 7 days a week for X event, they will need a higher protein:
	JT	So, activity level and sex will be factored in?
	AR	Yes, 100%.

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	JT	What are your thoughts around where you set the fat prescription?
	AR	Remaining energy.
3	JT	And then with the energy prescription, do you have rough guidelines for your prescriptions?
	AR	I will use Schofield, using activity level and desired weight.
4	JT	Are there specific foods that you recommend including in your dietary interventions?
	AR	Low-carb foods? I wouldn't be saying – you need to eat this; you need to eat this – it's just the list of lower carb foods.
	JT	So, are you giving them a list of lower carb foods?
	AR	I do have lower carb snack lists, I've got lower carb convenient snack lists, we go through the low carb vegetable options, we go through fat options as well. I don't love to give hand-outs so much as I like to write – I feel like the patients get more out of if they are watching me write it down as we go. And it feels more personalized rather than going – here take this, look at this, look at this.
5	JT	Are there specific foods that you recommend restricting or avoiding in your RC dietary interventions?
	AR	No because it will totally depend on what their level of carbohydrate intake is. KFC…? [laughs]
	JT	I could tell that when I was looking through your notes, you were very much working with the patients' desires and preferences and it didn't seem, from what I could see, that you were giving a blanket food list or anything like
		that, so it was good to just clarify that with you. Would you agree with that?
	AR	Yep.
6	JT	Do you give your clients education relating to the dietary interventions? If so, what topics do you commonly
		cover?
	AR	Education around low-carb or…?
	JT	Any education that helps them adhere to the dietary intervention.
	AR	Yeh, so it depends on where they're coming into it, and most of them will have come into it having looked into low-carb knowing what the low-carb foods are, but obviously some will need covering in that. The education more lays around how reducing your carb intake is going to then impact your insulin requirements, so education around adjusting insulin, education around hypoglycemia treatment and monitoring ketones, also education around, quite often you'll get the questions of – if I am eating all this fat, am I going to gain weight? Am I going to get increased cholesterol? – so education around that aspect of using the fat as an energy source, evidence in terms of that it's not going to increase cholesterol and that kind of thing. And making a variety of fat choices – that's probably a big one actually. Because I'll say, now we need to make up the rest up with fat – and they are like, well how do I do that? Where is fat?
4	JT	Do you recommend specific types of fats?
	AR	I just talk through all different types of fats, so yeh, just going through a variety. And what they like, and what they don't.
1	JT	You said that people usually come to you for low-carb support, so what does that look like? Are people enquiring saying specifically or are health practitioners recommending to you because they know you do low-carb?
	AR	Both. I quite often get referrals to discuss low-carb. From endos and GPs.
6	AR	Bec just had a good point, that quite often in the education there will be, if I feel like they need carb counting education / carb identification education, we've got the Cyber Carbs course – online carb counting course. I would say that 90% of my patients do that.
	JT	When did you launch that?
	AR	July 2019.
	JT	While we are talking about that, when did you launch Drive Your Diabetes?
	RJ	Around November 2019.
1	JT	It seems that it's quite crucial to be doing both [diet and insulin support] alongside each other. It doesn't seem like you're doing just diet or just insulin, it's both, right?
	AR	Yes.
6	JT	Bec, are there any other education programs that people are involved in at the centre?
	RJ	Not programs, but I would probably raise the value of the peer support aspect of what the family centre does because the majority of our patients would belong to the community.
	AR	Yeh, probably like 60% of my patients.
	RJ	And if they are part of a community of hundreds of other people with T1D that's monitored by the family centre team, there's a lot of information that's exchanged and there's a lot of peer-to-peer learning that happens at the centre. So, it's not solely a clinical intervention per say, there's also that exchange that's happening outside of the clinic experience.

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	JT	You guys do cook lessons and group events - I have noticed on Facebook - so has that been going on for the duration that the Family Centre has been in action?
	RJ	We only opened out to our adult services 2 years ago this month. So, we've only had an online adult's community and adult social and educational events for the last couple of years.
	JT	I am sure that still covers most of the patients in this study though, because there aren't that many that would have entered it being under 18.
	RJ	No, well you didn't have Paediatric patients [to Amy]?
	AR	No.
	JT	That's good to know. While we are talking about this, so the peer support - there's an online community, there's events being held at the centre…?
	RJ	At the centre and outside the centre. So, social events, it's one of those things where you see people who are like, I am going on a low-carb diet or I want to start eating lower carb lunches, and they will come in and see Amy and get some guidance, but there's also often a conversation that happens around, what do you guys do for this? And picking up lots of tips and ideas there.
	JT	How frequently, on average, would participants engage in this type of peer support or community learning at the centre?
	RJ	That's really hard to say.
	AR	Some of them, like daily, on the [Facebook] page.
	RJ	We have 700 members on our online community, and I think in that community, we have about 3000 engagements per month, but we have top contributors in there every day and there are people who kind of lurk a couple of times a week.
	JT	So, did you start the peer support or the Facebook page when you started seeing adult patients?
	RJ	You were already seeing patients for about 12 months before that, easily. Amy had been taking adult patients because adult patients were showing up at the family centre and saying, hey you just do Paediatrics – what about us? And it was sort of happening in an informal way, and then we went, right, we are re-branding, we are opening the service up to adults, we are starting a community, we're employing someone to manage that community, and that's when the momentum sort of began, both with Amy's clinic and the other aspects of the community events.
1	JT	Just going back to what you said that people come to you for low carb support a lot of the time – do you promote a low-carb program or anything like that? How are people learning from you that you support low-carb?
	RJ	I think it's word of mouth.
	AR	Yeh.
	RJ	Are you on Low Carb Down Under [to Amy]?
	AR	As an option to find me? Yes.
	RJ	So, Amy's on Low Carb Down Under, but it's largely the type 1 community, and you see them in groups all over Facebook, not just the Family Centre group, and when someone says, "oh I need help with my diabetes", Amy gets tagged by other patients.
	AR	And referrals.
	RJ	And we went around to see a lot of the local GPs last year, in quite an intensive effort, to let them know about our services and I think that built quite a few referrals in as well. Our marketing has been largely, unusually for a private practice, which normally goes to the referring providers, we went direct to consumer, and did it through building online community largely, and that sense of face to face and online community helped build a patient base as well.
	JT	And I think this an important part of it, because when you're saying that people come to us for low-carb support, and then GPs/endos are referring for low-carb support, I think that's really interesting in and of itself because it's something that people aren't talking about enough, this option for people with T1D, yet there seems to be such a demand for it, and even that in itself is evidence of that.
	AR	I get referrals from GPs and endos over East because the demand is there but no one's doing it.
6	RJ	I think as well, the Family Centre, from 3 months after we opened 5 years ago, our first major educational event was flying Troy Stapleton over here for a talk about low-carb in T1D management, and from the get-go, whether it was a good move or not, we created that space for ourselves, and really carved out, we are going there, as a clinical provider and as an organization. We talk about it. It's actually something that's really normalized in our community.
	AR	It doesn't feel like a thing, does it?
	RJ	Yeh, it's not a thing. This diet has been called dangerous and not supported by the evidence, but where is the evidence, of safety and efficacy, in recommending the Australian Guide to Healthy in Eating for people with T1D? It's never been tested, and I think people need to remember that. Because we're actually referring people into a diet that's not evidence-based right now, and it's actually causing an extraordinary number of issues, that are all in the evidence, but we just seem to be studiously ignoring.
7	JT	What resources or tools, if any, do you provide to help your patients understand and follow your dietary interventions?
	AR	Just ones that I make myself.

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	JT	I noticed, in your notes that you did a lot of meal plans and things like that?
	AR	Yeh, so, I don't like calling it a meal plan, but I've never been able to come up with a word that better suits it. It's more: we work out your requirements, so that might be 50g of carbs, 100g of protein and 100g and fat, and it aim for at breakfast, lunch and dinner to meet that [your requirements]? But again – that's not prescriptive. It's not an omelet with 2 eggs, it's more like, it would be - here would be your protein options – you could have 2 eggs, or you might have bacon or you might have something, and give them portion sizes plus whatever. Lunch might be that you need to aim for around 100g of cooked protein – you can add as many of those low-carb veggies in as you like, just carb count them. And these are the number of fats serves that you should add. What's a fat serve? Then we've got our list of fat serves and what that could possibly look like and ideas for how they can make that into different types of meals. I need a word for it because meal plan is not the word.
	JT	It's like a build your own meal prescription or something like that?
	AR	Yeh.
	JT	That makes sense. Because you do mention in the notes "meal plan provided" or "meal plan created to suit requirements", whether you have pre-written meal plans or you were just writing?
	AR	No.
	JT	So, this is again, personalized based on the individuals' diet and I suppose, their routine?
	AR	Their routine, likes, dislikes, do they want to snack? Do we have to put snacks into the requirements for them to meet that energy demand? Do they want to fast? So many of the day? people come in – I don't eat breakfast and say – I want to fast through breakfast, it helps with my blood sugars – awesome, great, how do we make that work for the rest
	JT	So, you don't have any set meal times for people, or even a meal structure – like breakfast, lunch, dinner, snacks – things like that – it's all based on what they want to do by the sounds of things?
	AR	Yep.
7	JT	What about recipes and books and thinks like that? Do you ever recommend any?
	AR	We've got a tonne of recipe books out in our lobby area. People more so bring books to me, and recipes to me. I don't honestly say, go here or go there, because I guess to me, eating low-carb, I want to make out that it doesn't require recipes, it just doesn't. It is the simplest and easiest way to prepare food – that you don't require recipes. As soon as you look at low carb recipes, there is so much… You'll never get a meat and vegetable recipe, it's like – add this flour and add this xanthan gum – and it becomes so confusing that people go – oh this is too hard. It's not too hard, it's meat and vegetables and fat. You don't need a recipe for that.
	JT	So, real food then, is what you're promoting?
	AR	Yep.
8	JT	Do you monitor compliance to your RC dietary interventions? If so, how do you go about doing this?
	AR	Yep – I'll get them to bring in a food diary. That's super important, mainly because I need to be able to help them adjust insulin, and I need to know what they're eating to see if their insulin is working or not working. I need that.
		I am getting that dietetics part just as an adjunct to that.
	JT	With a food diary, would that be that every person does something like that? Or are there specific patients that I am getting that dietetics part just as an adjunct to that.
	AR	No, really everyone will need to in the short term.
7	JT	Bec, in terms of the online groups – are there people that are admins who are posting content for people to read and look at?
	RJ	There are 3 staff members here at the family center, so me, Gabby and Carly who are all admins on that group. And Amy – her and her page – are attached to that group and contributing content. We also have a mod squad of I think its 10 community moderators of people who volunteered to also contribute content and discussion.
	JT	So, they are receiving education and content on that website, and it's being monitoring by Amy in a way?
	RJ	I would say it's monitored by our team, and if it gets to a pointy question, you [Amy] gets tagged, generally, for a response. But it's an organic process. We monitor all the content for safety because we don't want insulin exchange – and people asking about what should I dose? And all that sort of stuff. They are all our red flags. But we want to allow, we don't want it to be a Q&A forum for people to ask the Family Centre stuff, the whole point is for organic peer-led learning, and that's what happens and that's what we really allow.
1	JT	What would you say, as someone who does both (diet and insulin management), what would you say are the main considerations for insulin management with this type of dietary intervention?
	AR	So, the patient needs to be able to carb count and accurately dose their insulin for carb intake to be able to lower their carb intake and then safely dose, because immediately, their rapid acting insulin will decrease. Their requirements will decrease. So, if you're eating less carb, you'll need less rapid acting insulin. So, they need to be able to do that. So that's why if someone comes to me who is on set dosages, our first step will be, well you need to learn to carb count and accurately dose for carbohydrate to start with. Which is a lot to learn. So that's going to organically happen, that decrease in rapid acting insulin, and that's enough at the start. But very quickly, within 2, 3, 4 weeks, their background or basal insulin needs are also going to start decreasing. That's why in the interim, in the short term, I am seeing patients fairly regularly while those major changes are happening.

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	JT	And what would you ideally like as those regular follow ups?
	AR	I don't like to start a low carb diet and not see a patient within 2 weeks. And even if a patient is reluctant to do a follow up within 2 weeks. Within a day or 2, that thought's gone, because they can see straight away – holy crap this is making such a difference – and quite often they will see if they can get in earlier.
	JT	And they'll email you as well?
	AR	Yes.
1	JT	What about, because you mentioned before that protein affects blood glucose levels, and what I noticed with quite a few of your patients, you do eventually get to a discussion around blousing for protein, so is that something that every person on a lower carb diet needs to consider, or is that only some people that are eating higher than X amount of protein, for example?
	AR	I want to say the majority. It's kind of inevitable at some point.
	JT	So, if we were having a rough flow for what goes on with insulin, would you say that: (1) they need to learn how to count carbs accurately and have flexible insulin dosing according to their carb intake, (2) their rapid acting insulin decreases, (3) their basal requirements decrease, and (4) protein blousing comes in.
	AR	Yeh.
1	JT	And I guess the other thing I want to clarify is, do you have a gram or %TEI range that you consider to be "low-carb"?
	AR	Not really.
	JT	So really, your definition of low-carb is any carb reduction from their baseline diet?
	AR	Yeh. If someone is demanding, like tell me tell me tell me, I'll go back to the Feinman [definitions]. But, for my own use, don't have something that says right if you are below this, that's what I'd say is low carb.
3	RJ	Is there a percentage reduction? So, if someone came in and said, I want to drop my carbs from 200g/day to 160g/day – you're like, that's only 20%, that's not a low carb intervention? Is there an average percentage reduction that you use?
	AR	It depends on where they're at, but I would always want to try at least 50%.
	JT	So that might be a general starting point, around 50% reduction?
	AR	Yeh, I would say, on average.
	JT	We might talk about it [the intervention] being goal-focused / patient-focused, but as a general starting point, around 50% reduction, and then monitor based on their outcome changes, and for you it seems that the carbs are mainly changed according to blood glucose levels, would that be right?
	AR	Yeh, so say they've been eating 300g/day and we drop them down to 150-200g/day, and they see this awesome change in blood glucose, then yeh they are going to be coming back saying - can we drop this further? This is easy, I am doing great, my blood sugars are great, we can go further.
3	JT	So, people are becoming motivated by the changes that they can see in their blood glucose, and I am sure other things as well, and that's actually causing them to come back to you and ask to go lower carb?
	AR	Yeh, often. And that's a big benefit of T1D I guess in that it's immediate feedback. It's not like I am waiting a month to lose 2 kg.
	RJ	And that goes back to the sustainability piece as well. A lot of the criticisms levied at low-carb is that it's not sustainable, but constant positive reinforcement by our improved glucose which shows up on your screen multiple times a day, is, for many people, very motivating.
8	AR	And that's a benefit of having them on a CGM, which I am lucky enough to have the ability to give people, quite often, CGM or flash glucose monitoring trials, which I will do in those first couple of weeks. That's one of the reasons, as well, that I like to do it.
	JT	When did this start that you were giving people CGMs? Has that been this whole 2 years, or just more recently?
	AR	Yep [whole time].
	JT	Is there a specific number of CGMs you can give?
	AR	I generally have enough that I can give it to whoever I want.
	JT	Would you say that, people who haven't tried a CGM or aren't using a CGM, you'd usually give them one?
	AR	Yep, or flash glucose monitoring (FGM).
	JT	So that would be Freestyle Libre, and what would be the other one that you give them?
	AR	Either. I've got both – Dexcom and Medtronic versions. I'll either give them one or lend them mine.

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	JT	And if they were just lending, how long would they lend for?
	AR	One week or 2 weeks, depending.
	JT	Would there be anything that makes you prefer the Libre, over the Dexcom, over the Medtronic, or one or the other?
	AR	Whichever really. It's what I've got available at the time.
7	JT	The only other thing that hasn't been mentioned is the Diabetes Detective Program. You did this with a few of the participants. Do you want to briefly describe it?
	AR	Diabetes Detective is where they have, it's basically like 24/7 access to me. I am watching their CGM on my end. They are messaging or emailing me every time they are about to do something. So, I am about to have this for BF, what kind of way do you think I should bolus for this? We talk about what we think we should do, we watch what happens, then we discuss afterwards. Okay did we make the right call there? How would we adjust it for next time? I am about to go and exercise, what do you think I should do in terms of reduction for my insulin? Let's try this, did that work, what will we do next time?
	JT	So, is it insulin and dietary changes?
	AR	Yeh, it could be both. Really, it's whatever they want to talk about.
	JT	That's pretty amazing. So how do people access that program, is that like an extra service that they would buy on top of consults with you?
	AR	Yep.
	JT	Is there anyone that you would recommend that service to more than others?
	AR	We used to recommend it a lot, but I don't really recommend it at all anymore – people come to me and ask for it. I guess it wouldn't be something I recommend from the get-go, it would be, if I feel like they are continuously struggling or we are finding it really difficult to work out insulin-wise what we need to do here. Motivation. If they just keep begging – how can I do this? How can I do this? I want to be able to do this but I just can't. Then, maybe then.
-	JT	Is there anything else that we haven't already spoken about that you want to add about your interventions or
		what's available at the family centre for people to access when they are there?
	AR and RJ	No.

Carbs: Carbohydrates; TEI: Total Energy Intake.

Supplementary Table 10: Ineligible participants (n=12) and reasons for exclusion.

Participant ID	Eligibility	Reason(s)
5	Not eligible	No outcomes reported on 2 time points ≥2 weeks apart.
7	Not eligible	Record of only 1 appointment with CDE/APD.
10	Not eligible	No outcomes reported on 2 time points ≥2 weeks apart.
12	Not eligible	No outcomes reported on 2 time points ≥2 weeks apart.
16	Not eligible	Record of only 1 appointment with CDE/APD.
21	Not eligible	65 years old at initial appointment.
25	Not eligible	Started seeing nutritionist and trainer for dietary advice for which instructions/advice was unknown.
29	Not eligible	No outcomes reported on 2 time points ≥2 weeks apart.
32	Not eligible	Record of only 1 appointment with CDE/APD.
33	Not eligible	Participant completed survey twice (duplicate).
36	Not eligible	No outcomes reported on 2 time points ≥2 weeks apart.
38	Not eligible	Survey completed after cut-off date (9th Dec 2019).

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