

Original Article

A randomised trial of the feasibility of a low carbohydrate diet vs standard carbohydrate counting in adults with type 1 diabetes taking body weight into account

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Background and Objectives: To determine the effect of a low carbohydrate diet and standard carbohydrate counting on glycaemic control, glucose excursions and daily insulin use compared with standard carbohydrate counting in participants with type 1 diabetes. **Methods and Study Design:** Participants (n=10) with type 1 diabetes using a basal; bolus insulin regimen, who attended a secondary care clinic, were randomly allocated (1:1) to either a standard carbohydrate counting course or the same course with added information on following a carbohydrate restricted diet (75 g per day). Participants attended visits at baseline and 12 weeks for measurements of weight, height, blood pressure, HbA1c, lipid profile and creatinine. They also completed a 3-day food diary and had 3 days of continuous subcutaneous glucose monitoring. **Results:** The carbohydrate restricted group had significant reductions in HbA1c (63 to 55 mmol/mol (8.9-8.2%), $p<0.05$) and daily insulin use (64.4 to 44.2 units/day, $p<0.05$) and non-significant reductions in body weight (83.2 to 78.0 kg). There were no changes in blood pressure, creatinine or lipid profile and all outcomes in the carbohydrate counting group were unchanged. There was no change in glycaemic variability as measured by the mean amplitude of glycaemic excursion in either group. **Conclusions:** A low carbohydrate diet is a feasible option for people with type 1 diabetes, and may be of benefit in reducing insulin doses and improving glycaemic control, particularly for those wishing to lose weight.

Key Words: type 1 diabetes, carbohydrate metabolism, low carbohydrate diet, glycaemic control, carbohydrate counting

INTRODUCTION

Very strict low carbohydrate diets were once the only therapy to treat type 1 diabetes mellitus (type 1 DM). With the discovery of insulin, and subsequent development of flexible insulin regimens, low carbohydrate diets were replaced with more usual patterns of eating where insulin delivery can be matched to food intake and current blood glucose levels. Accordingly most current guidelines recommend a flexible approach to dietary prescription matched with intensive insulin therapy.¹ This is facilitated by education programmes such as DAFNE (Dose adjustment for normal eating).² The cornerstone of this approach is carbohydrate counting, giving people the skills to match short acting insulin boluses with chosen carbohydrate intake. When done well, this gives great flexibility to carbohydrate intake. However, many people with type 1 DM do not optimise this approach, for a variety of reasons, including the imprecision of estimating carbohydrate or best dosing of insulin, especially when carbohydrate intake is high.³ In a recent qualitative review of participants who had undergone the DAFNE course, flexible

insulin therapy had led some patients to severely restrict carbohydrate as they found that large amounts of carbohydrate coupled with large insulin doses led to unpredictable blood glucose results.⁴

Much work has been focussed on carbohydrate quality in recent years with the glycaemic index, and secondarily on quantity with glycaemic load.⁵ Very little has been written about a low carbohydrate diet in the management of type 1 diabetes in the last 30 years, despite a resurgence of interest in use of the diet in the general population and in those with type 2 diabetes. While there has been some confusion over terminology, the most recent

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review suggests a low carbohydrate diet should consist of less than 130 g of carbohydrate per day.⁶ Nielsen et al report an audit of 48 patients with type 1 DM who have self-chosen to follow a low carbohydrate diet. Mean HbA1c reduced from 7.7% to 6.4% (57 to 46 mmol/mol) after 3 months and remained at this level for 4 years.⁷

With the development of both short and long-acting insulin analogues, the practice of matching short acting insulin to carbohydrate intake has become much more precise. This gives patients greater flexibility to vary carbohydrate intake, or if desired, to greatly reduce carbohydrate intake. This small randomised controlled trial tests the feasibility of a low carbohydrate diet compared with a standard diet, both matched with carbohydrate counting, on glycaemic control, glucose variability, total daily insulin dose, and quality of life in a group of participants with type 1 DM.

METHODS

Study design

This was a randomised controlled trial of a carbohydrate restricted diet compared with a standard diet, both utilising carbohydrate counting, on glycaemic control in people with type 1 DM. The study was a parallel design with 1:1 allocation to dietary prescription. Researchers collecting and analysing data were blinded to allocation, but it was not possible to blind participants.

Participants were included if they had type 1 DM and were using multiple daily injections of insulin, including meal-time rapid acting insulin. Participants needed to be willing to self-monitor glucose and learn and utilise carbohydrate counting skills. People were excluded if they were pregnant or breastfeeding, or had very poor glycaemic control (HbA1c ≥ 85 mmol/mol (10%). The study was undertaken at the Endocrine, Diabetes and Research Centre at Wellington Regional Hospital, Wellington, New Zealand.

Recruitment

All those referred for carbohydrate counting education to the Endocrine, Diabetes and Research Centre were approached to participate in the study. Those wishing to take part, signed a written informed consent form, had baseline measurements taken and were then randomised into one of the two treatment groups. Randomisation was achieved by computer generated random numbers put into sealed envelopes. Envelopes were then given out consecutively as participants enrolled.

Intervention

After enrolment all participants took part in a group-based carbohydrate counting course. To avoid contamination of treatments, participants following the carbohydrate restricted diet were separated from those following a standard diet. The course was 1-1.5 hour sessions per week over four weeks, conducted by a dietitian and a diabetes nurse. The course covered: what is carbohydrate, estimating carbohydrate quantities, the action of insulin, insulin to carbohydrate ratios, correction factors and managing sick days. In addition, those prescribed a low carbohydrate diet also received information on achieving and maintaining 50-75 g carbohydrate per day, and the

amount of insulin likely to be required to match this. This level of 50-75 g per day was chosen to match that in the study by Nielsen et al.⁷ All participants had access to the dietitian and diabetes nurse by telephone between sessions for added support. Participants were given written resources on the carbohydrate content of common foods and encouraged to use carbohydrate tracking applications on smart phones to ensure compliance to carbohydrate restrictions.

Participants returned for a follow up group session 12 weeks after starting the course where a focus group was conducted to gain insights into participant satisfaction, experience and impact on lifestyle.

Outcome measures

The primary outcome for this study was glycaemic control, as measured by HbA1c and continuous glucose monitoring (CGMS). Participants attended a clinic visit at baseline and 12 weeks. Anthropometric measures taken were weight and resting blood pressure. A venous blood sample was taken to analyse HbA1c, serum creatinine, and blood lipid profile. All blood samples were analysed on completion of the study using standard commercial assays (Roche Diagnostics New Zealand) by an accredited laboratory (Diabetes and Lipid Laboratory, University of Otago, Dunedin, New Zealand). In addition 3 days of continuous subcutaneous glucose monitoring were recorded using the Guardian REAL time CGMS monitoring system (Medtronic Minimed, United States). Two subjects used the CGMS Gold monitoring system (Medtronic Minimed, United States). Individual subjects used the same system for both baseline and 12 week measurements. Glycaemic variability was assessed with the mean amplitude of glycaemic excursion (MAGE)⁸ by applying a computer algorithm⁹ to the captured CGMS data.

Participants also completed a 3 day food diary at baseline and after 12 weeks with data analysed using Food works 7 Professional Edition (© 2012 Xyris Software Australia). Total daily insulin doses were recorded by participants in a record book. Ketone monitoring was by Optium Free Style meter (Abbott).

Quality of life was measured by the diabetes specific Audit of Diabetes Dependant Quality of Life (ADD QoL) (Health Psychology Research Limited) and the Diabetes Empowerment Scale (DES) (Michigan Diabetes Research and Training Centre). The ADD QoL gives a score of the effect of diabetes on quality of life for each of 19 domains from -9 (maximum negative impact) to +3 (maximum positive impact) and a total average weighted index (AWI) score.¹⁰ The DES measures a patients' self-efficacy in regards to psychosocial management, readiness to change and diabetes goals.¹¹ Interviews were also conducted at the twelve week time point by an experienced qualitative researcher to gain insights into participant experience, adverse effects and impact on lifestyle.

Statistical methods

As this was a pilot study, it was decided to mimic usual clinic conditions for carbohydrate counting courses. Carbohydrate counting classes are run regularly in groups of 5 participants. As the expected change in HbA1c or glucose variability was unknown, a sample of 10 subjects,

with five allocated to each treatment, was chosen to pilot the intervention. Data were analysed using IBM software SPSS 20.0. The primary outcome results are presented as means and standard deviations. Assessment for significance between means was tested through application of students paired t-test. Univariate Analysis of Variance (ANOVA) was used to assess between group interactions. Continuous variables were log transformed before running tests that require normal distribution of the data. All tests were two-sided and p values of <0.05 were considered to be statistically significant.

Funding and ethics

The study was funded by grants from the Capital and Coast District Health Board, the Cranfylde Charitable Trust and the Eli Lilly research award from the New Zealand Society for the Study of Diabetes. Ethics approval was granted by the New Zealand Ministry of Health Central Health and Disability Ethics Committee (13/CEN/16/AM02) and the trial was registered on the Australian New Zealand Clinical Trials Registry (ACTRN12612001138875). The trial conformed to the provisions of the Declaration of Helsinki in 1995 and the Edinburgh revision of 2000.

RESULTS

Details of those recruited into the study are shown in Figure 1 and Table 1. Ten participants, three women and seven men, aged 44.6 ± 8.9 years, entered and completed the study. The mean duration of diabetes was 21.8 ± 11.1 years with a range from 8–36 years. Mean total daily dose of insulin was 52.5 ± 27.1 units per day. Participants were all using a basal bolus regimen of insulin with insulin glargine as the basal insulin, and either as part or lispro as bolus insulin. There were no significant differences between groups at baseline. Although the total daily insulin dose was greater in the carbohydrate restricted group it did not reach significance ($p=0.08$).

Glycaemic control as measured by HbA1c improved and total daily insulin use reduced in the low carbohydrate group ($p<0.05$) (Table 2). Mean glucose from the CGMS reduced in the carbohydrate restricted group, though was not significant. The change in insulin use between groups was significant; however there was no difference between groups in glycaemic control. Weight change may confound changes in insulin doses; therefore a generalised estimating equation method was used including weight, time, group allocation and an allocation \times time interaction. The effect of weight change was highly

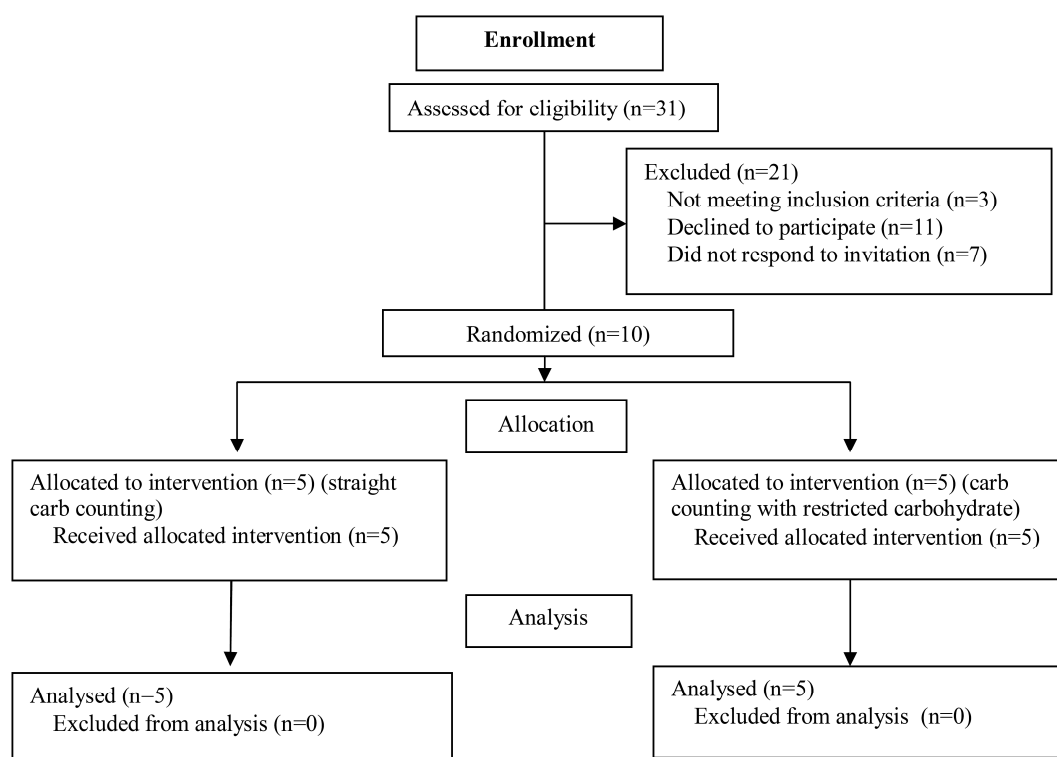


Figure 1. Enrolment, randomisation and allocation of participants.

Table 1. Characteristics of participants at baseline (n=10)

	Standard carbohydrate group (n=5)	Carbohydrate restricted group (n=5)	Total (n=10)
	Mean (SD) or n	Mean (SD) or n	Mean (SD) or n
Age (years)	44.8 (8.3)	44.5 (10.4)	44.6 (8.9)
Gender			
Women	2	1	3
Men	3	4	7
Ethnicity – European	5	5	10
Duration of diabetes (years)	20 (13.1)	23.6 (9.9)	21.8 (11.1)

Table 2. Outcome measures by dietary group

	Standard carbohydrate group (n=5)		Carbohydrate restricted group (n=5)	
	Mean (SD)		Mean (SD)	
	Baseline	12 weeks	Baseline	12 weeks
Weight (kg)	82.3 (25.6)	81.9 (25.3)	83.2 (11.0)	78.0 (6.4)
BMI (kg/m ²)	27.7 (6.2)	27.6 (6.1)	27.5 (2.2)	25.8 (1.0)
HbA1c (mmol/mol)	57 (9)	57 (9)	63 (10)	55 (4) [†]
(%)	7.4 (0.9)	7.4 (0.9)	7.9 (0.9)	7.2 (0.4)
Total daily insulin (units)	40.6 (7.8)	44.8 (12.4)	64.4 (25.3)	44.2 (16.5) ^{**}
Mean CGMS glucose (mmol/L)	9.3 (1.9)	10.1 (2.9)	10.2 (2.3)	8.9 (0.8)
MAGE	7.26 (1.34)	8.32 (3.53)	8.46 (1.22)	8.62 (1.16)
Systolic blood pressure (mmHg)	119 (26.1)	125 (25.3)	120 (10.9)	114.5 (16.0)
Diastolic blood pressure (mmHg)	74.2 (15.5)	71.1 (17.9)	72.4 (11.3)	64.8 (6.7)
Serum creatinine (μmol/L)	76.8 (14.1)	78.2 (14.1)	84.6 (15.1)	83.6 (15.8)
Total cholesterol (mmol/L)	4.7 (0.8)	4.6 (0.6)	4.7 (0.9)	4.6 (1.0)
LDL (mmol/L)	2.5 (0.7)	2.5 (0.5)	2.7 (0.9)	2.8 (0.8)
HDL (mmol/L)	1.8 (0.3)	1.8 (0.4)	1.7 (0.2)	1.5 (0.2)
Triglycerides (mmol/L)	0.7 (0.1)	0.7 (0.2)	0.8 (0.2)	0.8 (0.3)

CGMS: Continuous Glucose Monitoring System; MAGE: Mean Amplitude of Glycaemic Excursions.

* $p < 0.05$ between groups change from baseline, [†] $p < 0.05$ for change within group baseline to 3 months.

Table 3. Dietary intake measures by dietary group

Nutrient	Standard carbohydrate group (n=5)		Carbohydrate restricted group (n=5)	
	Mean (SD)		Mean (SD)	
	Baseline	12 weeks	Baseline	12 weeks
Energy (kcal)	1922 (410)	1854 (551)	1988 (659)	1391 (159)
Protein (g)	97 (32)	85 (42)	77 (15)	76 (16)
Total Fat (g)	68 (17)	77 (15)	78 (23)	69 (13)
Saturated Fat (g)	24 (9)	30 (7)	34 (9)	24 (7)
Carbohydrate (g)	221 (89)	203 (92)	219 (90)	103 (22) ^{**}
Sugars (g)	81 (22)	82 (35)	93 (26)	44 (17) ^{**}
Alcohol (g)	6 (9)	2 (4)	15 (28)	6 (8)
Dietary fibre (g)	21 (5)	18 (4)	23 (8)	19 (3)
Vitamin C (mg)	70 (52)	71 (40)	126 (34)	147 (62)

* $p < 0.05$ between groups.

[†] $p < 0.05$ for change within group baseline to 3 months.

significant ($p=0.001$) on total insulin dose, but controlling for this confirmed that insulin doses increased in the standard carbohydrate counting group and reduced in the carbohydrate restricted group ($p=0.003$). There was no change in glycaemic variability as assessed by MAGE in either group, and no difference between groups. There were no differences observed in blood pressure, creatinine or lipid profile.

Nutritional intake data are shown in Table 3. There was no difference between groups at baseline where mean total energy intake was 1955 kcal per day, with 43% derived from carbohydrate, of which 17% were sugars. Although calorie restriction was not prescribed, nor discussed, both groups trended to a lower total energy intake at 12 weeks. Total carbohydrate and sugar intakes reduced significantly in the carbohydrate restricted group at 12 weeks ($p < 0.05$).

Qualitative interview analysis of participants' experiences highlighted three main points; participant acknowledgement of diabetes as complex and gaining empowerment from greater knowledge, problems matching insulin to food intake on the low carbohydrate diet and the difficulties faced when changing dietary patterns. There were no adverse effects reported in the carbohydrate counting group. In the low carbohydrate group, one participant

reported experiencing a greater number of minor illnesses than usual and another participant reported greater feelings of irritability while restricting carbohydrate. There were no significant differences in the average weighted index of the ADD QoL questionnaire within groups or between the groups at baseline and 12 weeks.

The Diabetes Empowerment Scale average scores did not change over time for the carbohydrate restricted group but trended to improvement in the standard carbohydrate counting group (3.9 ± 0.3 to 4.16 ± 0.3 , $p=0.077$).

DISCUSSION

This small study provides preliminary evidence that a carbohydrate restricted diet may be a lifestyle option for adults with type 1 diabetes, particularly those wishing to lose weight. Although not statistically significant, the carbohydrate restricted group lost a mean of 5 kg over 12 weeks, reducing the average BMI from 27 to 25 kg/m². Insulin requirements and HbA1c were significantly reduced. A larger study is required to confirm these benefits in a wider cohort.

The relative importance of HbA1c compared with glucose variability on the overall risk of developing diabetes related complications remains controversial.¹² However, as glucose control improves the risk of hypoglycaemia

increases, with glucose variability one factor in this.¹³ Whilst matching rapid acting insulin to ingested carbohydrate intake is intuitively sensible, individuals are often inaccurate in their estimation of carbohydrate content of their food.¹⁴ This error is likely to be greater when carbohydrate intake is high. Therefore there is good reason to believe that restricting carbohydrate will enable more accurate estimates, matching of insulin doses and therefore reduced glucose variability. However this was not observed in the small sample in this study.

Carbohydrate intake was halved in the restricted group to 100 g on average per day. The prescription was for 50-75 g carbohydrate per day, and this demonstrates the difficulty of adhering to this dietary advice and estimating carbohydrate intake. Although the desired prescription was not reached, 100 g per day is still considered a low carbohydrate diet.⁶ Other dietary factors were unchanged, including vitamin C which was a concern expressed by participants before starting the study. While fruit intake was limited, vitamin C containing vegetables are able to be included in the low carbohydrate diet.

The total daily insulin dose reduced significantly in the carbohydrate restricted group, but did not match that predicted by carbohydrate intake. This was elucidated in the qualitative interviews, where three participants reported that the insulin predicted by the amount of carbohydrate eaten, was not enough to control post-prandial blood glucose concentrations. For example, based on a pre-study carbohydrate to insulin ratio of 1 unit of insulin to 15 g carbohydrate, one participant was expected to require 2 units of insulin to match 30 g of carbohydrate in one meal. However in reality 10 units of insulin were required to achieve the same post prandial blood glucose concentration. This is not explained by ketosis, or an increase in saturated fat intake that may have caused insulin resistance. Whilst some of this variation may be due to inaccuracy in estimating carbohydrate content, a plausible explanation is that with carbohydrate restriction, gluconeogenesis from protein became a significant source of glucose.¹⁴ It may be that for those wishing to reduce carbohydrate intake, a protein to carbohydrate ratio will be relevant for determining insulin doses. Further research is required to understand this process, at what quantity of carbohydrate intake this occurs, and practically what advice could be given to patients who wish to follow a restricted carbohydrate diet to do so successfully.

There has been a number of adverse effects of a low carbohydrate diet reported in the literature, with the most common being an increase in LDL cholesterol.¹⁵ This study did not find any significant change in LDL in the restricted carbohydrate group from baseline to 3 months, or any difference when compared to the carbohydrate counting group. There did not appear to be any significant effect of carbohydrate restriction on quality of life as measured by questionnaire. However adverse effects were reported as irritability and greater experience of illness, and some expressed difficulty in matching insulin to carbohydrate when carbohydrate was restricted. Following any dietary prescription can be difficult and adherence to dietary restrictions of any form is often poor in the long term.¹⁶ This was not observed in this study, though three

months is too short in a well-motivated group to truly assess this.

The main limitations of this study are the sample size and the differences in insulin dose, albeit not statistically significant, between groups at baseline. This feasibility study shows the possibility of a restricted carbohydrate approach, and enables a more specific sample size calculation for a larger study. A larger sample would give added power to determine if the observed weight changes, which are clinically important, are statistically significant. It would also allow a better examination of glycaemic variability. Furthermore the short duration also limits the ability to conclude if such a dietary strategy is sustainable. A larger and longer term study over a minimum of 12-24 months is required.

Conclusion

A carbohydrate restricted diet is a feasible option for people with type 1 DM when combined with a flexible insulin regimen and carbohydrate counting. It allows for reduced total daily insulin requirements and was associated with improved glycaemic control. This study did not demonstrate improvements in glucose variability. It may be particularly useful for those wishing to lose weight. Further research is required to determine if non-carbohydrate sources of glucose confound the usual estimates of carbohydrate to insulin ratios when carbohydrate intake is low, and need to be factored into advice on insulin dosing for those with type 1 DM following a low carbohydrate diet.

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AUTHOR DECLARATION

The authors declare that this is original research and has not been published elsewhere. All authors contributed to the writing of the manuscript and authorised the final copy. JK designed the study and oversaw the project. APS was responsible for meeting ethical and funding requirements. PC and AH contributed to study design and ran the intervention. AR and SH undertook the statistical analysis. The authors have no conflict of interest.

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Original Article

A randomised trial of the feasibility of a low carbohydrate diet vs standard carbohydrate counting in adults with type 1 diabetes taking body weight into account

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成人 1 型糖尿病患者低碳水化合物摄入与标准碳水化合物计数结合体重计数随机试验的可行性

背景与目的：在 1 型糖尿病患者中，与标准碳水化合物计数比较，确定低碳水化合物饮食对血糖控制、血糖波动以及每日胰岛素使用的影响。**方法与研究设计：**参加二级保健门诊使用普通膳食以注射胰岛素为治疗方案的 10 例 1 型糖尿病患者，按照 1:1 的比例随机分配到一个标准的碳水化合物计数组，或限制碳水化合物饮食组（每天 75 g）。测量了所有志愿者基线和 12 周的体重、身高、血压、糖化血红蛋白、血脂和肌酐，志愿者完成了为期 3 天的食物日记和 3 天持续皮下血糖监测。**结果：**碳水化合物限制组 HbA1c（63-55 mmol/mol（8.9-8.2 %）， $p<0.05$ ）和每日胰岛素用量（64.4-44.2 U/d， $p<0.05$ ）显著减少，体重（83.2-78 kg）的变化无显著差异。碳水化合物计数组血压、肌酐或血脂所有指标均无显著改变。通过平均血糖波动幅度计算的血糖变异性在任何一组中均无改变。**结论：**低碳水化合物饮食是 1 型糖尿病患者一个可行的选择，可以减少胰岛素剂量和改善血糖控制，特别是对那些希望减肥的患者。

关键词：1 型糖尿病、糖代谢、低碳水化合物饮食、血糖控制、碳水化合物计数