ORIGINAL ARTICLE

New obesity treatment: Fasting, exercise and low carb diet - The NOT-FED study

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Abstract

Introduction: Due to high rates of obesity in Canada, weight loss is an important primary care challenge. Recent innovations in strategies include intermittent fasting and low-carbohydrate diets, with limited research in a rural setting.

Methods: This prospective 1-year observational study provided patients in Sioux Lookout, Northwestern Ontario with information on fasting and low-carbohydrate diets. Patients were recommended to attend every 3 months for measurements of weight, waist circumference, body mass index (BMI) and blood pressure. Initial and 6-month bloodwork included A1c and Lipids. A survey of health status and diet was administered at 6 months.

Results: Of the 94 initial registrants, 36 participants completed 1 year and achieved a 9% weight loss and an 8.6% decrease in BMI and waist circumference. Most participants were female with an average age of 60 years. Clinically insignificant changes in blood pressure and serology were observed. Participants reported few side effects and good compliance with intermittent fasting, averaging 15 h/day, 6 days/week. As in other dietary studies, the dropout rate was high at 62%.

Conclusion: This low-resource initiative was successful in assisting self-selected patients at a rural primary care clinic to achieve significant weight loss at 1-year. This approach is practical and is fertile ground for ongoing research.

Keywords: Diabetes, intermittent fasting, low carbohydrate diets, obesity, rural

Résumé

Introduction: En raison du taux élevé d'obésité au Canada, la perte pondérale est un énorme défi en première ligne. Les récentes innovations stratégiques incluent le jeûne intermittent et les régimes faibles en glucides, qui ont fait l'objet de peu de recherche dans les contextes ruraux.

Méthodologie: Cette étude prospective d'observation d'un an a fourni aux patients de Sioux Lookout, du Nord-Ouest de l'Ontario de l'information sur le jeûne et les régimes faibles en glucides. On recommandait aux patients de se présenter tous les 3 mois pour mesurer le poids, le tour de taille, l'IMC et la tension artérielle. Les analyses sanguines initiales et à 6 mois comptaient les taux d'HbA1C et de lipides. Un sondage sur l'état de santé et le régime alimentaire était administré à 6 mois.

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Résultats: Sur les 94 personnes initialement inscrites, 36 participants ont terminé l'étude d'un an et ont perdu 9 % de leur poids et ont réduit l'IMC et le tour de taille de 8,6 %. La plupart des participants étaient de sexe féminin et l'âge moyen était de 60 ans. Des variations significatives sur le plan clinique de la tension artérielle et de la sérologie ont été observées. Les participants ont signalé peu d'effets indésirables et ont bien observé le jeûne intermittent, en moyenne pendant 15 heures/jour, 6 jours sur 7. Tout comme dans les autres études sur les régimes alimentaires, le taux d'abandons était élevé, à 62 %.
Conclusion: Cette initiative nécessitant peu de ressources a réussi à aider les patients volontaires recrutés dans une clinique rurale de première ligne à perdre significativement de poids à un an. Cette approche est pratique et est un terreau fertile pour la recherche qui continue.

Mots-clés : diabète, obésité, régimes faibles en glucides, jeûne intermittent

INTRODUCTION

Over 63% of adult Canadians were overweight (27%) or obese (36%) in 2018.[1] As an independent risk factor for diabetes, hypertension and cardiovascular disease, obesity is an important primary care challenge, particularly in rural communities: the age group with the highest prevalence of obesity in Canada are boys living in towns with a population under 20,000.[2-6] Apart from disease modification, weight loss is a common patient goal for self-esteem, increased mobility and improved quality of life.

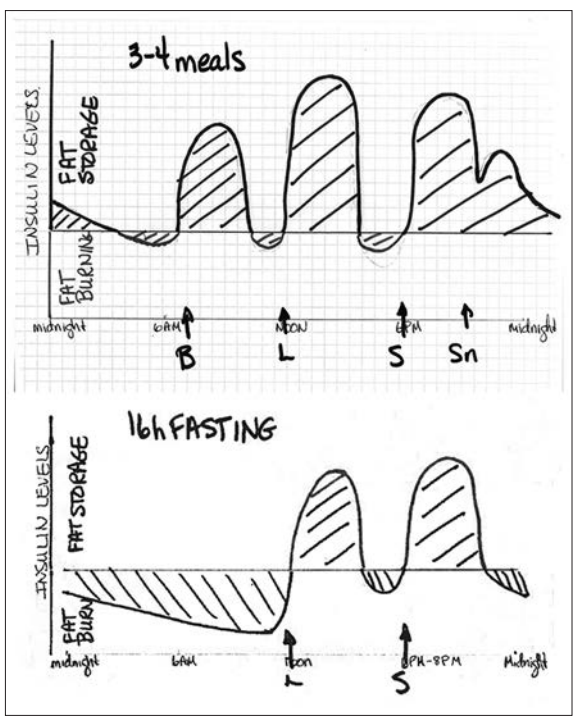


Figure 1: Community poster indicating theoretical insulin and metabolism response to 3-4 meals per day versus overnight and morning fasting and lunch and supper meals. L = lunch; S = supper.

There are few successful strategies that physicians can recommend. Calorie-reduced diets typically lead to limited short-term weight loss. The Women's Health Initiative, a large observational study of over 40,000 postmenopausal women, disappointingly demonstrated that calorie restriction combined with increased exercise failed to produce significant weight loss or improved metabolic profiles.[4,5] Recent health and weight loss strategies include intermittent fasting and low carbohydrate diets.[7,8] This approach is informed by an 'endocrine theory of obesity', with a focus on insulin. There is a lower insulin response to fat or protein consumption than to carbohydrates.[9]Lower insulin levels decrease fat storage and allow its mobilisation by gluconeogenesis, with a resultant weight loss, accompanied by a clinically insignificant ketosis ('ketogenic').[9,10] The focus is on lowering 'carbs' rather than calories [Figure 1].

The purpose of this study was to measure the effect of a primary care initiative combining fasting, low carbohydrate diet and exercise recommendations in a rural community.

METHODS

Study design

This prospective, patient-managed initiative measured weight loss, quality-of-life indicators and metabolic risk factors in self-referred patients in a rural primary care practice. The setting was the town of Sioux Lookout in NW Ontario, with a population of 5000.

Participants were self-referred adults (18+) interested in weight loss who were offered weight loss information, baseline measurements and a 3-monthly follow-up. Patients with diabetes

were eligible if they were not taking or could safely discontinue medications associated with hypoglycaemia (e.g., insulin and sulphonylureas) for a 3-month period. Frail or medically unstable patients were excluded. Patients were initially engaged by a physician or nurse at registration; compliance with follow-up attendance at the recommended 3-monthly follow-up was left to patients. There was some limited 'reminder' telephone support in the early months of the study.

We gave general advice about lowering carbohydrates. Patients decided on their own specific approach including Mediterranean, paleo and ketogenic diets, all of which have decreased carbohydrate content.

The fasting and dietary recommendations included 'intermittent fasting' (a daily 16-h fast), for up to 7 days/week. We recommended the 16-h daily fast and *ad libitum* low-carb consumption.

A low carbohydrate diet was described as eliminating simple sugars and processed foods and minimising other common carbohydrates in our diet: potatoes, pasta and bread. Participants chose their dietary macronutrient balance, by either increasing their fat or protein consumption. Online and written resources for 'low-carb diets' and intermittent fasting were supplied in an orientation package (available at: hughallenclinic.com). Exercise recommendation mirrored the standard General Physical Activity Guidelines of 150 min of moderate exercise per week.[11] Information posters were placed at the clinic, library and other public bulletin boards.

Variables

Anthropometric variables including weight, height, waist circumference and blood pressure were recommended at 3-month intervals and measured by clinic nursing staff. Serology assessments of A1C and lipids occurred at baseline and at 6 months. Self-reported quality of life surveys were offered at the 6-month clinic visit, identifying initial and present health status, dietary and lifestyle changes and adverse events.

Statistical analysis

This was an open-ended patient-led observational initiative, with recommended dietary and fasting interventions. Patients joined at individual starts over a 2-year period, 1 April 2017–1 April 2019 and data collection ended on 1 October 2019. All variables were analysed for those in the 12-month cohort. Weight measurements were recorded for all participants, including those who participated for <1 year. Self-reported 6-month health status and dietary changes were analysed using 3-or 5-point Likert scales. Data are presented as the mean and standard deviation for continuous variables and proportions for discrete variables. Ethics was approved by the Sioux Lookout Meno Ya Win Health Centre Research Review and Ethics Committee.

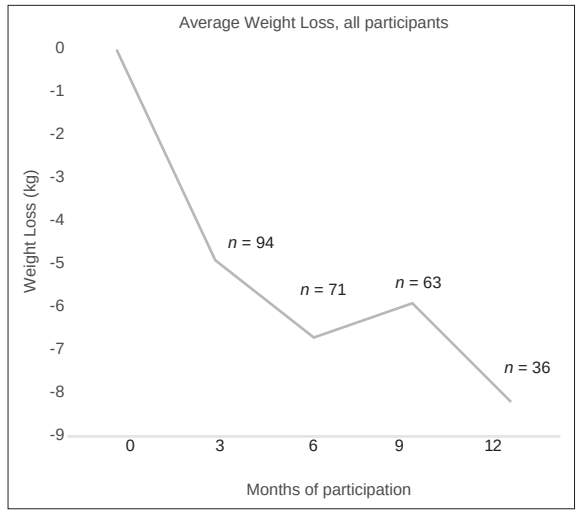


Figure 2: Weight loss for all participants at 3-monthly intervals.

Table 1: Initial and 12-month measurements (*n*=36)

	Baseline	12 months	*P*
Weight, kg	92.5±17.76	84.3±15.60	0.0411
BMI, kg/m^2	35.3±6.14	32.2±5.6	0.0284
Waist circumference, cm	113±14.20	103.7±14.5	0.0076
Systolic BP	142±15.6	139±18.27	0.4562
Diastolic BP	82±5.3	81±5.38	0.7534

BP: Blood pressure, BMI: Body mass index

Table 2: Initial and 6-month laboratory results (*n*=24/36)

	Baseline	6 months	*P*
A1C, %	5.8±0.78	5.5±0.49	0.0547
HDL (mmol/L)	1.4±0.49	1.4±0.45	1.00
LDL (mmol/L)	3.1±0.94	3.4±1.10	0.2176
TC (mmol/L)	5.2±1.01	5.4±1.27	0.4621
TG (mmol/L)	1.6±0.69	1.3±0.70	0.0713

HDL: High-density lipoprotein, LDL: Low-density lipoprotein, TC: Total cholesterol, TG: Triglycerides

Table 3: Self-reported health status at 6 months (*n*=13/36)					
Health status (%)	Excellent	Very good	Good	Fair	Poor
Baseline	0	2 (15)	11 (85)	0	0
6 months	4 (31)	7 (54)	2 (15)	0	0

Table 4: Self-reported dietary changes at 6-months (*n*=13/36)			
Percentage participants with dietary change	Increased	Unchanged	Decreased
Fat	6 (46)	3 (23)	4 (31)
Protein	9 (69)	4 (31)	0
Carbohydrate	0	0	13 (100)

RESULTS

Of the 94 initial registrants, 36 participants completed 12 months. This 12-month cohort was primarily female (34/36) with an average age of 60 years [Table 1]. Many received anti-hypertension medications (16/36), 5 received statin and 8 metformin.

The 12-month participants experienced an average weight loss of 8.2 kg (9% decrease). Body mass index and waist circumference decreased by 8.6% [Figure 2]. Blood pressure, lipids and A1c underwent clinically insignificant changes in 24 of the 36 participants [Tables 2 and 3]. Short-term participants also experienced a 4.9 and 6.7 kg weight loss at 3 and 6 months, respectively [Figure 2]. The dropout rate was 62% (58/94).

The 6-month self-report health survey was completed by 13 participants. Most (10/13) maintained their previous level of exercise and reported improved health status [Table 4]. Self-reported fasting compliance was high at 6 months: participants fasted an average of 15 h/day, on an average of 6.3 days/week. More patients lowered their carbohydrate by increasing protein versus fat consumption [Table 4]. Few side effects were reported; there were several reports of constipation or headache and no episodes of hypoglycaemia.

All weight-loss discussions and clinical surveillance occurred without any increase in staffing/hours and took place during a typical clinic day.

DISCUSSION

Rural populations have lower socioeconomic status, access to recreational facilities and dietary support services than urban centres.[6,12,13] We demonstrated that a 'low resource' intervention is possible in a busy rural practice to facilitate weight loss.

The combination of intermittent fasting and a low carbohydrate diet was effective in achieving a 9% 1-year weight loss in 36 participants in a busy rural clinic. This level of weight loss is equivalent to other more resource-intense dietary studies but had none of the standard components for successful recruiting and retention (e.g., financial incentives, meal replacements).[14,15] The dropout rate of 62% is high but is similar to other dietary studies.[15] There was no increase in staffing/hours due to weight loss discussions and clinical surveillance. Patients were largely healthy and self-selected. We chose the combination of intermittent fasting and a carbohydrate reduced diet as there was good supporting evidence and several authors had achieved weight loss using these two strategies.[6,7,15]

The typical Canadian diet contains 48% of caloric intake from carbohydrates; 'low-carb' generally refers to a reduction to <40% and a 'very low-carb' restriction (ketogenic) to <30%.[16,17] Cochrane reviews in 2018 and 2019 show low carbohydrate diets to be effective for weight loss.[18,19] Patients in our study had strong preferences regarding increasing either protein or fat in their diet, the consumption of animal versus plant protein and consumption of saturated versus unsaturated fat.

Intermittent fasting commonly consists of a daily fasting period of 16 h (e. g. 8 pm to noon), or two 24-h fast periods per week ('5:2').[6] Another format is 'alternate day fasting' where caloric intake is restricted to 500–600 kcal/day every second day, followed by a feast day.[6] A recent literature review of 27 studies of intermittent fasting

documented that weight loss was equivalent to calorie-restricted diets.[20] Our recommended 16-h daily fast and *ad libitum* low-carb consumption could be gradually introduced and seemed more tolerable, an important concern for new initiates to fasting.

Several recent studies combined intermittent fasting and a low-carb diet.[10,14-16] Kalam *et al*. combined alternate day fasting and a calorie-restricted ketogenic diet over 6 months. Thirty-one participants had an average weight loss of 6.3 kg. With a dropout rate of 62%.[15] Extensive resources were dedicated to follow up and meals were provided. Five other studies of 12–36-week duration combined intermittent fasting and a low-carbohydrate diet. They all demonstrated a 5%–10% weight loss among their study participants (n = 26–244).[21-25]

Most of the 13 participants completing the 6-month health survey described improved health status, although none reported 'poor' or 'fair' initial health. Their macronutrient changes included an increase in protein more frequently than increased fat consumption. Similar to other low-carb diets, serology testing showed minimal changes and was accompanied by a small decrease in systolic and increase in diastolic blood pressure.[9,21-26]

Our study was not designed to improve glycaemic control; only 8 patients using metformin were enrolled. The slight drop in A1C (0.3%) among the 13 participants at 6 months was from a normal baseline of 5.8% but suggests that this strategy may be useful for patients with diabetes, which would require a study with more rigorous education and clinical supervision.[27] Exercise is not known to effect weight loss but was included in our recommendations to promote a healthy lifestyle.[28-30] The majority of patients (75%) maintained their self-reported prior level of exercise. One barrier to a low-carbohydrate diet may be financial; many approaches increase food costs and that may be a limitation for many rural families.[31]

One of the unforeseen and perhaps most significant benefits of the study was the community effect. Study information spread by word of mouth and became a common topic of discussion around town. Posters were up in the library and clinic. The initiative created an atmosphere for thoughtfulness and discussions around healthy eating and wellness, both for patients and health-care providers It was easily integrated into the care of clinic patients, providing an opportunity to address weight loss. Interested patients could either 'check with the nurse on your way out' or visit the clinic website for study information. This focus on what we eat and how we live has had a positive community effect. Not only has this weight loss initiative energised Sioux Lookout community members, it has also been adopted by several other rural communities in Alberta, Manitoba and Ontario. The level of evidence even if reproduced in other rural communities will remain limited. A prominent American diabetes researcher commented on the state of low-carbohydrate diet research: 'Given the current state of research funding and the palpable bias against low-carbohydrate approaches, it is unlikely that an RCT can be performed that will satisfy everybody. The seriousness of diabetes suggests that we have enough evidence of different types to re-evaluate our current recommendations for treatment'.[27]

Limitations

There are notable limitations in this study. It is a small study of self-selected participants. Inconsistent attendance of participants was a barrier, creating gaps in the data. Our study recommended a low-carbohydrate approach but did not quantify or measure actual dietary intake and had no direct measure of 'carb-content'.

We relied on self-reports of health status and dietary changes and a self-selection bias is inherent in this healthy cohort of participants. Recall bias may exist for baseline health status which was reported retrospectively in the 6-month survey. While a more rigorous follow-up would have resulted in better participant retention, choosing to proceed with our existing resources made the initiative possible.

CONCLUSION

The combination of intermittent fasting and a low carbohydrate diet promoted meaningful weight loss among a self-selected population in a rural primary care clinic. The initiative promoted community awareness of healthy living. This low-resource approach is a practical intervention for motivated patients interested in weight loss and is deserving of further consideration and investigation.

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Conflicts of interest: There are no conflicts of interest.

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