

Sequential diets and weight loss: Including a low-carbohydrate high-fat diet with and without time-restricted feeding

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ABSTRACT

Objective: The aims of this study were to assess the effectiveness of a low-carbohydrate high-fat (LCHF) diet with and without a time-restricted feeding (TRF) protocol on weight loss and participating in three sequential dietary interventions (standard calorie-deficit diet, LCHF, and LCHF + TRF) on weight loss outcomes.

Methods: Data from 227 adults from the Wharton Medical Clinic (WMC) were analyzed using a unidirectional case crossover design. Data was imputed for 154 patients to create a pseudo-sample in which everyone participated in three dietary interventions: standard calorie restriction, LCHF, and LCHF + TRF.

Results: Patients lost an average of 11.1 ± 1.3 kg ($9.8 \pm 1.1\%$) after three sequential dietary interventions ($P < 0.0001$). Patients lost a statistically significant amount of weight from the standard WMC, LCHF, and LCHF + TRF diets ($P < 0.05$). With and without adjustment for age, sex, body mass index at the start of the dietary protocol, and treatment time, patients lost a similar amount of weight regardless of the dietary intervention ($P > 0.05$). Approximately 78.6% of patients achieved $\geq 5\%$ weight loss with at least one of the diets.

Conclusion: Patients can lose a similar amount of weight regardless of the diet they are following. Approximately 78.9% of patients achieved 5% weight loss with at least one of the diets and lost an average 11.1 kg (or 9.8%). This is nearly double what has been previously reported for one dietary intervention. Thus, participating in sequential diets may be associated with greater absolute weight loss, and likelihood of achieving a clinically significant weight loss

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Introduction

Excess weight is a serious and prevalent medical condition. As of 2016, almost 40% of adults worldwide had overweight or obesity [1]. Excess weight has been associated with the development of several chronic conditions such as diabetes [2] and cardiovascular disease [3,4]. Fortunately, research has suggested that achieving a modest

weight loss of $\geq 5\%$ can improve clinical outcomes [5]. The primary mode of intervention for weight loss is behavioral intervention, which involves changing one's diet to decrease calorie intake.

Low-carbohydrate high-fat (LCHF) and intermittent fasting diets have increased in popularity in the past few years. This is demonstrated by the existence of several news articles regarding potential benefits or harm of LCHF [6–9], and intermittent fasting [10–13] diets. There has also been a growing body of scientific, peer-reviewed literature suggesting that LCHF diets are associated with significant decreases in weight [14–17], similar to what is observed with more traditional calorie-restrictive diets [15–17] such as those low in fat. Although fasting has been incorporated for religious reasons for centuries [18], the use of intermittent fasting as a dietary intervention is comparatively new.

There are several types of intermittent fasting, but one of particular interest is time-restricted feeding (TRF). TRF diets involve decreasing the time period that a person can eat every day. There is little evidence

RAGC is employed as a research consultant for projects not related to this manuscript at the Wharton Medical Clinic. SH was employed as a physician at the Wharton Medical Clinic, and the lead physician for the pilot program analyzed in this manuscript. SH is also the medical director of the High Metabolic Clinic and has received payments from Novo Nordisk for advisory work. SW is the medical director of the Wharton Medical Clinic and an internal medicine specialist with privileges at Toronto East General Hospital and Hamilton Health Sciences. SW reports payments from Astra Zeneca, Eli Lilly, Janssen, and Novo Nordisk for advisory work. EK, MD, MF, and JLK have no conflicts of interest to declare.

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examining the effectiveness of a TRF diet in individuals with obesity, and even less that compares results to a control group. To our knowledge, there are only three controlled TRF studies examining weight loss in individuals with excess weight [19–21]. None of these studies provided guidelines on the macronutrient composition of the diet during the feeding window. LCHF diets decrease hunger [22], which could benefit patients who are incorporating periods of fasting. Thus, the primary objective of the present study was to assess the effectiveness of a LCHF diet with or without the addition of a TRF protocol compared with a more traditional calorie-restrictive diet for weight loss, which usually involves eating three meals a day with healthy snacks and balanced macronutrient diet. The secondary objective was to assess the weight loss associated with attempting several different diets sequentially.

Methods

The Wharton Medical Clinic (WMC) is an interdisciplinary bariatric clinic with multiple locations in southern Ontario. The clinic operates under the principles outlined in the Canadian Clinical Practice Guidelines for the prevention and treatment of overweight and obesity [5]. Patients at WMC are cared for by a team of nutritionists, dietitians, and medical doctors. Care at WMC is covered by the Ontario Health Insurance Plan, and therefore patients are not charged for treatment. Patients are approached at baseline to consent for their clinical data to be used for research purposes and were informed that their participation or lack thereof would not affect their care.

In 2017, a pilot program was launched at the Burlington WMC location, which instructed patients on a LCHF diet with or without TRF. Patients enrolled in the pilot program for a variety of reasons:

- They were unsuccessful with the standard WMC protocol (e.g., not losing weight);
- They had a specific interest in the LCHF or TRF diet and asked to be referred from the standard WMC clinic; or
- They were referred directly to the pilot program from a physician external to WMC.

Only patients who enrolled in the pilot program and consented to allowing their medical records to be used for research purposes were included in this analysis (N = 227). This study was approved by the York University Human Participants Review Committee in accordance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, second edition.

Standard WMC protocol

The protocol for the WMC has been described in greater depth elsewhere [23]. At their initial visit, patients complete a comprehensive intake package that collects information on demographic characteristics and comorbidities. Patients meet with a physician and nutritionist to discuss their weight management goals and management of their comorbid conditions. At their second or third visit, patients are provided with an individualized calorie prescription that is ≥ 250 kcal/d below their total daily calorie requirement as estimated using the Mifflin St. Jeor equation. The diet has a macronutrient breakdown of 40% carbohydrates, 30% protein, and 30% fat, which has a slightly higher in protein recommendation than the Canadian Food Guide in circulation until 2019. This was and still is the standard dietary intervention provided to most patients at all WMC locations other than those participating in the 2017 pilot program, and therefore will be referred to as the standard WMC protocol or diet throughout this study. Patients involved in the standard WMC protocol are encouraged to attend the clinic every 3 to 4 wk for follow-up but could attend more frequently if they wished.

LCHF + TRF protocol

Patients in the pilot program completed a comprehensive intake questionnaire regarding demographic characteristics and weight history at baseline. Patients were provided with a 2-wk meal plan with 100 g net carbohydrates (defined as total carbohydrates minus fiber) daily or less as tolerated, at their initial visit. The majority of patients elected to consume a very low-carbohydrate diet of <25 g net carbohydrates daily. Patients were also encouraged to consume ≥ 4 to 6 oz of protein at each meal. Unlike the standard WMC protocol, patients in the LCHF pilot program were not provided with a specific calorie target. Rather, this diet assumes that hunger will decrease with prolonged lower carbohydrate intake thereby lowering overall calorie consumption.

There are side effects from decreasing carbohydrate intake (referred to colloquially as *induction flu*) such as headaches, leg cramps, and other flu-like symptoms, and techniques to manage these symptoms are discussed. Patients are also

prescribed vitamin D and magnesium dietary supplements, with the latter supplement meant to ameliorate some of the induction flu symptoms.

TRF is introduced during the third or fourth visit to interested patients; however, patients may request to initiate TRF earlier. Patients are encouraged to follow an 18:6 fasting protocol in conjunction with the LCHF diet. This means they are asked to refrain from consuming any calories for 18-h consecutively (*fasting window*), and then consume all their calories within a 6-h daytime window (*feeding window*). Patients are also instructed to cease eating by 1900 h. Patients who are more experienced with fasting incorporate some extended fasts for 24 to 36 h, once or twice per week. Although the standard WMC clinic is monitored by multiple physicians, only one physician (Dr. Sasha High) monitored patients in the pilot program. Patients were encouraged to attend the clinic every 3 to 4 wk, but due to the high volume of patients in the pilot program, they typically returned every 6 to 8 wk.

Enrollment in the LCHF pilot program was initially restricted to patients who had participated in the standard WMC (n = 73). Following WMC, most participants first initiated the LCHF only and then added TRF. However, after a time, patients were referred directly to the LCHF pilot program (n = 154) and a small number of patients switched directly from the standard WMC to the LCHF + TRF (n = 5).

Patients in the standard WMC, LCHF, and LCHF + TRF programs undergo comprehensive blood testing at baseline and every 3 to 6 mo follow-up as indicated by the physician. Trained technicians measure patient weight and blood pressure at each appointment. Patients receive group educational sessions or watch videos focused on the core principles of each program at baseline and subsequent appointments. Patients also meet with a trained nutritionist, and a physician who monitors them for comorbidities and orders any specialized testing (e.g., sleep test, blood test, or resting metabolic rate test) as needed.

All data were abstracted from electronic medical records by two of the authors (EK and MD). The data set then underwent data cleaning, and analysis by two other authors (RAGC and JLK). Patient height, treatment time, age, and sex were abstracted. Additionally, weight, and systolic and diastolic blood pressure measurements were abstracted from four different time points: start of standard WMC diet, start of LCHF diet, start of LCHF + TRF diet, and at the end of follow-up.

Statistical analysis

Owing to the real-world nature of the clinic, the weight management program varied between patients. Although the order in which the programs are presented were consistent, patients were free to choose which dietary interventions they wished to participate in and how long they participated in each program. This resulted in imbalanced treatment times and sample sizes across the three interventions:

- Standard WMC: n = 73 (32.1%),
- LCHF: n = 222 (97.8%), just and/or
- LCHF + TRF: n = 83 (36.6%)

Predictive mean matching imputation with 100 repetitions was undertaken to create a pseudo-sample in which all patients participated in each of the three dietary interventions. After imputation, data were analyzed as a unidirectional case crossover design where participants initiated the standard WMC protocol at baseline, then transitioned to an LCHF diet, and finally incorporated TRF. Continuous variables are presented as mean \pm SE, and categorical variables as frequency (prevalence). Repeated measures analysis of variance was undertaken to assess for significant changes in absolute weight, and blood pressure, and differences based on diet type. In order to assess for significant change in percentage weight loss, 95% confidence intervals (CIs) were constructed and assessed for unity.

Generalized estimating equation (GEE) regression was used to account for clustering (i.e., repeated measures in each participant), with an unstructured covariance matrix specified in all regression models. Linear GEE regression was undertaken to examine the association between absolute weight loss and each dietary intervention, with adjustment for age, sex, body mass index (BMI) at start of each dietary intervention, and treatment time for that dietary intervention. Modified Poisson regression (i.e., a GEE regression with a Poisson distribution and log-link) [24] was undertaken to estimate the risk ratio for achieving a clinically significant weight loss (i.e., $\geq 5\%$ weight loss) with LCHF, and LCHF + TRF based on whether they achieved $\geq 5\%$ with the standard WMC and/or LCHF diets.

To ensure initiating weight loss medications during treatment (15.9%, 36 of 227) did not affect the results, we conducted the analyses excluding these individuals. Also, due to the relatively high proportion of imputed data (e.g., 49.2% of weight measurements) a per-protocol analysis was also conducted with the subsample of patients who participated in all three dietary interventions, respectively.

All analyses were conducted using SAS version 9.4 (SAS, Cary, NC, USA). MIANALYZE (SAS) was used to account for imputed data. All tests were two-tailed, and $P < 0.05$ was considered statistically significant.

Results

Patient characteristics by each dietary protocol are presented in Table 1. Of the 227 patients, 163 (71.8%) were women, and on

Table 1
Characteristics of imputed patients' data by dietary protocol

Variable	Standard WMC diet	LCHF	LCHF + TRF
Sample size (n, %)	227 (100)		
Age (y)	51.2 ± 0.8		
Women (n, %)	163 (71.8)		
Baseline BMI (kg/m ²)	39.4 ± 0.9 ^{*,†}	38.2 ± 0.8 ^{†,‡}	36.6 ± 0.7 ^{*,†}
Baseline SBP (mm Hg)	125.1 ± 1.1	127 ± 0.8 [†]	124.5 ± 1 [*]
Baseline DBP (mm Hg)	76.5 ± 0.8	76.1 ± 0.6	73.8 ± 0.7 ^{*,‡}
Weight change (kg)	−3 ± 1.2 [‡]	−4.4 ± 0.9 [‡]	−3.6 ± 0.7 [‡]
Weight change (%)	−2.8 ± 1.1 [‡]	−3.3 ± 0.7 [‡]	−3.6 ± 0.7 [‡]
≥5% weight loss, n (%)	83 (37.5)	82 (37.1)	87 (39.2)
SBP change (mm Hg)	2 ± 1.1 [*]	−2.5 ± 1.1 [‡]	0.6 ± 1.2
DBP change (mm Hg)	−0.4 ± 0.9	−2.3 ± 0.8 [‡]	1.6 ± 1
Treatment time (mo)	10.5 ± 1 ^{*,†}	5.7 ± 0.4 [†]	6.6 ± 0.5 [†]

BMI, body mass index; DBP, diastolic blood pressure; LCHF, low carbohydrate high-fat; SBP, systolic blood pressure; TRF, time-restricted fasting.

^{*}Significantly different from LCHF diet ($P < 0.05$).

[†]Significantly different from LCHF + TRF.

[‡]Significantly different from standard WMC diet.

[§]Significant change while participating in that dietary intervention ($P < 0.05$).

average had class II obesity at the start of each dietary protocol (standard WMC = 39.4 ± 0.9 kg/m², LCHF = 38.2 ± 0.8 kg/m², and LCHF+TRF = 36.6 ± 0.7 kg/m²). Patients lost 11.1 ± 1.3 kg ($9.8 \pm 1.1\%$) after all three dietary protocols ($P < 0.0001$). Patients lost 3 ± 1.2 kg with the standard WMC protocol ($P = 0.01$; Fig. 1), another 4.4 ± 0.9 kg ($P < 0.0001$) with the LCHF diet, and 3.6 ± 0.7 kg ($P = 0.0002$) with the LCHF + TRF diet. There was no significant difference in the amount of weight patients lost with each of the three dietary interventions with or without adjustment for age, sex, BMI at start of the diet protocol, and treatment time ($P > 0.05$ for all comparisons).

Approximately 178 patients (78.6%) lost $\geq 5\%$ of their body weight with at least one of the three dietary interventions. Eighty-three patients (37.5%) lost $\geq 5\%$ of their body weight while following the standard WMC diet (Fig. 2). When these patients switched to an LCHF diet, 18 of 83 (22.5%) who achieved 5% weight loss with the standard WMC diet were able to lose an additional $\geq 5\%$ of their remaining body weight. Conversely, 64 of 144 patients (45.3%) who did not achieve 5% weight loss with the standard WMC protocol did achieve $\geq 5\%$ weight loss when they switched to the LCHF diet. Patients who did not achieve 5% weight loss following the

standard WMC protocol had a slightly greater odds of achieving a 5% weight loss with the LCHF diet than those who did achieve a 5% weight loss with the standard WMC diet ($P = 0.02$). Patients who lost $\geq 5\%$ of their body weight on the standard WMC diet had similar odds of losing another $\geq 5\%$ of their body weight when consuming the LCHF + TRF diet, regardless of whether (7 of 18; 42%) or not (25 of 64; 40.9%) they achieved a clinically significant weight loss with the LCHF diet. In fact, there was no statistically significant difference in the odds of a patient achieving a 5% weight loss with the LCHF + TRF diet based on whether they lost 5% of their body weight with the standard WMC or LCHF diet ($P > 0.05$ for all comparisons).

The pattern of results were similar after excluding patients who initiated weight loss medication during the intervention ($n = 36$) or restricting analyses to patients who participated in all three dietary interventions ($n = 20$), although power was limited in some of the restricted analyses (data not shown).

Discussion

The present study compared weight loss in individuals participating in three successive dietary interventions: standard calorie-deficit diet (WMC), LCHF, and LCHF + TRF. Results of the present study suggested that individuals may be able to lose a similar amount of weight with each of the three dietary interventions. Although each dietary intervention was associated with a significant weight loss, patients were able to achieve >11 kg or 9.8% of weight loss; almost 79% of patients lost a clinically significant amount of weight following three successive diets. This suggests that patients may benefit from introducing several different dietary interventions to increase weight loss and their likelihood of achieving a clinically significant weight loss.

To date, three studies have directly compared weight loss outcomes between individuals following a TRF protocol to a no weight loss treatment. Two of these studies report no significant difference in weight loss [19,20]; whereas the other reports slightly greater decreases in weight for individuals following a TRF regimen [21]. Comparatively, more studies have examined differences between low-carbohydrate diets and standard calorie-restrictive diets. A meta-analysis of five randomized controlled studies comparing low-carbohydrate diets without calorie restriction to low-fat diets with calorie restriction reported no significant difference in weight loss [16]. We also observed no significant differences in weight loss based on the type of diet. Thus, findings from this study and others may suggest that traditional calorie-

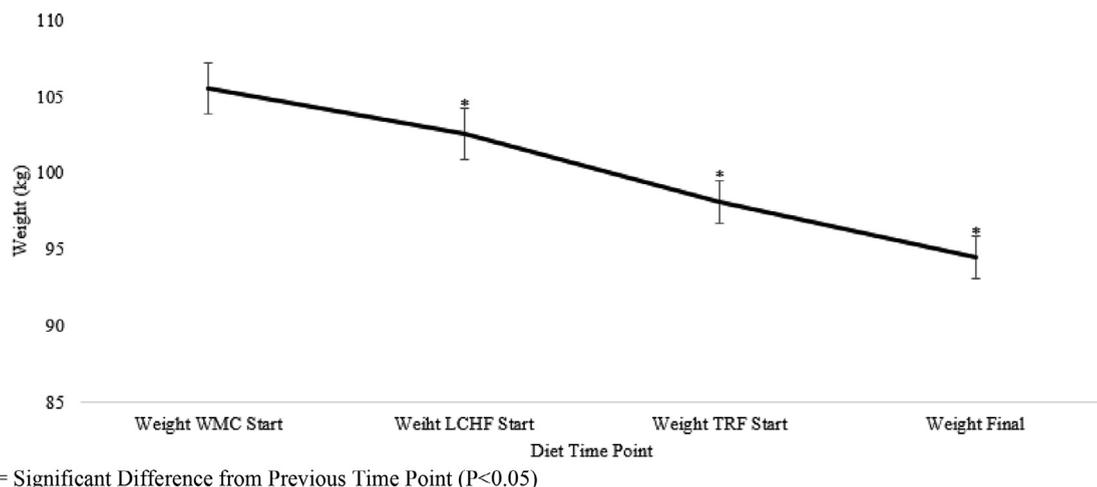


Fig. 1. Average participant weight when they started the standard WMC diet, the LCHF diet, the LCHF + TRF diet, and end of follow-up. *Significant difference from previous time point ($P < 0.05$). LCHF, low-carbohydrate high-fat; TRF, time-restricted feeding; WMC, Wharton Medical Clinic.

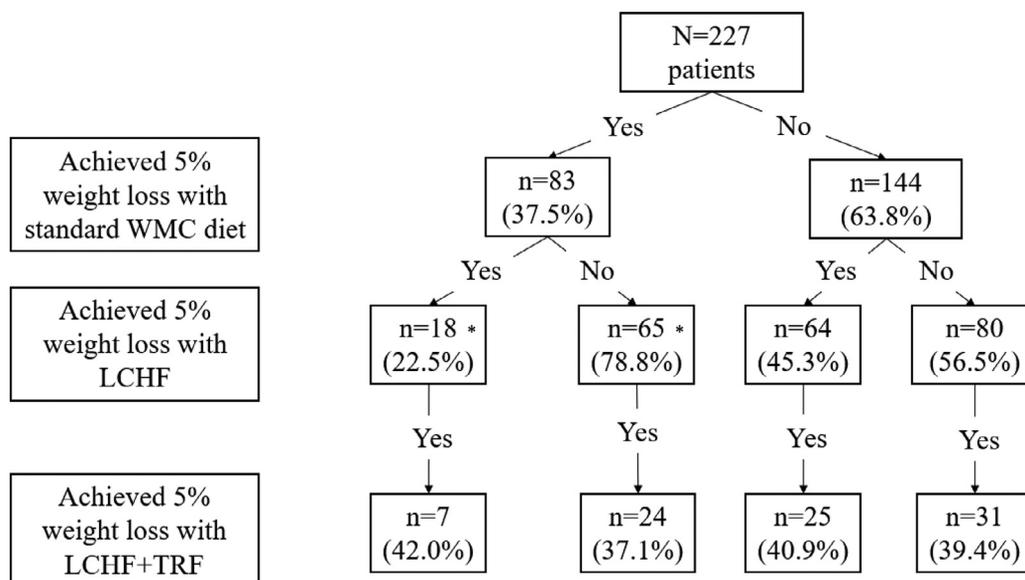


Fig. 2. Flowchart of percent and number of imputed patients who achieved 5% weight loss on the standard WMC diet, the LCHF diet, and the LCHF+TRF diet. *Significantly different than individuals participating in the LCHF diet who did not lose 5% of their body weight with the standard WMC diet in the same category ($P < 0.05$). LCHF, low-carbohydrate high-fat; TRF, time-restricted feeding; WMC, Wharton Medical Clinic.

restrictive diets and other diets such as an LCHF with or without TRF can be used by patients to lose weight. This suggests that there may not be one perfect diet; but instead many different macronutrients and eating schedules may be as beneficial for weight loss as standard calorie restriction.

Previous research from the WMC observe an average weight loss of 6.6 kg (5.9%) with a standard calorie-restrictive diet over 1 y [25]. Research from other multidisciplinary weight loss clinics report similar weight loss over a longer time frame. For example, research from 15 publicly funded weight management centers in Italy report 5.2% weight loss on average in patients who received primarily a lifestyle or pharmaceutical treatment over a 3-y period [26]. In the present study, patients lost almost double what has previously been observed from patients in the same and other publicly funded clinics where patients participated in only a standard calorie-restriction intervention. This suggests that switching to different dietary interventions may aid patients in improving weight loss.

It is important to consider that absolute weight loss may not be the best indicator of weight loss success. Clinical guidelines recommend individuals achieve $\geq 5\%$ reduction in body weight, as this has been associated with improvements in weight-related comorbidities and other clinical markers of health [5,27]. Previous research from WMC has reported $\sim 43\%$ of patients achieve a clinically significant weight loss of $\geq 5\%$ of their body weight at 1 y. When this is restricted to persistent patients, the proportion of patients achieving a clinically significant weight loss increases to $> 53\%$ at 1.5 y [25]. In publicly funded weight management centers in Italy, 41% of persistent patients lost $\geq 5\%$ of their body weight over 3 y [26]. In the present study, 38% of patients achieved a clinically significant weight loss over the first year with the first dietary intervention, whereas almost 79% of the patients achieved a clinically significant weight loss over ~ 2 y of multiple interventions: 50% more patients achieving a clinically significant weight loss. This suggests switching diets may increase not only the amount of weight a patient will lose, but also their likelihood of achieving a clinically significant weight loss.

Strengths of the present study included a relatively large sample size. We used g^* power [28,29] to determine the effect size for a repeated-measures multivariate analysis of variance for within-

factors effect. We set α to 0.05 and power to 0.80. For an analysis with 227 participants, and four repeat measures of weight, we would be sufficiently powered to observe small effect sizes (Cohen's f of 0.10) [30] if there was a correlation as low as 0.1 between repeat measures. To the our knowledge, this was the largest study of patients following a TRF protocol. Additionally, this was also the first study to examine individuals who are consuming an LCHF diet while also following a TRF protocol. This study examined patients from a publicly funded weight loss program, meaning the findings from this study may be more generalizable to individuals who seek treatment for weight management. However, this study population may not be as representative as those in other WMC papers, as this pilot program was only available at the Burlington location, which may have created barriers to patient participation. There are also some important limitations that warrant mentioning. We did observe slightly less weight loss while patients were consuming the calorie-restrictive diet compared with the LCHF and LCHF + TRF diets, possibly because some patients were referred to the pilot program because they were not losing weight following the standard WMC diet. Patients also self-reported their adherence to dietary protocols, and therefore may not have been following the type of diet they reported. There was also no wash-out period between diets. This means some of the weight change observed could be attributed to the previous intervention and contributed to us not observing significant differences between diet types. Owing to the observational nature of this study, we were unable to control for these potential carryover effects of the previous diet, but this may be more representative of dietary interventions in the real world where there would likely be no washout period between diets. Finally, owing to the real-life nature of the data, patients may not have participated in each intervention. Therefore, we imputed weight at multiple different times, with a maximum of ≤ 154 weight values imputed for a given dietary intervention. However, the pattern of findings were similar with the per-protocol analysis to those presented from the imputed data but were limited in power with 20 patients. In fact, participants lost slightly more weight on average in the per-protocol analysis than the imputed results suggesting the findings from this study are a more conservative estimate of effect.

Conclusion

Patients in the present study lost a similar amount of weight while they were consuming a standard calorie-deficit diet, LCHF diet, and LCHF+TRF diet. In fact, there was a <1.5 kg difference in the amount of weight patients lost with each of the diets. This suggests that patients can lose weight by consuming diets with different macronutrient content, or eating times, regardless of whether they are given a calorie prescription. After following the three successive diets, patients lost >11.1 kg of weight. This is nearly double the weight loss previously reported with only the standard dietary intervention at the same clinic. Additionally, >75% of patients achieved a clinically significant weight loss with this variable intervention. This may suggest that trying multiple different diets, with the supervision of medical weight management clinic, may help patients lose more weight and improve their likelihood of achieving a clinically significant weight loss.

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