Intermittent fasting, Paleolithic, or Mediterranean diets in the real world: exploratory secondary analyses of a weight-loss trial that included choice of diet and exercise

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ABSTRACT

Background: Intermittent fasting (IF) and Paleolithic (Paleo) diets produce weight loss in controlled trials, but minimal evidence exists regarding long-term efficacy under free-living conditions without intense dietetic support.

Objectives: This exploratory, observational analysis examined adherence, dietary intake, weight loss, and metabolic outcomes in overweight adults who could choose to follow Mediterranean, IF, or Paleo diets, and standard exercise or high-intensity interval training (HIIT) programs, as part of a 12-mo randomized controlled trial investigating how different monitoring strategies influenced weight loss (control, daily self-weighing, hunger training, diet/exercise app, brief support).

Methods: A total of 250 overweight [BMI (in kg/m^2) $\geq$27] healthy adults attended an individualized dietary education session (30 min) relevant to their self-selected diet. Dietary intake (3-d weighed diet records), weight, body composition, blood pressure, physical activity (0, 6, and 12 mo), and blood indexes (0 and 12 mo) were assessed. Mean (95% CI) changes from baseline were estimated using regression models. No correction was made for multiple tests.

Results: Although 54.4% chose IF, 27.2% Mediterranean, and 18.4% Paleo diets originally, only 54% (IF), 57% (Mediterranean), and 35% (Paleo) participants were still following their chosen diet at 12 mo (self-reported). At 12 mo, weight loss was −4.0 kg (95% CI: −5.1, −2.8 kg) in IF, −2.8 kg (−4.4, −1.2 kg) in Mediterranean, and −1.8 kg (−4.0, 0.5 kg) in Paleo participants. Sensitivity analyses showed that, due to substantial dropout, these may be overestimated by ≤1.2 kg, whereas diet adherence increased mean weight loss by 1.1, 1.8, and 0.3 kg, respectively. Reduced systolic blood pressure was observed with IF (−4.9 mm Hg; −7.2, −2.6 mm Hg) and Mediterranean (−5.9 mm Hg; −9.0, −2.7 mm Hg) diets, and reduced glycated hemoglobin with the Mediterranean diet (−0.8 mmol/mol; −1.2, −0.4 mmol/mol). However, the between-group differences in most outcomes were not significant and these comparisons may be confounded due to the nonrandomized design.

Conclusions: Small differences in metabolic outcomes were apparent in participants following self-selected diets without intensive ongoing dietary support, even though dietary adherence declined rapidly. However, results should be interpreted with caution given the exploratory nature of analyses. This trial was registered with the Australian New Zealand Clinical Trials Registry as ACTRN12615000010594 at https://www.anzctr.org.au. *Am J Clin Nutr* 2019;0:1–12.

Keywords: obesity, fasting, intermittent energy restriction, weight loss, Mediterranean diet, Paleolithic diet, whole foods

Introduction

Given that obesity and metabolic dysfunction drive most chronic diseases, there is a need for simple, sustainable, and safe dietary approaches that promote good dietary choices, effective weight control, and favorable metabolic outcomes. Although the well-established Mediterranean diet has proven efficacy (1, 2), less is known regarding the ability of alternative dietary approaches to influence diet quality and health outcomes.

Periodic, temporary restriction of energy intake by intermittent fasting (IF) has been shown in controlled trials to lead to similar

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Supplemental Tables 1–3 are available from the "Supplementary data" link in the online posting of the article and from the same link in the online table of contents at https://academic.oup.com/ajcn/.

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Data described in the manuscript will be made available upon request.

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Abbreviations used: CRP, C-reactive protein; HbA1c, glycated hemoglobin; HIIT, high-intensity interval training; IF, intermittent fasting; Paleo, Paleolithic; SWIFT, Support strategies for Whole-food diets, Intermittent Fasting and Training.

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weight and metabolic outcomes as continuous energy restriction (3, 4), with advocates suggesting better long-term adherence occurs as permanent restriction of energy intake is not required (5). However, trials to date typically report high attrition (6, 7), with few studies lasting >6 mo; these studies typically report modest outcomes (4, 8). Many also have prescribed rigid and personalized meal plans, including regular communication with a dietitian (4, 6), providing limited indication of effect in real-world situations when such support is not available.

Advocates of the Paleolithic (Paleo) diet promote that eating like our hunter-gatherer ancestors will improve health and prevent chronic disease (9) through restriction of grains, legumes, and dairy. Although several randomized controlled trials have demonstrated superior weight and body fat reduction and metabolic improvements (10, 11), these have generally required very restricted diets, which may not be sustainable for most people. Eliminating whole grains also conflicts with evidence regarding their benefits for chronic disease prevention (12) and, together with restriction of dairy, may affect nutrient intakes (13).

Whether IF and Paleo diets result in weight loss and metabolic improvements in overweight adults without intensive dietetic or other clinical support is uncertain (14–16). We recently reported no differences in weight, body composition, blood markers, exercise, or eating behavior in a randomized controlled trial investigating how different monitoring strategies influenced weight loss over 1 y (17, 18). As part of this trial, participants could choose whether to follow a Mediterranean, IF, or Paleo diet. The aims of this secondary, exploratory analysis were as follows: *1*) to assess adherence to these self-selected diets, *2*) to describe the participants who chose these diets and their food intakes at 6 and 12 mo, and *3*) to compare changes in weight, body composition, and metabolic outcomes between diets after 12 mo.

Methods

This is a secondary, exploratory analysis of data from the Support strategies for Whole-food diets, Intermittent Fasting and Training (SWIFT) trial. As further details are described in the published protocol article (17), only relevant aspects are outlined below. SWIFT is registered with the Australian New Zealand Clinical Trials Registry (ACTRN12615000010594), and ethical approval was obtained from the University of Otago Human Ethics Committee (H14/024). All participants provided written informed consent.

SWIFT was a 12-mo, 5-arm (control and 4 intervention arms) randomized controlled trial that examined the effect of adding different monitoring strategies (brief support visits, self-monitoring of body weight, self-monitoring of dietary intake, or hunger training) to a single dietary and exercise educational session, in an attempt to mirror real-world approaches to dieting and weight loss (**Figure 1**). Funding was not obtained to undertake a planned follow-up at 24 mo. The different monitoring strategies were brief support visits (monthly individual meetings where the participant was weighed and had the opportunity to discuss ongoing successes and challenges), daily self-monitoring of body weight (with entry to an online database that displayed a graph over time and monthly e-mails that provided personalized feedback and encouragement), self-monitoring of dietary intake [using the MyFitnessPal app (myfitnesspal.com) daily for the first month and for 1 wk per month for months 2–12], or hunger training (where participants are taught to eat only when blood glucose is below a certain level) (18). As part of the study design, participants were able to choose whether to follow a Mediterranean, IF, or Paleo diet, allowing us to examine how being able to choose which diet to follow affected long-term adherence, dietary intake, and health outcomes. Participants were also able to choose 1 of 2 exercise interventions: following standard recommendations or a home-based high-intensity interval training (HIIT) program (**Supplemental Table 1**).

Overweight but otherwise healthy adults were recruited by advertisement between November 2014 and April 2015, with interested subjects first undertaking online screening to check eligibility [age ≥18 y, self-reported BMI (in kg/m^2) of ≥27, and residing in the locality]. Participants at high risk of a cardiovascular event were excluded based on a modified American Heart Association/American College of Sports Medicine health/fitness facility pre-participation questionnaire (19, 20). If deemed eligible, participants attended a physical screening to measure height, weight, blood pressure, and blood glucose (finger-prick blood sample after a 12-h fast using a portable glucometer to check for undiagnosed diabetes). Exclusion criteria were as follows: type 1 or 2 diabetes; any significant systemic disease or disorder including malignancy, inflammatory, or endocrine conditions; pregnancy or breastfeeding; BMI <27; systolic blood pressure >160 mm Hg or diastolic blood pressure >100 mm Hg; or fasting blood glucose >7 mmol/mol. In order to be representative of the target population, participants with managed depression or anxiety, impaired glucose tolerance, unmedicated stage 1 hypertension, hyperlipidemia, and controlled asthma were included. Potential participants attended a screening appointment to confirm eligibility. Once baseline measures had been obtained and participants had chosen which diet and exercise plan they wished to follow, random assignment to an intervention arm (control or 1 of 4 monitoring strategies) was performed using sequentially numbered, opaque, sealed envelopes prepared by the statistician, stratified by sex and random-length blocks.

Dietary interventions

Following baseline assessments, participants chose whether to follow the Mediterranean diet, IF using the 5:2 method (normal intake for 5 d/wk, markedly reduced energy intake for 2 d/wk) (21), or a modified Paleo diet (22) before being randomly assigned to a monitoring strategy (17, 18). These diets were chosen due to their popularity, effectiveness for weight loss, and diversity in macronutrient ratios and protocols. Participants were initially provided with information on all 3 diet options to allow them to choose which one suited them best but were not permitted to change diets during the study. Trained researchers (dietitian, medical doctor) advised participants on how to follow their chosen diet and exercise plan in 1 face-to-face session (30 min) at baseline. Extensive written resources were provided for each diet plan, plus a comprehensive resource outlining a variety of behavioral weight-loss strategies known to influence weight-loss success, including goal setting, improving sleep, stress management, grocery shopping, problem solving, and time management (23).

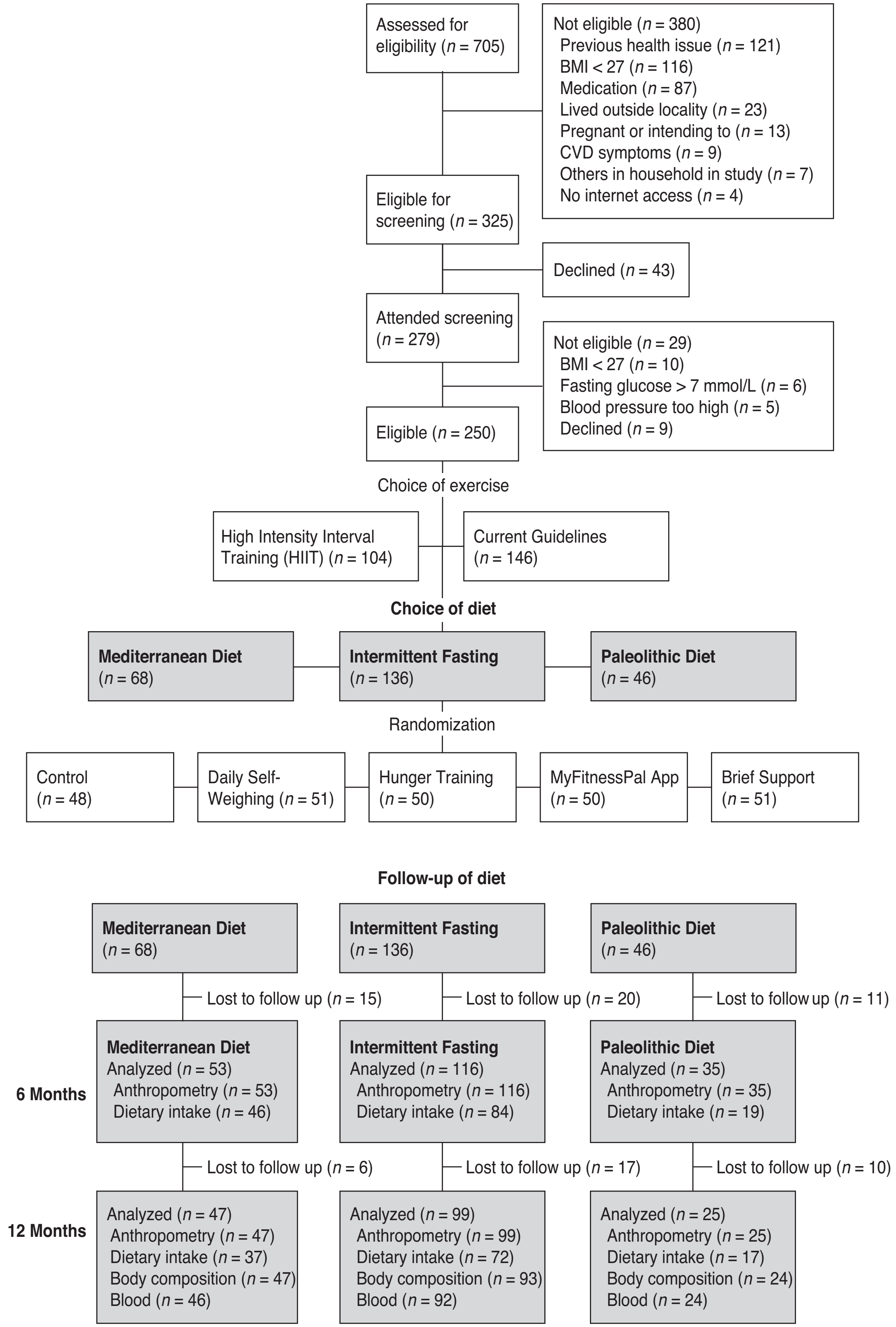

FIGURE 1 Flow of participants through the study. CVD, cardiovascular disease.

The Mediterranean diet was modeled on the Healthy Eating pyramid by the Harvard School of Public Health (24). The emphasis was on high amounts of fruit, vegetables, whole-grain breads and cereals, legumes, nuts, seeds, and olive oil, with moderate amounts of fish, chicken, eggs, and dairy, and red meat once per week or less. If participants chose to drink alcohol, the recommendation was ≤1 glass (or 2 for men) of wine per day with meals. Foods to avoid included butter, refined grains, and sugary foods and drinks.

For those following IF, energy intake was limited to 500 kcal for women and 600 kcal for men (usual daily intake: 1800–3000 kcal) on 2 self-selected days per week ("fasting days"), with participants eating ad libitum on the other 5 days ("nonfasting days"). In order to improve adherence, fasting days could be consecutive or nonconsecutive and vary week to week. Participants could choose the number and composition of the meals within their fasting periods; however, meals rich in protein and low-carbohydrate vegetables were recommended for satiety. The diet on the nonfasting days was not dictated, other than a general recommendation to eat a sensible healthy diet.

The Paleo diet consisted of predominantly less-processed foods, with an emphasis on eating fruit and vegetables, animal protein, coconut products, butter, and extra-virgin olive oil. Occasional ("eat some") foods included nuts and seeds (partly limited because they are energy dense and widely available), dairy [≤1 serving/d, introduced because of concern regarding calcium intakes (25)], legumes [≤1 serving/d (26), some hunter-gatherer societies consumed legumes in small amounts], dark chocolate, honey, and fresh juices from fruits and vegetables. Foods to limit included all grains (both whole grains and refined grains), processed seed oils (e.g., canola, margarines), sugar, other sweeteners, and soft drinks. While original "Paleo" diets strictly excluded all legumes, dairy, and grains, this modified version was intended to be more of a "whole foods" approach so some full-fat dairy could be included , as well ≤1 serving/d of legumes and grain-based foods. This was to improve adherence and to allow a wider intake of foods and nutrients, while still embracing the general philosophy of eating natural, unprocessed hunter-gatherer–type foods (25, 26).

Outcome measurements

All measures were taken by research assistants blinded to intervention (monitoring strategy) or diet group allocation. Demographic data were only collected at baseline. Anthropometric measures, blood pressure, physical activity, dietary intake, and questionnaire data were collected at 0, 6, and 12 mo. Measures of body composition and blood markers were taken at 0 and 12 mo only.

Questionnaires were completed by all participants to assess the demographic characteristics age, sex, ethnicity, education, and employment status using questions from the New Zealand census (stats.govt.nz/Census). Dietary intake was assessed at all 3 time points using weighed diet records (27). At baseline, all participants completed 3 d of records. At 6 and 12 mo, those following Mediterranean and Paleo diets completed another 3 d of records, whereas those following IF completed 4 d: 2 fasting and 2 nonfasting days. Records were checked upon return and any missing or unclear data was clarified by telephone. Food intake was converted to energy and nutrient intakes using Kai-culator software (University of Otago, Dunedin, New Zealand), which used the New Zealand Food Composition Database (www.foodcomposition.co.nz). To calculate average daily intakes for the IF diet, dietary data from fasting and nonfasting days were averaged with weighting by the reported number of days per week that a participant fasted. At 6 and 12 mo, participants were asked which diet (if any) they were following (to check whether they were still following the diet they initially chose) and specific questions related to that diet to assess adherence to dietary guidelines. Adherence to the physical activity intervention was measured using heart rate monitors worn during purposeful HIIT sessions in those who chose to follow HIIT, and in all participants using 7-d accelerometry (Supplemental Table 1) (28).

Dietary quality was assessed using the NOVA classification. All food items and recipes listed in the weighed diet records were categorized using the NOVA system for classifying foods according to their degree and purpose of processing (29). The NOVA classification has 4 categories: un- or minimally processed food, processed culinary ingredient, processed food, or ultra-processed food. Individual food items were each placed directly into 1 of the 4 categories, and recipes were disaggregated and proportioned by ingredient weight across the 4 categories. For each participant, daily averages of energy intake and percentage energy intake for each of the NOVA categories were calculated. For consistency, 1 researcher (LJF) was responsible for all NOVA categorization, with other researchers being consulted for a consensus in cases in which the classification of an item or ingredient was initially unclear.

At 6 and 12 mo, participants were asked to rate their enjoyment of their chosen diet with the Diet Score (30), which had a Cronbach's α of 0.80. Participants rated the diet they were following on a 10-point scale with regard to hunger, cravings, meal preparation, ease of following the diet at home and away from home, food variety, expense, physical well-being, and satisfaction with the diet. The total score was a sum of the responses to the 10 items, which could range from 10 to 100.

Duplicate measures of height (Heightronic; QuickMedical), weight (Tanita BC-418; Tanita Corp), waist circumference (nonelastic tape), and blood pressure (Omron HEM-907 automated sphygmomanometer; Omron Corp) were assessed using standard procedures (31), with a third measure taken if the first 2 measures differed by >1%. Average values were then calculated, with the 2 closest values used if a third measure was taken. DXA (GE Lunar Prodigy; GE Healthcare) was used to measure body composition, with visceral fat volume estimated using the Lunar Encore software CoreScan (version 16; GE Healthcare) (32). Physical activity levels were assessed by ActiGraph accelerometers (GT3X; ActiGraph), which were worn continuously for 7 d, initialized using 15-s epochs, with data analyzed using an automated program (available from the authors upon request) developed in MATLAB (MathWorks) (33).

Venous blood samples were collected by a registered nurse following a 12-h fast. Glycated hemoglobin (HbA1c) was measured by enzymatic methods on a Cobas Mira Plus Analyzer (Roche Diagnostics). High-sensitivity C-reactive protein (CRP) was measured using a CRP Unimate kit (Roche Diagnostics), and acylated ghrelin was assessed via immunoassay (Human Gut Hormone Panel LINCOplex Kit; LINCO Research). Plasma total cholesterol, HDL-cholesterol, and triglyceride concentrations were ascertained by enzymatic methods using a Cobas Mira Plus Analyser, and LDL-cholesterol concentrations were derived using the Friedewald formula (34).

Statistical analysis

The original randomized controlled trial was powered to detect a 4-kg difference in weight change between any 2 randomized groups with ≥42 participants in each group. Post hoc power calculations were not undertaken because this article refers to secondary exploratory analyses (35) for which dependence on "statistical significance" (i.e., $P < 0.05$) is not ideal (36). All statistical analysis was undertaken on Stata 15.1 (Stata Statistical Software; StataCorp LLC). The analysis was based on intention to treat. Differences between all 3 groups at baseline were described and assessed with either a chi-square test (for categorical variables) or linear regression (for continuous variables).

To describe the diets in terms of energy, nutrient, and processed food intake at 6 and 12 mo, mean intakes were determined for each diet and differences between all 3 diets assessed using ANCOVA, adjusting for baseline intake. The same analysis was carried out to describe differences in physical activity between groups.

For the weight and blood outcomes, mean differences in change from baseline were estimated using mixed-effects regression models with an interaction term between diet and time, and participant as a random effect. All models to estimate change were adjusted for age, sex, exercise group, randomized support group, and physical activity, but not energy intake as our objective was to estimate differences in outcomes between the diets, not to estimate differences in outcomes between the diets independent of energy intake. Mean changes and 95% CIs were calculated for each diet group along with a P value from a Wald test of the interaction term between diet group and time. Residuals for models were plotted and visually assessed for homogeneity of variance and normality.

Sensitivity analyses were undertaken to determine if differences in outcomes were sensitive to adherence to diet, and to missing values. Because missing data may be "missing not at random," missing weight data were imputed to baseline values, providing a conservative estimate of the effect of diet choice (37).

Results

IF was the most popular option, chosen by 54% of participants over Mediterranean (27%) or Paleo (18%) diets (**Table 1**). While a greater proportion of men chose to follow IF rather than Paleo (44.8% vs 26.1%), choice of diet was not strongly associated with any other demographic or physical characteristics, except for exercise choice. Because fewer participants in the Mediterranean group tended to choose HIIT (21 of 68 participants; 30.9%) than in the IF (60 of 136 participants; 44.1%) or Paleo (23 of 46 participants; 50%) groups, exercise group was adjusted for in all subsequent analyses.

Although overall study retention was 82% at 6 mo and 68% at 12 mo (Figure 1), only approximately half of those who chose the Mediterranean ($n = 39/68$) or IF (73/136) diets were still adhering to their respective diets, and only one-third of people reported adherence to the Paleo diet ($n = 16/46$) by 12 mo. Participants following the Mediterranean diet were generally adherent in terms of using olive oil as their main oil, limiting red meat intake to a few times a week or less, and consuming nuts or seeds at least weekly, but only one-third of participants avoided processed meat and white varieties of bread or cereal (**Figure 2**A). Most IF participants reported fasting the recommended 2 d/wk at 6 (81/106, 76.4%) and 12 (54/74, 73.0%) mo. However, relatively few managed to meet the calorie targets for men (<600 kcal/d) or women (<500 kcal/d) at either 6 mo (12/34 or 35.3% of men and 14/43 or 32.6% of women) or 12 mo (12/32 or 37.5% of men and 9/32 or 28.1% of women). Mean (SD) energy intakes on fasting days were 784 (402) kcal at 6 mo and 786 (380) kcal at 12 mo. On nonfasting days, participants consumed an average of 2001 (788) kcal at 6 mo and 1902 (574) kcal at 12 mo. Participants tended to forgo breakfast and lunch more than dinner on fasting days (Figure 2B). Most participants following the modified Paleo diet avoided eating breakfast cereals, sweetened drinks, and margarine and seed oils, and consumed animal protein daily, but continued to consume grains and sugar/sweet food at least weekly (Figure 2C). There were no differences in overall diet scores between diets at 6 mo [mean (SD): 67 (12) for the Mediterranean diet, 65 (15) for IF, and 64 (15) for the Paleo diet; $P = 0.567$]. Similarly, diet scores at 12 mo were comparable between groups [mean (SD): 71 (13) for the Mediterranean diet, 67 (13) for IF, and 65 (17) for the Paleo diet; $P = 0.483$].

Dietary intake was analyzed regardless of whether the participant reported adhering to his/her diet using intention-to-treat analysis. As **Table 2** demonstrates, some minor dietary differences were observed at baseline, principally demonstrating that those who chose to follow the Paleo diet already consumed a diet that aligned with the Paleo philosophy by having lower intakes of carbohydrates and ultra-processed foods. Participants following the Mediterranean diet consumed more fiber and calcium despite not having significantly higher energy intakes. Energy intakes decreased in all diet groups but were most different at 12 mo, with IF followers having lower energy intakes than participants following the other 2 diets. Fat intakes differed across diets, with Paleo participants consuming more fat and less carbohydrate, although the lowest intakes of fiber were observed in those following IF. In terms of the NOVA classification, those following the Paleo diet obtained a lower proportion of their energy intake from ultra-processed foods than both other groups, particularly at 6 mo when adherence was higher. However, at 12 mo, group differences were attenuated for the consumption of ultra-processed foods, and for other categories of processing (Table 2). Differences in change in physical activity between groups were also evident (Table 2), with those following IF showing greater increases than the other 2 groups. Physical activity was therefore included in all models assessing health outcomes.

The Wald tests in **Table 3** illustrate that no statistically significant differences were observed between the 3 diets in terms of changes in body composition or physical outcomes over time. All diet groups lost weight at 6 mo, but continued weight loss was observed only in the IF (mean change: −4.0 kg; 95% CI: −5.1, −2.8 kg) and Mediterranean (mean change: −2.8 kg; 95% CI: −4.4, −1.2 kg) groups at 12 mo. At 12 mo, decreases in body fat, visceral fat, waist circumference, and diastolic blood

TABLE 1 Baseline characteristics of participants choosing different diets[1]

Variable	Mediterranean	IF	Paleo	P[2]
Choice of diet, n (%)	68 (27.2)	136 (54.4)	46 (18.4)	
Randomized monitoring strategy, n (%)				0.976
Control	11 (16.2)	28 (20.6)	9 (19.6)	
MyFitnessPal app	13 (19.1)	27 (19.9)	10 (21.7)	
Brief support	13 (19.1)	28 (20.6)	10 (21.7)	
Hunger training	17 (25.0)	24 (17.7)	9 (19.6)	
Self-weighing	14 (20.6)	29 (21.3)	8 (17.4)	
Exercise type, n (%)				0.069
Current guidelines	47 (69.1)	74 (54.4)	23 (50.0)	
HIIT	21 (30.9)	60 (44.1)	23 (50.0)	
Female, n (%)	46 (67.7)	75 (55.2)	34 (73.9)	0.041
Age, y	44.2 (11.7)	43.9 (11.1)	42.6 (9.6)	0.721
Ethnicity, n (%)				0.201
New Zealand European and others	63 (92.7)	129 (94.9)	40 (87.0)	
Māori	5 (7.4)	7 (5.2)	6 (13.0)	
University degree, n (%)	44 (64.7)	72 (52.9)	22 (47.8)	0.151
Partnered, n (%)	58 (85.3)	112 (82.4)	36 (78.3)	0.626
Had previously dieted, n (%)	52 (76.5)	103 (75.7)	36 (78.3)	0.941
Weight, kg	93.6 (16.4)	96.5 (15.0)	97.6 (19.1)	0.368
BMI, kg/m^2	32.5 (4.1)	32.9 (4.2)	34.1 (5.3)	0.161
Weight status, n (%)				0.686
Overweight (BMI ≥25 but <30)	21 (30.8)	36 (26.5)	11 (23.9)	
Obese (BMI ≥30)	47 (69.1)	100 (73.5)	35 (76.1)	
Percentage body fat, %	40.4 (7.5)	39.4 (7.6)	41.0 (6.6)	0.411
Visceral fat, cm^3	1429 (957)	1534 (930)	1281 (979)	0.282
Systolic blood pressure,[3] mm Hg	122 (14)	126 (16)	121 (14)	0.166
Diastolic blood pressure,[3] mm Hg	78 (10)	79 (10)	79 (11)	0.686
Estimated $\dot{V}O_2$ max, mL· kg^{-1} · min^{-1}	28.3 (7.2)	28.7 (6.3)	28.6 (6.5)	0.908
Physical activity, counts/min	349 (131)	325 (103)	328 (103)	0.345
HbA1c, mmol/mol	33.8 (3.2)	33.4 (2.7)	33.3 (3.0)	0.533
hs-CRP, median (25th, 75th percentile), mg/L	1.5 (0.7, 3.1)	1.4 (0.7, 3.5)	1.5 (0.8, 3.0)	0.921
Total cholesterol, mmol/mol	5.3 (0.8)	5.5 (1.1)	5.4 (1.0)	0.419
LDL cholesterol, mmol/mol	3.4 (0.8)	3.6 (1.0)	3.4 (0.9)	0.205
HDL cholesterol, mmol/mol	1.3 (0.3)	1.3 (0.3)	1.4 (0.4)	0.185
TGs, mmol/mol	1.4 (0.5)	1.4 (0.5)	1.4 (0.7)	0.921
Ghrelin, pg/mL	47 (14)	50 (19)	49 (15)	0.675

[1]Values are means (SDs) unless otherwise indicated; $n = 250$. HbA1c, glycated hemoglobin; HIIT, high-intensity interval training; hs-CRP, high-sensitivity C-reactive protein; IF, intermittent fasting; Paleo, Paleolithic; TG, triglyceride; $\dot{V}O_2$ max, maximal oxygen uptake.

[2]Comparison across all 3 diet groups analyzed using chi-square test (categorical variables) or linear regression (continuous variables), except for hs-CRP, which was analyzed using median regression as the data were skewed.

[3]One missing blood pressure measure from the Mediterranean group, 5 missing physical activity data (3 from IF, 1 each from Paleo and Mediterranean).

pressure were evident in all groups, whereas reductions in systolic blood pressure were only observed in the IF (mean change: −4.9 mm Hg; 95% CI: −7.2, −2.6 mm Hg) and Mediterranean (mean change: −5.9 mm Hg; 95% CI: −9.0, −2.7 mm Hg) diet groups at 12 mo.

There were only minor changes in the groups at 12 mo (**Table 4**). Participants in the Mediterranean group exhibited the greatest mean reduction ($P = 0.036$) in HbA1c (−0.8 mmol/mol; −1.2, −0.4 mmol/mol). There were no meaningful changes in measures of cholesterol, systemic inflammation (indicated by high-sensitivity CRP), triglycerides, or ghrelin.

Sensitivity analyses (**Supplemental Table 2**) for missing data showed that group mean effects of the diet choice on weight loss may be overestimated by as much as 1.0 to 1.2 kg if all missing values were assumed to have no weight loss. All estimates of change were attenuated in these sensitivity analyses, but differences between the diets became more marked, mostly likely because the drop-out rate was higher in the Paleo group and, to a lesser extent, the Mediterranean group.

Further sensitivity analyses (**Supplemental Table 3**) showed that, when using data only from adherent participants, estimated mean weight loss was increased by 1.8 kg (Mediterranean), 1.1 kg (IF), and 0.3 kg (Paleo). In adherent participants, the Paleo diet showed the least weight loss compared with the other 2 diets.

Discussion

Adherence to dietary change declines rapidly over time in overweight participants without regular dietetic input, with just 35–57% of participants continuing to follow their chosen diet at 12 mo. However, even a single dietary education session (alongside support strategies) can produce weight loss over 12 mo, although absolute differences were only modest. Similar

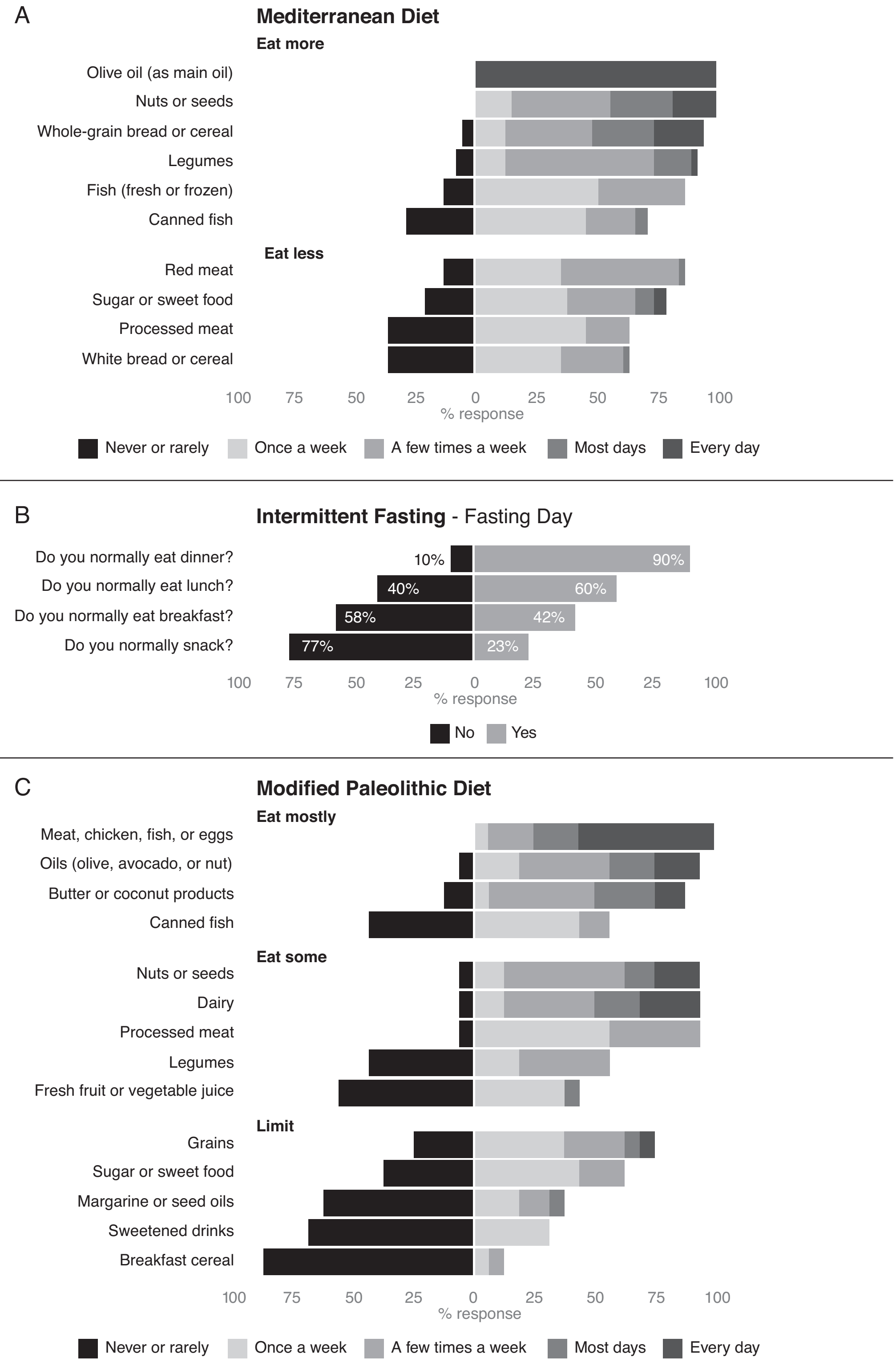

FIGURE 2 Adherence at 12 mo for each diet. (A) Food-group intake at 12 mo of those who chose to follow the Mediterranean diet ($n = 39$). (B) Meal consumption on fasting days at 12 mo for those who chose to follow the intermittent fasting diet ($n = 73$). (C) Food-group intake at 12 mo of those who chose to follow the Paleolithic diet ($n = 16$).

small decreases in waist circumference and percentage body fat were observed in all diet groups.

Adherence to the Mediterranean diet guidelines was high, as has been observed previously (38). By contrast, although most IF participants did fast 2 d/wk, very few were able to restrict energy intakes to the recommended amount, supporting earlier work (4). In reality, this is likely to be even lower given general issues with underreporting in diet records (39). However, IF did lead to a

TABLE 2 Dietary adherence and energy and nutrient intakes at baseline and 6 and 12 mo by chosen diet[1]

Variable and month	Mediterranean	IF[2]	Paleo	Difference between diets, *P*[3]
Still in study, *n* (%)				
6	53 (77.9)	116 (85.3)	35. (76.1)	0.250
12	46 (67.6)	99 (72.8)	25 (54.3)	0.068
Physical activity, cpm				
6	323 (115)	326 (117)	322 (119)	0.143
12	335 (112)	370 (143)	320 (91)	0.045
Dietary adherence, *n* (%)				
6	49 (72.1)	105 (77.2)	30 (65.2)	0.431
12	39 (57.4)	73 (53.7)	16 (34.8)	0.059
Participants with diet records, *n*				
0	68	128	45	
6	46	84	19	
12	37	72	17	
Energy, kcal				
0	2383 (731)	2211 (631)	2083 (704)	0.058
6	1794 (557)	1706 (676)	1696 (574)	0.446
12	1897 (524)	1644 (492)	1711 (537)	0.008
Protein, % of energy				
0	17 (4)	17 (3)	18 (4)	0.133
6	19 (4)	19 (4)	21 (4)	0.331
12	18 (5)	20 (4)	21 (5)	0.030
Fat, % of energy				
0	36 (7)	36 (6)	40 (8)	0.009
6	37 (6)	35 (7)	46 (10)	<0.001
12	36 (4)	35 (7)	45 (10)	<0.001
Monounsaturated fat, % of energy				
0	13 (3)	13 (3)	16 (3)	<0.001
6	14 (4)	13 (3)	19 (5)	<0.001
12	13 (3)	13 (3)	18 (6)	<0.001
Polyunsaturated fat, % of energy				
0	5 (2)	5 (2)	6 (2)	0.020
6	6 (2)	5 (1)	8 (3)	<0.001
12	6 (2)	5 (2)	7 (2)	<0.001
Saturated fat, % of energy				
0	14 (4)	14 (3)	14 (4)	0.982
6	14 (3)	13 (3)	16 (5)	0.005
12	12 (3)	13 (3)	15 (4)	0.011
Carbohydrates, % of energy				
0	45 (8)	45 (7)	40 (8)	0.001
6	43 (8)	44 (9)	32 (10)	<0.001
12	45 (7)	44 (9)	33 (9)	<0.001
Fiber, g				
0	29 (17)	25 (9)	23 (10)	0.010
6	24 (9)	19 (8)	23 (9)	<0.001
12	26 (9)	19 (7)	24 (11)	<0.001
Sodium, mg				
0	2840 (1128)	2773 (1114)	2724 (2152)	0.902
6	2377 (953)	2057 (945)	1616 (589)	0.004
12	2087 (833)	2035 (818)	1838 (649)	0.497
Calcium, mg				
0	1141 (622)	957 (369)	913 (378)	0.011
6	987 (508)	783 (356)	695 (299)	0.001
12	950 (383)	720 (301)	823 (492)	0.001
Iron, mg				
0	14 (7)	13 (4)	13 (4)	0.079
6	11 (4)	10 (4)	11 (5)	0.067
12	12 (4)	10 (4)	12 (4)	0.018
NOVA classification, % of energy				
Ultra-processed food				
0	44.6 (13.7)	44.7 (14.2)	36.6 (17.1)	0.004
6	35.0 (13.0)	38.1 (13.9)	19.5 (18.5)	0.001
12	35.9 (12.2)	39.3 (14.4)	28.0 (19.6)	0.055

(*Continued*)

TABLE 2 (*Continued*)

Variable and month	Mediterranean	IF[2]	Paleo	Difference between diets, *P*[3]
Processed food				
0	11.1 (6.7)	11.9 (8.2)	13.3 (8.1)	0.317
6	12.6 (6.7)	11.3 (8.2)	10.7 (5.1)	0.115
12	13.0 (8.8)	12.0 (8.3)	11.1 (9.3)	0.284
Minimally processed food				
0	39.0 (12.0)	38.0 (12.8)	45.5 (16.2)	0.005
6	47.6 (12.6)	45.6 (14.0)	63.7 (17.4)	<0.001
12	46.8 (15.5)	44.4 (15.3)	57.1 (15.9)	0.052
Culinary ingredients				
0	5.4 (4.1)	5.4 (4.0)	4.6 (4.0)	0.464
6	4.7 (3.3)	5.0 (4.1)	6.1 (4.2)	0.131
12	4.3 (3.7)	4.3 (3.8)	3.8 (3.1)	0.924

[1]Values are means (SDs) unless otherwise indicated. cpm, counts per minute; IF, intermittent fasting.
[2]Average IF day weighed by the reported number of days that each participant fasted.
[3]Comparison between all 3 diet groups at 0 mo analyzed using ANOVA; 6- and 12-mo differences analyzed using ANCOVA adjusted for baseline intake.

greater overall energy deficit and weight loss than the other diets, even with these modest adherence rates. Although participants were advised to follow a "sensible" diet on their nonfasting days, IF participants had the highest intakes of ultra-processed foods and lowest intakes of fiber at 12 mo, with lower fiber intakes also reported previously (4, 6). Greater attention to good fiber sources is relevant, given their role in preventing chronic disease and encouraging satiety (12). It is not surprising that Paleo consumers had the lowest consumption of ultra-processed foods, given that this is a primary tenet of the Paleo diet approach (9). It was also reassuring to see that previous concerns regarding inadequate intakes of fiber and calcium (13) were not observed with our more lenient Paleo diet.

Despite some evidence from controlled trials indicating that Paleo diets (10, 40) and IF (41) can produce superior weight loss, fat reduction, and metabolic improvements compared with standard guidelines, we observed more modest outcomes. This may have arisen because our Paleo diet was more lenient than that typically tested, although this seems unlikely given previous research showing a modified Paleo diet to have physiological benefits similar to a more restrictive option (22). Our modest outcomes more likely reflect the difficulties of consistently adhering to diets in a free-living environment without intensive ongoing support. As others have shown, the nature of dietary recommendation (i.e., macronutrient composition) appears largely irrelevant over the longer term (42–44), with adherence to a

TABLE 3 Changes in body composition and physical outcomes by diet group

	Mediterranean ($n = 68$)		Intermittent fasting ($n = 133$)		Paleo ($n = 46$)		
Variable and month	*n*	Mean change from baseline (95% CI)	*n*	Mean change from baseline (95% CI)	*n*	Mean change from baseline (95% CI)	Comparison between diets, *P*[1]
Weight, kg							
6	53	− 2.1 (−3.7, −0.6)	116	− 4.2 (−5.2, −3.2)	35	− 2.8 (−4.8, −0.9)	0.067
12	47	− 2.8 (−4.4, −1.2)	99	− 4.0 (−5.1, −2.8)	25	− 1.8 (−4.0, 0.5)	0.167
Body fat, %							
12	47	− 1.9 (−2.8, −0.9)	93	− 1.6 (−2.4, −0.9)	24	− 1.6 (−3.0, 0.2)	0.939
Visceral fat, cm^3							
12	46	− 252 (−397, −108)	93	− 243 (−351, −136)	24	− 182 (−388, 25)	0.846
Waist circumference, cm							
6	53	− 2.8 (−4.5, −1.2)	116	− 4.1 (−5.2, −3.0)	35	− 3.5 (−5.6, −1.4)	0.419
12	47	− 4.0 (−5.7, −2.3)	99	− 3.9 (−5.2, −3.0)	25	− 2.4 (−4.8, −0.02)	0.499
Systolic blood pressure, mm Hg							
6	52	− 3.0 (−6.0, 0.1)	115	− 0.9 (−3.0, 1.1)	35	− 3.0 (−6.9, 0.8)	0.444
12	46	− 5.9 (−9.0, −2.7)	99	− 4.9 (−7.2, −2.6)	25	− 1.6 (−6.0, 2.7)	0.296
Diastolic blood pressure, mm Hg							
6	52	− 2.6 (−4.8, −0.3)	115	− 1.7 (−3.3, 0.2)	35	− 2.5 (−5.4, 0.4)	0.794
12	46	− 3.3 (−5.6, −0.9)	99	− 2.9 (−4.6, −1.2)	25	− 3.1 (−6.4, −0.2)	0.967

[1]Outcomes were analyzed using mixed-effects regression models, with a random effect for participant and an interaction term between diet group and time, adjusting for age, sex, exercise group, randomized support group, physical activity (counts per minute), and baseline. *P* values for overall difference between diet groups at each time are from a Wald test of the diet group and time interaction term.

TABLE 4 Changes in circulating biomarkers at 12 mo by diet group[1]

	Mediterranean (n = 68)		Intermittent fasting (n = 133)		Paleo (n = 46)		
Variable	n	Mean change from baseline (95% CI)	n	Mean change from baseline (95% CI)	n	Mean change from baseline (95% CI)	Comparison between diets, P[2]
HbA1c, mmol/mol	46	− 0.8 (−1.2, −0.4)	92	− 0.2 (−0.5, 0.1)	24	− 0.2 (−0.7, 0.3)	0.036
hs-CRP, mg/L	46	− 0.2 (−0.8, 0.4)	92	0.0 (−0.4, 0.5)	24	0.0 (−0.8, 0.9)	0.800
Total cholesterol, mmol/mol	46	− 0.3 (−0.5, −0.1)	92	− 0.1 (−0.2, 0.01)	24	− 0.3 (−0.6, −0.02)	0.188
LDL cholesterol, mmol/mol	46	− 0.2 (−0.4, −0.03)	92	− 0.1 (−0.2, 0.01)	24	− 0.3 (−0.6, −0.01)	0.144
HDL cholesterol, mmol/mol	46	− 0.01 (−0.07, 0.05)	92	0.06 (0.02, 0.10)	24	0.06 (−0.02, 0.14)	0.139
TGs, mmol/mol	46	− 0.1 (−0.2, 0.1)	92	− 0.2 (−0.3, −0.1)	24	− 0.2 (−0.4, 0.04)	0.716
Ghrelin, pg/mL	45	− 0.7 (−6.5, 5.2)	92	0.5 (−3.8, 4.8)	24	4.9 (−3.1, 12.9)	0.531

[1]HbA1c, glycated hemoglobin; hs-CRP, high-sensitivity C-reactive protein; TG, triglyceride.

[2]Changes in circulating biomarkers were analyzed using mixed-effects regression models, with a random effect for participant and an interaction term between diet group and time, adjusting for age, sex, exercise group, randomized support group, physical activity (counts per minute), and baseline. P values for overall difference between diet groups at each time are from a Wald test of the diet group and time interaction term.

specified diet seeming more important for long-term weight-loss success (45).

It is noteworthy that the Mediterranean diet resulted in marginally better blood glucose control than IF or Paleo diets in the current study. Although benefits of the Mediterranean diet on glycemic control are well documented (2, 46), recent work has indicated that IF could produce superior results for fasting insulin and insulin sensitivity (6, 41, 47). Clearly, food choice while following fasting diets is important given that, although our SWIFT participants did manage to reduce their energy intake, they consumed less fiber and a greater proportion of ultra-processed foods than the other diets, potentially reducing any favorable impact of fasting on blood glucose. It may be that Mediterranean-type diets, which recommend selecting less-processed and higher-quality foods, may be a more realistic intervention to improve blood glucose control if fasting cannot be sustained long term or as part of a consistently healthy diet.

However, both IF and the Mediterranean diets were associated with clinically significant reductions in systolic blood pressure at 12 mo, more so than was observed in those following the Paleo diet. This is likely to be a consequence of the weight loss, and is also consistent with other work showing that Mediterranean and plant-based diets may lead to improvements in blood pressure (42, 48). Increasing the intake of fruit and vegetables can lead to meaningful reductions in blood pressure due to a greater intake of potassium and reduction in sodium amounts (49). The lower carbohydrate intake recorded by the Paleo SWIFT participants may indicate lower intakes of potassium-rich plant-based foods, such as legumes, given that the latter, in particular, are restricted.

Strengths of this study include the large number of participants, the use of researchers blinded to intervention or diet group for outcome assessment, the relatively long duration for a diet intervention, and the study design, which allowed participants to choose their diet, more realistically representing real-world implementation. Our results are therefore directly relevant to the thousands of people following weight-loss diets with little supervision and are more indicative of the likely outcomes of public health diet recommendations. Accurate assessment of body composition was undertaken using DXA, and the use of NOVA classification adds an indication of diet quality that is useful for comparing the degree of processed foods in each diet.

However, this study also has some limitations. Overall attrition was relatively high at 31.6%, and dropout was different across diets and intervention arms, which may have influenced findings. In particular, few continued to follow the Paleo diet and were likely different than those who dropped out. While intentional, participants were not randomly assigned to diet groups, so despite minimal differences between the diet groups at baseline, it is possible that both known and unknown variables influenced outcomes. This is also relevant to choice of exercise group, particularly given that variation in exercise modality was observed across diet groups, with fewer participants in the Mediterranean group choosing to try the HIIT option. While we had excellent completion of diet records at baseline, the rates at 6 and 12 mo were lower and may have affected results. Furthermore, bias in reporting is a known issue with diet records, particularly for weight-loss studies and for questionnaires such as those used to assess self-reported adherence to dietary goals. As both diet and health are assessed with numerous outcome measures, the chance of type 1 error is relatively high. However, conclusions have been made without relying on P values alone.

In summary, overweight adults who chose to undertake Mediterranean, IF, or Paleo diets in a real-world setting were only moderately adherent over time, leading to modest benefits after 12 mo, with IF and Mediterranean diets leading to greater weight loss. The Mediterranean diet was associated with a marginal improvement in glycemic control, which supports current evidence for regular consumption of whole plant-based foods (50). This study provides evidence that, in the real-world environment, IF and Mediterranean diets can be effective for weight loss, and any of these dietary approaches may positively influence health.

The authors' responsibilities were as follows—RWT: is the principal investigator of SWIFT and designed the project along with HO, MRJ, MR, and RCB; MRJ, MR, KM-J, LJF, and EAF: conducted the research; JJH: designed and undertook the statistical analyses; MRJ and MR: wrote the first and subsequent drafts of the manuscript and are joint first authors; RWT: has primary responsibility for final content; and all authors: critically revised the manuscript for important intellectual content and read and approved the final manuscript. The authors report no conflicts of interest.

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