

SHORT COMMUNICATION

Predictive equations highlight limitations of self-reported dietary adherence in a randomized, controlled, plant-based feeding intervention

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Citation: Moore CJ, Yan F, Staimez LR, Badri K, Rooke J. Predictive equations highlight limitations of self-reported dietary adherence in a randomized, controlled, plant-based feeding intervention. *J Clin Transl Res*.
doi: 10.36922/JCTR026030005

Received: January 13, 2026

Revised: June 24, 2026

Accepted: July 1, 2026

Published online: July 15, 2026

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Abstract

Background: Randomized controlled feeding trials are ideal for studying diet-disease relationships, but interpreting results requires accurate dietary adherence measures. **Aim:** This study assesses dietary adherence using self-reported measures and estimates from predictive equations in the National Institute of Diabetes and Digestive and Kidney Diseases Body Weight Planner and evaluates differences in adherence across diet treatments and study periods in a feeding trial. **Methods:** In a randomized, counterbalanced, crossover trial, 12 African American adults with prediabetes or early, untreated type 2 diabetes received either a plant-based diet (PBD) or an isocaloric control diet for eight weeks, followed by a washout period and the alternate diet. Primary measures included self-reported dietary adherence and estimates of actual caloric intake using predictive equations. T-tests evaluated differences by treatment and period. **Results:** Nine participants completed the study. Study completers ($n = 9$) consumed a greater caloric excess beyond the kilocalories provided by the study diets during the control treatment (480.6 ± 525.9 kcal/day) versus the PBD treatment (126.0 ± 585.4 kcal/day; $p = 0.025$) and in the second period (464.8 ± 592.4 kcal/day) versus the first period (141.8 ± 529.5 kcal/day; $p = 0.033$). Participants also reported omitting more kilocalories from the study diets during the PBD treatment (422.4 ± 289.1 kcal/day) versus the control treatment (276.4 ± 185.0 kcal/day; $p = 0.015$). **Conclusion:** Predictive equations showed significant differences in dietary adherence by treatment and period, underscoring the limitations of self-reported intake and highlighting the need for more objective measures. **Relevance for patients:** Variable adherence to study diets suggests the original study should be viewed as an effectiveness study, not an efficacy study.

Keywords: African Americans; Dietary adherence; National Institute of Diabetes and Digestive and Kidney Diseases Body Weight Planner; Plant-based diet; Randomized controlled trial

1. Introduction

Randomized controlled trials are the gold standard for establishing causal relationships between exposures and clinical outcomes,¹ and controlled feeding studies that provide the foods and beverages to be consumed during a dietary intervention period are among the best methods for evaluating diet-disease relationships.^{2,3} However, understanding the degree of dietary adherence within a controlled feeding study is critical to interpreting the validity and generalizability of study results.^{1,3,4}

In an inpatient study, direct observation and measured plate waste can be used to assess adherence to dietary protocols. Unfortunately, these studies are often cost-prohibitive and involve a high participant burden, with subjects being removed from their usual environments for the duration of the intervention.⁵ Outpatient studies deliver interventions in free-living conditions with participants receiving study foods and beverages at regular intervals and consuming the provisions in the context of their usual environments. In these studies, dietary adherence is typically monitored with daily food logs or checklists, as direct observation is not feasible⁶ and few biomarkers exist to objectively measure dietary intake.⁷ In the absence of more objective measures, some outpatient feeding studies have combined multiple methods to cross-validate dietary logs and checklists, such as weigh-back of returned food containers, measurement of select urinary biomarkers, observation of a limited number of meals, and technology-based image capture; however, these methods increase participant burden and still require participants' cooperation and transparency in collecting necessary data.^{1,3,4,6,8}

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Body Weight Planner is a validated tool that allows users to develop personalized plans for caloric intake and physical activity to maintain or reach a specified body weight.^{9,10} While this tool was designed primarily for prospective use, data can be entered retrospectively to infer caloric intake over a specific time interval.¹¹ Thus, the predictive equations within this tool can provide an independent, model-based estimate of adherence to study diets that are prescribed at specific calorie levels.

The current study evaluates dietary adherence in a small randomized controlled trial assessing the impact of a whole-food, plant-based diet (PBD) on indicators of glycemic control in an African American study population. Dietary adherence was assessed with self-reported measures from dietary adherence checklists, and predictive equations in the NIDDK Body Weight Planner were used to estimate the magnitude of caloric deviation from the provided

study diets. The objectives of this study are to compare dietary adherence data from self-reported measures with adherence estimates derived from predictive equations and to test whether adherence differed across study treatments and study periods in this outpatient, controlled feeding study.

2. Methods

The pilot study that provided the context for this analysis was a randomized controlled trial with a counterbalanced, crossover design. The study involved two eight-week dietary intervention periods, separated by a washout period ranging from 8 to 16 weeks, during which participants resumed self-selected diets. During one dietary intervention period, participants received a pre-portioned PBD that excluded all animal products. During the alternate dietary intervention period, participants received a pre-portioned, isocaloric, control diet that included animal products. Participants were randomized to one of two treatment groups, and the order of dietary periods was counterbalanced so that half received the PBD first and the other half received the control diet first (Figure 1). The Morehouse School of Medicine Institutional Review Board approved the study protocol. All study participants provided written informed consent and were compensated for their time and effort.

2.1. Study population

Eligible study participants were self-identified African American adults between 18 and 79 years of age with a measured hemoglobin A1c (HbA1c) between 5.7% and 7.0%. Individuals were excluded from the study if they were taking medications or supplements that impact blood glucose or cholesterol levels. Individuals taking permitted medications were required to maintain stable dosages for the three months prior to enrollment and throughout the study. Individuals were ineligible for the study if they were current smokers; were pregnant or lactating; received a blood transfusion within three months of the study recruitment period; were diagnosed with any stage of renal failure; had a previously diagnosed blood disorder; reported taking biotin supplements; reported food allergies or intolerances; or reported consuming a vegan, vegetarian, or other PBD within three months of the study recruitment period. All eligible study participants reported the capability to safely store a one-week supply of prepared meals and a commitment to consuming the provided food and beverages for each dietary intervention period.

A total of 12 participants were enrolled in the study. This sample size was calculated to reach 80% power to detect a 1% change in HbA1C, the primary outcome of the original study, with an anticipated attrition rate of 10%.

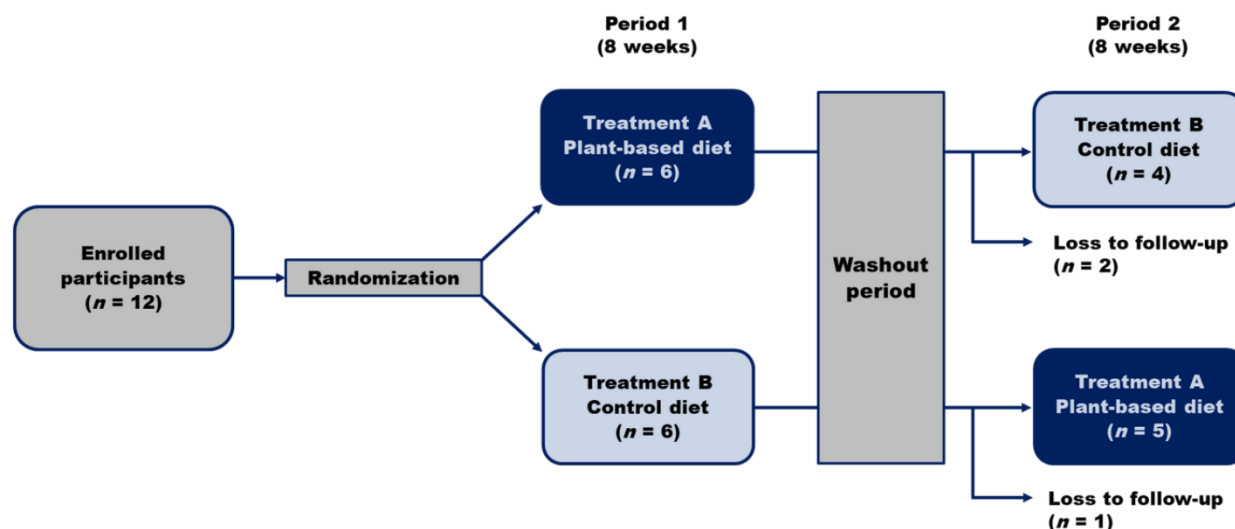


Figure 1. Counterbalanced, crossover study design showing study attrition

Participants were predominantly female ($n = 10$, 83%) with a mean age of 59.3 ± 10.3 years and a mean body mass index (BMI) of 36.2 ± 7.8 kg/m².

2.2. Study diets

Study diets were designed and analyzed by a registered dietitian nutritionist (RDN) using the Nutrition Data System for Research (NDSR) software version 2022 (University of Minnesota, United States of America [USA]). The PBD was a whole-food diet that eliminated all animal products and refined oils.¹² The control diet was an isocaloric diet that adhered to the 2020–2025 Dietary Guidelines for Americans and incorporated meat, fish, poultry, eggs, dairy products, and refined oils based on serving recommendations.¹³ In addition to meeting the defined study criteria, menus were designed to include culturally familiar foods to enhance acceptability and adherence to the study protocol. Calorie levels of the diets were based on sex assigned at birth, with females receiving an average of 1,800 kcal/day and males receiving 2,200 kcal/day. These calorie levels were based on the average estimated needs of a sedentary middle-aged female and a sedentary middle-aged male.¹³ Macronutrient levels for each diet fell within the acceptable macronutrient distribution range for fat (20–35%), protein (10–35%), and carbohydrates (45–65%).¹⁴ Menus followed two-week cycles that repeated four times during each eight-week dietary intervention period. Daily menus consisted of

three meals and one or two snacks. The average daily food weight, food group servings, and nutrient content of the diets are shown in Table 1.

2.2.1. Permitted food and beverage additions

Participants were given a case of bottled water each week to be consumed throughout the day as desired. Habitual coffee drinkers were allowed to consume coffee during each dietary intervention period; however, self-identified coffee drinkers were required to use a plant-based milk in place of creamer during the PBD intervention. Additionally, because weight loss was not a primary aim of the original study and because study participants' individual baseline caloric needs exceeded the calories provided by the study diets to varying degrees, participants were permitted to add additional servings of fruits and vegetables each day if they felt hungry after consuming the study meals. Study participants were instructed that added fruits and vegetables should not contain any added sugar, fat, or sauces, and a list of acceptable fruit and vegetable add-on choices was provided at the start of each dietary intervention period.

2.2.2. Study meal distribution

All study meals and snacks were prepared in the Metabolic Research Kitchen of the Morehouse School of Medicine Clinical Research Center (CRC) following standardized recipes. Diet components were measured, packaged, and

Table 1. Average daily food weight, food group servings, and nutrient content of the control diet and plant-based diet at each calorie level (i.e., 1,800 kcal and 2,200 kcal)

Dietary component	1,800 kcal diets				2,200 kcal diets			
	Control diet	% Daily value	Plant-based diet	% Daily value	Control diet	% Daily value	Plant-based diet	% Daily value
Energy	1,813 kcal	-	1811 kcals	-	2,200 kcal	-	2,205 kcal	-
Daily food weight	1,456 g	-	1,710 g	-	1,672 g	-	2,048 g	-
Daily fruit servings	3.3	-	4.3	-	4.5	-	5.6	-
Daily vegetable servings	4.7	-	8.1	-	5.0	-	9.5	-
Daily grain servings	5.5	-	5.3	-	6.7	-	6.3	-
Daily servings of meat, fish, poultry, eggs, nuts, and seeds	6.4	-	4.0	-	7.8	-	5.2	-
Daily dairy & non-dairy alternative servings	1.7	-	0.8	-	1.9	-	0.9	-
Daily sweets servings	0.7	-	1.8	-	0.8	-	2.0	-
Total fat	66.8 g	86%	54.6 g	70%	82.8 g	106%	68.5 g	88%
Saturated fat	18.9 g	95%	9.4 g	47%	22.8 g	114%	12.1 g	60%
Trans fat	1.1 g	-	0.1 g	-	1.2 g	-	0.1 g	-
Cholesterol	265 mg	88%	1 mg	0%	282 mg	94%	1 mg	0%
Sodium	2,650 mg	115%	2,370 mg	103%	2,932 mg	127%	2,690 mg	117%
Total carbohydrate	234.6 g	85%	299.0 g	103%	286.7 g	104%	359.0 g	131%
Dietary fiber	33.5 g	120%	50.9 g	182%	39.5 g	141%	62.4 g	223%
Soluble fiber	7.1 g	-	10.2 g	-	8.5 g	-	12.2 g	-
Insoluble fiber	23.2 g	-	40.2 g	-	27.9 g	-	49.6 g	-
Total sugars	95.3 g	-	114.9 g	-	120.1 g	-	137.8 g	-
Added sugars	33.4 g	67%	39.1 g	78%	43.2 g	86%	43.1 g	86%
Protein	84.8 g	-	58.6 g	-	98.1 g	-	72.2 g	-
% Calories from fat	32.4%	-	25.5%	-	32.9%	-	26.2%	-
% Calories from carbohydrates	49.3%	-	63.5%	-	49.8%	-	62.6%	-
% Calories from protein	18.2%	-	10.9%	-	17.3%	-	11.1%	-
Vitamin D	3.2 µg	16%	2.2 µg	11%	3.8 µg	19%	2.4 µg	12%

(Cont'd...)

Table 1. (Continued)

Dietary component	1,800 kcal diets				2,200 kcal diets			
	Control diet	% Daily value	Plant-based diet	% Daily value	Control diet	% Daily value	Plant-based diet	% Daily value
Calcium	1,090 mg	84%	840 mg	65%	1,246 mg	96%	974 mg	75%
Iron	18.2 mg	101%	19.6 mg	109%	21.1 mg	117%	23.2 mg	155%
Potassium	2,816 mg	60%	3,820 mg	81%	3,263 mg	69%	4,631 mg	99%
Vitamin A (RAE)	1,015 µg	113%	812 µg	90%	1,121 µg	125%	903 µg	100%
Vitamin C	194.8 mg	216%	249.4 mg	277%	242.7 mg	270%	302.5 mg	336%
Vitamin E	13.0 mg	87%	18.8 mg	126%	16.0 mg	107%	23.2 mg	155%
Vitamin K	396.9 µg	331%	392.5 µg	327%	432.8 µg	361%	472.9 µg	394%
Thiamin	1.9 mg	160%	4.4 mg	364%	2.1 mg	178%	4.8 mg	401%
Riboflavin	2.2 mg	171%	3.9 mg	302%	2.5 mg	193%	4.2 mg	326%
Niacin (NE)	43.9 mg	274%	41.8 mg	261%	50.4 mg	315%	47.6 mg	298%
Vitamin B6	2.4 mg	141%	4.4 mg	256%	2.7 mg	161%	4.8 mg	284%
Folate (DFE)	533 µg	133%	642 µg	161%	585 µg	146%	786 µg	196%
Vitamin B12	4.7 µg	197%	2.4 µg	101%	5.4 µg	224%	2.6 µg	110%
Pantothenic acid	5.5 mg	111%	5.2 mg	105%	6.3 mg	125%	6.2 mg	125%
Phosphorus	1,387 mg	111%	1,361 mg	109%	1,679 mg	134%	1,653 mg	132%
Magnesium	347 mg	83%	582 mg	138%	451 mg	107%	700 mg	167%
Zinc	11.9 mg	108%	11.2 mg	101%	14.0 mg	256%	13.4 mg	122%
Selenium	126.1 µg	229%	82.3 µg	150%	140.3 µg	255%	94.6 µg	172%
Copper	1.4 mg	154%	2.9 mg	319%	1.9 mg	216%	3.5 mg	394%
Manganese	4.7 mg	205%	7.7 mg	335%	5.9 mg	256%	9.2 mg	398%
Choline	345.1 mg	63%	236.3 mg	43%	389.9 mg	71%	291.0 mg	53%

Abbreviations: DFE: Dietary folate equivalents; NE: Niacin equivalents; RAE: Retinol activity equivalents.

labeled with the day and meal when each item should be consumed. Study meals were distributed to participants on a weekly basis. The importance of consuming all provided food and beverages and avoiding any unapproved additions was emphasized at each meal distribution session. The RDN was on call throughout each dietary intervention period to address questions or concerns that arose regarding the

study diets.

2.3. Measures of dietary adherence

2.3.1. Self-reported measures of dietary adherence

Participants reported dietary adherence using daily checklists that were provided at each meal distribution

session. The checklists presented each menu item for each daily eating occasion (e.g., breakfast and lunch) and required participants to indicate if they consumed the full portion, a partial portion, or did not consume the item. The checklists also included a section for participants to record any foods or beverages consumed that day that were not part of the study diet, and another section for participants to provide feedback that may be helpful to the kitchen staff or investigators (e.g., quality or palatability issues, events that affected dietary adherence). Crude counts of added items and omitted items were tallied for each day for which study participants returned a dietary adherence checklist. Lists and quantities of omitted menu items were compiled from the dietary adherence checklists for each study participant, and the caloric value of omitted study menu items was analyzed using NDSR version 2024.

2.3.2. Estimating actual caloric intake with predictive equations

Height and weight were measured in the Morehouse School of Medicine CRC at the beginning and end of each eight-week dietary intervention period by trained laboratory technicians. Height was measured to the nearest 0.1 cm using a standing stadiometer. Weight was measured to the nearest 0.1 kg with a calibrated digital scale after an overnight fast, with participants wearing light clothing. Self-reported physical activity was assessed at the beginning and end of each eight-week dietary period using the International Physical Activity Questionnaire (IPAQ).¹⁵ Participants were advised not to change their exercise routines or physical activity levels during the dietary intervention periods.

The NIDDK Body Weight Planner was used to estimate average daily energy intake during each dietary intervention.¹⁰ The tool incorporates dynamic mathematical models that account for changes in energy expenditure due to variations in body composition.⁹ Participants' age, sex, height, and baseline weight were entered to estimate baseline energy needs. Physical activity levels were assigned based on IPAQ responses using the tool's activity rubric. Post-intervention weight and the duration of each intervention period (e.g., 56 days) were entered to estimate each participant's actual caloric intake for each intervention period. Entering historical body weight data over a specified interval permitted the models to calculate the average energy imbalance necessary to produce the observed weight trajectory.^{9,11} These models have been validated with longitudinal feeding studies and calorie-restriction studies.⁹

2.3.3. Equation-derived measures of dietary adherence

The degree to which average daily caloric intake differed from the caloric content of the study diets was calculated by subtracting the caloric value of the assigned study diet from the equation-derived caloric intake. Post-hoc analyses were performed to determine if differences in caloric intake across study treatments and periods were driven by omissions of provided study foods and/or by the addition of foods and beverages to the study diets. These values combined self-reported data and caloric estimates from the predictive equations.

Because documentation of added foods and beverages varied in the level of detail provided, the average kilocalories added per day were interpolated by subtracting the average kilocalories consumed from the study diet based on self-report (i.e., kilocalories provided by the study diet minus the caloric value of the self-reported omissions) from each participant's estimated actual daily caloric intake, as derived from the predictive equations.

2.4. Statistical analysis

The SAS 9.4 (SAS Institute Inc., USA) software was used for data management and analysis. Descriptive statistics were generated to summarize the baseline characteristics of participants who enrolled in the study and individuals who completed it. Means with standard deviations ($\pm$ SD) were calculated for continuous variables, and frequencies with percentages were reported for categorical variables. The same descriptive statistics were also used to summarize dietary adherence across treatments and periods among study completers.

Non-parametric Wilcoxon rank-sum tests and Fisher's exact tests were performed to examine baseline differences between study completers and non-completers due to the small sample size. Necessary assumptions were verified, and *t*-tests for crossover studies were performed using the SAS CROSSTAB statement to compare measures of dietary adherence across diet treatments and study periods among study completers. A *p*-value <0.05 was considered statistically significant.

3. Results

Figure 1 illustrates study attrition in the counterbalanced, crossover design. Three participants withdrew from the study prior to completing the second period, resulting in an attrition rate of 25% and an analytic sample of nine participants. Table 2 provides a comparison of baseline

variables for non-completers versus completers. Relative to completers, non-completers were younger (48.7 ± 6.7 vs. 62.8 ± 8.9 years) and had higher BMIs (42.4 ± 7.4 vs. 34.1 ± 7.2 kg/m²), though the differences did not reach statistical significance ($p = 0.078$ and $p = 0.222$, respectively). Comparison of available dietary adherence data showed that the caloric intake of non-completers exceeded the calories provided by the study diets by a greater degree (412.7 ± 303.0 kcal) than that of study completers (141.8 ± 529.5 kcal) during the first period, though this difference did not reach statistical significance ($p = 0.375$). Reasons for withdrawal included relocation, loss of interest, and investigator-initiated termination.

Among study completers ($n = 9$), participants completed and returned $87\% \pm 10\%$ of the dietary checklists on average during the PBD treatment and $84\% \pm 20\%$ on average during the control diet treatment. Participants reported consuming foods containing animal products an average of 1.8 ± 2.2 times during the eight-week PBD treatment, thereby violating the study protocol; diet violations ranged from 0 to 6 incidents across study participants (0% to 10.7% of the intervention days).

A comparison of dietary adherence measures across diet treatments and study periods among study completers is presented in Table 3. Predictive equations indicated greater excess caloric intake beyond the calories provided by the study diets in the control condition (480.6 ± 525.9 kcal) versus the plant-based condition (126.0 ± 585.4 kcal; $p = 0.025$). Predictive equations also indicated greater excess caloric intake beyond the calories provided by the study diets in the second period (464.8 ± 592.4 kcal) versus the first period (141.8 ± 529.5 kcal; $p = 0.033$).

Study completers reported adding an average of 1.1 ± 1.1 items per day and omitting 2.2 ± 1.5 items per day

during the PBD treatment while adding 1.1 ± 1.1 items per day and omitting 1.6 ± 1.1 items per day during the control diet treatment. Unapproved added items accounted for 0.6 ± 0.6 items per day in the PBD treatment and for 0.6 ± 0.9 items per day in the control diet treatment. There were no statistically significant differences in the number of self-reported added and omitted items across diet treatments or periods.

Study completers also reported omitting significantly more kilocalories from the study diets during the PBD treatment (422.4 ± 289.1 kcal/day) relative to the control treatment (276.4 ± 185.0 kcal/day; $p = 0.015$). Differences between estimated added kilocalories during the PBD treatment (551.5 ± 689.0 kcal/day) versus the control treatment (767.6 ± 548.1 kcal/day) did not reach statistical significance. No significant period effects emerged regarding the average kilocalories added or omitted per day.

4. Discussion

Participants who completed this study consumed a greater excess of kilocalories beyond the provided diets during the control treatment than during the PBD, and during the second period than during the first period. However, further analysis suggested that participants omitted significantly more kilocalories from the PBD, while added kilocalories did not differ significantly by diet or period. Despite participants reporting about one added item per day—half of which were unapproved (i.e., items other than coffee or fresh produce)—predictive equations indicated that participants added 550 kcal/day and 800 kcal/day to the PBD and control diet, respectively.

Given the nature of the diets, blinding participants was not possible. The initial observation that participants

Table 2. Comparison of baseline characteristics for non-completers vs. study completers

Variable	Non-completers ($n=3$)	Completers ($n=9$)	p -value ^a
Age (years)	48.7 (± 6.7)	62.8 (± 8.9)	0.078
Household size (individuals)	2.3 (± 1.2)	1.3 (± 0.5)	0.173
Baseline BMI (kg/m ²)	42.4 (± 7.4)	34.1 (± 7.2)	0.222
Female sex	100%	77.8%	1.000
Employed	100%	77.8%	1.000

Notes: ^aWilcoxon rank-sum tests used for continuous variables; values are presented as mean ($\pm$ SD); Fisher's exact tests used for categorical variables. Abbreviation: BMI: Body mass index.

Table 3. Measures of dietary adherence reported as mean ($\pm$ SD) across treatments and periods among study completers ($n = 9$)

Dietary adherence measures	Treatment effects			Period effects		
	Plant-based diet	Control diet	<i>p</i> -value ^c	Period 1	Period 2	<i>p</i> -value ^c
Self-reported values						
Days with omitted items (% of reported total)	68% ($\pm$ 28%)	65% ($\pm$ 32%)	0.081	67% ($\pm$ 32%)	65% ($\pm$ 32%)	0.620
Days with added items (% of reported total)	48% ($\pm$ 31%)	54% ($\pm$ 31%)	0.095	50% ($\pm$ 29%)	52% ($\pm$ 33%)	0.447
Days with unapproved added items (% of reported total) ^a	33% ($\pm$ 31%)	30% ($\pm$ 32%)	0.533	32% ($\pm$ 31%)	31% ($\pm$ 32%)	0.708
Omitted items (average count per day)	2.2 ($\pm$ 1.5)	1.6 ($\pm$ 1.1)	0.075	1.9 ($\pm$ 1.4)	1.9 ($\pm$ 1.2)	0.734
Added items (average count per day)	1.1 ($\pm$ 1.1)	1.1 ($\pm$ 1.1)	0.597	1.1 ($\pm$ 1.1)	1.1 ($\pm$ 1.1)	0.278
Unapproved added items (average count per day) ^a	0.6 ($\pm$ 0.6)	0.6 ($\pm$ 0.9)	0.425	0.6 ($\pm$ 0.6)	0.7 ($\pm$ 0.9)	0.168
Caloric value of omitted items (average kcal/day) ^b	422.4 ($\pm$ 289.1)	276.4 ($\pm$ 185.0)	0.015*	371.8 ($\pm$ 292.7)	327.0 ($\pm$ 207.4)	0.238
Equation-derived values						
Caloric deviation from study diets (average kcal/day) ^c	126.0 ($\pm$ 585.4)	480.6 ($\pm$ 525.9)	0.025*	141.8 ($\pm$ 529.4)	464.8 ($\pm$ 592.4)	0.033*
Caloric value of added items (average kcal/day) ^d	551.5 ($\pm$ 689.0)	767.6 ($\pm$ 548.1)	0.122	525.9 ($\pm$ 484.6)	793.2 ($\pm$ 725.54)	0.075

Notes: ^a Added items not included on the approved diet additions list specified in the study protocol. ^b Estimated caloric value of omitted study foods, calculated using the Nutrition Data System for Research (NDSR) version 2024. ^c Difference between the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) equation-derived estimate of actual daily calorie intake and the caloric value of the assigned study diet. ^d Estimated caloric value of added foods, derived from the caloric deviation from the assigned study diet and the caloric value of omitted items. ^e *T*-tests used to compare dietary adherence across treatments and periods; * $p < 0.05$.

exceeded the caloric content of the study diets to a greater degree on the control diet led investigators to hypothesize that participants may have had better adherence to the dietary protocol and were less likely to add foods during the PBD treatment, possibly due to expectancy bias.³ However, participant expectancy was not measured, and the subsequent analysis of added and omitted kilocalories generated an alternate hypothesis suggesting this effect may have been primarily driven by participants omitting more kilocalories from the PBD. The latter hypothesis aligns with previous reports that eating all foods provided appears to be a greater challenge than refraining from eating foods not allowed within the context of controlled feeding studies.^{6,16}

The greater omissions of items from the PBD treatment may have resulted from a higher satiety value and/or lower palatability of the PBD. These potential explanations also remain speculative as the present study did not employ direct measures of satiety or palatability. However, one of the proposed mechanisms through which PBD interventions promote weight loss is that higher-bulk, less calorically dense plant-based foods increase satiety and displace more calorically dense foods to reduce energy intake.^{17,18} As shown in [Table 1](#), the average daily fiber content and food mass were greater for the PBD compared to the control diet. Additionally, qualitative feedback from the dietary checklists indicated that some menu items did not meet taste preferences. Future investigations should

consider employing direct measures of satiety and formal evaluations of consumer acceptance to assess the degree to which satiety and palatability influence dietary adherence across different dietary treatments.^{19,20}

The finding that participants consumed a greater caloric excess in the second period relative to the first aligns with the expectation that dietary adherence may wane as the duration of a dietary intervention increases,²¹ though this effect was driven by a combination of diet additions and omissions, and findings in this area have been mixed.^{4,6,16} The incongruence between the magnitude of estimated added calories and the low number of self-reported added items within the two treatments and periods suggests that participants did not disclose all non-study food and beverage additions to the study diets, emphasizing the need for dietary assessment methods that are not dependent on self-reports.²²

Importantly, the variable dietary adherence observed in this study has implications for interpreting the results of the original pilot study. Although no universally accepted adherence threshold exists for defining a controlled feeding study as an efficacy trial, previous controlled feeding studies have generally targeted adherence rates of 80–95%.^{3,4,6,23} In contrast, participants in the present study frequently deviated from the prescribed diets, omitting study foods on approximately two-thirds of recorded days and consuming unapproved foods or beverages on roughly one-third of recorded days (Table 3). Thus, the intention-to-treat analyses from the original study may be best interpreted as an evaluation of the effectiveness of prescribing a whole-food PBD under free-living conditions rather than an evaluation of the efficacy of consuming the study diets exactly as provided.²⁴

An evident limitation of this study is the small analytic sample size, which reduces statistical power and increases the risk of type II error. Although crossover study designs require fewer participants than parallel designs and permit each subject to serve as his/her own control,³ the high attrition rate (25%) reduced power to detect modest intervention effects. In crossover trials, unrecognized carryover effects can also complicate interpretations by obscuring true treatment differences.²⁵ Significant carryover effects were not observed in the present study, suggesting that any residual effects from the first treatment period may have been adequately buffered by the washout period and counterbalanced study design. However, the absence of statistically significant findings in this study should be interpreted cautiously, as insignificant findings may reflect a combination of limited power, sparse data, and variability in adherence behaviors rather than

conclusive evidence that no meaningful differences exist across treatments and periods or between completers and non-completers. Additionally, the generalizability of findings is further limited by the homogeneity of the study sample, which consisted predominantly of middle-aged African American women with obesity and prediabetes. Therefore, the results should be viewed as preliminary and hypothesis-generating rather than definitive, and adequately powered studies with more diverse populations are needed to reevaluate the observed trends.

Furthermore, values for actual caloric intake were based on predictive equations, and although these equations have been repeatedly validated with more objective measures,^{9,26} they provided estimates—not exact measurements—of actual caloric intake. Of note, the predictive equations used in this study incorporated self-reported measures of physical activity based on a two-item submodule.¹¹ While incorporating a measured value for physical activity may have strengthened the predictive value of estimates of energy intake, objective measures of physical activity are also lacking, and some evidence suggests that predictive equations may be more accurate at estimating energy expenditure relative to other techniques, such as accelerometers and motion sensors.²⁷ Nonetheless, for this specific study, the physical activity component of the NIDDK equation had minimal impact on the final calculated values for actual caloric intake because study participants were predominantly sedentary.

5. Conclusion

Despite acknowledged limitations, this study generates notable findings and responds to the call for researchers to share methods and best practices for diet design, delivery, and adherence metrics in controlled feeding studies.⁶ To the authors' knowledge, this is the first study to use predictive equations in the NIDDK Body Weight Planner to estimate actual caloric intake as an independent comparator for self-reported measures of dietary adherence within an outpatient controlled feeding study. Results suggest that caloric intake was not held constant across the two dietary treatments and that participants likely did not disclose all non-study foods and beverages that were consumed during dietary interventions, though equation-derived caloric deviations may reflect not only undisclosed food and beverage intake but also some degree of uncertainty associated with model assumptions and physical activity assessments. The present findings echo ongoing challenges with dietary assessment in free-living conditions and emphasize a need for more objective measures of dietary adherence in controlled feeding investigations.²² Importantly, these findings also indicate that the analysis

of the original study outcomes may be more appropriately viewed as an effectiveness study rather than an efficacy trial.

Acknowledgments

The authors wish to thank the staff of the Morehouse School of Medicine Clinical Research Center for assistance with data capture and data entry for this study, with special thanks extended to Shanell Robinson and Daisha Temple of the Bionutrition Core and Helen Tyree of the Bioinformatics Core.

Funding

This work was supported by the Morehouse School of Medicine 2021–2022 T^x™ Pilot Project Grant.

Conflict of interest

The authors declare there are no conflicts of interest to disclose.

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Ethics approval and consent to participate

The Morehouse School of Medicine Institutional Review Board approved the study protocol (approval no.: 1708340). All study participants provided written informed consent for all study procedures and received compensation for their time and effort.

Consent for publication

All study participants provided written informed consent for all study procedures and received compensation for their time and effort. No personally identifying information appears within this publication.

Availability of data

Data from this study are not currently housed in a public repository. De-identified data are available via the corresponding author upon reasonable request.

Further disclosure

Parts of the findings presented in this manuscript were presented in November 2024 at Obesity Week, the annual meeting of the Obesity Society, in San Antonio, Texas,

USA. The abstract from that presentation was published in the November 2024 supplemental issue of *Obesity*, Volume 32(S1), pages 239–240, doi: 10.1002/oby.24195.

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