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Use of Self-Reported Data to Determine the Effect of Nutrient-Dense Meals on Body Weight and Quality of Life

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Abstract

Seventy percent of the United States population is overweight or obese, which increases the risk of chronic conditions and premature death. Strategies for losing weight have so far proved unsuccessful, and compounding the problem is that funding for clinical nutritional research studies is limited. Food companies can fund clinical studies, supervised by nutritional researchers. Herein is such a study where a food company's customers were provided five, free, portion-controlled, nutrient-dense meals each day for 15 days to help improve their diet quality and lose weight. In exchange, participants completed data collection forms and posted video and comments on social media. Both normal weight (n=46) and overweight and obese subjects (n=97) participated. Subjects consumed four to five of the nutrient-dense meals, which contributed about 1,250 kcal daily and about 140%-165% of the Daily Value for all vitamins and minerals, except sodium. In addition, they consumed other foods adding another 250-300 kcal. The group lost a significant amount of weight (1.5 ± 4.5 kg; P<0.0001). After 15 days, more than 60% of the participants reported feeling better, having better sleep, and having more energy. In the subgroup of overweight and obese subjects, weight loss was 2 ± 2 kg in the overweight group (P<0.001) and for obese subjects, it was 2 ± 7 kg (P<0.01). Of this group, 17 lost at least 5% body weight, which is medically significant. Waist circumference decreased significantly for overweight women (P<0.001), overweight men (P=0.005), and obese men (P<0.0001). Waist circumference normalized in 12 individuals, indicating a reduction in the risk of hypertension, type 2 diabetes, and cardiovascular disease. The findings suggest that nutrient-dense meals, promote weight loss and improve health. Spontaneous energy-restriction occurred without hunger by consuming nutrient-dense foods. Weight loss strategies of the future may focus on nutrient-counting rather than calorie-counting.

Keywords: Weight loss; Nutrient-dense meals; Quality of life; Nutritional research

Introduction

Seventy percent of the United States population is overweight or obese, which leads to increased risk of chronic conditions and premature mortality [1,2]. The number of obese and severely obese individuals increased over the last decade [3]. Now, 40% of the population is obese and 8% is severely obese. Compared to other high-income countries, the United States has the most overweight population with the lowest mortality despite spending twice as much on healthcare [4].

Despite the myriad of commercial diet programs available, weight loss is minimal, and both drop out and recidivism rates are high [5,6]. Participants on these programs lost about 3%-5% body weight over six months, with drop out rates of about 50%. Most popular programs restrict the intake of foods that people like, requiring significant behavior change, which contributes to a high drop out rate and little weight lost. Compounding the problem of diets not working is that all energy-restricted diets provide inadequate essential nutrient intake, which promotes hunger causing weight to regain [7,8]. We previously showed that weight loss is facilitated without hunger using nutrient-dense, portion-controlled meals [9]. In that study, we looked at weight loss and change in waist circumference over three months in 89 overweight and obese subjects, who consumed nutrient-dense, portioned meals like what were used in this study. The study was prospective, single-armed, and data were self-reported; and subjects consumed two to three meals and two snacks daily. During the study, subjects lost 7.5 ± 3.7% body weight loss and waist circumference reductions were: 11 ± 7 cm and men by 12 ± 11 cm. Eight-six percent reported no hunger. Others have shown that inclusion a nutrient-enriched food bars with no other dietary manipulations resulted in weight loss and lowering the risk of cardiovascular disease and type 2 diabetes [10].

New strategies are needed to help people lose weight, but hampering that process is the lack of funding for nutritional research [11]. We proposed a new model for conducting nutritional research studies termed Live Clinicals™. This is a partnership between a food company and a research team, where meaningful data are obtained for both parties-marketing information for the company and publishable data for the researchers.

The fundamentals of conducting clinical research using the Live Clinical model are like in an academic setting. All components of clinical trials are adopted but co-planned by a company and the researcher. What is new with Live Clinicals is that the data are obtained in real-time. This capability has only recently been realized and embraced by consumers.

For the first test of this Live Clinical model, we explored the effect of portion-controlled, nutrient-dense meals on weight loss, waist circumference measurement, and changes in quality of life measures. Participants were customers of the food company (hereafter referred to as the Company).

Methods

This prospective, single-arm study looked at the effect of consuming

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portion-controlled, nutrient-dense meals over 15 days. Participants completed daily data collection forms and posted videos and comments on their own social media sites and on the Company's website. All data were self-reported.

Participants

All the Company's customers were contacted via email, about participating in a weight loss study using nutrient-dense foods. Enrollees signed a consent form, acknowledging the risks and permitting the Company to share their postings on social media. Normal weight individuals were advised to remain weight stable, but that their diet quality would improve. Overweight and obese individuals were told that they were likely to lose weight.

Initially, 197 subjects enrolled in the study and 54 dropped before completing day-15 data collection form (73% compliance rate). The 143 remaining participants, being both normal weight and overweight, had an average age of 47 ± 4 years and were comprised of 60% females (Table 1). At least 80% of the group had tried to lose weight before.

Diets

The company provided at no charge five meals each day for 15 days. Participants selected from a variety of flavors and types of meals: breakfast items (e.g., cereal, oatmeal), shakes, bars, and warm meals (e.g., Pad Thai, Cheesy Noodle, Beef Rice). The bars provide at least 25% of the Daily Value (DV) for all vitamins and minerals; other items provide at least 35%. The exception is sodium, which is limited to 4% to 27% DV. Thus, five nutrient-dense meals provide 165%-175% DV for all nutrients, except sodium. Each meal contains less than 10 grams of sugar and had at least 5 grams of dietary fiber.

The macronutrient distribution of the Company's meals was approximately: 55% carbohydrates, 25% protein, and 20% fat. Average energy provided by a meal is 280 kcal. Thus, five meals provided about 1,400 kcal and 82 g dietary protein. Participants were told to consume all five meals and anything else that they wanted, as long as they recorded what they ate on the daily data collection forms.

Data collection

At the beginning and end of the study, body weight and waist circumference measurements were obtained. In addition, a series of questions about quality of life were asked at the beginning and end using Yes, No, or Not Applicable. Participants completed daily data collection on body weight, the number of nutrient-dense consumed meals consumed provided by the Company, and what else they ate.

Determination of energy and macronutrient percentages from foods that were not supplied by the Company were made using My Fitness Pal App by one of us (RAB) (https://www.myfitnesspal.com/). Each food item and amount were entered the App (e.g., salad with grilled chicken or beef chunks in gravy). The most similar food was selected if an identical match was not found. If no amount was provided by the participant, a typical serving size was selected (e.g., 8 oz. milk for a shake, ½ cup milk used in cereal, 6 oz. yogurt, and medium-size fresh fruit and vegetable or 1 cup any type of fruit and vegetable).

Definitions of overweight (body mass index of 25-29.9 kg/m^2) and obesity (30 kg/m^2 and above) were adopted from the National Institutes of Health [12]. Waist circumference is gender specific with high risk for hypertension, type 2 diabetes, and cardiovascular disease occurring at 88 cm or greater for overweight and obese women, and 102 cm or higher for overweight and obese men. A weight loss of at least 5% or more was medically significant [13].

Statistics

Data were reported as means ± standard deviations (S.D.). Since the data set was of sufficient size (143 subjects in whole group; and 97 subjects in overweight and obese group) and normally distributed, pre- and post-weight and waist changes were compared by two-sided paired t-test. P values lower than 0.05 were accepted as significant. The correlations between the baseline body weight and weight loss, and between the energy intake from non-study food and the weight loss were calculated by comparing paired values, respectively, with P values<0.05 being considered significant.

For quality of life questions, subjects responding with No at baseline and Yes at day 15, were considered to have gotten better. Those who answered Yes at the beginning and No at the end were considered to have gotten worse. Responses that were the same at the beginning and end were deemed to have no change.

Results

Entire data set (n=143)

Of this group of normal- and overweight subjects, after 15 days, the average weight loss was 1.5 ± 4.5 kg (-1.8 ± 5%) (Table 2; P<0.0001). Males lost more than females but were heavier at the onset of the study; initial body weight was somewhat predictive of how much weight loss occurred during the study (Figure 1). Body mass indexes (BMIs) significantly decreased from baseline to day 15 in this group using a paired t-test (P<0.001). Initial BMI was 29 ± 6 kg/m^2 and at day-15 was 28 ± 6 kg/m^2.

Dietary intake

Subjects typically consumed four to five of the Company's meals each day over the 15 days. This provided 1,100 to 1,400 kcal and 65 g to 80 g of dietary protein. All but five subjects consumed other foods. Most participants (65%) consumed fewer than 300 kcal from foods not provided by the Company; only 8% consumed 500 kcal or more. The average daily energy intake from foods not provided by the Company was 246 ± 165 kcal, which was not significantly related to how much weight was lost (Figure 2).

	Totals	Males	Females
Number of subjects*	143	56 (39%)	87 (61%)
Age (years)	47 ± 4	51 ± 14	45 ± 14
Height (cm)	171 ± 10	178 ± 7	165 ± 6
Weight (kg)	83 ± 20	95 ± 18	75 ± 17
Previously tried to lose weight	123 (86%)	45 (80%)	78(90%)
Note: *Considered to have completed the study, because data were available at baseline and day 15			

Table 1: Baseline demographics of all participants.

	Total subjects	Females	Males
Number of subjects	143	87	56
Baseline weight (kg)	83 ± 20	75 ± 17	95 ± 18
Day 15 weight (kg)	81 ± 19*	74 ± 17*	92 ± 17*
Weight lost (kg)	1.5 ± 4.5	1.2 ± 3.9	2.0 ± 5.3
Percentage change	-1.8 ± 5%	-1.6 ± 4.8	- 2.1 ± 4.7
Note: *P<0.0001 vs. baseline weight, by paired t-test			

Table 2: Changes in body weight over 15 days of all participants.

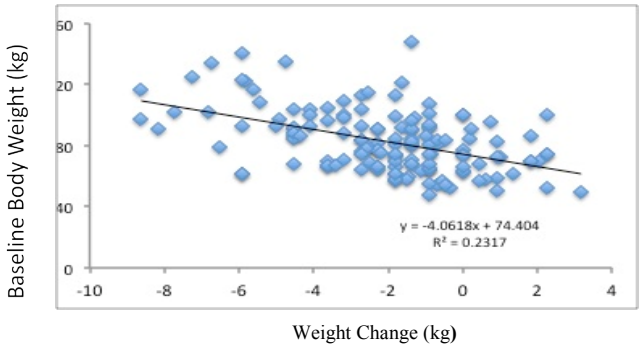

Figure 1: The correlation between baseline body weight and weight change. The trend is that those who weighed more at baseline lost more weight, but the relationship is not significant.

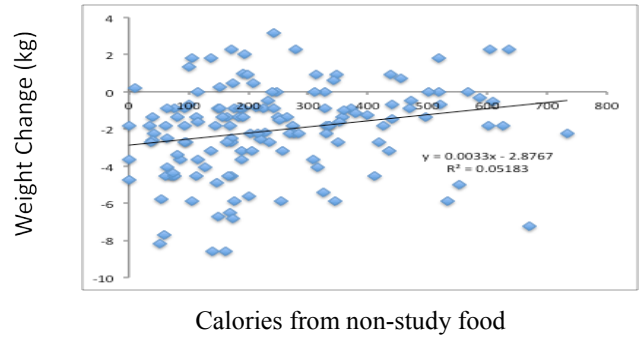

Figure 2: The correlation between calories from non-study food and weight change in the entire data set (n=143). The amount of weight lost was somewhat related to energy consumed from non-company foods, but not significant. Obtaining more than 300-400 kcal/day from non-Company supplied foods was associated with a slower rate of weight loss.

Quality of life

Subjects were asked questions about how they felt each time at the beginning and day-15 (Table 3). Fewer than 10% of the group reported a worse response during the study. In contrast, more than 50% reported improvements in all measures except for passion and skin. More than 60% of respondents reported improvements in feeling better, fewer mid-day crashes, better sleep, and energy. At the end of the 15-day study, 92% said that they would recommend the nutrient-dense meals to a friend.

Overweight and obese subjects (n=97).

A subgroup of the (97 of 143; 68%) subjects was classified at baseline as being overweight or obese, and further assessed separately. Of the overweight and obese subjects, 83 (86%) lost weight; 11 (11%) gained weight; and 3 (3%) were weight stable. The average weight gain in 11 subjects was 1.2 ± 0.8 kg. Four of them gained 1.8 to 2.2 kg, while the other seven gained less.

Weight

Overweight individuals lost 2 ± 2 kg, which was significant (P<0.001) as compared to their original weight, and obese subjects lost 2 ± 7, which was also significant (P<0.01) (Table 4). This represented an average weight loss of 2.30 ± 2.15% for overweight subjects, and 1.49 ± 7.06% for obese individuals. Medically significant weight loss of 5% or more was observed in 17 individuals (range 5% to 9%). Over 15 days, BMI for overweight and obese subjects decreased significantly (31.4 ± 5 kg/m^2 at baseline and 30.5 ± 5 kg/m^2; P<0.001).

Waist circumference

After 15 days, waist circumferences decreased significantly for overweight, but not obese, females by 5.5 ± 5 cm (Table 5; P<0.001). Overweight (P=0.005) and obese males (P<0.0001) experienced significant reductions in waist circumference measurements. Overweight males lost 4 ± 7 cm, and obese males, 5 ± 4 cm. Four females and eight males experienced enough of a reduction in waist size that they went from a high-risk category for hypertension, type 2 diabetes, and cardiovascular disease to a low risk status. Of this group, two (one male and one female) also experienced a medically significant weight loss of at least 5%.

Discussion

The purpose of this 15-day study was to determine if a new way to conduct clinical research was possible and effective. We described a partnership between a food Company and researchers as a Live

Questions*	N	Worse		Better			No change
		N	%	N	%	N	%
Fullness	79	7	8.9	43	54.4	29	36.7
Improved energy	79	1	1.3	5	68.4	24	30.4
Feel better	79	1	1.3	49	62	29	36.7
Less stress	79	1	1.3	46	58.2	32	40.5
Better sleep	79	3	3.8	49	62	28	35.4
Less moodiness	79	4	5.1	42	53.2	33	41.8
More passion	79	4	5.1	33	41.8	42	53.2
Fewer mid-day crashes	78	1	1.3	56	71.8	22	28.2
Faster recovery from injury	47	4	8.5	26	55.3	17	36.2
Nicer skin	73	4	5.5	32	43.8	38	52.1

Note: *Worse was defined as answering Yes and then No at the end; Better was defined as answering No and then Yes; and No Change had the same response at the beginning and end

Table 3: Quality of life in all participants: comparisons between baseline response and day 15.

BMI (kg/m^2)	N	Baseline weight (kg)	Day 15 weight (kg)	Weight loss (kg)	% change
≥ 25-30	46	82 ± 11	80 ± 10*	2 ± 2	-2.30 ± 2.15
> 30	51	101± 17	98 ± 17**	2 ± 7	-1.49 ± 7.06

Note: *P<0.001 vs. baseline weight, by paired t-test
**P<0.01 vs. baseline weight, by paired t-test

Table 4: Weight change in overweight and obese individuals.

BMI (kg/m^2)	N	Baseline waist circumference (cm)	Day 15 waist circumference (cm)	Change (cm)
Females				
≥ 25-30	21	90 ± 9	84 ± 9*	-5.5 ± 5
≥ 30	26	105 ± 15	103 ± 15**	-2 ± 5
Males				
≥ 25-30	22	95 ± 8	91 ± 7+	-4 ± 7
≥ 30	24	109 ± 15	105 ± 15++	-5 ± 4

Note: *Females: P<0.001 and **P=0.1029, vs. baseline waist circumference by paired t-test^
+Males: P = 0.005 and ++P<0.0001, vs. baseline waist circumference by paired t-test^
^A paired t-test was used because five subjects (4 females and 1 male) were deleted, because they did not provide day 15 waist circumference measurements

Table 5: Changes in waist circumference in overweight and obese subjects.

Clinical model [11]. Data were obtained in a prospective, single-arm study, where evaluation of the effectiveness of portion-controlled, nutrient-dense meals was made for changes in body weight, waist circumference, and quality of life questions. Social media postings occurred in real time during the study. Enough food for five meals daily was provided at no charge to 143 normal weight and overweight customers. More than 50% reported feeling fuller, having more energy, feeling better, improved sleep, and having less moodiness. Individuals consumed about 1,250 kcal from the Company's meals and an average of 246 ± 165 kcal from other foods. The Company's meals contributed about 140-165% DV for all nutrients except sodium. Significant weight loss was observed (1.5 ± 4.5 kg [-1.8 ± 5%]; P<0.0001); and in a sub-group of overweight (2 ± 2 kg; P<0.001) and obese participants (2 ± 7 kg; P<0.01). This represented a healthy rate of weight loss of one to two pounds per week.

In the overweight and obese sub-group (n=97), 17 (17.5%) subjects lost at least 5% or more of their body weight, which is medically significant; and 12 (12.4%) experienced waist circumference changes that equated to risk reduction for hypertension, type 2 diabetes, and CVD [12,13]. Two subjects experienced both medically significant improvements based on body weight and waist circumference. Thus, 28% (27 of 97) of participants had an overall disease risk reduction. Use of portion-controlled, nutrient-dense meals fosters healthy weight loss and improved health without hunger, allowing participants to include other foods that they enjoy. It is likely that provision of adequate nutrients contributed to the spontaneous reduction in energy intake, weight loss, and reduced health risks.

Consumers, who would like to lose weight, are often confused about which program is best for them. One popular approach is the ketogenic diet, which is low enough in carbohydrates to produce ketosis [14]. This approach has been effective at reversing type 2 diabetes, but dietary restrictions are severe and not sustainable expect for a highly motivated population like this. Another popular approach to weight loss is calorie restriction of 15% to 25% (equaling 1,500-1,700 kcal per day) [15,16]. Calorie restriction was studied in normal weight individuals, and shown to preserve fat-free mass, promote fat loss, and reduce oxidative stress. For both approaches of losing weight – ketogenic diet and calorie restriction – people need to restrict what they like to eat and avoid certain food and food groups.

The present study took the approach that the participants could eat what they wanted if they recorded their intake. The results showed that most ate at least four of the Company's nutrient-dense meals (1,250 kcal and 140%-165% DV for all nutrients except sodium), and ate, in addition, about 250 kcal from foods of their choosing. However, these people still lost body weight at a healthy rate of one to two pounds each week and without hunger.

Our results confirmed previous findings that showed getting sufficient nutrients suppresses appetite allowing for healthy weight loss to occur without placing restrictions on dietary intake. We and others have shown this to be true [9,10]. Given that the participants had free-reign to eat what they wanted, they simply didn't eat in excess. Some included healthy options (e.g., raspberries, kale, almond milk), while others did not (e.g., fast-food burgers, fried chicken, tacos; potato chips, onion rings). Admittedly, weight loss slowed with higher calorie intakes, but still occurred even when calories from non-Company meals exceeded about 300-400 kcal/day but were less than 600 kcal/day. It seems that the need to restrict carbohydrates (ketogenic diet) or fat (calorie restriction) is not necessary when nutrient-dense foods are consumed. Weight loss was unaffected by the macronutrient composition of foods consumed outside of what the Company provided (e.g., low-carbohydrate foods did not produce more weight loss than high-protein foods; data not shown). In this study, the participants were instructed to consume what they liked. The emphasis on nutrient-counting over calorie-counting seems to make sense at promoting satiety and weight loss.

For some reason, the ingestion of nutrient-dense foods signaled a reduction in the consumption of other foods, especially those that are addictive and typically eaten in large quantities like pizza, fried foods, and alcohol. This finding is analogous to the ileal break theory, which suggests that macronutrient, especially fat and fiber, sufficiency provides a feedback to the upper GI tract and brain satiety center that the body is satiated and to stop eating [17]. In this present study, it appears that the micronutrients also serve as the feedback messengers to control appetite. Another hypothesis is related to taste bud regeneration. Obesity causes inflammation and slows the rate that taste buds regenerate, which occurs within a couple of weeks [18]. In an animal model, this disruption leads to poor eating habits. It is possible that the essential nutrients normalized taste bud regeneration rates during this study period.

Despite the short duration of the study, 12 overweight and obese subjects experienced reductions in waist circumference size to remove them from the high-risk category for hypertension, type 2 diabetes, and CVD. Similarly, a medically significant weight loss of at least more than 5% occurred in 17 overweight and obese individuals. This amount of weight loss is associated with reductions in blood glucose and lipids [13]. Two subjects experienced these improvements in weight and waist circumference. It appears that nutrient-dense meals improve health in two, independent ways, and this finding deserves further exploration. And, that the improvement to health occurs in a short period.

The strengths of the study are the large sample size (n=143) and low drop-out rate (27%). In addition, statistical significance was achieved at levels better than P<0.05 for some measurements. Some have suggested making significance to P<0.005 [19]. Adopting lower P value may help promote a research agenda with fewer, larger, and more carefully conceived and designed studies with sufficient power. P values of 0.005 were met or were exceeded for weight loss data in all participants and in overweight men and women; and for reductions in waist circumferences for overweight women and overweight and obese men.

The major study limitations are that the study is not randomized and that the data are self reported. However, based on our previous work using nutrient-dense meals like those used in this study, we expected to see the 2%-3% weight loss seen in this current study [9]. Energy intake is often under-reported by as much as 50% in obese subjects, who have tried to lose weight on multiple occasions [20]. It is possible that these participants failed to accurately report everything that was consumed from the meals provided by the Company and another 300 kcal from other foods. This combined caloric intake would result in the weight loss observed in this study. Another limitation was that activity level was not encouraged or tracked. Admittedly, exercise fosters good health and supports weight loss diet, but it is not the focus of the Company.

Conclusion

Consuming portion-controlled, nutrient-dense meals and other foods lead to a healthy rate of weight loss and decreases in waist circumference measurements. A subset of overweight and obese subjects experienced chronic disease risk reductions. Indicators of quality of life showed that the participants had more energy, felt

full, and slept better. We conclude that the Live Clinical model is an effective means of obtaining useful data. Weight loss diets of the future should focus on nutrient-counting rather than calorie-counting to allow people to lose weight safely and without hunger.

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Conflicts of Interest

Dr. Bell and Ms. Baker are full-time employees at Nutrient, a company that manufactures and sells nutrient-dense foods. Mr. Marsland founded the company.

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