Original Article

Portion controlled ready-to-eat meal replacement is associated with short term weight loss: a randomised controlled trial

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Background and Objectives: Strategies to prevent and treat overweight/obesity are urgently needed. This study assessed the effect of a short-term intake of ready-to-eat cereal on body weight and waist circumference of overweight/obese individuals in comparison to a control group. **Methods and Study Design:** A randomized, controlled 2-arm trial was carried out on 101 overweight/obese (Body Mass Index – 29.2±2.4 kg/m^2) females aged 18 to 44 years, at St. John's Medical College Hospital. The intervention group received a low fat, ready to eat cereal, replacing two meals/day for two weeks. The control group was provided with standard dietary guidelines for weight loss and energy requirements for both groups were calculated similarly. Anthropometric, dietary, appetite and health status assessments were carried out at baseline and at the end of two weeks. **Results:** At the end of two weeks, the mean reductions in body weight and waist circumference were significantly greater in the intervention group, -0.53 kg; 95% CI (-0.86 to -0.19) for body weight and -1.39 cm; 95% CI (-1.78, -0.99) for waist circumference. The intervention group had a significantly higher increase in dietary intakes of certain vitamins, fiber and sugar, and significantly higher reductions in total and polyunsaturated fats and sodium intakes, as compared to the control group ($p \leq 0.05$). No significant differences were observed between the groups, in change of appetite, health and perception scales. **Conclusions:** Portion controlled, ready to eat cereal could be effective for short-term weight loss, with some improvements in the nutrient intake profile. However, studies of longer duration are needed.

Key Words: weight loss, meal replacement, portion control, ready to eat cereal, Indian women

INTRODUCTION

Overweight and obesity have become global epidemics, affecting both developed and developing countries. The co-morbidities associated with these conditions create a profound health burden.[1] While their causes are multifactorial, the most evident contributing factors of overweight and obesity are an increased intake of energy-dense foods, sedentary lifestyle and a lack of physical activity.[2] Asians have higher risks of obesity related co-morbidities compared with their white European counterparts, and this occurs at a lower body mass index (BMI).[3,4] In India, overweight and obesity rates are 3 times higher in urban than rural areas and are more common among women.[5] About 24% of women in urban areas are overweight or obese and these rates increase with advancing age and higher incomes.[5] India has a dual burden of diseases with increasing prevalence of overweight and obesity existing along with persisting rates of under-nutrition and micro-nutrient deficiency, with 36% of the women being underweight and having micro-nutrient deficiency.[5] Thus, strategies which can be used to prevent/treat weight gain and improve the micro-nutrient status are warranted in India.

The optimal management of overweight and obesity requires a combination of diet, exercise, and behavioral modification. Potential weight reduction diets include low calorie, low fat, low carbohydrate, low glycemic index, high protein or high fibre and these diets have shown to effectively reduce body weight, with improvements in diabetes and cardio-vascular risk factors.[6] The principal of energy balance, however, still remains the cornerstone of weight control.

Portion controlled meal replacement programs are

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popular dietary interventions designed to replace higher calorie meals and include beverages, frozen entrees, breakfast cereals, and meal/snack bars.[7] Meal replacement diet plans offer a viable strategy for controlling weight, positively impacting health outcomes,[8] with results of greater weight loss,[7] adequate intake of essential nutrients[9,10] and long-term maintenance of weight loss.[10] Participants consuming meal replacements reported better dietary compliance and convenience, when compared to conventional weight-loss programs.[11] Ready to eat cereals have been used successfully for weight loss[12-14] and their effectiveness has been attributed to their palatability, which is resistant to hedonic shifts, and increased acceptance, since it is a dietary staple.[12] A recent review[15] summarized that ready to eat breakfast cereals are relatively inexpensive, nutrient-dense and convenient foods, which when consumed regularly may ensure adequate nutrient intake and help in reducing the risks of being overweight or of developing cardiovascular disease or diabetes.

In spite of excessive dietary consumption, overweight/obese individuals could have micronutrient deficiencies.[16] Portion controlled, fortified ready to eat cereals could provide an effective way for reducing/maintaining weight, with beneficial effects on the micro-nutrient status. A well-controlled study conducted in India, where the socio-cultural and economic imperatives are different from affluent countries, could provide new insights on the prevention/management of weight gain.

The objectives of the present study were to primarily assess the change in body weight and waist circumference of overweight/obese individuals who consumed a low fat ready-to-eat cereal for two weeks, in comparison to a control group provided with standard dietary guidelines, and secondarily, to assess the change in dietary, appetite, and health status.

METHODS

The study was conducted in the Nutrition & Lifestyle Clinic of St John's Medical College Hospital, India, from August 2014 to February 2015. The subjects were recruited by posted flyers and through word of mouth. The inclusion criteria were normal, healthy, premenopausal women with a BMI of 25 to 34.9 kg/m^2, and an age range of 18 to 44 years. The subjects were mainly administrative staff, nurses and doctors. The exclusion criteria were any history of surgical intervention for the treatment of obesity, weight loss or gain greater than 4.5 kg in the two months prior to visit, use of any medications that could affect weight, history or presence of any clinically significant medical conditions such as diabetes, polycystic ovary syndrome, thyroid disease, cardiac, renal or hepatic disorders. A sample size of 42 subjects per group was considered adequate to detect a difference in weight loss of 1.3 kg between the intervention and control groups, assuming a pooled standard deviation of 1.6 kg with a two-tailed alpha of 0.05 and 90% power. The study was approved by the Institutional Ethical Review Board (IEC Study Ref No. 52/2014) of St. John's Medical College, Bangalore. Informed consent was obtained from all the participants.

Study design

The study was a randomised, controlled, open label trial with two groups. After recruitment, the subjects were randomised into either a low fat cereal group (Intervention group) or the usual care group (Control group), using simple randomisation. An online random sequence generator was used by the statistician, to generate a digit sequence containing 1 s and 2 s (50 each) in random order that was kept in a folder in the co-investigators office. Group assignment was performed by a staff member referring to the sequence and assigning the participant to the group represented by the next digit in the sequence. The sheet was kept safely in the custody of the co-investigator. None of the study staff, except the nutritionist who planned the diet and served the breakfast, were aware of the group to which the participants were assigned. The participants were not blinded to the intervention. The study has been registered under the Clinical Trials Registry of India (Clinical Trial Registry - India - Ref No: Ref/2014/11/007883).

Intervention

The intervention was a fixed energy (250 kcal per meal) control program with dietary energy allocated for two meals (breakfast and another meal of the day), for a duration of two weeks. Each time, the intake of a sachet of 30 g of low fat cereal (ingredient and nutrition information are provided in Table 1) was advised, with 120 mL skim milk and a serving of fruit or vegetables. Subjects were instructed not to consume any additional food for breakfast or for the second meal eaten at lunch or dinner. The third meal was recommended as a normal meal (the meal that they routinely ate). Individualized dietary advice was provided to all the subjects, with options for snacks and the third meal. The subjects were provided with a week's supply of the intervention product and were asked to bring back the empty sachets during their visits. They were also asked to fill in a compliance log to record the consumption of the intervention product and were asked to register if they consumed/did not consume the intervention at breakfast, lunch or dinner.

Control group

The control group was only prescribed dietary advice, along with a diet sheet/ handout with recommendations for portion sizes and exchanges for the whole day. No meals were provided to the control group.

The energy requirement for the subjects of both the intervention and control groups were calculated based on BMI, ideal body weight (IBW) and activity levels.[17] About 25 kcal/kg IBW was prescribed for overweight subjects, while obese subjects were prescribed energy at 22 kcal/kg IBW. The macronutrient distribution was 60-65% of total energy for carbohydrates, 12-15% for protein and 20-25% of fat. All the participants received a handout which provided an individualized diet plan. The energy requirements for the day were divided into three meals and two snacks. Dietary advice on portion size, meal frequency, food exchanges and recommended foods were also provided to the patients as per these guidelines,[17] in order to translate the macronutrient advice to food. Trained nutritionists advised the individuals on

Table 1 Nutrient and ingredient information of the intervention

	Nutrition and ingredient information[†]		
	Typical value for 30 g	30 g serving with 120 mL of skim milk[‡]	(% RDA)[§]
Energy	109 kcal	144 kcal	
Energy from fat	3 kcal	4 kcal	
Total fat	0.3 g	0.4 g	
Saturated fatty acids	0.1 g	0.2 g	
Monounsaturated fatty acids	0.1 g	0.1 g	
Polyunsaturated fatty acids	0.1 g	0.1 g	
Trans fatty acids	0.0 g	0.0 g	
Cholesterol	0.0 mg	0.0 mg	
Total carbohydrates	25.6 g	31.1 g	
of which sugar (Sucrose)	7.5 g	7.5 g	
Dietary fibre	1.5 g	1.5 g	
Protein	2.5 g	5.5 g	
Sodium	0.20 g	0.25 g	
Vitamin A	30.0 µg	35.4 µg	6
Vitamin C	9.9 mg	11.1 mg	28
Thiamine (Vit B-1)	0.3 mg	0.3 mg	30
Riboflavin (Vit B-2)	0.3 mg	0.3 mg	32
Niacin (Vit B-3)	4.1 mg	4.2 mg	35
Vitamin B-6	0.5 mg	0.5 mg	25
Vitamin B-12	0.1 µg	0.7 µg	68
Folate	25.2 µg	25.2 µg	13

[†]Ingredients: rice (36.15 %), whole wheat (33.24 %), sugar, wheat bran (4.74 %), liquid glucose, iodised salt, malt extract, vitamins, minerals and antioxidant (INS320). Contains gluten, may contain traces of almond (tree-nut).
[‡]If cereal is had with cow's milk, the energy value will increase by 46 kcals and the fat by 4.8 g.
[§]RDA, Recommended Dietary Allowance. RDA per day for sedentary women basis. Nutrient Requirements and RDA for Indians by ICMR, 2010.

their food intake.

Anthropometry

Fasting body weight was recorded using a calibrated digital weight scale (Salter, Germany) to the nearest 0.1 kg. Height was measured to the nearest 0.1 cm using a mobile stadiometer (Seca 213, USA). BMI was calculated as Weight (kg)/Height (m^2). Waist circumference, abdominal waist and hip circumference were measured using a non-stretchable tape (ADC396, USA) using standard procedures.[18] Waist circumference was measured at the narrowest part between the last rib and the iliac crest. Abdominal waist circumference was measured at the level of the greatest anterior extension of the abdomen in a horizontal plane (usually at the level of the umbilicus), between the last rib & the iliac crest, while hip circumference was measured with the tape placed around the buttocks in a horizontal plane at the level of maximum extension of the buttocks.[18] All the measurements were measured thrice to the nearest 0.1 cm and the mean of the three readings was taken. These measurements were carried out on Days 1 and 14 by trained nutritionists. Measurements on each subject on different visits were done by the same examiner to reduce variability. The within and between measurer coefficient of variation (CV) was 0.2% and 0.3% respectively.

Dietary intake

The dietary intake of each subject was assessed using a 3-day food record method on two occasions (before the start of study and end of study) and included two weekdays and a weekend day. The subjects were trained on how to record their intake. The training of participants on recording their dietary intake was performed by a nutritionist, while another nutritionist analysed the dietary records. Energy and nutrient intake was computed using a nutrient database for Indian foods[19] and from the United States Department of Agriculture, USDA.[20]

Visual analogue scale

Four 100 mm visual analogue scales (VAS)[21] were used to assess satiety on days 1 and 14. The four variables were hunger, fullness, urge to eat and thoughts of food. Subjects were requested to make a vertical mark on each line that best matched how they were feeling at the time. Each score was determined by measuring the distance from the left side of the line to the mark. The VAS was first administered in the fasted state. The subjects were then provided breakfast at the study site, under the supervision of the study staff. The intervention group received the product, while the control group was provided with a breakfast (south Indian idli with chutney) which was equal in calories (250 kcals) to the intervention product. The VAS scale was administered again after breakfast. Each time, the VAS was administered in triplicate, and the scores were calculated from the mean of the three readings for both time points (pre- breakfast and post breakfast).

Questionnaires

Health status (SF-36)[22] and physical activity[23] questionnaires were administered on days 1 and 14, perception and program acceptability questionnaires were administered on day 14, and compliance to dietary intervention was administered on days 7 and 14. The perceived compliance of the subjects to the prescribed dietary advice

was recorded at the end of two weeks, by asking the subjects to orally express their level of compliance on a scale of 0-100%.

Statistical Methods

Assumption of normality was assessed using a Q-Q plot. The data were presented as mean ± standard deviation for normally distributed continuous variables. The primary outcome of the study was the change in weight and waist circumferences from baseline. The analyses for the primary objective was carried out using both per protocol (PP) and "Intention to Treat" (ITT) principle. In the ITT analysis, all subjects randomized into the study, were considered for statistical analyses. For the 9 subjects who dropped out for the end measurement, the baseline observation carried forward approach was used. The change (difference) in each parameter was computed between two time points (Day 14- Day 1) for all the parameters. Baseline characteristics were compared between the study groups using an independent t test. The independent 't' test was used to compare the change in anthropometric characteristics between the study groups for both PP and ITT analysis. The change in the secondary outcomes of VAS parameters, which were not normally distributed, were analyzed using the Mann Whitney U test. Within group comparison was carried out using paired t test analysis. In addition, anthropometric parameters were analyzed using analysis of covariance (ANCOVA) to assess the effect of intervention at endline and adjusting for baseline measurements as a covariate. Dietary intake parameters were analyzed between groups using the Mann Whitney U test. Additionally, for dietary intake parameters that were significantly different at the baseline (vitamin A, sugar and protein) between the study groups, ANCOVA was carried out, adjusting for baseline values. All analyses were carried out using SPSS version 22 and the significance level was set at $p \leq 0.05$ (two-sided).

RESULTS

The flowchart of the subjects is provided in Figure 1. A total of 110 subjects were recruited. The mean age of the subjects was 30.9±6.4 years, with no significant difference between the two groups. The monthly income and educational status were comparable between the groups. The mean weight, BMI, waist circumference, abdominal waist circumference and hip circumference of the subjects were 70.8±7.4 kg, 29.2±2.4 kg/m^2, 84.8±6.1 cm, 95.3±7.0 cm and 105.9±6.3 cm respectively. There were no significant differences in the anthropometric parameters between the two groups at the baseline. The demographic characteristics of the non-responders (loss to follow up) were comparable to the responders of the study.

Figure 2 depicts the comparison of pre – post difference in measures between the study groups for body weight, waist and hip circumferences.

Table 2 depicts the baseline parameters of the two groups and there were no significant differences between the study groups. The mean change (ITT analysis) in body weight, waist circumference, abdominal waist and hip circumferences from Day 1 to Day 14 were signifi-

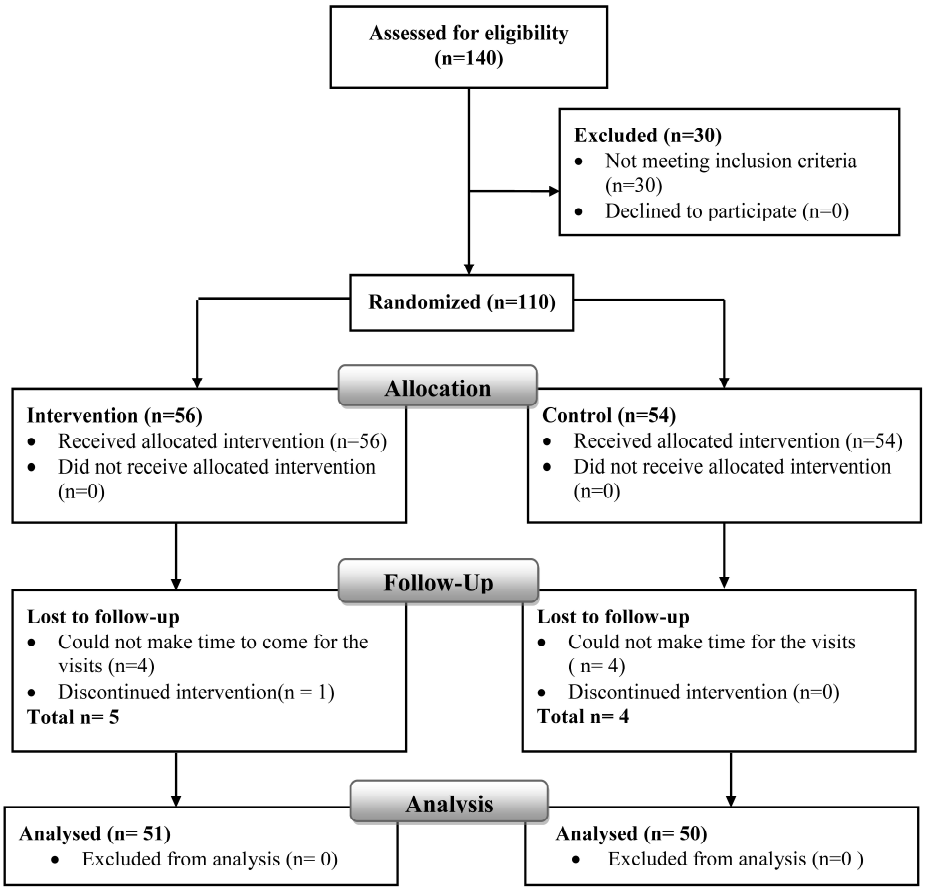

Figure 1. Participant flow diagram.

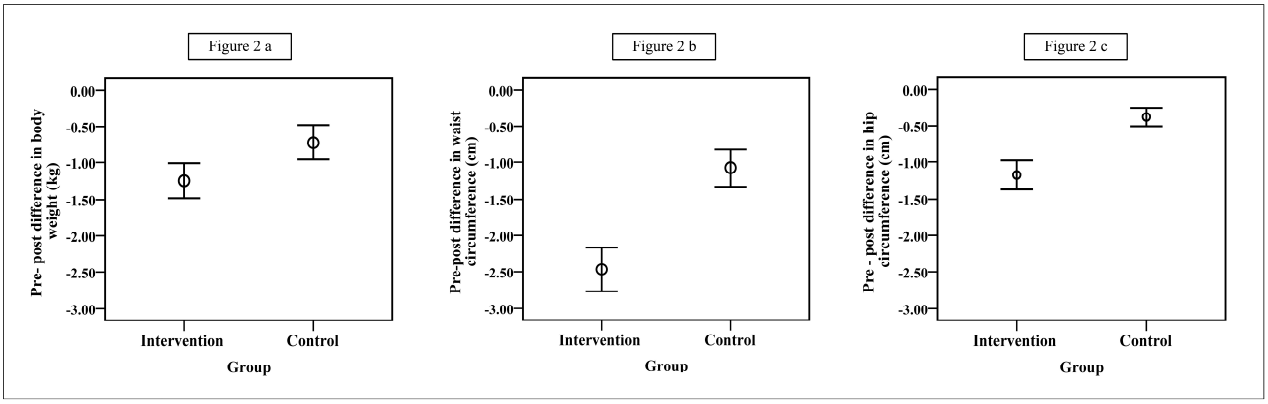

Figure 2. Comparison of pre – post difference in measures between the study groups for body weight, waist and hip (Intention to Treat – ITT analysis). (a) Pre-post difference in body weight between the two groups; (b) Pre-post difference in waist circumference between the two groups; (c) Pre-post difference in hip circumference between the two groups. N=56 (Intervention Group) and N=54 (Control Group).

cantly higher in the intervention group as compared with the control (p<0.01) (Table 3). The results of the PP analysis were similar and the mean change was significantly higher in the intervention group as compared with the control group (p<0.01). The ANCOVA results (not depicted) also showed that the body weight, waist circumference, abdominal waist and hip circumferences were significantly different between the groups at the end of the study, after adjusting for baseline values. For analyses performed within each study group, significant reductions were observed in both groups from day 1 to day 14 for all anthropometric parameters (p<0.001), although the reductions were significantly greater in the intervention group (p<0.01). The effect size for Body weight and BMI was 0.3 for both PP and ITT analysis, while waist circumference, abdominal waist and hip circumference was 0.5 for PP analysis and 0.6 for ITT analysis.

The mean change in appetite assessment parameters were not significantly different between groups (Table 4). In both groups, paired analysis of the mean change at the end of the study showed significant reductions in the thoughts of food, urge to eat and hunger, with significant increases in the feeling of fullness (p<0.001; data not shown).

The dietary analysis data showed that, when compared to the control group, the reductions in intakes of total fat, polyunsaturated fatty acid (PUFA) and sodium, along with the increases in the intakes of niacin, vitamin B-6, B-12, fiber and sugar were significantly greater in the intervention group (p<0.01). The dietary intake of vitamin B-6 in the intervention group increased by 20% (from an intake of 65% of daily recommended value[24] to 85%) from Day 1 to Day 14, while in the control group, it decreased by 15% (from an intake of 70% of daily recommended value to 55%). Similarly, dietary fiber increased by 3% (from an intake of 22% to 25% of daily recommended value) in the intervention group, while it decreased by 1.4% (from an intake of 21% to 19.6 % of daily recommended value) in the control group. The dietary intakes of niacin and vitamin B-12 of both the groups met the recommended intakes on Day 1 and further increased in the intervention group, but decreased in the control group on Day 14 (Table 5). Conversely, total dietary fat intake reduced from 27.5% of total energy to 20.5% in the intervention group, while in the control group it decreased from 27.5% total energy to 25.2%. PUFA levels decreased by 3% (from 10% to 7% of total energy) in the intervention group. Sodium intake in the intervention group was 126% of the recommended intake (1.9 g/day) on Day 1, but reduced to 63% of the recommended intake on Day 14, while in the control group the sodium intake did not decrease to the level of recommended intake. These results are depicted in Table 5. The results of ANCOVA analysis (data not shown) had

Table 2. Baseline parameters of the study groups

Parameter	Overall (N=101)	Intervention group (N=51)	Control group (N=50)	p value[§]
Age (yrs)	31.0±6.5	30.5±6.3	31.6±6.6	0.38
Weight (kg)	70.8±7.4	70.6±7.9	71.1±7.0	0.76
BMI (kg/m^2)	29.2±2.4	29.0±2.3	29.3±2.5	0.54
Waist circumference (cm)[‡]	84.8±6.1	85.3±5.4	84.3±6.8	0.40
Abdominal waist circumference (cm)[‡]	95.3±6.9	95.3±6.8	95.3±7.3	0.98
Hip circumference (cm)[‡]	105.9±6.3	104.9±6.4	107.0±6.0	0.09
Physical activity level[‡]	1.59±0.16	1.61±0.16	1.57±0.15	0.17

BMI: body mass index.
[†]All values are Mean±SD.
[‡]Waist circumference was measured at the narrowest part between the last rib & the iliac crest; abdominal waist circumference was measured at the level of the greatest anterior extension of the abdomen in a horizontal plane (usually at the level of the umbilicus), between the last rib & the iliac crest; hip circumference was measured with the tape placed around the buttocks in a horizontal plane at the level of maximum extension of the buttocks.[18] Physical activity level was assessed using a validated questionnaire.[23]
[§]p value - Values were analyzed between study groups using independent t test

Table 3. Comparison of anthropometric parameters between study groups – Intention to Treat (ITT) analysis

Parameter		Intervention group (N=56)	Control group (N=54)	*p* value[§]
Weight (kg)	Day 1	70.4±8.1	70.8±7.8	0.75
	Day 14	69.2±8.1	70.2±7.8	0.53
	Change	-1.2±0.9	-0.7±0.8	<0.01*
BMI (kg/m^2)	Day 1	29.0±2.3	29.2±2.7	0.66
	Day 14	28.5±2.4	28.9±2.7	0.39
	Change	-0.5±0.4	-0.3±0.3	<0.01*
Waist circumference (cm)[‡]	Day 1	84.9±5.9	84.5±7.3	0.77
	Day 14	82.6±5.7	83.5±7.3	0.45
	Change	-2.3±1.2	-1.0±0.9	<0.001*
Abdominal waist circumference (cm)[‡]	Day 1	94.9±7.5	95.7±7.5	0.58
	Day 14	92.7±7.5	94.9±7.5	0.13
	Change	-2.2±1.3	-0.8±0.8	<0.001*
Hip circumference (cm)[‡]	Day 1	105.0±6.8	106.8±6.1	0.16
	Day 14	103.9±6.8	106.4±6.1	<0.05*
	Change	-1.1±0.8	-0.4±0.4	<0.001*

BMI: body mass index.
[†]All values are Mean±SD.
[‡]Waist circumference was measured at the narrowest part between the last rib & the iliac crest; abdominal waist circumference was measured at the level of the greatest anterior extension of the abdomen in a horizontal plane (usually at the level of the umbilicus), between the last rib & the iliac crest; hip circumference was measured with the tape placed around the buttocks in a horizontal plane at the level of maximum extension of the buttocks.[18]
[§]*p* value - Day1, Day 14 and change in values were analyzed between study groups using independent t test.

Table 4. Comparison of Visual Analogue Scale parameters on Day 1, for pre and post breakfast between study groups

Parameter		Intervention (N=51)	Control (N=50)	*p* value[§]
Day 1 - Thoughts of food	Pre breakfast	30.8±23.7	25.7±17.1	0.48
	Post breakfast	16.3±15.5	12.7±13.9	0.33
	Change	-14.4±18.6	-13.0±19.7	0.97
Day 1 - Urge to eat	Pre breakfast	31.2±25.0	26.0±14.5	0.71
	Post breakfast	14.0±16.3	10.1±10.6	0.35
	Change	-17.1±21.4	-15.9±13.7	0.60
Day 1 - Hunger	Pre breakfast	32.0±23.8	33.4±18.5	0.39
	Post breakfast	15.4±17.3	13.3±16.4	0.46
	Change	-16.6±19.3	-20.1±21.0	0.22
Day 1 - Feeling of fullness	Pre breakfast	21.5±20.0	34.5±25.9	<0.01*
	Post breakfast	71.5±26.2	81.1±20.8	0.12
	Change	50.0±29.9	46.6±27.8	0.74
Day 14 - Thoughts of food	Pre breakfast	30.2±27.5	26.0± 18.5	0.94
	Post breakfast	13.0±13.0	9.9±11.2	0.27
	Change	-17.2±25.8	-16.1±18.2	0.43
Day 14 - Urge to eat	Pre breakfast	34.1±28.6	31.1±19.1	0.99
	Post breakfast	13.0±13.8	7.7±8.2	0.08
	Change	-21.1±25.2	-23.3±18.5	0.28
Day 14 - Hunger	Pre breakfast	33.0±26.2	33.6±21.9	0.70
	Post breakfast	13.0±13.0	10.6±12.6	0.25
	Change	-20.1±24.3	-23.1±19.8	0.25
Day 14 - Feeling of fullness	Pre breakfast	28.9±25.5	34.1±23.6	0.21
	Post breakfast	77.0±21.7	82.1±19.2	0.35
	Change	48.1±34.3	48.0±25.3	0.99

[†]All values are mean±SD.
[‡]Change calculated as Post Breakfast- Pre Breakfast.
[§]*p* value – Pre, Post and Change in values were analyzed between study groups using Mann Whitney U test.

similar statistical significance. Thiamine and Vitamin A intakes did not show any significant differences for both groups at the end of the study, compared with the baseline.

There were no significant changes observed in the health and perception assessment parameters between the groups at the end of the study. The self-reported compliance of the subjects to the prescribed dietary advice was significantly higher in the intervention group compared with the control group (90.1% vs 81.5%; $p<0.01$) at the end of the study. There were no changes in the physical activity levels in either group from day 1 to day 14.

Table 5. Comparison of average dietary intake of the study subjects between study groups

Parameter		Intervention (N=51)	Control (N=50)	*p* value[§]
Energy (kcals)	Day 1	1548.4±465.8	1587.0±447.5	0.67
	Day 14	1074.7±260.7	1145.6±207.3	0.14
	Change	-470.4±408.4	-433.8±433.8	0.47
Protein (g)	Day 1	49.8±14.8	55.4±18.6	0.09
Protein (% Energy)		13.0±2.2	13.9±2.5	0.05
Protein (g)	Day 14	38.0±9.5	37.6±8.8	0.85
Protein (% Energy)		14.2± 1.8	13.2±2.6	0.71
	Change(g)	-11.6±13.0	-17.3±19.4	0.19
Fat (g)	Day 1	48.8±21.7	49.3±18.2	0.89
Fat (% Energy)		27.5±5.8	27.5±4.4	0.99
Fat (g)	Day 14	25.4±10.9	32.3±9.1	<0.01*
Fat (% Energy)		20.5±4.7	25.2±4.4	<0.01*
	Change (g)	-23.1±18.8	-16.7±17.3	0.05*
Carbohydrate (g)	Day 1	228.6±64.4	231.6±63.0	0.81
Carbohydrate (% Energy)		59.7±5.9	58.8±5.6	0.43
Carbohydrate (g)	Day 14	176.7±37.1	176.8±33.7	0.98
Carbohydrate (% Energy)		65.8±5.1	61.9±5.7	0.80
	Change(g)	-51.9±59.9	-54.0±61.7	0.97
Fiber intake (g)	Day 1	6.7±2.9	6.3±2.7	0.55
	Day 14	7.5±2.3	5.9±2.4	<0.01*
	Change	1.0±3.0	-0.5±4.0	0.03*
Saturated fat (g)	Day 1	16.9±9.1	18.1±8.4	0.51
	Day 14	8.3±4.2	10.9±4.1	<0.01*
	Change	-8.5±7.7	-7.1±8.3	0.33
Monounsaturated fat (g)	Day 1	10.9±5.1	11.3±4.9	0.69
	Day 14	5.8±2.7	7.3±2.4	<0.01*
	Change	-5.1±4.7	-3.9±4.9	0.07
Polyunsaturated fat (g)	Day 1	17.2±8.1	16.3±5.9	0.50
	Day 14	8.4±4.7	11.8±4.0	<0.001*
	Change	-8.7±7.4	-4.4±6.0	<0.01*
Cholesterol (mg)	Day 1	114.2±99.5	128.6±87.5	0.44
	Day 14	49.5±37.3	69.9±51.6	<0.05*
	Change	-64.2±93.1	-55.0±82.8	0.53
Vitamin A (mcg)	Day 1	337.3±229.2	263.8±108.5	<0.05*
	Day 14	313.5±158.3	254.3±124.1	<0.05*
	Change	-25.3±228.1	-4.2±144.6	0.68
Thiamin (mg)	Day 1	1.4±2.2	1.1±1.1	0.49
	Day 14	1.1±0.2	0.84±0.2	<0.001*
	Change	-0.3±2.3	-0.3±1.2	0.006
Riboflavin (mg)	Day 1	0.9±0.4	0.9±0.3	0.89
	Day 14	0.8±0.2	0.7±0.2	<0.05*
	Change	-0.1±0.4	-0.2±0.3	0.05*
Niacin (mg)	Day 1	13.0±4.4	14.1±5.2	0.26
	Day 14	14.8±2.8	9.4±3.0	<0.001*
	Change	1.8±4.2	-4.7±6.0	<0.001*
Vitamin C (mg)	Day 1	72.5±44.6	64.7±80.5	0.55
	Day 14	95.2±61.7	68.6±70.6	0.05
	Change	23.5±68.6	3.2±106.7	0.39
Vitamin B-6 (mg)	Day 1	1.3±0.5	1.4±0.5	0.40
	Day 14	1.7±0.3	1.1±0.3	<0.001*
	Change	0.4±0.5	-0.3±0.5	<0.001*
Folate (mcg)	Day 1	202.2±85.9	195.1±105.4	0.71
	Day 14	153.4±49.5	149.0±40.8	0.64
	Change	-43.1±77.3	-43.6±117.5	0.43
Vitamin B-12 (mcg)	Day 1	1.3±1.3	1.6±1.5	0.24
	Day 14	2.1±0.8	0.9±0.8	<0.001*
	Change	0.9±1.4	-0.63±1.6	<0.001*
Sugar (g)	Day 1	18.9±11.8	23.6±15.5	0.09
	Day 14	28.5±10.4	14.6±8.5	<0.001*
	Change	9.6±10.2	9.0±15.8	<0.001*
Sodium (g)	Day 1	2.4±1.0	2.4±1.0	0.92
	Day 14	1.2±0.6	2.0±0.6	<0.001*
	Change	-1.2±1.0	-0.5±0.8	<0.001*

[†]All values are mean±SD

[‡]Day 1values refer to 3 day food recall before the start of the study; Day 14 values refer to 3 day food recall at the end of the two weeks. "Change" was calculated as Day 14 – Day 1

[§]*p* value – Day1, Day 14 and Change in values were analyzed between study groups using Mann Whitney U test.

[¶]All values were calculated from our database using recipes which used values obtained from both NIN & USDA.[19,20]

DISCUSSION

Portion-controlled meal replacements, included as part of a structured meal plan, have been shown to be a safe and effective method for increasing dietary compliance and providing clinically meaningful and sustainable weight loss and improvements in weight-related disease risk factors.[8,25,26] The present study showed that significantly greater reductions were observed in body weight and waist circumference of overweight and obese individuals, consuming a portion controlled low fat ready-to-eat cereal for two weeks, when compared with the control group. Additional beneficial changes in the intervention group included a significantly lower dietary intake of total fat, polyunsaturated fats and sodium. The intervention group had higher intakes of niacin, vitamin B-6, B-12 and fiber at the end of the two week program. The reduction in body weight and waist circumference observed in the present study was similar to previous studies conducted in other populations.[12,15,27]

The rapid initial weight loss observed within the first week of weight reducing programs are thought to be due to the diuresis associated with loss of glycogen stores.[28,29] The amount of glycogen in skeletal muscle is about 400-500 g, while about 70-100 g is stored in the liver.[30] When glycogen stores are completely depleted, along with the loss of associated water (1 g of glycogen carries 3 g of water with it), then the expected weight loss would be about 1-1.5 kg. The observed weight loss of the present study was within this range, however the intervention in the present study would not have completely depleted the entire glycogen stores, since the carbohydrate intake of the subjects of the intervention group was high -176 g/day (~65% of the total energy) at Day 14. It is not possible to estimate the proportion of fat loss in the body weight loss, however, one can surmise that since the waist circumference of the intervention group decreased by 2.3 cm, compared with 1cm in the control group, it is reasonable to assume that this would be abdominal fat loss. A recent study with an adult intervention of a ready to eat cereal, as part of meal replacement plan for two weeks reported a significant reduction of 1.6 (1.4) kg in body weight, of which a significant 0.7 (0.8) kg reduction in body fat mass (measured by Dual energy X-ray absorptiometry) also occurred.[31] This indicates that in this paradigm of rapid weight loss, about 50% of the weight lost was body fat.

The two week intervention period of the present study assessed only short-term weight loss. As such, short term meal replacement plans (for ~14 days) have been used previously as motivation tools to encourage long term dietary change, and have reported about 2 kg reductions in body weight in otherwise healthy overweight and obese individuals.[12,13,27] That this weight loss is sustained, is demonstrated from the observation that initial weight loss (percentage weight loss after one month) was observed to be one of the strongest predictors of long term weight loss success, in a weight reduction programme.[32] The reason for the sustained weight loss could be due to an improvement in quality of life factors such as general appearance, body image, physical mobility, energy and perceived health during the first four weeks of a weight control program, which have been associated with greater weight reductions at end of treatment. Positive quality of life changes may serve as re-inforcers, increasing healthy behaviors and healthy habit learning, leading to successful weight loss and maintenance.[33] Equally, failures of weight loss programs are also common, and while short term interventions for initial weight loss can be useful as an effective motivator, continued interventions for a longer duration of time are needed to sustain the weight loss/weight management.

The participants in the intervention group showed some ancillary beneficial effects in the dietary intake, with a decrease in dietary fat and sodium intake, while the intake of fiber and vitamins such as niacin, vitamin B-6, and B-12 significantly increased at the end of two weeks, when compared to the control group. The low fat ready to eat cereal was fortified with B vitamins and enriched with whole grains which increased the fiber content, and helped in improving the diet quality, even while on a reduced energy diet. Since biomarker levels were not measured in this study due to budgetary constraints, future studies need to confirm these beneficial findings by estimating biomarker levels. The fat intake of the intervention group decreased significantly by 47% at the end of the study compared with the baseline, which was similar to earlier reports in meal replacement programs.[9,10] Partial meal replacement plans, especially ready to eat cereals, have been earlier associated with higher micronutrient intake when compared with controls,[9,16,34,35] suggesting that these plans could help in assisting weight loss along with improvement in the quality of the diet. The intervention of (cereal+ milk) together in the present study provided 7.5 g total sugar per serving of 30 g (25% sugar by weight). Converse to these beneficial changes in the diet, the intake of free sugar in the intervention group increased from 5% of total energy intake on Day 1 to ~10% on Day 14. However, this increase was within the upper limit (5-10% of total energy intake) set by the WHO[36] for the intake of free sugars. Data are not available from previous studies on the magnitude of change in the dietary sugar intake, following the consumption of ready to eat cereals, but in the light of new recommendations on restricting free sugar intake,[36] attention should also be given to this aspect of the diet. It is worth noting that significant weight loss and reductions in waist circumference were observed in the intervention group, in spite of the significant increase in dietary sugar intake. Possible reasons include the significant decrease in total energy intake and dietary fat. Existing evidence supporting a link between total sugar intake and obesity is lacking or weak and it has been suggested that advice relating to sugar in the context of weight management should be directed at ensuring adequate nutrient intakes.[37] Thus, the small but significant increase in sugar intake of the intervention group (from day 1 to day 14) compared with the control group, did not have an effect on the weight loss results.

Participants consuming meal replacements have previously reported greater compliance and convenience compared to those in a conventional weight-loss program,[11] which are characteristics that could enhance adherence. In the present study, the compliance (self-reported) of the intervention group to the prescribed dietary advice was significantly higher than the control group, suggesting

that the ready-to-eat portion controlled cereal intervention could have augmented greater compliance to the diet and dietary advice provided, resulting in subsequent weight loss. An additional plausible behavioral mechanism that has been postulated, is that the amount of food offered as a meal replacement may be accepted by the individual as the ''norm'' for the meal, and they then may not compensate, i.e. eat extra at the next meal, thus leading to an energy deficit.[38]

To our knowledge, this is the first study in which subjects of both an intervention and control group were prescribed similar daily energy intakes, and is therefore novel, as the increased weight loss in the intervention group occurred within a rigorously conducted intervention trial format. The present study also demonstrated reductions in waist and hip circumferences about 2.5 and 3 times greater, respectively, in the intervention group compared with the control group, in spite of similar energy intakes. The observed beneficial effects on body weight and circumferences were not likely to be due to differences or changes in physical activity, since the physical activity of both the groups were not significantly different at the start of the program and all study participants were advised to continue with their existing physical activity patterns for the two week duration.

The cause for the increased weight loss is likely to be multifactorial, as discussed below. The energy intake of subjects in both the groups decreased progressively by approximately 400 kcal/day (470 in intervention group and 434 in control group) at the end of the two week program, but the intervention group had significantly greater reductions in body weight and waist circumference. The significant difference in weight loss, in the absence of a significant difference in reported energy intake between the two groups, may be due to better compliance to the program, as reported by the intervention group, or it could be an indication of higher inaccuracies in dietary intake reporting by the control group. One of the reasons for the efficacy of a meal replacement program in weight reduction is attributed to better portion control, which could result in reduced errors in reporting dietary intake, due to automatic portion control of the pre-weighed meal. Self-reported dietary intake data has been shown to be under-reported in overweight individuals and individuals wanting to lose weight.[39,40] It has also been observed that individuals who under-report, generally report consuming a greater amount of healthy foods like fruits and vegetables and consuming less unhealthy foods such as pastries.[41] Thus, while under-reporting may have occurred in both groups, it is possible that there was a greater degree of under-reporting in the control group, and this could have been one of the reasons for conflicting findings of similar energy intakes, but greater reductions in body weight and waist circumference in the intervention group.

The cost of the intervention (cereal, milk and fruit) was about Rs 125-135 (~1.8-2 USD/day) and Rs 1900 (~28 USD) for the two week duration. The intervention replaced two meals in a day, and since the cost of the two regular meals would approximately be the same or more, the cost implications of the intervention were not high, even if continued for a follow up period of greater than two weeks.

The present study had certain limitations – the study was only performed for two weeks and did not schedule any follow up visits. Only female participants were studied and it is also possible that in these premenopausal women of both study groups, menstrual cycle could have been a confounder. Blinding of the subjects to the assigned groups was not possible in the present study and this could have had some effect on compliance. The provision of free intervention product as compared with the usual care advice may have introduced some bias, however this was not explored.

Conclusion

Portion controlled meal replacements can be used as an effective strategy for short term weight loss with significant improvement in the nutrient profile of the individual. However, for prolonged maintenance of weight loss, a judicious combination of diet, physical activity and behavior modifications needs to be followed. Future studies need to investigate the effects over long periods of time in obese and overweight populations to gauge the efficacy of ready to eat cereals on sustained reduction in body weight.

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AUTHOR DISCLOSURES

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REFERENCES

1. Guh DP, Zhang W, Bansback N, Amarsi Z, Birmingham CL, Anis AH. The incidence of co-morbidities related to obesity and overweight: a systematic review and meta-analysis. BMC Public Health. 2009;9:88. doi: 10.1186/1471-2458-9-88.
2. Prentice AM. The emerging epidemic of obesity in developing countries. Int J Epidemiol. 2006;35:93-9. doi: 10.1093/ije/dyi272.
3. Deurenberg-Yap M, Schmidt G, Van Staveren WA, Deurenberg P. The paradox of low body mass index and high body fat percentage among Chinese, Malays and Indians in Singapore. Int J Obes. 2000; 24:1011-7.
4. Wen CP, Cheng TY, Tsai SP, Chan HT, Hsu HL, Hsu CC, Eriksen MP. Are Asians at greater mortality risks for being overweight than Caucasians? Redefining obesity for Asians. Public Health Nutr. 2009;12:497-506. doi: 10.1017/S1368980008002802.
5. International Institute for Population Sciences. India National Family Health Survey (NFHS-3), 2005-06. Mumbai, India. International Institute for Population Sciences; 2007.
6. Makris A, Foster GD. Dietary approaches to the treatment of obesity. Psychiatr Clin North Am. 2011;34:813-27. doi: 10.1016/j.psc.2011.08.004.
7. Heymsfield SB, Van Mierlo CA, Van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: meta and pooling analysis from six studies. Int J Obes. 2003;27:537-49. doi: 10.1038/sj.ijo.0802258.
8. Davis LM, Coleman C, Kiel J, Rampolla J, Hutchisen T, Ford L, Andersen WS, Hanlon-Mitola A. Efficacy of a meal replacement diet plan compared to a food-based diet plan after a period of weight loss and weight maintenance: a randomized controlled trial. Nutr J. 2010;9:11. doi: 10.1186/

1475-2891-9-11.
9. Ashley JM, Herzog H, Clodfelter S, Bovee V, Schrage J, Pritsos C. Nutrient adequacy during weight loss interventions: a randomized study in women comparing the dietary intake in a meal replacement group with a traditional food group. Nutr J. 2007;6:12.
10. Ditschuneit HH, Flechtner-Mors M. Value of Structured Meals for Weight Management: Risk Factors and Long-Term Weight Maintenance. Obes Res. 2001;9:284S-9S.
11. Noakes M, Foster PR, Keogh JB, Clifton PM. Meal replacements are as effective as structured weight-loss diets for treating obesity in adults with features of metabolic syndrome. J Nutr. 2004;134:1894-9.
12. Mattes RD. Ready-to-eat cereal used as a meal replacement promotes weight loss in humans. J Am Coll Nutr. 2002;21: 570-7. doi: 10.1080/07315724.2002.10719257
13. Vander Wal JS, McBurney MI, Cho S, Dhurandhar NV. Ready-to-eat cereal products as meal replacements for weight loss. Int J Food Sci Nutr. 2007;58:331-40.
14. Ortega RM, López-Sobaler AM, Rodríguez RE, Bermejo LM, García GL, López PB. Response to a weight control program based on the approximation of the diet to the theoretical ideal. Nutr Hosp. 2005;20:393-402.
15. Williams PG. The benefits of breakfast cereal consumption: a systematic review of the evidence base. Adv Nutr. 2014;5: 636S-73S. doi: 10.3945/an.114.006247
16. Via M. The malnutrition of obesity: micronutrient deficiencies that promote diabetes. ISRN Endocrinol. 2012; 2012:103472. doi: 10.5402/2012/103472.
17. Misra A, Sharma R, Gulati S, Joshi SR, Sharma V, Ibrahim A, Joshi S, Laxmaiah A, Kurpad A, Raj RK, Mohan V. Consensus dietary guidelines for healthy living and prevention of obesity, the metabolic syndrome, diabetes, and related disorders in Asian Indians. Diabetes Technol Ther. 2011;13:683-94. doi: 10.1089/dia.2010.0198.
18. Callaway CW, Chumlea WC, Bouchard C, Himes JH, Lohman TG, Martin AD, Mitchell CD, Mueller WH, Roche AF, Seefeldt VD. Circumferences. In: Anthropometric Standardization Reference Manual, Lohman TG, Roche AF, Martorell R, editors. Illinios: Human Kinetics Book: 1988. pp. 44-6.
19. Bharathi AV, Kurpad AV, Thomas T, Yusuf S, Saraswathi G, Vaz M. Development of food frequency questionnaires and a nutrient database for the Prospective Urban and Rural Epidemiological (PURE) pilot study in South India: methodological issues. Asia Pac J Clin Nutr. 2008;17:178-85. doi: 10.6133/apjcn.2008.17.1.25.
20. USDA. National Nutrient Data base for Standard Reference. 2012; Release 25. [cited 2016/03/04]; Available form: http://ndb.nal.usda.gov/ndb/foods/list
21. Silverstone T, Goodall E, Brambilla F. Measurement of hunger and food intake. Disorders of eating behaviour, a psychoendocrine approach. Oxford: Pergamon Press; 1986. pp. 129-34.
22. Hays RD, Sherbourne CD, Mazel RM. The rand 36-item health survey 1.0. Health Econ. 1993;2:217-27. doi: 10. 1002/hec.4730020305.
23. Vaz M, Bharathi AV, Thomas T, Yusuf S, Kurpad AV. The repeatability of self reported physical activity patterns in rural South India. Asia Pac J Clin Nutr. 2009;18:71-5. doi: 10.6133/apjcn.2009.18.1.11.
24. Nutrient Requirements and recommended dietary allowances for Indians. A report of the Expert Group of the Indian Council of Medical Research. National Institute of Nutrition, Hyderabad, India. 2010.
25. Heymsfield SB. Meal replacements and energy balance. Physiol Behav. 2010;100:90-4. doi: 10.1016/j.physbeh.2010. 02.010.
26. Coleman C, Kiel J, Hanlon-Mitola A, Sonzone C, Fuller N, Davis L. Use of the Medifast meal replacement program for weight loss in overweight and obese clients: a retrospective chart review of three Medifast Weight Control Centers (MWCC). Food Nutri Sci. 2012;3:1433-44.
27. Kirk T, Crombie N, Cursiter M. Promotion of dietary carbohydrate as an approach to weight maintenance after initial weight loss: a pilot study. J Hum Nutr Diet. 2000;13: 277-85. doi: 10.1046/j.1365-277x.2000.00237.x.
28. Astrup A, Larsen TM, Harper A. Atkins and other low-carbohydrate diets: hoax or an effective tool for weight loss?. Lancet. 2004;364:897-9. doi: 10.1016/S0140-6736(04)1698 6-9.
29. Radulian G, Rusu E, Dragomir A, Posea M. Metabolic effects of low glycaemic index diets. Nutr J. 2009;8:5. doi: 10.1186/1475-2891-8-5.
30. Jensen J, Rustad PI, Kolnes AJ, Lai YC. The role of skeletal muscle glycogen breakdown for regulation of insulin sensitivity by exercise. Front Physiol. 2011;2:112. doi: 10. 3389/fphys.2011. 00112.
31. Jakeman P, Shaw P and Walton J. The Effects of the Special K Challenge on Body Composition and Biomarkers of Metabolic Health in Healthy Adults. J Nutr Health Sci. 2015; 2:407.
32. OrtnerHadžiabdić M, Mucalo I, Hrabač P, Matić T, Rahelić D, Božikov V. Factors predictive of drop-out and weight loss success in weight management of obese patients. J Hum Nutr Diet. 2015;28:24-32. doi: 10.1111/jhn.12270.
33. Carels RA, Cacciapaglia HM, Douglass OM, Rydin S, O'Brien WH. The early identification of poor treatment outcome in a women's weight loss program. Eat Behav. 2003;4:265-82.
34. Tovar AR, del Carmen Caamaño M, Garcia-Padilla S, García OP, Duarte MA, Rosado JL. The inclusion of a partial meal replacement with or without inulin to a calorie restricted diet contributes to reach recommended intakes of micronutrients and decrease plasma triglycerides: A randomized clinical trial in obese Mexican women. Nutr J. 2012;11:44. doi: 10.1186/1475-2891-11-44.
35. Raynor HA, Anderson AM, Miller GD, Reeves R, Delahanty LM, Vitolins MZ et al. Look AHEAD Research Group. Partial meal replacement plan and quality of the diet at 1 year: action for health in diabetes (Look AHEAD) Trial. J Acad Nutr Diet. 2015;115:731-42. doi: 10.1016/j.jand. 2014.11.003.
36. World Health Organization. Guideline: Sugars intake for adults and children. Geneva. 2015. [cited 2016/07/14]; Available form: http://www.who.int/iris/handle/10665/ 149782.
37. Shrapnel B. Amount of sugar in Australian breakfast cereals is not associated with energy density or glycaemic index: results of a systematic survey. Nutr Diet. 2013;70:236-40. doi: 10.1111/1747-0080.12014.
38. Levitsky DA, Pacanowski C. Losing weight without dieting. Use of commercial foods as meal replacements for lunch produces an extended energy deficit. Appetite. 2011;57:311-7. doi: 10.1016/j.appet.2011.04.015.
39. Bedard D, Shatenstein B, Nadon S. Underreporting of energy intake from a self-administered food-frequency questionnaire completed by adults in Montreal. Public Health Nutr. 2004;7:675-81. doi: 10.1079/PHN2003578.
40. Olafsdottir AS, Thorsdottir I, Gunnarsdottir I, Thorgeirsdottir H, Steingrimsdottir L. Comparison of women's diet assessed by FFQs and 24-hour recalls with and without underreporters: associations with biomarkers. Ann Nutr Metab. 2006;50:450-60. doi: 10.1159/000094781.

41. Mendez MA, Popkin BM, Buckland G, Schroder H, Amiano P, Barricarte A et al. Alternative methods of accounting for underreporting and overreporting when measuring dietary intake-obesity relations. Am J Epidemiol. 2011;173:448-58. doi: 10.1093/aje/kwq380.