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Efficacy of water preloading before main meals as a strategy for weight loss in primary care patients with obesity: RCT

Helen M Parretti[1], Paul Aveyard[2], Andrew Blanin[3], Susan J Clifford[1], Sarah J Coleman[3], Andrea Roalfe[1] and Amanda J Daley[1]

1. Primary Care Clinical Sciences, University of Birmingham, Birmingham, B15 2TT, UK
2. University of Oxford, Nuffield Department of Primary Care Health Sciences, Radcliffe Observatory Quarter, Woodstock Road, Oxford, OX2 6GG, UK
3. School of Sport, Exercise and Rehabilitation Sciences, University of Birmingham, Birmingham, B15 2TT, UK

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Corresponding author:
Dr Helen Parretti
Primary Care Clinical Sciences,
University of Birmingham
Birmingham, B15 2TT, UK
h.m.parretti@bham.ac.uk
+44 121 414 3766

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Author's contributions: AD conceived the original idea for the study. HMP, AJD and PA designed the study. HMP, AJD, and PA drafted the paper with additional input from AB, AR, SJCl and SJCo. HMP and AR conducted the statistical analyses and HMP, AJD and PA wrote the results. AB conducted the urine analyses. SJCl was responsible for data collation and management. SJCo was responsible for data collection and collation. All authors have read and agreed the final version of the manuscript.

What is already known about this subject

- Laboratory test studies have found that participants ingest less energy at meals after consuming a preload of 500ml of water 30 mins before the meal
- Only one previous small RCT examining water preloading before main meals for weight loss (combined with a hypocaloric diet, in middle/older aged adults, who were overweight or with obesity) and found that the intervention group lost approximately 2kg more than comparators
- Test meal studies have shown that consuming water before and during meals increases satiety, but the exact mechanism of the potential effect of water preloading is unclear

What this study adds

- Adults with obesity recruited from general practices, instructed to consume 500ml of water 30mins before main meals (water preloading) lost 1.3kg more than comparators over 12 weeks
- Water preloading before main meals leads to a moderate weight loss at follow up and is a simple message that could easily be disseminated by healthcare professionals and in public health campaigns

Abstract

Objective: To investigate the efficacy of water preloading before meals as a weight loss strategy for adults with obesity.

Methods: Two group randomized controlled trial conducted in Birmingham, England. 84 adults with obesity were recruited from general practices. All participants were given a face to face weight management consultation at baseline (30 minutes) and a follow-up telephone consultation at two weeks (10 minutes). At baseline participants were randomized to either drinking 500mls of water 30 minutes before their main meals or an attention control group where participants were asked to imagine their stomach was full before meals. The primary outcome was weight change at 12 weeks follow up. Several measures of adherence were also used, including 24hr total urine collections.

Results: 41 participants were randomized to the intervention group and 43 to the comparator group. The water preloading group lost -1.3kg (95% CI -2.4 to -0.1, p=0.028) more than comparators at follow up. Adjusting for ethnicity, deprivation, age and gender resulted in the intervention group losing -1.2kg (95% CI -2.4 to 0.07, p=0.063) more than the comparator.

Conclusion: There is preliminary evidence that water preloading before main meals leads to a moderate weight loss at follow up. **ISRCTN33238158**

Introduction

Obesity and water consumption

There is a need to investigate the effectiveness of simple, pragmatic interventions that could reach the many people needing to lose weight. These types of intervention will likely result in modest reductions in weight, but even small reductions across the whole population can have important public health benefits [1]. Daily water consumption is widely advocated as a useful tool to aid weight loss and is often included within weight loss programmes [2], yet there is little evidence to support this practice, as highlighted by a recent systematic review of the association between water consumption and body weight [3]. Recent studies have focused more on replacing caloric beverages with water/diet beverages [4] or comparing non-nutritive sweeteners and water as part of intensive complex interventions [5], rather than directly assessing the potential benefits of increasing water intake on weight loss.

Water preloading before meals

One potential strategy to reduce meal energy intake is to modify individuals' perception of fullness prior to eating by consuming a 'preload' of water. A systematic review [6] identified only two small laboratory studies that specifically investigated whether water preloading reduced energy intake. Both studies compared participants given a water preload of 500ml 30 minutes before an ad libitum meal with those not given a preload and found that energy intake at the meal was lower for the preload group compared with the no-preload group [7, 8]. Thus water preloading may improve the effectiveness of weight loss programmes.

The only RCT [9] to directly examine the effects of water preloading before meals on weight loss recruited 48 adults who were overweight or with obesity allocated to a hypocaloric diet plus 500ml of water before meals every day (water preload group) or a hypocaloric diet alone intervention (non-water group) over 12 weeks. The water group lost about 2kg more than the non-water group. Overall diet energy density decreased significantly more in the water preload group than the non-water group, this study however,

recruited primarily white, older - middle aged adults and excluded those with common co-morbidities. Thus these results may not be applicable to a general adult population.

Mechanisms for the effects of preloading

The mechanism(s) responsible for the potential effects of water preloading is unclear. Test meal studies have shown that consuming water prior to and during meals increases satiety [7, 8, 10] and changes in subjective sensations of satiety have been associated with a reduced meal energy intake. Whether this reduction results in weight loss is unclear, although the recent RCT by Dennis [9] suggests it might, at least in the short term. However, if changes to satiety did not last until the next scheduled main meal, it may increase snacking between meals and snacking usually involves consumption of high calorie dense food [11].

Here we have investigated the efficacy of preloading with water before main meals as a weight loss intervention, by conducting an attention controlled RCT in patients with obesity recruited from general practices and also collected objective data to assess adherence.

Methods

Design

Two group RCT (individual randomization) with participants allocated to the water preloading group or a comparator group. Participants were blinded to the purpose of the study.

Participants

Four general practices within Birmingham assisted with recruitment. Adult patients with a BMI ≥30kg/m^2 recorded within their primary care notes in the last 12 months were invited to take part by letter, from their GP. Interested patients completed a screening questionnaire to assess eligibility. A baseline home visit was arranged for potentially eligible participants.

Participants were excluded if they were pregnant, intending to become pregnant, or breastfeeding within the study period, could not understand or speak English sufficiently to participate, currently attending a weight management programme or had taken part in a weight management programme, lost >2kg or changed medication that affects weight/energy expenditure in the last three months. Participants who were using insulin were also excluded.

Sample Size

We calculated that 49 randomized to each group would be sufficient to detect a 1.5kg difference between groups in weight change at 12 weeks from baseline (SD 2.0kg) [12] with 90% power and 5% significance level (includes 20% loss to follow up at 12 weeks). We chose this difference in weight because the intervention is brief and because even small amounts of weight loss maintained over the lifetime has important clinical health benefits [1, 13].

Allocation and randomization

Baseline data and consent were collected from participants at an initial home visit. Participants were then randomized to groups at a second home visit (consultation 1), thus ensuring that all baseline data were collected before group allocation was revealed. We used block randomization of randomly mixed size (2, 4 or 6) sequenced blocks. A randomization sequence was prepared by an independent statistician to ensure blinding, with allocation placed in an opaque, consecutively numbered envelope, which were used in order.

Blinding

Neither group was informed that the trial was about water preloading and the participant information sheet informed patients that the study was concerned with two different approaches to weight loss. Neither group was aware of what the other group was asked to do. The statistical analysis of the primary outcome was performed by an independent researcher blinded to allocation. Researchers who conducted the urine

analyses were also blinded to group allocation. The researchers who measured weight at follow-up could not be blinded to group allocation.

Settings

Both groups had the initial weight loss consultation and all follow up appointments at home, carried out by a researcher.

Intervention group

After the initial baseline data visit participants were offered two consultations; one face-to-face at baseline (consultation 1) and one by telephone in week 2 (consultation 2). Consultation 1 lasted 30 minutes and involved a brief discussion around weight management strategies, similar to a consultation that a GP or practice nurse might offer. Since the primary purpose of the study was to test specifically the effects of water preloading both groups of participants were given the same standard healthy lifestyle advice (for example healthy diet composition, reducing fat intake, increasing fruit and vegetable intake, regular physical activity). Participants in both arms were offered general information about replacing caloric drinks with water as in any standard dietary advice intervention. In addition, the intervention group was asked to consume 500ml of water (0.8 pints or 2 cups) 30 minutes prior to main meals each day and to consume additional water during their meals and throughout the day as desired. Thirty minutes was used in previous effective interventions [7, 8, 9]. The importance of water for health and for weight management was also discussed with the intervention group. Participants were encouraged to drink water from the tap or could choose to drink still bottled water. Participants were discouraged from drinking soda water, sparkling and carbonated waters as water preloads. Participants were given reusable 500ml water bottles to aid measurement and promote adherence. Participants were telephoned two weeks later (consultation 2, lasting around 10 minutes) to review adherence to the water preloading principles discussed in consultation 1. For those reporting low adherence, we discussed barriers and means to overcome them to enhance

adherence. As a reminder, weekly text messages were sent during the 12 week intervention.

Comparator group

This group received exactly the same consultations as the intervention group, but were asked to follow a dummy procedure that disguised the true intent of the study and provided a non-specific intervention that in some ways matched preloading. Participants were asked to imagine their stomachs were full 30 minutes prior to each meal and received text prompts, as did the preload group. This comparator was purposefully chosen as an attention control, to improve retention in this group, to give credibility to the comparator and to ensure both groups had the same follow-up.

Assessments/follow up

At baseline, researchers asked participants to report socio-demographic data including: age, gender, ethnicity, postcode, occupation and co-morbidities. Objective height and weight were measured at baseline and at six and 12 week follow up. All outcomes were assessed at baseline, six and 12 week follow up in participants' homes.

Outcomes

The pre-specified primary outcome was weight change from baseline to 12 weeks follow up. The secondary outcome was the percentage of participants who lost 5% or more body weight. Adverse events reported were recorded.

Adherence

Adherence to water preloading was assessed in several ways. At the baseline data collection visit all participants were provided 24 hour total urine collection to assess total urine volume and osmolality as an objective assessment of water consumption. Follow-up urine collections were completed at six and 12 weeks. The urine was delivered to the laboratory within a few hours, weighed to the nearest 0.1g using Sartorius CP8201, USA weighing scales and the volume recorded. A 30ml aliquot was then frozen at -70°C for analysis of osmolality using a freezing-point depression osmometer (Model 3320 Micro-

Osmometer, Advanced Instruments Inc, USA). The osmometer was calibrated using standards of known osmolality (Osmolality Linearity Set, Advanced Instruments Inc, USA).

In addition, both groups completed a phone questionnaire at weeks two, three, six and nine indicating how often they engaged in water preloading or imagining their stomach was full (depending on allocation), prior to each meal. Participants were offered the response options to this question of “not at all”, “once a day”, “twice a day” or “three times a day”.

Exploratory analysis

To assess whether there were changes in physical activity levels (that could affect weight loss) the IPAQ-short [14] questionnaire was recorded at baseline and at 12 week follow up. The Beverage and Snacking 2 Questionnaire [15] was also completed at these times. The data from these questionnaires are not reported here, but are available upon request from the authors.

Previous studies have suggested that consuming water prior to meals increases satiety [7, 8, 10] and to explore this we asked participants to report their feelings of fullness and satisfaction after their most recent main meal on a scale of 1-10 during each phone questionnaire.

Exit questionnaire

At the end of the study all participants were asked to complete an exit questionnaire asking what they believed the purpose of the study had been.

Analysis

Primary outcome

We estimated the difference in weight change (baseline to 12 weeks) between the groups using repeated measures mixed modeling. Participants for whom objective weight at follow up was not available were assumed to have maintained their baseline weight (BOCF). In addition to the primary analysis, the difference in weight change from baseline to 12 weeks was estimated adjusted for age, gender, ethnicity and deprivation (based on

postcode). A sensitivity analysis was undertaken where missing data were not imputed (available case analysis). All analyses were conducted using the intention to treat principle.

Secondary outcomes

A two sample test of proportions was used to compare the percentage of participants who lost 5% body weight in each group.

Adverse events

Adverse events were compared without inferential statistics.

Adherence and exploratory analysis

Repeated measures mixed modeling methods were used for the analysis of fullness and satiety scores, self-reported adherence and 24 hour total urine collections. Analysis of covariance between groups (ANCOVA) was used within the intervention group to investigate the difference in weight change between people who had high (three times a day) and low (once a day or less) adherence to preloading using Bonferroni adjustment for between group comparisons. All statistical analyses were conducted using Stata v12.1.

Results

Recruitment

Participants were recruited between July 2013 - March 2014. 172 patients were assessed for eligibility and 84 randomized (41 in intervention group and 43 in comparator group) (Figure 1). Follow-up rates for the primary outcome (objectively measured) were high in both groups with 95% and 88% follow-up for the intervention and comparator groups, respectively. Participants in both groups had similar characteristics (Table 1). Participants had a baseline mean BMI of 34.1kg/m^2, baseline mean age of 56.5 years and 64.3% of participants were female.

Primary outcome

The mean weight loss over 12 weeks in the intervention group was 2.4kg (SD 3.4) and 1.2kg (SD 2.9) in the comparator group, a difference of -1.3kg (95% CI -2.4 to -0.14, p=0.028) using the baseline observation carried forwards (BOCF) method to impute missing data. A marginally smaller effect size was observed for the available case analysis

(p=0.066) (Table 2). Adjusting for ethnicity, deprivation, age and gender resulted in the intervention group losing -1.2kg (95% CI -2.4 to 0.07, p=0.063) more than the comparator, using BOCF.

Secondary outcomes

A total of 27% of the participants in the preloading group lost at least 5% of their body weight and 5% in the comparator group. The difference (95% CI) was 22.2% (7.2 to 37.1).

Adverse events

No adverse events were recorded.

Adherence and exploratory analysis

Urine analysis

Repeated measures mixed modeling analyses of total urine volume and osmolality at six and 12 weeks showed a significant difference between groups, with the intervention group having a greater total urine volume and lower urine osmolality at follow-ups; consistent with the intervention group having a higher fluid intake (Table 3).

Self-reported adherence

In the comparator group 15 participants (34.9%) reported that they were imagining their stomachs were full at least twice a day in the first six weeks of the trial, increasing to 16 participants (37.2%) by week nine (Table 4). Adherence was higher in the intervention group and 36 participants (87.8%) reported preloading at least twice a day in the first six weeks of the intervention and this dropped to 27 (65.8%) by week nine (Table 4). At 12 weeks, there was also a significant difference in weight between those reporting preloading water three times a day and those reporting preloading water least frequently (only once a day or not at all) (mean difference in weight change between drinking water three times a day versus not at all/once a day was -3.6kg (SD 9.0, 95% CI -7.0 to -0.2)). At six weeks there was no significant difference in weight between frequency of preloading groups.

Fullness and satiety scores

There was no evidence of a significant difference between groups at any time point. Repeating the analysis using BOCF did not change the results. On average the intervention

fullness scores were 4% higher than those in the comparator group. Satiety scores were on average 7.5% higher in the intervention group than the comparator group (Table 6).

Exit questionnaire

15% of the intervention group correctly identified water preloading as the purpose of the study. No participants in the comparator group identified water preloading as the purpose of the study.

Discussion

Participants who were instructed to consume 500ml of water 30 minutes before main meals lost 1.3kg more than the comparator group. 27% of those in the preloading intervention group lost ≥ 5% body weight compared to only 5% in the comparator group and those who reported preloading three times a day lost 4.3kg (SD 4.0) (compared with 0.8kg (SD 1.8) if preloading once or not at all).

Comparison with existing literature

A difference of 1.3kg is moderate weight loss, but even small amounts of weight loss maintained over the lifetime can have important clinical health benefits and the relationship between weight loss and health is linear [1]. The effect was achieved with a minimal intervention that may prove easy to maintain by participants and costs them nothing. The mean difference in weight loss observed is larger than the effect of other brief interventions for weight loss, such as self-weighing [16]. Dennis [9] reported a greater difference in weight loss (2.0kg) than that reported here (1.3kg), but this is likely due to a greater adherence to water preloading since they reported an average weekly water intake compliance of 90 ± 2%. It is interesting to note in our trial that the amount of weight loss in those who preloaded with water three times a day was similar to that which can be achieved with commercial weight loss programmes and that the percentage who lost ≥ 5% body weight in the preloading intervention group is similar to other primary care and community based interventions [17].

Implications

We found preliminary evidence that preloading with 500ml of water before meals can lead to weight loss. Water preloading as an intervention for weight loss could have public health significance and is a simple, straightforward message that can be easily disseminated to the general public. This intervention directly addresses inequalities in health since tap water is freely available to almost everyone in high and middle income countries.

Strengths and limitations of study

We recruited participants from general practices in different geographical locations across Birmingham, UK. We had high retention of participants in the study (over 90% in the intervention group and 88% in the comparator group). A high percentage of participants living in the most socioeconomically deprived communities (46%) were recruited and 18% of participants were from non-white ethnic groups. We included objective measures of water consumption in the form of 24 total urine collections at baseline and follow ups. Participants were not aware of the nature of either intervention prior to randomization, therefore this study did not attract patients who were particularly motivated by the concept of water preloading. The comparator condition used in the design of this trial successfully disguised the true intent of the study and provided a non-specific intervention that in some ways matched preloading. This comparator was an attention control, which gave credibility to the comparator and ensured both groups had the same follow-up. However, it is possible that the comparator used may have had unexpected effects such as the participants consuming more due to focusing on hunger prior to the meal.

We were not able to fully explore potential mechanisms of action and future studies on this question would be valuable, particularly related to portion size at later meals after preloading. In addition, one potential explanation for the observed effect is that the consumption of water before a meal reduces the energy density of stomach contents. Previous controlled trials and cohort studies have shown that the consumption of lower energy density foods can have an effect on body weight in the short term, but that this effect may not be maintained longer term [18, 19, 20]. Therefore, an assessment of whether the

short-term benefit of water preloading is maintained would be important. It is also noted that whilst the pre-declared primary outcome was significant, the available case analysis was of borderline significance. Therefore definitive evidence that this intervention is effective will require a trial with a longer-term assessment of weight, for example assessed at 12 months. It is also clear that adherence reduced over time and strategies to improve this may increase weight loss further.

Conclusions

This trial has shown preliminary evidence that water preloading before main meals may be an effective weight loss strategy though the mechanism of action remains unknown.

Ethical approval

Ethical approval for this study was given by NRES Committee West Midlands, England 8/03/2013 Reference: 13/WM/0043.

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Table and Figure Legends

Table 1: Baseline characteristics of randomized participants (n=84) and baseline data of outcomes

*IMD = index of multiple deprivation [21]

Table 2: Analyses of weight change between baseline and 12 weeks and mean difference between groups at 12 weeks follow up

Table 3: Mixed modeling analysis for urine osmolality and total urine volume at 6 and 12 weeks follow up (BOCF)

Intervention group: n=35 at 6 weeks and n=34 at 12 weeks
Comparator group: n=36 at 6 weeks and n=36 at 12 weeks

Table 4: Self-reported adherence for both groups

*I=intervention, n=41
[†]C=comparator, n=43

Table 5: Self-reported fullness and satiety scores for both groups

*I=intervention , [†]C=comparator
Note fullness and satiety scores can range from 1 to 10

Figure 1: Consort trial flow diagram

Table 1: Baseline characteristics of randomized participants (n=84) and baseline data of outcomes

	Comparator	(%)	Intervention	(%)	Total	(%)
Randomized	**43**		**41**		**84**	
Gender						
Male	15	(34.9)	15	(36.6)	30	(35.7)
Female	28	(65.1)	26	(63.4)	54	(64.3)
IMD*						
Quartile 1 (least deprived)	0	(0)	0	(0)	0	(0)
Quartile 2	5	(11.6)	1	(2.4)	6	(7.1)
Quartile 3	20	(46.5)	19	(46.3)	39	(46.4)
Quartile 4 (most deprived)	18	(41.9)	21	(51.2)	39	(46.4)
Smoked						
Yes	4	(9.3)	7	(17.1)	11	(13.1)
No	39	(90.7)	34	(82.9)	73	(86.9)
Ethnicity						
White	31	(72.1)	35	(85.4)	66	(78.6)
Non-White	12	(27.9)	6	(14.6)	18	(21.4)
Children						
None	5	(11.6)	6	(14.6)	11	(13.1)
One or More	38	(88.4)	35	(85.4)	73	(86.9)
Marital Status						
Living alone	14	(32.6)	14	(34.1)	28	(33.3)
Not living alone	29	(67.4)	27	(65.9)	56	(66.7)
Employment						
Employed	23	(53.5)	26	(63.4)	49	(58.3)
Not employed	20	(46.5)	15	(36.6)	35	(41.7)
Education						
University Educated	9	(20.9)	9	(22.0)	18	(21.4)
Not University Educated	34	(79.1)	32	(78.0)	66	(78.6)
Long Term Illness/Disability						
Yes	15	(34.9)	11	(26.8)	26	(31.0)
No	28	(65.1)	30	(73.2)	58	(69.0)
Age Mean (SD)	57.8 (9.8)		55.1 (10.5)		56.5 (10.2)	
Weight Mean (SD)	93.5 (14.2)		92.2 (12.3)		92.9 (13.2)	

BMI Mean (SD)	34.0 (2.6)	34.1 (2.1)	34.1 (2.4)
Physical activity MET minutes per week Mean (SD)	2006 (2385) (n=40)	1925 (62) (n=34)	1969(2146) (n=74)
Urine total volume ml Mean (SD)	1958 (814)	2085 (885)	2020 (847)
Urine osmolality mOsmol/kg Mean (SD)	463 (170)	458 (179)	461 (173)

*IMD = index of multiple deprivation [21]

Table 2: Analyses of weight change between baseline and 12 weeks and mean difference between groups at 12 weeks follow up

	Mean weight change from baseline to follow up		**Mean difference between groups at follow up (unadjusted)**
	Comparator	**Intervention**	
Primary analysis - baseline observation carried forwards kg (95% CI)	-1.2 (-2.1 to -0.31) (n=43)	-2.4 (-3.5 to -1.3) (n=41)	-1.3 (-2.4 to -0.14) p=0.028 (n=84)
Available case analysis kg (95% CI)	-1.3 (-2.3 to -0.35) (n=38)	-2.5 (-3.6 to -1.4) (n=39)	-1.15 (-2.4 to 0.08) p=0.066 (n=77)

Table 3: Mixed modeling analysis for urine osmolality and total urine volume at 6 and 12 weeks follow up (BOCF)

	Mean difference at 6 weeks intervention vs. comparator	**Mean difference at 12 weeks intervention vs. comparator**
Urine osmolality (mOsmol/kg)	-116 (95% CI -170 to -62), p<0.001	-72 (95% CI -127 to -18), p=0.009
Total urine volume (ml)	598 (95% CI 278 to 918), p<0.001	524 (95% CI 204 to 844), p=0.001

Intervention group: n=35 at 6 weeks and n=34 at 12 weeks

Comparator group: n=36 at 6 weeks and n=36 at 12 weeks

Table 4: Self-reported adherence for both groups

Self-reported frequency of drinking water or imagining stomach is full before main meals	Week 2		Week 3		Week 6		Week 9	
	I*	C†	I*	C†	I*	C†	I*	C†
Not at all/once a day n (%)	3 (7.3)	21 (48.8)	3 (7.3)	14 (32.6)	8 (19.5)	21 (48.8)	9 (22.0)	20 (46.5)
Twice a day n (%)	14 (34.1)	10 (23.3)	20 (48.8)	12 (27.9)	9 (22.0)	7 (16.3)	11 (26.8)	12 (27.9)
Three times a day n (%)	22 (53.7)	10 (23.3)	16 (39.0)	9 (20.9)	20 (48.8)	8 (18.6)	16 (39.0)	4 (9.3)
No answer n (%)	2 (4.9)	2 (4.7)	2 (4.9)	8 (18.6)	4 (9.8)	7 (16.3)	5 (12.2)	7 (16.3)

*I=intervention, n=41

†C=comparator, n=43

Table 5: Self-reported fullness and satiety scores for both groups

	Fullness scores							
	Week 2		**Week 3**		**Week 6**		**Week 9**	
Group	**I***	**C†**	**I***	**C†**	**I***	**C†**	**I***	**C†**
Score (SD)	8.0 (1.7)	7.8 (1.7)	8.2 (1.6)	7.8 (2.0)	8.4 (1.6)	8.0 (1.7)	8.3 (1.4)	8.1 (1.7)
	Satiety scores							
	Week 2		**Week 3**		**Week 6**		**Week 9**	
Group	**I***	**C†**	**I***	**C†**	**I***	**C†**	**I***	**C†**
Score (SD)	8.4 (1.5)	7.6 (1.9)	8.3 (1.7)	7.9 (2.1)	8.7 (1.6)	8.2 (1.8)	8.5 (1.3)	8.1 (1.8)

*I=intervention , †C=comparator

Note fullness and satiety scores can range from 1 to 10