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Research

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Effects of Protein Load Prior to the Main Meal of the Day: A Pilot Trial

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ABSTRACT

Background: High protein diets increase satiety and may decrease energy intake. Many overweight people overeat in the evening. We hypothesized that ingesting protein prior to the evening meal may limit successive calorie intake and generate weight loss.
Aims: To explore whether protein pre-load before the evening meal will lead to weight loss compared to eating as usual.
Methods: 129 adults with a Body Mass Index (BMI) ≥25 reporting eating large evening meals were randomized to either consume a 20 g protein bar 30 minutes before their evening meal daily for two weeks (Protein pre-loading (PP) arm) or not (No protein pre-loading (NP) arm). Hunger ratings were recorded, immediately prior to each evening meal. Participants returned at the end of weeks one and two to provide their weight and rating of hunger and any changes in evening food consumption since baseline.
Results: There was no significant difference in weight loss between the study arms (Week1 PP: -0.13 kg, [SD=0.74] *vs.* NP: -0.06 kg, [SD=0.75], not significant (NS); Week2 PP: +0.06 kg, [SD=0.82] *vs.* NP: -0.005 kg, [SD=0.82], NS). Participants in the PP arm reported less hunger before evening meals than those in the NP arm (Week1: 4.97 [SD=0.94] *vs.* 3.72[SD=0.65], $p<.001$; Week2: 4.95 [SD=0.94] *vs.* 3.69[SD=0.71], $p<.001$). They also reported eating less at their evening meals (Week1: 2.59[SD=0.53] *vs.* 2.11[SD=0.54], $p<.001$; Week2: 2.63[SD=0.49] *vs.* 2.10[SD=0.50], $p<.001$).
Conclusion: Consuming 20 g of protein before the evening meal reduced hunger and self-reported food intake in the evening, but had no effect on weight.

KEYWORDS: Weight loss; Protein; Hunger; Randomized-controlled trial.

ABBREVIATIONS: BMI: Body Mass Index; WAP: Weight Action Programme; RDA: Recommended Dietary Allowance; ANOVA: Analysis of variance; GCP: Good Clinical Practice; NS: Not Significant.

INTRODUCTION

Weight management programs often advise dieters to avoid skipping meals.[1,2] The advice seems to be linked to an observation that obese women consume fewer calories in the morning compared to lean women, but consume more calories in the evening.[3] It is not clear whether this implies a causal link between skipping meals and obesity, but it has been proposed that breakfast-skipping and prolonged fasting may lead to an increase in blood insulin levels, which may promote lipogenesis.[4] Another possible causal route would be if the accumulated calorific deficit leads to overcompensation at the next meal.

If it is true that the caloric deficit accumulated by skipping meals generates weight gain due to overeating later, interventions which reduce hunger prior to main meals may provide a weight management benefit.

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Protein increases satiety and decreases subsequent energy intake more than the other macronutrients, which is the usual explanation for high protein/low carbohydrate diets leading to greater weight loss than high carbohydrate/low protein diets.[5,6] Apart from effects on satiety, increased thermogenesis[7] and enhanced glycaemic control[8] could also be contributing to this effect.

We tested the hypothesis that consuming protein prior to the evening meal reduces appetite and subsequent food intake. This was a 'proof-of-principle' exploratory study to inform a possible future trial with a larger sample and longer follow-up.

MATERIALS AND METHODS

Participants

Participants were recruited through local advertising and from a pool of service users who enquired about joining free local weight management courses (Weight Action Programme (WAP))[9] Participants were included if they had a Body Mass Index (BMI) ≥25 and if they reported that their largest meal of the day was the evening meal. Exclusion criteria were: age<18 years, diagnosis of diabetes, and allergies to nuts.

Study Design

This was a randomized controlled trial with two arms. Participants in the experimental arm were asked to eat a protein bar 30 minutes before their evening meal (Protein pre-loading (PP)) and rate their hunger immediately prior to their evening meal for two weeks. Participants in the control arm were asked to rate their hunger only (No protein pre-loading (NP)). The study used commercially available protein bars (Body Build, Boots Pharmacy, UK). The bars are stated by the manufacturer to provide 20 g of protein per bar. The bars provide 154 kcals and 3.5 g of saturated fat, 11 g of carbohydrates and 3 g of dietary fiber. They were purchased from Boots pharmacy. The bars were selected to provide a sufficient dose of protein to generate the hypothesized effect while trying to keep the daily protein intake reasonably close to the Recommended Dietary Allowance (RDA), which is around 60 grams per day.[10]

Procedures

Prospective participants were mailed study information prior to the baseline session. At the baseline session, eligibility criteria were checked and informed consent and baseline weight were collected. The study was approved by London City & East Research Ethics Committee (REC number 09/H0703/114).

Participants in both conditions were asked to monitor their hunger immediately before their evening meal (the main meal of the day for all participants). In addition to this, those in the PP condition were provided with a one-week's supply of protein bars to eat 30 minutes prior to their evening meal each day.

Both groups received an identical explanation of the study. It stated that the effects of hunger-monitoring and protein-pre-load prior to evening meals on caloric consumption during the meal are not known. They were also told that the study was investigating how practicable these two interventions are, how well clients adhere to them and whether they have any effect on weight in people who make no other changes to their lifestyle or daily routines.

Participants were asked not to change any of their usual routines, and not to go on a diet, or take any other steps to lose weight over the next two weeks. They were invited to attend the WAP programme immediately after completion of the study.

Two further sessions took place one and two weeks after the baseline session. At Week one, participants were weighed and asked to complete ratings of the procedures and report their adherence to them. PP participants were provided with a second batch of bars and both groups were asked to continue with the hunger monitoring exercise. At Week two, final weights and ratings were collected.

Participants were paid £10 for attending each session, contingent on adhering to the study procedures for at least 6 of the 7 days.

Measures

The same set of Omron Body Fat Scale BF400 was used with each volunteer on all three occasions.

The pre-meal hunger was rated on a 10-point scale ranging from 1='Starving' to 10='full to the point of feeling sick'. Participants were given a card, on which to record their hunger rating (Figure 1).

Front

Hunger rating card 1

Name: **Date:**

Please rate every day how hungry you feel (using the rating scale on the back on the back of the card) immediately before you eat your evening meal.

	Rating 1-10
Day 1	
Day 2	
Day 3	
Day 4	
Day 5	
Day 6	
Day 7	

Back

10 = Stuffed to the point of feeling sick
9 = Very uncomfortably full, need to loosen your belt
8 = Uncomfortably full, feel stuffed
7 = Very full, feel as if you have overeaten
6 = Comfortably full, satisfied
5 = Comfortable, neither hungry nor full
4 = Beginning signals of hungry
3 = Hungry, ready to eat
2 = Very hungry, unable to concentrate
1 = Starving, dizzy, irritable

Figure 1: The hunger rating card.

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The ratings of the previous week's experience included the following: Participants rated on a 3-point scale (More than before, Same as before, Less than before) the amount of food they had eaten during the day over the previous week and separately if the amount of food they had eaten at their evening meals had changed since starting the study. Participants were also asked to score how helpful they found the study procedures and how easy it was to follow them on a scale of 1-5 (1=not very helpful; 5=very helpful; and 1=very difficult; 5=very easy). Adherence to study procedures was recorded.

Randomization

The randomization list was generated by an independent researcher not involved in the study. Participants were sequentially allocated an opaque envelope which assigned them to one of the two conditions.

Sample Size

The awareness of taking part in a weight loss study together with the hunger monitoring exercise was expected to generate a small weight loss of some 0.5 kg. Increasing this to 1.5 kg would indicate a potentially useful effect. From data on previous WAP attendees, we estimated the average weight of participants as 94 kg (SD=18.7). To have 85% probability of detecting a difference of 1 kg ($p<.05$, one-tailed test) 52 participants would be needed in each arm. The study aimed to randomize 130 participants.

Data Analysis Plan

The weight change in the two groups and subjective ratings of hunger and amount of food consumed were compared by analysis of variance (ANOVA). Any significant differences between the study groups at baseline were entered as covariates. If the number of people who did not attend the session at Week two differed between the two study arms, an Intention-to-treat analysis would be performed with the assumption that study drop-outs lost no weight (i.e. baseline weight would be carried forward). If there were no difference in proportion of study drop-outs between the two groups, the per-protocol analysis would be used including only participants who provided 2-week weight data. This would prevent a risk of the imputed data from drop-outs masking a real study effect.

Ethics and Risk Assessment

The study was approved by London City & East Research Ethics Committee (REC number 09/H0703/114) and conducted in compliance with the principles of the World Medical Association (WMA) Declaration of Helsinki and ICH Good Clinical Practice (GCP). Participants signed informed consent and study records were kept confidential.

The trial was not expected to pose any risks to participants. The protein bars were standard bars available for over-the counter purchase in pharmacies and health food shops; and the study participation was expected to possibly generate a small weight loss.

RESULTS

129 participants were randomized, of whom 118 completed the study. 11 participants dropped out (did not attend appointments), 8 in the PP arm and 3 in the NP arm.

Table 1 shows baseline characteristics of the sample. The sample had the usual characteristics of people seeking help with weight loss in East London, i.e. they were mostly women in their 40 s (age range 19-68 years), with about half belonging to ethnic minorities.

	PP(N=65)	NP(N=64)	Difference
Age(SD)	42.98(11.50)	45.22(12.36)	NS
Weight(SD)	93.13(17.03)	91.14(16.14)	NS
% Women	80%	89.1%	NS
BMI(SD)	34.04(5.77)	33.69(5.73)	NS
In paid employment	52(80%)	49(77%)	NS
Educated to degree level or equivalent	26(40%)	30(47%)	NS
White British	28(43%)	33(52%)	NS
Entitled to free prescriptions	23(37.50%)	21(32.80%)	NS
Smokers	8(12.30%)	7(10.90%)	NS
Heart disease	2(3.2%)	3(4.7%)	NS
Concurrent medication	39(60.9%)	34(54%)	NS

Table 1: Baseline characteristics of the sample.

There were no significant differences between the study arms in any of the baseline characteristics reported above.

106 (82%) participants followed the study procedures on at least 12 of the 14 study days (49 in PP and 57 in NP arms). Both groups showed good adherence to hunger card completion in Week one, but in Week two, completion decreased somewhat in the PP group and, increased in the control group. In the PP condition, the adherence to the protein bar task decreased somewhat from Week one to Week two but this difference did not reach statistical significance (see Table 2).

Table 3 shows the weight change in the two study arms. The PP arm lost about 0.04 kg more than the control group, but the difference was not statistically significant.

The Table includes participants who provided complete data. The 'intention to treat' analysis with baseline weight carried forward (for participants who dropped out) yields very

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	PP (N=60, Wk 1; N=57, Wk2)		NP (N=63, Wk 1; N=61, Wk 2)		
Hunger cards	**Mean**	**SD**	**Mean**	**SD**	***p* value**
Days hunger cards completed (Week 1)	6.77	0.65	6.75	0.93	.89
Days hunger cards completed (Week 2)	6.56	1.34	6.84	0.93	.20
Protein bars	Week 1 (N=57)		Week 2 (N=57)		*p* value
Days protein bar consumed (PP arm)	6.54	0.91	6.33	1.07	.12

Table 2: Adherence to study procedures.

	PP (N=61 at Wk1 and N=56 at Wk 2)	NP (N=63 at Wk 1 and 61 at Wk 2)	Difference
Week 1 kg (SD)	-0.14(0.77)	-0.06(0.76)	NS
Week 2 kg (SD)	+0.06(0.82)	-0.005(0.82)	NS
	PP(N=56)	NP(N=61)	
Overall kg (SD)	-0.10(1.08)	-0.06(1.03)	NS

Table 3: Weight change from baseline.

similar results (weight loss of 0.13 *vs.* 0.06 kg in week one and a gain of 0.05 kg *vs.* loss of 0.005 kg in week two (PP *vs.* NP), NS, and overall weight loss of 0.08 kg *vs.* 0.06 kg in PP and NP, respectively, NS).

Table 4 shows the hunger ratings in the two study arms. The PP group reported significantly less hunger prior to the evening meal in both weeks.

	PP		NP		Difference
	Mean	SD	Mean	SD	
Week 1	4.97	0.94	3.72	0.65	*p*<.001
Week 2	4.95	0.94	3.69	0.71	*p*<.001

*Note that higher values indicate lower hunger.

Table 4: Effect of protein bars on hunger ratings prior to evening meal.

Protein bars also significantly reduced retrospective ratings of food consumption in the evening over the previous week (see Table 5). Those in the PP arm also tended toward reporting reduced eating during the day compared with NP arm, but these differences did not reach statistical significance.

Table 6 shows ratings of the ease of use and helpfulness of the two interventions. Participants in the NP arm found the study procedure easier to follow in the first week than those in the PP arm, but by the end of the second week this difference was no longer significant. Although, the PP group tended towards higher ratings of helpfulness of the intervention compared with the NP group, the difference was not significant.

DISCUSSION

The main finding of this study is that the protein pre-load significantly reduced ratings of pre-meal hunger (see Table 4) and also the self-reported amount of food eaten at the evening meals (see Table 5). This however had no effect on weight (there was virtually no weight change in either study arm, see Table 3). This was despite good adherence to study procedures (see Table 2) which were rated as reasonably easy to follow (see Table 6).

The study results provide further indirect evidence contradicting the hypothesis that hunger generates overeating leading to weight gain. We studied the effect of skipping meals on weight change previously using a more direct approach, looking at weight changes over the Ramadan fast.[11] During four weeks of Ramadan, religious Muslims do not eat during the day and only begin eating in the evening by which point they feel very hungry.[12] Literature search suggested that it is in fact not known whether Ramadan fasting generates weight loss or weight gain.[10] Only a small number of studies were identified, which used small samples, mostly of students and pregnant women, and reported inconsistent results: one found weight gain,[13] three reported weight loss,[14-16] and five found no significant weight change.[12,17-20] In order to investigate this further we took weight measurements in 202 Ramadan observers at baseline, at the end of Ramadan, and a month later. Ramadan generated a weight loss of about 1 kg, which was re-gained within the next four weeks.[10]

Correlational studies that link weight gain and being overweight with skipping meals,[21,22] have led to weight management programmes commonly suggesting that skipping meals undermines weight loss or generates weight gain, while regular spacing of food intake can help.[1-2,23-25] This is probably incorrect. Our two studies suggest that reducing hunger prior to the evening meal does not generate any reduction in overall calorie intake, and that skipping of meals may in fact generate a modest weight loss. The results of the present study however are only tentative and need to be interpreted with caution.

The study had several limitations. Participants

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	PP (N=61 Wk1, N=57 Wk2)		NP (N=63 Wk1, N=61 Wk2)		
	Mean	SD	Mean	SD	p value
Change in eating over week 1 (evening)	2.59	0.53	2.11	0.54	<.001
Change in eating over week 1 (daytime)	2.21	0.45	2.10	0.47	.16
Change in eating over week 2 (evening)	2.63	0.49	2.10	0.50	<.001
Change in eating over week 2 (daytime)	2.22	0.50	2.05	0.50	.07

*Note: higher values indicate eating less than before.

Table 5: Effect of protein bars on ratings of eating over the previous week.

	PP (N=61 Wk1, N=57 Wk2)		NP (N=62 Wk1, N=60 Wk2)		
	Mean	SD	Mean	SD	Difference
Ease following procedure (Week 1)	3.92	1.17	4.35	0.82	*p*=.02
Did you find it helpful? (Week 1)	3.73	0.94	3.51	0.93	*p*=.18
Ease following procedure (Week 2)	4.02	0.95	4.32	0.70	*p*=.06
Did you find it helpful? (Week 2)	3.89	0.88	3.61	0.97	*p*=.10

Table 6: Ease of use and helpfulness ratings.

were only followed up over a period of two weeks, the sample size was relatively modest, and the protein preload was limited to 20 g of protein. It could be argued that an effect could possibly emerge over a longer period of time (to allow the experimental manipulation to exert its influence), with a larger sample (to detect smaller effects), and/or with a higher protein pre-load (to enhance the pre-loading effect). The trial lasted for only two weeks, but the weight in both groups remained stable, with no sign of the two groups diverging during the second week. It is also unlikely that an effect would emerge with a larger sample size, because there was virtually no difference between the two study arms. Regarding the size of the protein pre-load, the dose was sufficient to generate a significant reduction in hunger, which was the key hypothetical mediator of any effect.

Another potential limitation is that the trial was not blinded, but expectations seem to have played little role as the weight in both study arms remained stable throughout the two week period. The lack of blinding could have in theory, influenced the subjective ratings, although this too seems unlikely. The PP arm reported a reduction in subsequent food intake and the protein pre-load seems to have indeed generated this as otherwise the additional 154 kcal consumed with the protein bar would induce a small weight gain. The reduction however seems to have been limited to maintaining the habitual overall calorie intake.

In conclusion, our two studies together suggest that increased hunger prior to evening meal does not generate weight gain, and reduction of hunger prior to evening meal does not generate weight loss. The advice to dieters to space eating episodes regularly throughout the day may have a good health rationale, but it may not contribute to weight loss.

DISCLOSURE

There were no competing interests and the study required no external funding.

AUTHORS CONTRIBUTIONS

PH, HJM, SJS and KEMS conceived the study and contributed to data analysis and study write-up, SJS and KEMS contributed to data collection and data analysis, SP and JAM contributed to data analysis and study write up.

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