

# **Effectiveness of a herbal supplement (Zotrim™) for weight management**

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## **Abstract**

**Purpose:** There are many herbal supplements on the market claiming to aid weight loss but few are evidence-based. This study aims to test one such formulation.

**Methodology:** An over-the-counter herbal supplement containing yerba maté, guarana and damiana (YGD) was tested in 73 overweight health professionals for 6-weeks. Subjects were not asked to make any lifestyle changes.

**Findings:** Self-reported weight, waist circumference and hip circumference reduced significantly, while 22% of subjects experienced a clinically significant weight loss. The anthropometric changes were in line with other commercial diet and exercise programmes. Reported between-meal hunger and consumption of snacks reduced across the 6 weeks. Reported satiety after meals increased and subjects claimed to be more in control of snacking, emotional eating and portion sizes. A follow-up at week 10, when 82% of subjects had stopped taking YGD, revealed no additional reductions in weight or hip circumference. Fullness ratings had stabilised, while hunger ratings had increased. There were no consistent adverse effects that could reasonably be related to YGD.

**Research Implications:** Taken alongside a 2001 randomised, placebo-controlled trial, this study provides evidence that a YGD supplement can aid weight loss and reduce waist and hip circumference, probably by increasing satiety.

**Value:** The growing market in weight management products brings with it a responsibility for manufacturers to provide evidence that their products work. This paper adds to the evidence base.

## Introduction

State-funded treatment of obesity in the UK is relatively scarce in relation to the problem. An industry-funded audit of 340 Primary Care Organisations (Dr Foster, 2004) found that less than 50% of these offered an obesity service and, where one existed, patients from only 25% of GP clinics were able to access it. The Health Select Committee report (2004) highlighted not only inadequate NHS resources for weight management, but a shortage of effective, evidence-based options. This led to the inclusion of obesity management within the Choosing Health white paper (Department of Health, 2004).

While NHS provision is under expansion, a considerable number of overweight people continue to seek help from the plethora of diet-related products. A consumer survey (Datamonitor, 2003) reported that the European diet food and drinks market was worth £62 billion (€92 billion) in 2002, with a predicted annual growth of 2%. This market includes herbal supplements that purport to aid weight loss; sales of which exceed £82 million per annum in the UK. The evidence-base for most products is sparse (Pittler & Ernst, 2005), although there are some data supporting the effects of individual ingredients on weight or energy expenditure, e.g. guarana, pyruvate, conjugated linoleic acid (Ruxton & Gardner, 2005). Most formulation-specific research has been done on a commercially-available product containing the South American herbal extracts, yerba maté, guarana and damiana (YGD).

Andersen & Fogh (2001) undertook a randomised placebo-controlled trial on 47 healthy overweight subjects who were instructed to consume YGD tablets before meals in the absence of any other lifestyle or diet advice. A statistically significant weight loss over the 45-day period was seen in the YGD group compared with the placebo group (5.1 kg vs. 0.3 kg respectively). YGD was thought to induce weight loss by impacting on satiety because ultrasound data (n=7) revealed that gastric emptying was 53% slower after YGD than after the placebo (Andersen & Fogh, 2001).

These findings were supported by a study testing the impact of YGD in 61 women (Ruxton et al, 2005). The protocol was designed to mimic the experience of consumers using weight management products at home and was not intended to be a controlled trial. Women were given a 28d sample of product and followed up, using telephone interviews, to ascertain any changes in self-reported weight, and waist and hip circumference. Questionnaires employing the Likert scale (ratings of 1-10) were used to track hunger and fullness around mealtimes. Mean weight loss in the group was 1.79kg (p<0.0001; 0.45kg per week). Hunger and fullness data suggested that subjects felt less hungry between meals and fuller after meals at weeks 1 and 4 compared with baseline. This is likely to have impacted on energy intake and may account for the weight loss. Mean waist circumference decreased by 4.3cm (p<0.001).

The studies to date suggest that YGD supports modest weight loss, possibly due to an impact on satiety. However, it is not clear what happens to weight, shape, hunger and fullness when provision of YGD is stopped. This led to the present study, the aim of which was to evaluate the impact of YGD provision and removal on weight, body mass index (BMI), waist circumference, hip circumference and perceived hunger and fullness, in a group of health professionals.

## Materials and Methods

Ethical approval for the study was given by Fife Local Research Ethics Committee. An overview of the study protocol is given in Figure 1. Following screening, baseline measurements were taken and subjects were provided with a 6-week supply of YGD. Follow-ups were conducted by telephone at weeks 1, 4, 6 and 10. The methodology and frequency of follow-ups were designed to be similar to the previous consumer study (Ruxton et al, 2005) in order to make comparisons. A decision was made to avoid compelling subjects to stop YGD at the end of the active phase as it was felt that this could not be enforced. Instead, the free supply of YGD was withdrawn and subjects were asked at week 10 whether they had continued to take a supply of the product.

*Take in Figure 1*

### Recruitment

Interest generated by an article in a nursing magazine (Ruxton, 2005) provided an opportunity for nurses to be recruited to the present study. Nurses were felt to be an appropriate group to study because obesity prevalence in nurses is similar to that seen in the general public (Hankey et al, 2004). The article prompted letters from 50 practice nurses wishing to try YGD. Based on the previous study (Ruxton et al, 2005), a final sample size of 60 was required for statistical power. This led to further recruitment via NHS Fife using the group email system, which generated over 200 enquiries within a month. As a 30% drop out rate was assumed, screening was continued until a starting sample of n=87 was achieved.

### Intervention

YGD has been marketed since 2001 as an herbal food supplement (*Zotrim™*, Natures Remedies) and is available over-the-counter in tablet form. The active ingredients of YGD are extracts of yerba maté (leaves of *Ilex paraguayensis*), guarana (seeds of *Paullinia cupana*) and damiana (leaves of *Turnera diffusa* var. *aphrodisiaca*). All have a history of use in traditional South American culture. No safety issues with YGD have been identified but, as a precaution, potential consumers of YGD are advised to consult their GP before embarking on a slimming programme. In a systematic review of the literature, Pittler et al (2005) identified anecdotal reports where consumption of guarana had been linked with adverse effects. A key point was that the guarana was mostly consumed alongside other herbal ingredients or prescription drugs. In two intervention studies where a guarana formulation had been used, one study (n=182) reported that the number of adverse effects was similar in the placebo and treatment groups, while the other (n=45) reported stomach pain or tachycardia in 4 individuals. In the latter study, no details were available on the composition of the guarana formulation. There were no data on adverse effects linked to yerba mate or damiana.

The dosage used in the study was in accordance with the manufacturer's instructions, i.e. 2 tablets 15 minutes before meals for the first week, increased to 3 tablets 15 minutes before meals for the remainder of the study. As guarana and yerba maté are natural sources of caffeine, each YGD tablet contains around 11.2 mg of caffeine, delivering 67 to 100 mg per day, which is similar to 1 cup of brewed coffee.

## Methods

Subjects expressing interest were sent the Screening Pack containing an information sheet, consent form, screening questionnaire, instructions for measuring waist and hips, and a calibrated measuring tape. The following inclusion criteria were applied to those returning a complete set of screening data:

1. Aged between 18 and 70 years;
2. Waist circumference  $\geq 94$ cm for men, or  $\geq 80$  cm for women;
3. Not currently under the care of a dietitian or obesity specialist for weight management;
4. Not currently taking medication that is contra-indicated with the level of natural caffeine supplied by YGD (i.e. 67-100 mg/d). Subjects were asked to consult their GP if possible contra-indications were suspected;
5. Not currently taking prescribed anti-obesity medication or over-the-counter supplements for weight management;
6. Not currently pregnant or breast-feeding;
7. Willingness to take YGD as per the protocol;
8. Access to weighing scales.
9. Currently working as a health professional (does not include long-term sick leave);
10. General health reported as 'good' or 'very good' as per Screening Questionnaire;
11. No thyroid disease or gastro-intestinal disease.

Subjects meeting the inclusion criteria and providing written consent were provided with a Baseline Pack containing a 6-week supply of YGD and a personalised plan showing when telephone follow-ups would occur. A date for starting YGD was set and a baseline questionnaire was conducted at D-1 by telephone. Follow-ups were done at weeks 1, 4, 6 and 10 using similar questionnaires.

Subjects were asked to take their anthropometric measurements just prior to each telephone follow-up. This involved measuring weight with the same set of scales throughout the study and waist/hip circumference using the measuring tape provided in the Screening Pack. If subjects had not complied with this at the time of the telephone interview, they were called back the following day. A grace period of 2 days was allowed before measurements were classified as missing.

## Questionnaires

Questionnaires were based upon those used by Ruxton et al (2005). The Likert scale was used to estimate hunger and fullness. Other questions related to compliance, perceived control over eating, frequency of snacking, whether subjects would recommend YGD to others, and positive/negative responses to consumption of YGD. The final questionnaire was used 4 weeks after the free supply of YGD was timed to run out. Questions were similar to those used in the week 6 questionnaire, except that subjects were asked if consumption of YGD had been continued.

## Data handling and analysis

Data were analysed using the Statistical Package for Social Sciences (© SPSS Inc.). Anthropometric measurements, and ratings for hunger and fullness at the various time points, were compared using repeated measures multivariate and univariate ANOVA. Responses to the questions about control over eating were analysed using the

McNemar test (cf. Siegel, 1956). Regression analysis and chi-squared tests were used to examine the impact of individual variables on weight loss success.

## **Results**

Screened subjects (n=105) generated a baseline sample size of 87, 98% of whom were women. Drop-outs resulted in the sample size reducing at weeks 1, 4, 6 and 10 to 86, 77, 73 and 68 respectively. The overall drop-out rate was 22%, which was less than anticipated. For the purposes of most statistical analyses, the 73 subjects with data for baseline up to week 4 were included. For other analyses, the 68 subjects with data from baseline to week 10 were included. This was done to avoid losing data for the 5 subjects who completed the 6-week 'active phase' of the study.

Reported compliance with YGD was good with 98.7% reporting missing no more than 2 tablets by week 1. This dropped to 71.2% by week 4 and rose again to 74% by week 6. The main reason for non-compliance was forgetfulness.

### Anthropometric results

These are presented in Table I. Weight, waist circumference and hip circumference decreased significantly between baseline and week 6. Mean weight loss was 2.3kg, while waist and hip circumference reduced by 3.4 cm and 3.7 cm respectively. There were also significant changes in waist circumference between weeks 6 and 10. A repeated measures MANOVA revealed a main effect of time across the 10 weeks ( $F(16, 52) = 9.13, p < 0.001$ ). Univariate tests revealed that weight ( $F(4, 268) = 34.06, p < 0.001$ ), BMI ( $F(4, 268) = 3.573, p < 0.01$ ), waist circumference ( $F(4, 268) = 29.25, p < 0.001$ ), and hip circumference ( $F(4, 268) = 35.95, p < 0.001$ ) all varied significantly with time.

*Take in Table I*

Pairwise comparisons showed that weight differed significantly between all timepoints ( $P < 0.001$ ), except between weeks 6 and 10. BMI was significantly lower than baseline at week 10 only ( $p < 0.001$ ). Waist circumference differed significantly between all the time points, except between weeks 4 and 6. Hip circumference differed significantly between all the time points, except between weeks 6 and 10. The differences between weeks 6 and 10 in waist circumference disappeared when subjects who continued to take YGD after week 6 (n=12) were excluded. Subjects who chose to continue YGD lost 1.79cm on average between week 6 and week 10, while those who did not take YGD lost 1.13cm.

While significant changes in weight and size are important, clinically significant weight loss is of more relevance to health. Haslam et al (2006) suggested that a modest weight loss of 5-10% baseline body weight could deliver 'striking benefits', particularly when weight was lost from intra-abdominal areas. Table II shows the percentage of subjects experiencing different levels of weight loss as a proportion of baseline weight. At all timepoints, around 85% of subjects had lost some weight while 8-10% of subjects experienced weight gain. At weeks 4, 6 and 10 respectively, the proportion of subjects losing  $\geq 5\%$  baseline weight was 5.5%, 19% and 22%.

*Take in Table II*

### Comparison with previous consumer study

The subjects in the present study were larger and heavier ( $p < 0.05$ ) than those recruited for a previous consumer study. In Ruxton et al (2005), mean baseline

measures were: weight 78 kg, BMI 29 kg/m<sup>2</sup>, waist circumference 94cm. In the present study, mean baseline weight was 84 kg, BMI was 31 kg/m<sup>2</sup>, and waist circumference was 98 cm. The differences occurred because Ruxton et al (2005) set an upper limit of BMI 35, while this restriction was removed for the present study. Despite these differences, the rate of weight change between baseline and week 4 was similar when the two studies were compared.

### Hunger, satiety and snacking

Figure 2 shows mean hunger ratings by time of day at various time points. A repeated measures MANOVA demonstrated a significant main effect for time in the study ( $F(12, 804) = 4.25, p < 0.001$ ). Univariate F tests revealed a significant effect of time for reported mid-morning hunger ( $F(4, 268) = 8.50, p < 0.001$ ), mid-afternoon hunger ( $F(4, 268) = 9.36, p < 0.001$ ), and evening hunger ( $F(4, 268) = 8.47, p < 0.001$ ). Pairwise comparisons revealed that reported hunger at mid-morning, mid-afternoon and evening for weeks 4 and 6 were lower than at baseline ( $p < 0.05$ ). However, between weeks 6 and 10 (when most subject had stopped YGD), reported hunger at mid-morning and evening was significantly higher. These differences were not affected by the exclusion of subjects choosing to take YGD after week 6.

*Take in Figure 2*

Figure 3 shows mean fullness ratings after the main meals at various time points. A repeated measures MANOVA demonstrated a significant main effect for time in the study ( $F(12, 804) = 6.01, p < 0.001$ ). Univariate F tests revealed a significant effect of time for reported fullness after breakfast, ( $F(4, 268) = 14.06, p < 0.001$ ), after lunch ( $F(4, 268) = 14.29, p < 0.001$ ), and after the evening meal ( $F(4, 268) = 4.01, p < 0.005$ ). Pairwise comparisons revealed that reported fullness after breakfast ( $p < 0.001$ ) and after lunch ( $p < 0.005$ ) for weeks 4 and 6 was higher than at baseline. Fullness after lunch and after the evening meal was also significantly lower between weeks 6 and 10. However, when subjects choosing to take YGD after week 6 were excluded, the difference relating to the evening meal disappeared.

*Take in Figure 3*

### Non-completers versus completers

At baseline, ANOVA revealed no significant differences in weight, BMI, waist/hip circumference and fullness after meals between completers ( $n=68$ ) and non-completers ( $N=19$ ). Non-completers reported snacking significantly more in the mid-morning and mid-afternoon periods compared with completers ( $p < 0.01$ ). However, non-completers also reported feeling less hungry in the evening compared with completers ( $p < 0.05$ ). Over the course of the study, there were no differences in weight or shape change between completers and non-completers. Non-completers even experienced *greater* reductions in mid-morning hunger, morning snacking and afternoon snacking.

### Other results

The presence of any adverse effects was investigated by asking subjects if they felt better, about the same or worse whilst taking YGD. Throughout the study, the majority of subjects reported feeling about the same. At weeks 1, 4 and 6, around 30% of participants reported feeling better, and this figure rose to 43% ( $n=29$ ) at week 10. Reasons included more energy, positive outlook, less bloated or thinking less about food. Six subjects reported feeling worse at week 4, while 3 reported feeling worse at

weeks 1, 6 and 10. Reasons varied, e.g. bloating, nausea, irritability, psoriasis, constipation, sleeplessness.

Subjects were asked to respond to a series of statements that described perceived lack of control over eating. Results are given in Figure 4. McNemar's tests revealed that the proportion of subjects agreeing with each of the statements significantly reduced between baseline and all other timepoints ( $p < 0.001$ ). Snack consumption at three timepoints was also estimated. A repeated measures MANOVA demonstrated a significant main effect for time in the study ( $F(12, 804) = 7.72, p < 0.001$ ). Reported number of snacks eaten mid-afternoon significantly reduced between baseline and week 6 (1.15 vs. 0.72 snacks;  $p < 0.01$ ). A similar results for seen for evening snacking (1.84 vs. 0.69 snacks;  $p < 0.01$ ). There was no significant difference in mid-morning snacking which remained around 0.6.

*Take in Figure 4*

Subjects were asked at week 6 whether they would recommend YGD to friends or patients. 85% said they would recommend YGD to friends, while 47% said they would recommend it to patients. The main reason given by subjects for not recommending the supplement to patients was that they believed they were not in a position to do so. Those who were more likely to recommend YGD to others ate significantly fewer evening snacks, and felt significantly less hungry in the morning, afternoon and evening at week 6. There were no differences in weight or shape compared with subjects who said they would not recommend YGD to others.

As reported above, 22% of subjects lost  $\geq 5\%$  baseline weight at week 10. Regression analysis was carried out to discover if any variables could predict what could be classed as 'successful' weight loss. No significant results were found. Chi-squared tests were then used to examine individual variables. This revealed that 'successful losers' at week 10 were less likely at baseline to report overeating when upset ( $\chi^2(1, 68) = 4.35, p < 0.05$ ). In addition, 'successful losers' were more likely to report feeling better than usual whilst taking YGD ( $\chi^2(1, 68) = 5.83, p < 0.05$ ).

## **Discussion**

This uncontrolled trial of a commercial weight management supplement demonstrated statistically significant mean weight loss over a 6-week period and clinically significant weight loss for 22% of subjects. The weight loss was modest (0.38 kg per week) but comparable with some other therapies. A randomised controlled trial of four commercial slimming regimes (Truby et al, 2006) reported that mean weekly weight loss in the first 8-week period was as follows: Slim-fast 0.46 kg, Rosemary Conley 0.5 kg, Weight Watchers 0.59 kg, and Atkins diet 0.65 kg. NICE (2001a) reported that studies on Orlistat reported "relatively small reduction(s) of some two to five kilograms per year" over and above placebo groups, while studies on Sibutramine found a weight loss of around 3kg at 8 weeks and 4 to 5kg at one year (NICE, 2001b). It should be noted that the anti-obesity drugs were generally tested in conjunction with a low-fat or calorie-reduced diet, while subjects given YGD were not asked to make any other changes to their diet or lifestyle. It would be interesting to evaluate the use of YGD as an adjunct therapy to energy restriction to find out if it improves compliance.

Studies suggest that waist circumference, independent of BMI, predicts the risk of chronic diseases such as diabetes and cardio-vascular disease (Zhu et al, 2004). In our study, mean waist circumference reduced by 3.4 cm (0.57 cm per week). Again,

this is comparable with other therapies. Truby et al (2006) reported the following mean weekly waist circumference losses: Slim-fast 0.6 cm, Rosemary Conley 0.56 cm, Weight Watchers 0.69 cm, and Atkins diet 0.84 cm. Modest reductions in baseline weight are now recognized as beneficial for long-term health. The definitions of this vary, i.e. 5-10 % (Haslam et al, 2006), 10 % (National Obesity Forum, 2004), 5 kg (SIGN, 1996).

Little work has been carried out on the mechanisms underpinning the effect of YGD. Andersen & Fogh (2001) reported within-person ultrasound data for 7 subjects. When exposed to YGD, subjects' gastric emptying was 53% slower ( $p < 0.05$ ). This suggests that YGD works by prolonging satiety, and data from the present study would seem to confirm this. Perceived hunger between meals significantly reduced over the course of the study, while fullness increased. This was found in the 4-week study of Ruxton et al (2005). Questions about control over eating revealed an interesting trend whereby subjects felt better able to resist snacking, control portion sizes and avoid emotional eating. This was reflected in differences in reported snacking in the mid-afternoon and evening periods, perhaps explained by prolonged satiety. Whatever the mechanism (and this should certainly be investigated in a future study), the reduction in weight (0.38 kg/week) implies an energy deficit of approximately 380 kcal/d if it is assumed that a loss of 1kg requires an energy deficit of 7000 kcal (Durnin, 1985).

It was our intention to measure the impact of YGD withdrawal but, in practice, this was compromised by the 12 subjects who chose to continue YGD after week 6. However, it was interesting to note the lack of significant differences between weeks 6 and 10 for all anthropometric variables except waist circumference. In addition, when the 12 YGD subjects were excluded, reported hunger significantly increased between weeks 6 and 10, while reported fullness stayed constant. These results suggest a loss of benefit when YGD supplementation ceased.

The limitations of the present study are acknowledged. It was not a randomised controlled placebo trial, but an intervention designed to mimic the experience of a consumer purchasing and using a product in an unsupervised environment. This design was selected to recreate a consumer setting in order to assess whether the benefits identified by the previous randomised placebo trial (Andersen & Fogh, 2001) could be translated to a less experimental setting. If more funds had been available, it would have been better to increase the sample size and include a placebo version of YGD. However, it is worth noting that the Andersen & Fogh study did not find a placebo effect, i.e. the placebo group lost only 0.3 kg compared with 5.1kg in the intervention group.

While minimal researcher contact reduces bias, it can introduce error through the use of self-measurement. According to the literature, female subjects may underestimate waist circumference compared with measurements made by technicians, although the effect of this on accuracy is small (Hall & Young, 1989; Freudenheim & Darrow, 1991). Weaver et al (1996) found that self-reported weight, waist and hip circumference were 'highly accurate'. Giving the training of nurses, it is not unreasonable to assume that measurement error in the present study would be less than that found in studies of the general public.

As obesity continues to affect greater numbers of people and the market for herbal supplements expands, more patients are likely to try alternative weight management

products. Health professionals need to be aware which ingredients and formulations have been tested for efficacy and safety in order to advise patients accordingly. A General Practice symposium identified herbal preparations, functional foods and obesity as three of the challenges for the future (Truswell et al, 2003). A white paper from the American College of Clinical Pharmacy recommended that pharmacists should approach the use of traditional and complementary therapeutic interventions with scientific rigour in order to provide better advice to patients wishing to try herbal products (Millar et al, 2000).

As the evidence-base for herbal weight management supplements improves, health professionals will be in a better position to ascertain the role of such products in the management of overweight and obese patients. The present study taken together with the placebo-controlled trial suggests a benefit for YGD, both for weight and waist circumference. Research on possible interactions between long-term YGD use, energy restriction and physical activity would be a logical next step in the process of establishing efficacy. Future studies should be randomised and placebo-controlled where possible.

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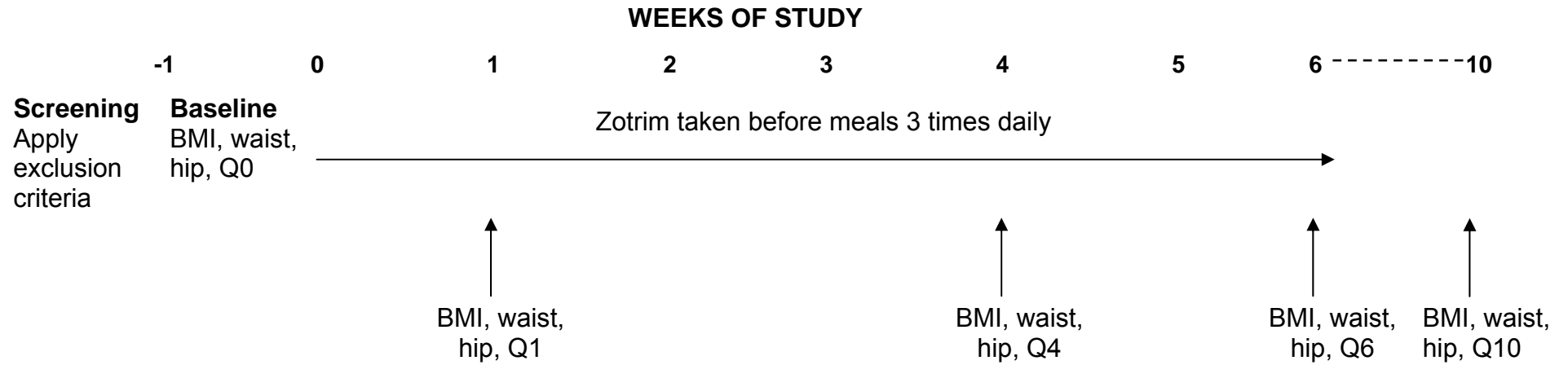
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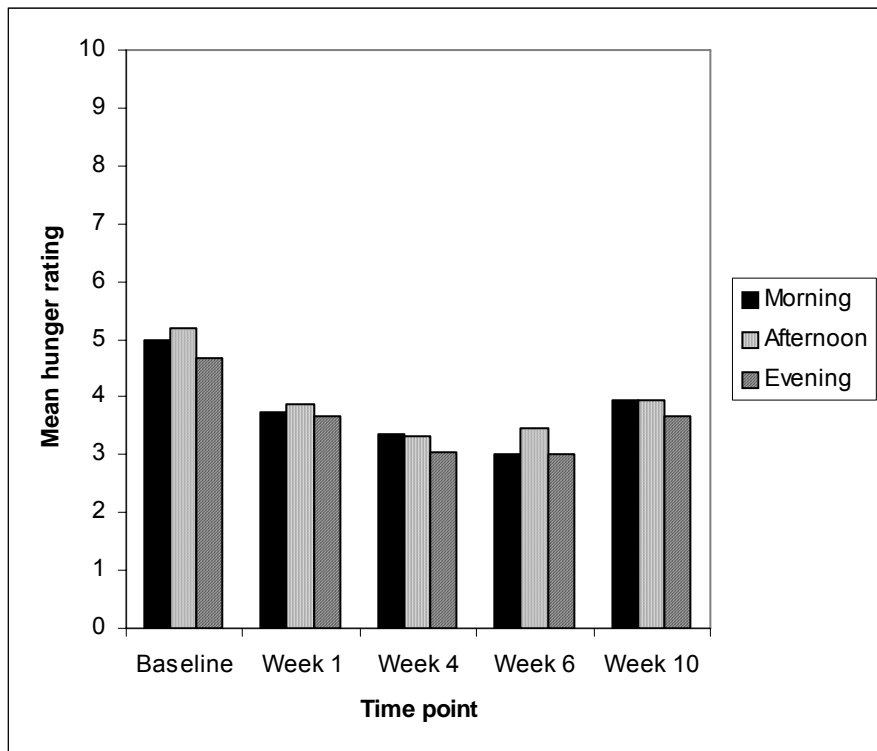
## FIGURES

Figure 1: Overview of study protocol

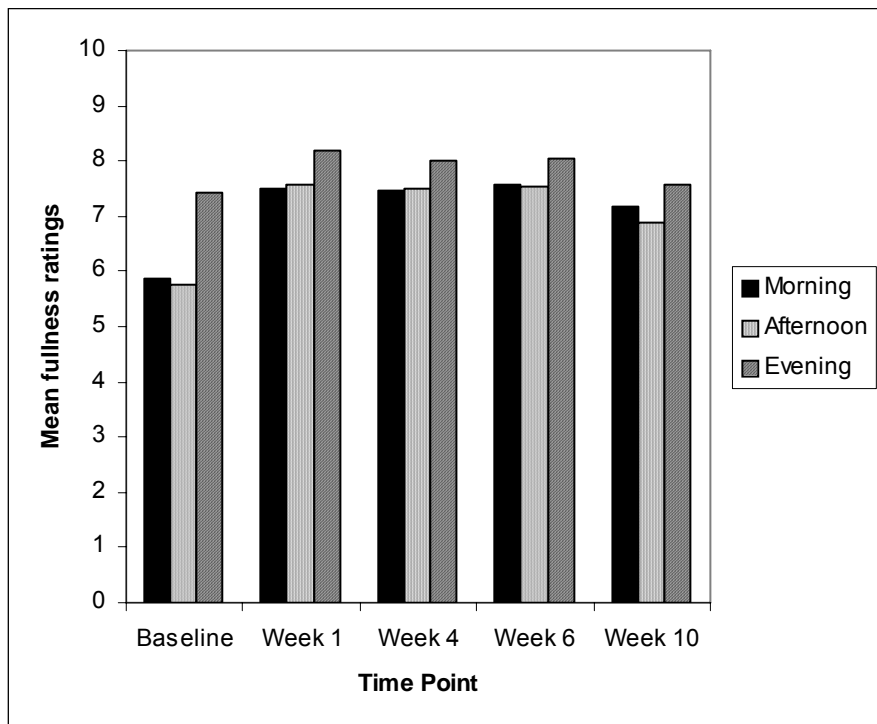


Q0 = baseline questionnaire; Q1, 4, 6 = follow-up questionnaires; Q10 = final questionnaire

**Figure 2: Mean between-meal hunger ratings by time of day**

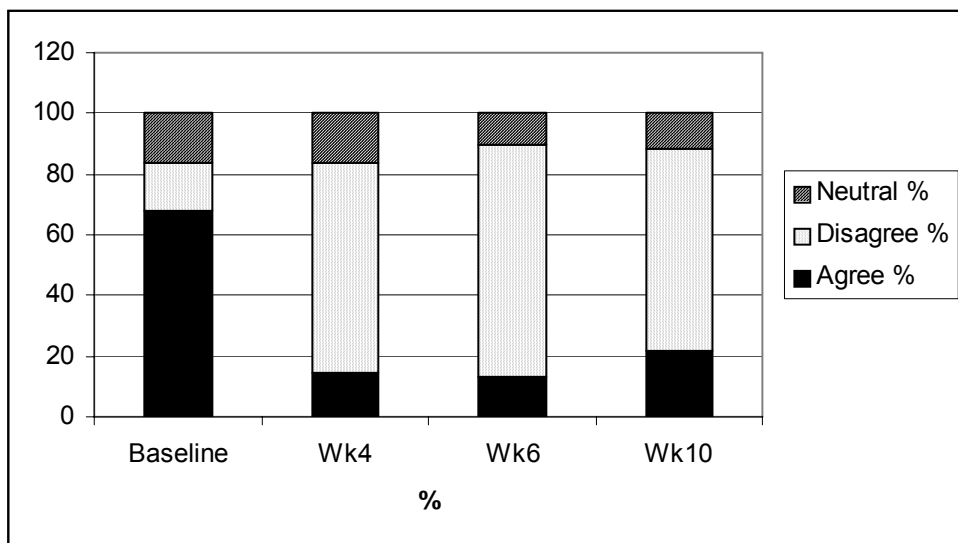


**Figure 3: Mean fullness ratings after meals**

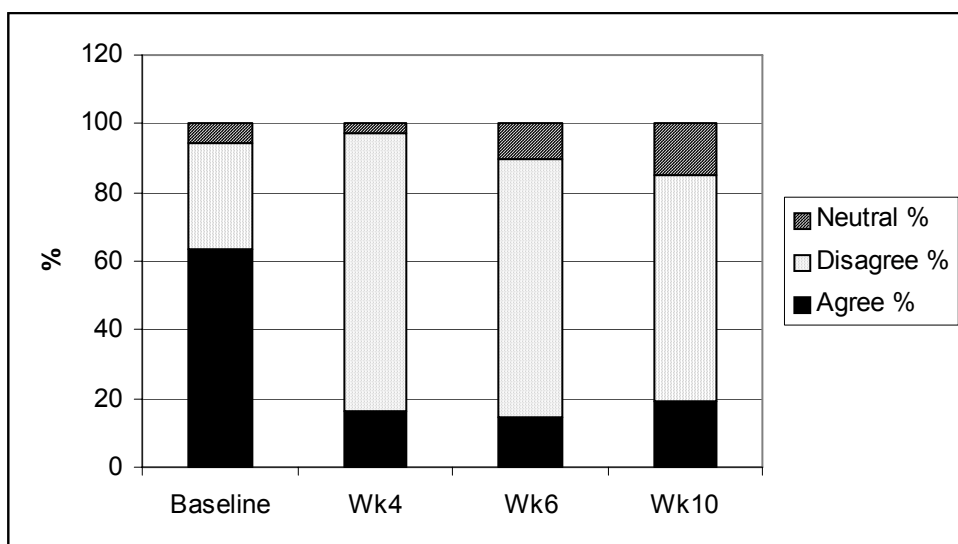


**Figure 4: changes in perceptions of eating control over the study**

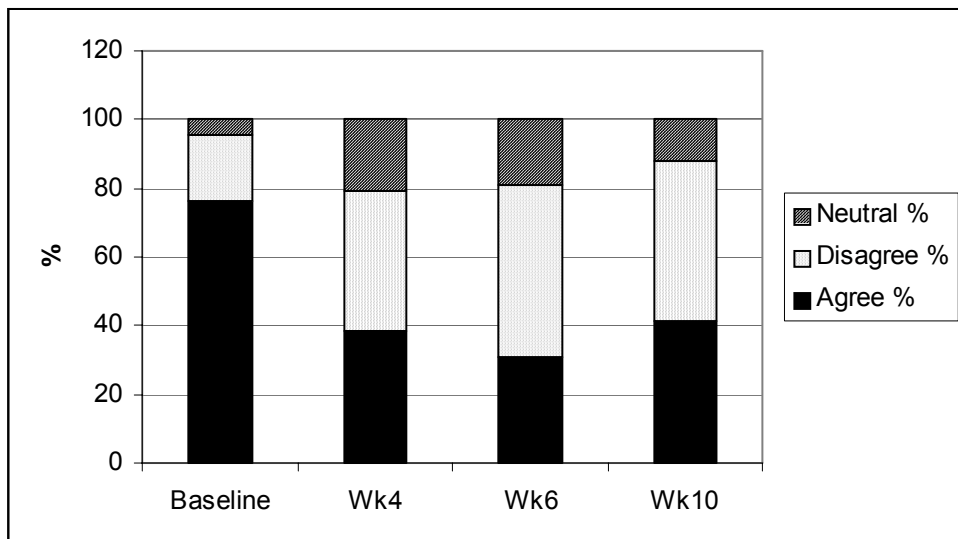
6a: "I often feel hungry and end up snacking too much between meals"



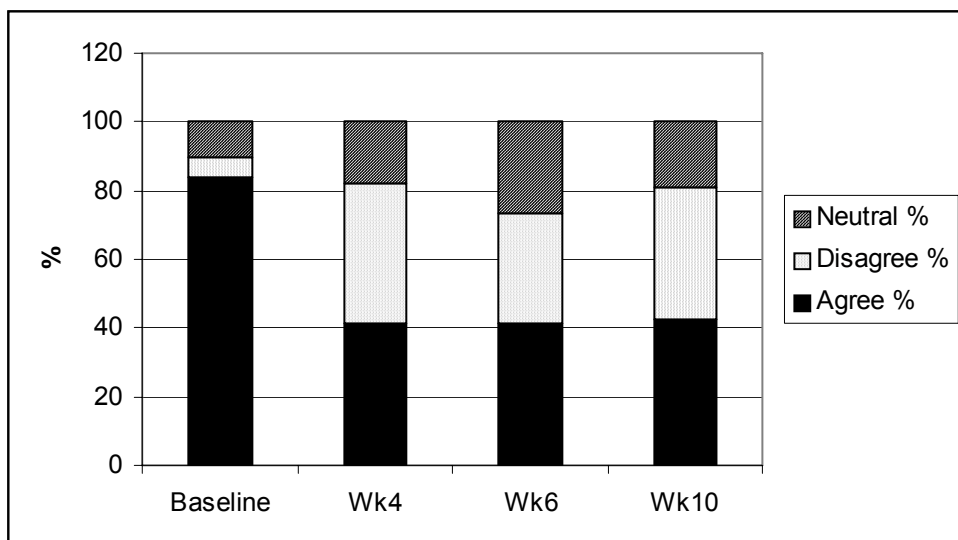
6b: "I don't feel full until I've eaten a large portion at meals"



**6c: "When I get upset, I find myself overeating high calorie foods"**



**6c "I find it difficult to refuse tempting food"**



## TABLES

**Table I: Mean anthropometric results from baseline to week 10**

	Baseline	Week 1	Week 4	Week 6	Week 10
Weight (kg)	84.4	83.6	82.6*	82.1*	81.5*
BMI kg.m <sup>2</sup>	30.8	30.5	30.2	30.0	29.6*
Waist (cm)	97.8	96.6	94.7*	94.2*	92.6*#
Hips (cm)	112.2	110.9	109.6*	108.5*	108.4*
N=	73	73	73	73	68

*Pairwise comparisons*

\* different from baseline (P<0.001)

# different from week 6 (P<0.001)

**Table II: Percentage of subjects experiencing different weight changes between timepoints**

	Weight loss as % baseline			No change	Weight gain as % baseline		
	>10%	5-10%	0-5%		0-5%	5-10%	>10%
Baseline to Wk 4 N=73	0	5.5	80.8	6.8	6.8	0	0
Baseline to Wk 6 N=73	0	19.2	67.1	4.1	9.6	0	0
Baseline to Wk 10 N=68	1.5	22.1	63.2	1.5	10.3	1.5	0