

ORIGINAL ARTICLE

Investigation of the medium-term effects of Olibra™ fat emulsion on food intake in non-obese subjects

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Objective: To investigate the effect of Olibra™ fat emulsion on medium-term food intake and appetite in non-obese subjects.

Design: Double-blind, placebo-controlled, within-subject crossover.

Setting: University of Ulster, Coleraine.

Subjects: A total of 28 subjects (14 male, 14 female).

Interventions: Subjects were randomly assigned to receive either a 200 g portion of test (5 g of Olibra™ fat) or control (5 g milk fat) yoghurt for breakfast for 2 × 3 week 'study' phases, separated by a 3-week 'wash-out' phase. On days 1, 8 and 22 of the study phases, food intake 4 h post-consumption of the yoghurt was assessed by pre- and post-covert weighing at an *ad libitum* buffet-style test lunch. Throughout each of these study days, appetite was assessed using visual analogue scales (VAS) at regular intervals. For the remainder of the study days, and the following 24 h ('post-study days'), subjects reported their food intake using weighed dietary records.

Results: Consumption of the Olibra™ emulsion had no significant effect on mean energy, macronutrient or amounts of food consumed at the lunch 4 h post-consumption. Self-reported food intakes indicated that there was no significant effect of the emulsion on energy intakes for the remainder of each study day and post-study days. There was considerable individual variation in food intakes following consumption of the Olibra™ emulsion, with 46, 59 and 57% of subjects reducing their energy intakes at lunch on days 1, 8 and 22. There was no consistent effect of the emulsion on appetite ratings.

Conclusions: In contrast to earlier studies, there was no evidence of a short- or medium-term effect of the Olibra™ emulsion on food intake or appetite. This could be owing to numerous confounding factors influencing eating behaviour and/or the different study design used in the present study.

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Keywords: fat emulsion; energy intake; satiety; appetite cues

Introduction

It is generally accepted that food intake in free-living humans is largely controlled by appetite. If this is the case,

it is logical to assume that the satiating power of food will play an important role in the regulation of eating behaviour (Blundell and Tremblay, 1995). In terms of food components, macronutrients are thought to exert independent effects on satiety, and although subject to controversy, protein is generally regarded as the most satiating macronutrient and fat as the least satiating (Cotton *et al.*, 1994; Blundell and MacDiarmid, 1997; Poppitt *et al.*, 1998). However, the effect of dietary fat on satiety and food intake may vary depending on physicochemical properties of the constituent fatty acids (French, 1999, 2004). For example, medium-chain triglycerides may be more satiating than long-chain triglycerides, and therefore may be capable of limiting the consumption of excess energy associated with high-fat diets (Rolls *et al.*, 1988; Stubbs and Harbron, 1996;

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Van Wymelbeke *et al.*, 1998). It is also possible that polyunsaturated fatty acids elicit more potent satiating properties compared to monounsaturated fatty acids and saturated fatty acids (Lawton *et al.*, 2000).

If the macronutrient of foods could be manipulated to increase their satiating properties, thereby assisting in attenuating positive energy balance, they could conceivably play a role in effective weight management strategies. Olibra™, a fat emulsion formulated from palm oil and oat oil fractions, is an example of a functional food ingredient that aims to reduce food intake by promoting and maintaining satiety. Although the exact mechanism is unclear, it is thought that the satiating power of the Olibra™ emulsion is owing to the physio-chemical stability of the emulsion, rather than the constituent of the emulsion *per se*. Undigested fat can delay or prolong the transit of food through the intestine in order to maximise digestion, a phenomenon referred to as the jejunal brake in the proximal intestines and the ileal brake in the distal intestines. It has been speculated that the Olibra™ emulsion may elicit its satiating power via the ileal brake, possibly by prolonging or altering the release or effect of peptides associated with the ileal brake. Previous studies demonstrated that consumption of yoghurt containing the Olibra™ fat emulsion significantly decreased energy intakes in lean, overweight and obese subjects for up to 8 h post-consumption relative to yoghurt containing milk fat only (Burns *et al.*, 2000, 2001). Moreover, self-reported energy intakes of the subjects showed that food intake remained suppressed for a further 24 h (Burns *et al.*, 2001, 2002).

Although these results appear promising, they provide no insight as to whether this suppression of food intake would persist in the longer-term. Energy compensation or habituation to the emulsion leading to lack of responsiveness are two possible outcomes that may result from longer-term consumption of the emulsion. In addition, the initial studies demonstrated that not all subjects reduced their food intake in response to the Olibra™ emulsion. Consequently, the aim of the present study is to investigate the effect of Olibra™ fat emulsion on medium-term (up to 3 weeks) food intake and appetite response in free-living non-obese subjects.

Subjects and methods

Subjects

The study protocol was advertised using posters and emails distributed within the University. Sixty subjects who expressed interest in participation were screened, and subsequently, 34 subjects who met the eligibility criteria were recruited and provided written informed consent before participating in the study. Inclusion criteria were age 20–55 years, non-obese (body mass index (BMI) <30 kg/m²), non-smokers, non-vegetarians, normal blood lipid profile, not consuming a special diet, no aversion to dairy products and not taking drugs that interfere with metabolism or food

intake. Height was measured using a stadiometer on day 1 of the intervention. Body weight, fat mass and fat-free mass were estimated using bioelectrical impedance (Tanita body composition analyser, Model TBF-410) and waist circumference of each subject were measured in the morning of each study day. This study was approved by the Research Ethical Committee of the University of Ulster.

Study design

The study was of a randomised, double-blind, placebo-controlled, within-subject crossover design, conducted over a 3-month period. Each subject was studied for a period of 9 weeks in total (2 × 3 weeks intervention phases, separated by a 3-week 'wash-out' phase). Hence, subjects were studied on three occasions in each phase with a 6-week interval between crossover. This differs from the previous short-term studies (Burns *et al.*, 2000, 2001, 2002), which had a 1-week interval between crossover. Similar to the previous Olibra™ studies, the Olibra™ fat emulsion was incorporated into yoghurt. Subjects were randomly assigned into two groups: group one received the test yoghurt in the first phase of the study and group two received the test yoghurt in the second phase of the study. The subject sequence was generated by simple randomisation, using random number sequence generated in SPSS. Each subject was asked to refrain from eating after 2100 hours on the evening before the first day of the study. At 0830 hours, subjects attended the metabolic suite at the University of Ulster where they consumed a 200 g portion of either the test or control yoghurt. All yoghurts were presented in plain white unmarked containers. After consuming the yoghurt, subjects resumed their normal morning activities, but were instructed not to eat or drink anything until lunchtime other than uncarbonated water if required. At 1300 hours, an *ad libitum* lunch was served in a private dining area within the University. All foods were covertly weighed before the meal and all uneaten foods were weighed after subjects had left the dining room. After lunch, subjects were permitted to eat and drink as they wished, but were asked to keep a weighed food record of all foods and beverages consumed during the remainder of the study day and the following day. The above protocol was followed on days 1 and 2, days 8 and 9 and days 22 and 23 of each study phase. In addition, fasting blood samples were drawn before yoghurt consumption on day 1 and day 22 of each phase. The subjects were free living, and during the intervening study days (days 2–7 and days 9–21), subjects consumed their habitual diet, but were asked to consume the 200 g portion of either the test or control yoghurt for breakfast. Subjects were free to eat other foods at breakfast and to follow their usual dietary patterns and activities. At the end of each phase, subjects completed a brief questionnaire, designed specifically for this study, to determine if there were any changes in self-perceived portion sizes of food eaten and in meal/lunch times during the study relative to usual.

Test foods

Test and control yoghurts. The composition of both yoghurts was matched for energy and macronutrient content (760 kJ, 6 g protein, 5 g fat, 28 g carbohydrate per 200 g portion). The test yoghurt was composed of 5 g Olibra™ fat, corresponding to 12.5 g Olibra™ emulsion, whereas the control yoghurt contained milk fat only (Lipid Technologies Provider AB, Stockholm, Sweden). Olibra™ is a food ingredient containing fractionated palm oil and fractionated oat oil in the proportions 95:5, dispersed in water to give a total fat content of 42% (w/w). The percentage fatty acid composition of Olibra™ compared to milk fat is as follows: palmitic (16:0), 42.1 vs 26.8; stearic (18:0), 4.3 vs 11.5; other saturates, 2.1 vs 25.8; oleic (18:1), 40.1 vs 28.7; linoleic (18:2), 10.4 vs 1.4; and other unsaturates, 1.0 vs 5.8.

Lunch meal. Lunch was presented in a buffet style meal, offering a wide range of sweet and savoury foods. Each subject had their own separate serving area. Foods varied in macronutrient composition (Appendix A). All foods were served in larger than estimated average portion sizes, so that choice was not influenced by quantity. Foods were also served in separate serving dishes so as not to influence food choice combinations. Subjects had a choice of beverages including uncarbonated water, carbonated soft drinks including low-calorie options and diluted fruit juices. Tea and coffee were also available on request. *Ad libitum* consumption was permitted, and unlimited eating time was given to each subject.

Assessment of appetite

Subjects rated their perceived hunger, fullness, desire to eat, amount they could eat and preoccupation with thoughts of food on visual analogue scales (VAS; in mm), by pen and paper method. For example, hunger was rated on a 100 mm line preceded by the question 'How hungry do you feel?' and anchored on the left by 'not at all hungry' and on the right by 'as hungry as I have ever felt'. The anchors for the questions on perceived fullness, desire to eat, amount you could eat and preoccupation with thoughts of food consisted of the phrases 'not at all full' against 'as full as I have ever felt', 'very weak' against 'very strong', 'nothing at all' against 'a large amount' and 'no thoughts of food' against 'very preoccupied'. Subjects were instructed to make a single vertical mark at the appropriate point between the two anchors on each scale to indicate subjective feelings of hunger, perceived fullness, desire to eat, amount they could eat and preoccupation with thoughts of food, respectively, at defined time points (immediately before and 15 min after yoghurt consumption, and thereafter at hourly intervals until 2200 hours on all test days). Similarly, yoghurts were also rated for pleasantness of taste 15 min post-consumption of the test and control yoghurts on each study day on a 100 mm line preceded by the question 'How pleasant did you

find the yoghurt' and anchored on the left by 'not at all pleasant' and on the right by 'very pleasant'.

Blood samples

In order to investigate if consumption of the Olibra™ fat emulsion had an effect on blood profile in the medium-term, fasting blood samples were drawn on the first and last day of each study phase (days 1 and 22, respectively). Samples were analysed for total cholesterol, low-density lipoprotein (LDL) cholesterol, high-density lipoprotein (HDL) cholesterol, triglycerides and glucose at the Causeway Laboratories, Causeway Hospital, Coleraine, UK. Additionally, plasma drawn at the beginning and end of each phase was stored at -70°C and insulin concentrations were then measured upon completion of the study at the Regional Endocrine Laboratory, Royal Victoria Hospital, Belfast, UK.

Questionnaires

On day 1 of the intervention, subjects completed the Dutch Eating Behaviour Questionnaire (DEBQ) (van Strien *et al.*, 1986), the Binge Eating Scale (Gormally *et al.*, 1982), and the Rosenberg Self-Esteem Scale (Rosenberg, 1965). The DEBQ measures dietary restraint using a 10-item scale, dietary emotional behaviour using a 13-item scale and dietary external behaviour using a 10-item scale. Scores are obtained by summing each scale and dividing by the number of items in each scale. Higher scores indicate higher restraint and greater vulnerability to emotional and external eating behaviour. The binge-eating scale assesses the severity of binge eating using a 16-item scale, with assigned scoring weights for each item (Gormally *et al.*, 1982). The Rosenberg Self-Esteem Questionnaire measures self-esteem using a 10-item scale. Higher scores indicated higher self-esteem, with 30 being the highest possible score.

Statistical analyses

Energy (MJ), macronutrient intakes (g) and weight of food consumed (g) at the *ad libitum* lunch and the subsequent self-reported intakes were calculated using Wisp V3 (Tinuviel Software, Warrington, UK). Food intake, VAS ratings, changes in anthropometric measurements and changes in blood profile were analysed using a general linear mixed effects model. Subjects were treated as random and the fixed effects were treatment, treatment phase and 'carry-over'. The treatment effect refers to differences in average food intakes, appetite ratings, changes in anthropometric measurements and changes in blood parameters between the test and control treatments. The treatment phase effect refers to differences in the average food intake, appetite ratings, changes in anthropometric measurements and changes in blood parameters between the first phase and the second phase of the study. The 'carry-over' term represents three possible effects that cannot be separated. These

are: differences in carry-over from test to control, and *vice versa*, treatment-by-treatment phase interaction and differences between the two groups of subjects. Ideally, differences in 'carry-over' should not be present, as they contaminate the data from the second phase. Independent-samples *t*-tests were used to determine differences in anthropometric measurements, food intake and questionnaire outcomes between males and females, and differences in food intake between restrained and non-restrained eaters. All analysis were preformed using SPSS V11 (Statistical Package for Social Sciences, Version 11); results were considered significant at the $P < 0.05$ level.

Results

Subject characteristics

The progress of subjects through the study is presented in Figure 1. Four subjects withdrew from the study: two owing to personal circumstances, one failed to attend the first day of the study and one owing to illness unrelated to the study. These withdrawals occurred at early stages during the first phase. A further two subjects were omitted from the analyses owing to non-compliance with the completion of the weighed food diaries. Subsequently, 28 subjects ($n = 14$ male; 14 female) were included in the final analysis. In addition, one subject was unable to attend the test lunch on day 8 of the second phase, and one subject was unable to provide a blood sample on day 22 of the second phase. Males had significantly greater heights, body weight, waist circumference and lean mass ($P < 0.001$), but lower percentage body fat

and fat mass ($P < 0.02$) than females (Table 1). There were no significant differences in age or BMI between males and females. The age range of the study population was 20–53 years and BMI ranged from 20.5 to 26.2 kg/m². Based on the median split (2.6), 14 subjects were classified as restrained eaters (four males, 10 females) and 14 subjects were classified as non-restrained eaters (10 males, four females), as assessed by the DEBQ (Table 5).

Energy and macronutrient intakes

There were no differences in mean energy, macronutrients or amounts of food consumed 4 h post-consumption of the test yoghurt compared to the control yoghurt on day 1, day 8 or day 22 in the total group, or in the gender-specific analyses (Table 2). Energy intakes at the test lunches were consistently

Table 1 Subjects characteristics^a

	Males (n = 14) Phase 1 Day 1	Females (n = 14) Phase 1 Day 1	P-value
Age (years)	31 ± 9	29 ± 7	0.654
Height (m)	1.75 ± 0.06	1.64 ± 0.08	0.000
Body weight (kg)	71.6 ± 7.3	61.2 ± 6.9	0.001
Waist circumference (cm)	83 ± 4	73 ± 4	0.000
BMI (kg/m ²)	23.3 ± 1.4	22.8 ± 1.2	0.322
% fat	16.9 ± 3.0	28.2 ± 5.5	0.000
Fat mass (kg)	12.2 ± 2.7	17.6 ± 5.1	0.002
Lean mass (kg)	59.4 ± 5.8	43.6 ± 2.3	0.000

Abbreviations: BMI, body mass index.

^aMean ± s.d. Differences between genders were determined using independent-samples *t*-tests.

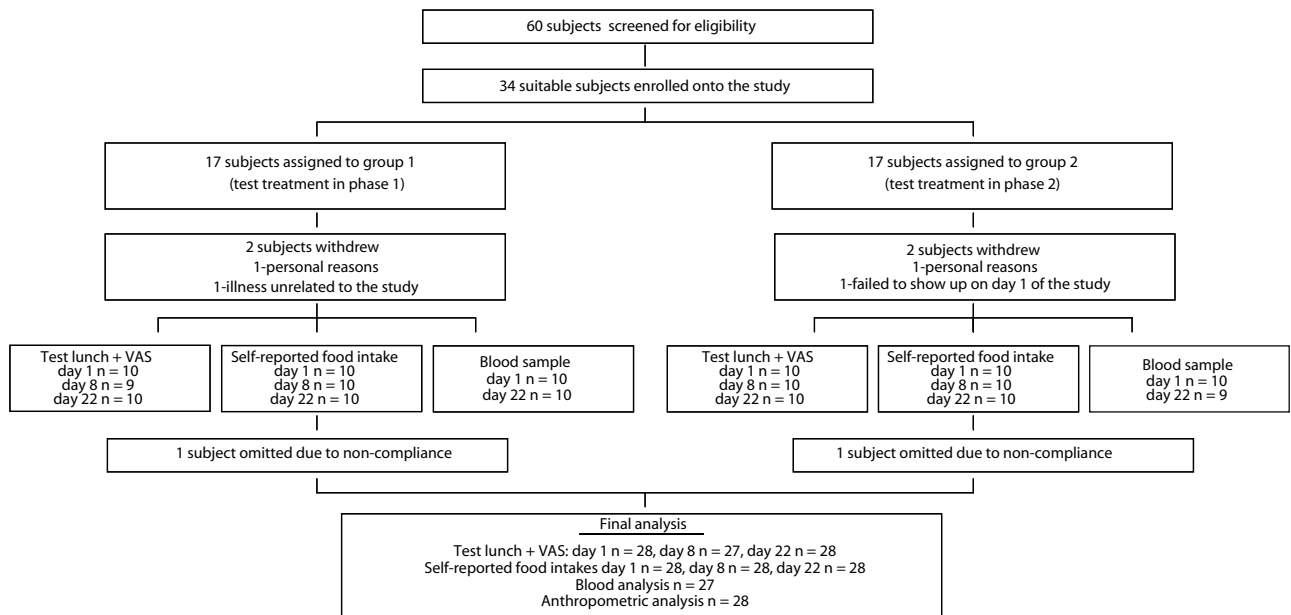


Figure 1 Flow of subjects through the study. Abbreviation: VAS, visual analogue scales.

Table 2 Energy and macronutrient intake 4 h post-consumption of the test and control yoghurts^{a,b}

	All subjects			Males			Females		
	Day 1 (n = 28)	Day 8 (n = 27)	Day 22 (n = 28)	Day 1 (n = 14)	Day 8 (n = 14)	Day 22 (n = 14)	Day 1 (n = 14)	Day 8 (n = 13)	Day 22 (n = 14)
Energy intake (MJ)									
Test	5.04±1.54	4.92±1.40	5.02±1.57	6.02±1.36	5.80±1.08	5.70±1.66	4.07±1.03	4.04±1.13	4.34±1.18
Control	5.06±1.66	5.22±1.67	5.06±1.46	6.35±1.25	6.17±1.55	5.96±1.31	3.77±0.76	4.19±1.12	4.16±0.99
% Difference	-0.2	-5.7	-0.8	-5.1	-6.0	-4.4	8.1	-3.6	4.3
Protein (g)									
Test	51.6±24.6	52.3±21.6	49.9±16.9	63.5±27.8	64.0±23.4	57.5±18.1	39.6±13.4	40.7±11.3	42.3±11.8
Control	52.8±22.3	52.1±23.9	52.5±25.6	66.5±21.7	64.3±25.5	65.2±28.1	39.1±12.6	39.0±13.0	39.8±15.1
% Difference	-2.4	0.4	-5.0	-4.4	-0.5	-11.8	1.1	4.2	6.2
Fat (g)									
Test	58.7±21.6	58.2±20.0	61.6±23.8	67.7±18.8	65.4±18.1	68.8±27.1	49.7±20.9	51.0±19.8	54.4±18.2
Control	60.7±24.2	63.7±25.0	60.1±20.6	76.9±21.6	71.1±26.7	67.6±20.1	44.6±13.8	55.9±21.3	52.6±19.0
% Difference	-3.4	-8.7	2.5	-11.9	-8.0	1.8	11.4	-8.7	3.4
Carbohydrate (g)									
Test	121.9±43.6	115.2±43.8	115.4±47.5	150.2±41.3	141.8±35.5	134.4±42.0	93.5±22.5	88.5±34.5	96.3±46.3
Control	116.1±48.0	121.1±48.6	118.3±46.7	146.0±43.4	151.3±38.2	144.4±39.1	86.1±31.2	88.7±36.6	92.2±39.1
% Difference	5.0	-4.9	-2.5	2.9	-6.3	-6.9	8.6	-0.1	4.4
Weight of food (g)									
Test	1173±522	1108±441	1069±387	1361±660	1239±560	1162±494	984±233	978±234	976±220
Control	1115±512	1124±353	1100±521	1298±665	1271±352	1255±644	931±169	965±289	945±312
% Difference	5.2	-1.4	-2.8	4.9	-2.5	-7.4	5.7	1.4	3.3

^aMean±s.d.

^bNo treatment effect ($P>0.05$). Treatment effect was determined using general linear mixed effects model.

higher in the male subjects compared to female subjects during both the control and test treatments ($P<0.05$).

Additionally, there was no consistent effect of the test treatment on mean energy, macronutrients or weight of food eaten during the remainder of each study day and the post-study days (Table 3). In the total group, fat intake was significantly higher following consumption of the test yoghurt compared to control conditions on days 8 and 9 (post-study day) (132.5 ± 58.7 vs 105.1 ± 60.6 g, $P=0.008$). In male subjects, protein intake was significantly higher on days 1 and 2 (post-study day) (165.6 ± 53.6 vs 143.0 ± 54.7 g, $P=0.048$), whereas female subjects demonstrated significantly lower carbohydrate intake on days 1 and 2 (post-study day) (291.8 ± 67.6 vs 346.3 ± 103.2 g, $P=0.035$), and significantly lower weight of food eaten on days 22 and 23 (post-study day) (3416 ± 945 vs 4024 ± 1190 g, $P=0.014$) following consumption of the test yoghurt. Self-reported energy intakes were significantly higher in male subjects compared to female subjects during both the control and test treatments ($P<0.05$). According to the questionnaire completed by each subject at the end of each phase, there were no differences in self-reported dietary habits during the test or control treatments compared to habitual dietary behaviours.

Furthermore, when subjects were analysed according to their degree of restrained eating, no treatment effect was

observed on mean energy, macronutrients or amounts of food consumed in either group 4 h post-consumption of the test yoghurt relative to control conditions on day 1, day 8 or day 22. During the remainder of the study day 22 and day 23 (post-study day), the weight of food consumed was significantly lower in the restrained eaters following consumption of the test yoghurt (3510.0 ± 984.1 vs 4451.4 ± 1232.7 g, $P=0.003$). This reduction remained significant following adjustment for alcohol intake (3486.1 ± 967.7 vs 4403.6 ± 1197.5 g, $P=0.003$). However, no reduction in weight of food eaten was observed on days 1 or 8 and the respective post-study days. Restrained eaters also had a significantly higher self-reported fat intake following consumption of the test yoghurt on days 8 and 9 (post-study day) (101.1 ± 24.4 vs 78.5 ± 38.4 g, $P=0.030$). Non-restrained eaters had a lower self-reported protein intake following consumption of the test yoghurt on days 1 and 2 (post-study day) (165.1 ± 50.3 vs 139.5 ± 54.8 g, $P=0.025$). Energy intakes at the test lunches were significantly lower in the restrained eaters compared to the non-restrained on days 1 and 8 of the test conditions and days 1, 8 and 22 of the control condition ($P<0.05$), but on day 22 of the test conditions, the difference was not significant. Additionally, self-reported energy intakes were also significantly lower in the restrained eaters compared to the non-restrained eaters for the remainder of study days 1, 8 and 22 and the

Table 3 Energy and macronutrient intake during the remainder of each study day and post-study days following the consumption of the test and control yoghurt^{a,b}

	All subjects			Males			Females		
	Day 1 (n = 28)	Day 8 (n = 28)	Day 22 (n = 28)	Day 1 (n = 14)	Day 8 (n = 14)	Day 22 (n = 14)	Day 1 (n = 14)	Day 8 (n = 14)	Day 22 (n = 14)
Energy intake (MJ)									
Test	14.80 ± 5.89	14.28 ± 5.25	13.35 ± 6.42	18.83 ± 5.50	17.07 ± 5.52	16.06 ± 7.91	10.77 ± 2.63	11.50 ± 3.18	10.63 ± 2.67
Control	14.89 ± 5.12	13.11 ± 6.04	13.10 ± 4.59	17.40 ± 5.22	16.01 ± 4.86	15.17 ± 4.99	12.37 ± 3.69	10.20 ± 5.84	11.03 ± 3.10
% Difference	-0.6	9.0	1.9	8.2	6.6	5.8	-12.9	12.7	-3.6
Energy intake less alcohol (MJ)									
Test	13.33 ± 5.07	13.44 ± 4.20	12.12 ± 4.74	16.74 ± 4.76	15.73 ± 4.12	14.33 ± 5.72	9.92 ± 2.38	11.15 ± 2.89	9.91 ± 1.87
Control	13.33 ± 4.29	11.86 ± 5.29	11.66 ± 3.81	15.05 ± 4.95	13.89 ± 4.91	13.42 ± 4.21	11.60 ± 2.71	9.84 ± 5.01	9.89 ± 2.38
% Difference	0.0	13.3	4.0	11.2	13.2	6.8	-14.4	13.4	0.3
Protein (g)									
Test	136.9 ± 51.7	125.8 ± 46.2	104.3 ± 44.5	165.6 ± 53.6 ^b	149.4 ± 50.9	121.2 ± 54.1	108.2 ± 30.2	102.3 ± 25.6	87.3 ± 23.7
Control	129.6 ± 43.2	112.6 ± 47.8	108.8 ± 36.8	143.0 ± 54.7	126.9 ± 53.3	128.1 ± 41.9	116.1 ± 22.4	98.2 ± 38.3	89.5 ± 15.8
% Difference	5.6	11.8	-4.2	15.8	17.7	-5.4	-6.8	4.1	-2.5
Fat (g)									
Test	124.4 ± 60.8	132.5 ± 58.7 ^b	117.6 ± 53.9	156.0 ± 65.9	156.5 ± 58.0	136.5 ± 64.1	92.8 ± 34.4	108.5 ± 50.4	98.7 ± 34.0
Control	129.6 ± 50.0	105.1 ± 60.6	111.5 ± 44.2	148.6 ± 56.2	123.0 ± 37.9	126.4 ± 48.9	110.7 ± 35.5	87.2 ± 74.2	96.7 ± 34.7
% Difference	-4.0	26.1	5.4	4.9	27.2	8.0	-16.1	24.5	2.0
Carbohydrate (g)									
Test	402.9 ± 168.2	402.3 ± 118.7	376.5 ± 156.5	514.0 ± 166.2	465.2 ± 114.2	453.8 ± 179.8	291.8 ± 67.6 ^b	339.5 ± 87.8	299.2 ± 75.2
Control	396.6 ± 149.4	382.0 ± 177.3	356.6 ± 149.4	446.9 ± 173.9	453.3 ± 198.8	413.8 ± 150.5	346.3 ± 103.2	310.7 ± 121.7	299.5 ± 129.1
% Difference	1.6	5.3	5.6	15.0	2.6	9.7	-15.7	9.3	-0.1
Weight of food (g)									
Test	4848 ± 2305	4645 ± 2377	4420 ± 2870	5826 ± 2818	5552 ± 3036	5424 ± 3747	3870 ± 1020	3739 ± 866	3416 ± 945 ^b
Control	4739 ± 2087	4647 ± 2338	4785 ± 2502	5356 ± 2309	5646 ± 2504	5545 ± 3216	4122 ± 1703	3649 ± 1712	4024 ± 1190
% Difference	2.3	0.0	-7.6	8.8	-1.7	-2.2	-6.1	2.5	-15.1
Weight of food less alcohol (g)									
Test	4797 ± 2260	4616 ± 2352	4378 ± 2825	5754 ± 2758	5506 ± 3009	5365 ± 3691	3841 ± 1014	3727 ± 857	3391 ± 926 ^b
Control	4685 ± 2042	4604 ± 2310	4735 ± 2478	5275 ± 2252	5573 ± 2483	5485 ± 3191	4095 ± 1684	3636 ± 1703	3985 ± 1167
% Difference	2.4	0.3	-7.5	9.1	-1.2	-2.2	-6.2	2.5	-14.9

^aMean ± s.d.^bTreatment effect ($P \leq 0.05$). Treatment effect was determined using general linear mixed effects model.

respective post-study days of the test conditions, and days 1 and 8 and the respective post-study days of the control conditions ($P < 0.05$), but on day 22 and 23 (post-study day) of the control conditions, the difference was not significant.

Individual differences in response to the test yoghurt containing the Olibra™ emulsion

The individual difference in energy intakes for each subject 4 h post-consumption of the yoghurts on days 1, 8 and 22 are presented in Figures 2–4. Thirteen subjects (46%; seven men and six women) had a lower energy intake at the test lunch following the consumption of the test yoghurt compared to the control yoghurt on day 1 (energy reduction ranged from -4 to -52%). Sixteen subjects (59%; eight men and eight women) had a lower energy intake at the test lunch on day 8 (energy reduction ranged from -4 to -39%), and 16 subjects

(57%; eight men and eight women) had a lower energy intake at the test lunch on day 22 (energy reduction ranged from -3 to -49%). Seven subjects had consistently lower energy intakes at the three test lunches following consumption of the test yoghurts compared to the control yoghurt (energy reduction ranged from -4 to -52%), whereas only three subjects consistently increased their energy intakes following consumption of the test yoghurts compared to the control yoghurt (energy increase ranged from +4 to +89%).

Appetite ratings

There was no consistent treatment effect on ratings of perceived hunger, fullness, desire to eat, prospective consumption or preoccupation with thoughts of food on any of the test days in the group as a whole, or in gender-specific analyses. Perceived pleasantness for the test yoghurt and the

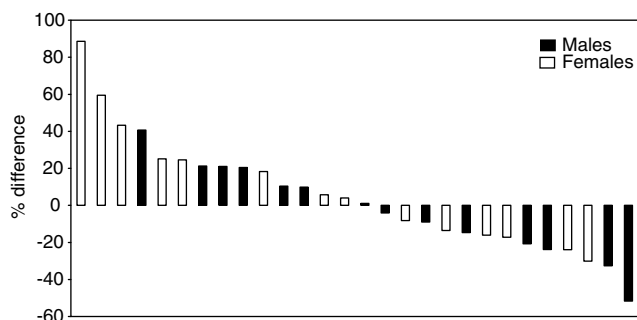


Figure 2 Individual variation of energy intake 4 h post-consumption of the yoghurts on day 1 % difference = ((test energy–control energy)/control energy × 100).

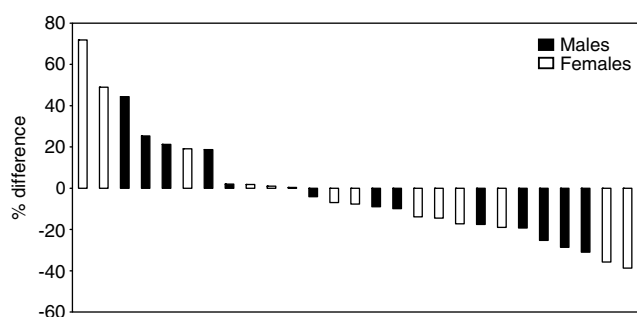


Figure 3 Individual variation of energy intake 4 h post-consumption of the yoghurts on day 8 % difference = ((test energy–control energy)/control energy × 100).

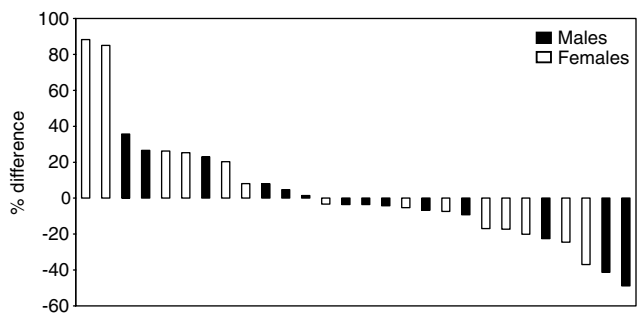


Figure 4 Individual variation of energy intake 4 h post-consumption of the yoghurts on day 22 % difference = ((test energy–control energy)/control energy × 100).

control yoghurt did not differ. Additionally, there was no treatment effect on water consumption during the test mornings following consumption of the test yoghurt relative to the control yoghurt.

Anthropometry and blood profile

There was no significant treatment effect on the changes in body weight (change during test treatment: $+0.3 \pm 0.7$ kg;

change during the control treatment: -0.1 ± 0.8 kg, $P=0.073$), or any of the other anthropometric measurements, in the total group or in the gender-specific analysis ($P>0.05$). Additionally, there were no significance differences in the changes in any of the anthropometric indices during the test treatment compared to the control treatment ($P>0.05$). Blood profiles during the test and control treatments are shown as Table 4. In the total group, a treatment effect was apparent for the mean change in fasting blood glucose concentration during the test treatment relative to the control treatment (-0.10 ± 0.38 vs $+0.18 \pm 0.60$ mmol/l, $P=0.018$). When the group was split on the basis of gender, the treatment effect remained significant in the male subjects (-0.16 ± 0.44 vs $+0.28 \pm 0.76$ mmol/l, $P=0.045$), but not in the female subjects. No treatment effect was observed on the concentration of plasma triglycerides, total cholesterol, HDL cholesterol, LDL cholesterol, total cholesterol:HDL cholesterol or on plasma insulin concentration in the whole group or the gender-specific analysis.

Questionnaires

Results from the eating behaviour questionnaires are presented in Table 5. Female subjects had significantly higher dietary restraint (2.1 ± 0.7 vs 2.9 ± 0.7 , $P=0.01$) and dietary emotional behaviour (2.3 ± 0.9 vs 3.3 ± 0.8 , $P=0.004$) scores compared to the male subjects.

Discussion

This study failed to confirm the short-term reduction in energy intake (over 4 h) following consumption of the Olibra™ emulsion which was reported in earlier studies (Burns *et al.*, 2000, 2001, 2002). Furthermore, the Olibra™ emulsion, did not appear to exert any suppressive effects on either mean food intake or appetite ratings in the medium-term (up to 3 weeks). The emulsion exerted no effect on food intakes 4 h post-consumption. Although significant treatment effects were observed on the self-reported food intakes for the remainder of the study days and post-study days, these findings were inconsistent, and thus are difficult to interpret. Perhaps, the most interesting observation is the significant reduction in carbohydrate intake and the trend towards a lower energy intake after the test yoghurt on day 1 in the female subjects. In contrast, such reductions were not evident in the male subjects. Perhaps, the higher energy intake observed in the male subjects compared to the female subjects indicates that females may be more responsive/sensitive to either, or both, the satiating potential of the emulsion or biological satiating signals.

The outcomes of three previous Olibra™ studies have already been published (Burns *et al.*, 2000, 2001, 2002). All studies used yoghurt as the food vehicle for the emulsion, and all test meals were buffet-style, self-selected meals. In the first study, a sample of non-obese subjects consumed a

Table 4 Blood profile on Day 1 and Day 22 of the test and control treatment^{a,b}

	All subjects (n = 27)		Males (n = 14)		Females (n = 13)	
	Test (mmol/l)	Control (mmol/l)	Test (mmol/l)	Control (mmol/l)	Test (mmol/l)	Control (mmol/l)
<i>Glucose</i>						
Day 1	4.63 ± 0.31	4.58 ± 0.52	4.72 ± 0.31	4.59 ± 0.63	4.54 ± 0.30	4.56 ± 0.41
Day 22	4.54 ± 0.36	4.75 ± 0.32	4.56 ± 0.35	4.87 ± 0.35	4.52 ± 0.38	4.64 ± 0.24
Change	-0.10 ± 0.38 ^b	+0.18 ± 0.60	-0.16 ± 0.44 ^b	+0.28 ± 0.76	-0.05 ± 0.30	+0.08 ± 0.39
<i>Triglycerides</i>						
Day 1	0.91 ± 0.47	0.87 ± 0.43	1.03 ± 0.56	0.99 ± 0.56	0.79 ± 0.35	0.74 ± 0.19
Day 22	0.88 ± 0.42	0.91 ± 0.34	1.00 ± 0.47	1.03 ± 0.30	0.75 ± 0.32	0.80 ± 0.34
Change	-0.01 ± 0.39	+0.05 ± 0.32	-0.03 ± 0.50	+0.05 ± 0.34	+0.01 ± 0.24	+0.05 ± 0.30
<i>Total cholesterol</i>						
Day 1	4.59 ± 0.85	4.59 ± 0.85	4.85 ± 1.04	4.78 ± 1.03	4.32 ± 0.52	4.40 ± 0.60
Day 22	4.66 ± 0.87	4.63 ± 0.78	4.79 ± 1.06	4.81 ± 0.97	4.52 ± 0.64	4.44 ± 0.51
Change	+0.09 ± 0.38	+0.04 ± 0.41	-0.06 ± 0.36	+0.03 ± 0.44	+0.25 ± 0.34	+0.05 ± 0.40
<i>HDL cholesterol</i>						
Day 1	1.64 ± 0.39	1.62 ± 0.40	1.47 ± 0.30	1.46 ± 0.33	1.81 ± 0.41	1.78 ± 0.40
Day 22	1.63 ± 0.44	1.63 ± 0.36	1.46 ± 0.33	1.47 ± 0.27	1.83 ± 0.47	1.79 ± 0.37
Change	+0.01 ± 0.16	+0.01 ± 0.19	-0.01 ± 0.12	+0.01 ± 0.22	+0.04 ± 0.20	+0.01 ± 0.15
<i>LDL cholesterol</i>						
Day 1	2.53 ± 0.81	2.58 ± 0.79	2.90 ± 0.94	2.88 ± 0.93	2.16 ± 0.42	2.28 ± 0.51
Day 22	2.63 ± 0.85	2.59 ± 0.78	2.89 ± 1.02	2.88 ± 0.94	2.36 ± 0.52	2.29 ± 0.42
Change	+0.09 ± 0.35	0.00 ± 0.30	-0.01 ± 0.38	0.00 ± 0.25	+0.20 ± 0.30	+0.01 ± 0.36
<i>TC:HDL ratio</i>						
Day 1	2.93 ± 0.82	2.96 ± 0.81	3.37 ± 0.83	3.37 ± 0.86	2.48 ± 0.54	2.56 ± 0.52
Day 22	3.00 ± 0.86	2.96 ± 0.79	3.40 ± 0.93	3.35 ± 0.83	2.57 ± 0.53	2.56 ± 0.51
Change	+0.06 ± 0.35	-0.01 ± 0.32	+0.03 ± 0.41	-0.02 ± 0.36	+0.08 ± 0.29	0.00 ± 0.29
<i>Insulin</i>						
Day 1	6.39 ± 3.01	7.18 ± 3.77	5.96 ± 2.47	7.80 ± 4.16	6.81 ± 3.51	6.56 ± 3.37
Day 22	6.47 ± 3.29	6.95 ± 3.31	6.76 ± 3.60	7.11 ± 4.14	6.17 ± 3.03	6.80 ± 2.35
Change	+0.06 ± 3.31	-0.23 ± 3.42	+0.79 ± 3.44	-0.69 ± 4.08	-0.74 ± 3.10	+0.24 ± 2.68

Abbreviations: HDL, high-density lipoprotein; LDL, low-density lipoprotein; TC, total cholesterol.

^aMean ± s.d.^bTreatment effect ($P \leq 0.05$). Treatment effect was determined using general linear mixed effects model.

defined breakfast, fasted until lunch when they received the yoghurt. Food intake was then covertly assessed 4 h post-consumption at an *ad libitum* meal and subjects recorded food intake for the remainder of the day using weighed dietary records. A subsequent study investigated the effect of the emulsion on food intake in groups of non-overweight, overweight and obese subjects. In this study, the yoghurt was consumed at breakfast, and food intake was covertly assessed 4 h post-consumption at an *ad libitum* lunch and again 4 h later at an *ad libitum* dinner. Weighed food diaries were completed for the remainder of the study day and the post-study day. The final study evaluated the effects of various doses of Olibra™. Subjects received, for breakfast, a 200 g portion of yoghurt containing 15 g of fat with 0 g (control), 2, 4 or 6 g of the Olibra™ fat, corresponding to 0, 5, 10 and 15 g of Olibra™ emulsion, respectively. Food intake was covertly assessed 4 h post-consumption at an *ad libitum* meal, and again self-reported weighed food diaries were used to assess food intake for the remainder of the study day and the

post-study day. However, owing to the difference in study designs, direct comparisons between the present study and previous studies can only be tentative.

It is also noteworthy that there was greater individual variation in response to the emulsion observed in this study compared to the previous studies. Data combined from the two previous studies, which tested the effect of a 12.5 g dose of Olibra™ emulsion, revealed that approximately 75% of the subjects who participated in these studies ($n=87$) reduced their energy intake 4 h post-consumption of the test yoghurt relative to control conditions (Burns *et al.*, 2000, 2001). In the present study, 46% of subjects ($n=13$) reduced their intakes at 4 h post-consumption on day 1, 59% ($n=16$) on day 8 and 57% ($n=16$) on day 22, respectively. However, only seven subjects in the present study consistently reduced their energy intakes at all three of the test lunches. Thus, it appears that in addition to human appetite, other factors may exert powerful effects on food intake and eating behaviour. It is highly probable that these factors will simply

Table 5 Questionnaire scores^a

	All subjects (n = 28)	Males (n = 14)	Females (n = 14)	P-value
Dietary restraint score ^b	2.5 ± 0.8 (range 1.0–4.0)	2.1 ± 0.7 (range 1.0–3.3)	2.9 ± 0.7 (range 1.2–4.0)	0.010
Dietary emotional score ^b	2.8 ± 1.0 (range 1.3–5.2)	2.3 ± 0.9 (range 1.3–3.9)	3.3 ± 0.8 (range 2.5–5.2)	0.004
Dietary external score ^b	3.1 ± 0.5 (range 1.8–4.0)	3.0 ± 0.6 (range 1.8–3.9)	3.2 ± 0.5 (range 2.3–4.0)	0.538
Binge eating score ^c	6.5 ± 5.3 (range 0.0–20.0)	4.6 ± 3.4 (range 0.0–12.0)	8.1 ± 6.2 (range 0.0–20.0)	0.097
Self-esteem score ^d	21.9 ± 5.0 (range 10.0–30.0)	23.0 ± 4.6 (range 16.0–30.0)	20.8 ± 5.4 (range 10.0–28.0)	0.253

^aMean ± s.d. Differences between genders were determined using independent-samples *t*-tests.

^bDEBQ.

^cBinge-eating scale.

^dRosenberg self-esteem scale.

over-ride normal appetite regulation in certain individuals. Hence, inter-individual differences in traits, such as restrained eating, may partially explain the differential responses in food intake between subjects in the present study. Given that the difference in eating behaviour between restrained eaters and non-restrained eaters is very evident throughout this study, this lends support for the above hypothesis.

Ideally, a functional food that aims to increase satiety should result in weight loss. In this study, the Olibra™ emulsion exerted no significant effects on any of the anthropometric indices measured. However, this is not a surprising result given that there was no reduction in food intake in response to the Olibra™ emulsion during the study. In order to determine the potential impact of the emulsion on body weight, a longer-term study would clearly be necessary. Additionally, a functional food should not exert any adverse health effects. In the present study, there was a reduction in blood glucose during the test treatment compared to the control conditions in the male subjects. This may suggest an association between Olibra™ consumption and altered glucose metabolism. However, further studies would be required to investigate this possible relationship and also to establish if indeed the effect is confined to male subjects only.

A number of factors can be proposed to explain the results of the present study. Firstly, in comparison to the earlier Olibra™ studies, the eating environment in the present study was more sociable, in that 10 to 12 subjects were present at each lunch occasion. It has been reported that ambience, including social and physical surroundings, can influence eating behaviour and food intake (de Castro and de Castro, 1989; Stroebele and De Castro, 2004; Weber *et al.*, 2004). In fact, it has been suggested that the magnitude of the effect of ambience may be underestimated (Stroebele and De Castro, 2004). It is possible that social facilitation attenuated by the relaxed atmosphere may have over-riden normal appetite. Additionally, the initial Olibra™ studies were conducted approximately 7 years ago. Considerable changes in dietary behaviour and patterns have been observed during this period of time, including increased portion sizes (Nielsen and Popkin, 2003), greater tendency to eat away from the

home and a greater reliance on convenience foods (Harnack *et al.*, 2000). Therefore, it could be speculated that these changes in dietary behaviour may have collectively resulted in a greater susceptibility to environmentally driven cues to overeat under the present study conditions.

There are a number of other issues, common to all food intake studies, which may have also influenced the study outcomes. Firstly, mis-reporting of food intakes by the subjects may have confounded results (Livingstone *et al.*, 1990). Although it could be argued that this may be the case in the previous studies, mis-reporting appears to be a problem that has intensified since it was first identified as a problem in studies assessing food intake (Heitmann *et al.*, 2000). Thus, self-reported intakes may not have been the most appropriate method to assess food intakes in a study aimed specifically at reducing food intake, as this method may not be sensitive enough to detect any change in energy intakes induced by the emulsion. Therefore, it is likely that a study conducted within a residential setting, in which all food consumed can be assessed by covert weighing would be a more suitable approach. Secondly, eating behaviour is likely to be influenced by a free lunch in which a wide range of foods served in extra large portion sizes are presented (Rolls, 1985; Rolls *et al.*, 2002; Sorensen *et al.*, 2003). This may have assumed greater relevance of late, given that the prevalence of obesity continues to increase (Flegal *et al.*, 2002; McCarthy *et al.*, 2002), and many people have become preoccupied, even obsessed with food, eating and body image. Thirdly, the statistical power of the study may have been inadequate. Initially, 34 subjects were involved in the study; however, only 28 were included in the final analyses. Perhaps, a larger sample size may have yielded more obvious trends and significant results. Finally, unquantifiable factors present in one phase of the study may not have been present in the other study phase. For example, this study was conducted between August and November, consequently seasonal effect may have influenced food intake (Shahar *et al.*, 2001). Although several issues have been highlighted that may partially explain these results, it may be that the Olibra™ emulsion simply did not exert any effect on food intake at mean level in this cohort of subjects.

In conclusion, the Olibra™ emulsion did not exert any short- or medium-term effects on food intake or appetite ratings in this study. At present, it is not possible to state if this lack of effect is real or apparent owing to a variable combination of factors discussed above. Hence, further studies, taking into account potential confounding factors and varying the dose of Olibra™ given, are necessary to establish the effects of the Olibra™ emulsion in the medium term. Furthermore, if, as the study suggests, that environmental cues are becoming the major driving force behind food intake, and people are becoming less responsive and less aware of physiological appetite signals, the development of a functional food aimed at reducing food intake will prove increasingly difficult.

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Appendix A

Nutrient composition (per 100 g) of foods offered at test meal 4 h post-consumption of the yoghurts (Table A1).

Table A1

Menu items	Portion size provided	Energy (kJ)	Protein (g) (% energy)	Fat (g) (% energy)	Total CHO (g) (% energy)	Sugars (g) (% energy)
White rolls (g)	96	1078	9.3 (13.95)	2.6 (8.78)	51.5 (77.27)	2.6 (3.90)
Wholemeal rolls (g)	102	1004	9.9 (15.99)	3.2 (11.63)	44.8 (72.37)	2.8 (4.52)
Coleslaw (g)	227	928	1.1 (1.96)	21.9 (87.72)	5.8 (10.32)	3.9 (6.94)
Potato salad (g)	227	923	1.5 (2.69)	18.4 (74.33)	12.8 (22.98)	1.1 (1.97)
Spring onions (g)	35	98	2.0 (32.65)	0.5 (18.37)	3.0 (48.98)	2.8 (45.71)
Lettuce (g)	100	53	0.7 (21.37)	0.3 (20.61)	1.9 (58.02)	1.9 (58.02)
Tomatoes (g)	170	73	0.7 (15.64)	0.3 (15.08)	3.1 (69.27)	3.1 (69.27)
Grated cheese (g)	75	1700	25.0 (24.39)	34.4 (75.51)	0.1 (0.10)	0.1 (0.10)
Sweet corn (g)	110	519	2.9 (9.01)	1.2 (8.39)	26.6 (82.61)	9.6 (29.81)
Ham (g)	130	395	19.6 (80.74)	1.5 (13.90)	1.3 (5.36)	0.3 (1.24)
Chicken (g)	200	645	30.2 (78.85)	3.6 (21.15)	0.0 (0.00)	0.0 (0.00)
Tuna (g)	140	422	23.5 (94.57)	0.6 (5.43)	0.0 (0.00)	0.0 (0.00)
Sausage rolls (g)	180	1457	8.3 (9.50)	21.8 (56.15)	30.0 (34.34)	2.6 (2.98)
Quiche (g) ^{a,b}	400	1277	10.3 (13.44)	20.9 (61.37)	19.3 (25.19)	1.7 (2.22)
Apples (g)	200	199	0.4 (3.22)	0.1 (1.81)	11.8 (94.97)	11.8 (94.97)
Banana (g)	200	403	1.2 (4.79)	0.3 (2.69)	23.2 (92.52)	20.9 (83.35)
Satsuma (g)	140	155	0.9 (9.35)	0.1 (2.34)	8.5 (88.31)	8.5 (88.31)
Rich tea biscuits (g)	21	1803	6.7 (6.01)	13.3 (26.86)	74.8 (67.13)	22.3 (20.01)
Digestive biscuits (g)	45	1956	6.3 (5.22)	20.3 (37.88)	68.6 (56.89)	13.6 (11.28)
Chocolate digestives (g)	54	2071	6.8 (5.33)	24.1 (42.52)	66.5 (52.15)	28.5 (22.35)
Semi-sweet biscuits (g)	28	1746	9.5 (8.82)	13.3 (27.78)	68.3 (63.40)	0.0 (0.00)
Crisps (g)	50	2215	5.7 (4.19)	34.2 (56.60)	53.3 (39.21)	0.7 (0.51)
Kit-Kat™ (g)	44	2098	7.5 (5.81)	26.0 (45.35)	63.0 (48.84)	50.1 (38.84)
Swiss min-rolls (g)	50	1760	5.4 (5.13)	20.7 (44.28)	53.2 (50.58)	38.3 (36.42)
Chocolate mousse (g)	100	959	4.1 (7.15)	11.4 (44.73)	27.6 (48.13)	24.3 (42.37)
Trifle (g) ^{a,b}	500	578	2.1 (6.10)	5.2 (34.01)	20.6 (59.88)	16.2 (47.09)
Apple pie (g) ^{a,b}	500	1335	2.0 (2.96)	11.0 (36.59)	40.9 (60.46)	17.5 (25.87)
Cream (g) ^{a,b}	250	328	0.5 (2.51)	8.0 (90.45)	1.4 (7.04)	1.4 (7.04)
Flora spread™(g) ^b	250	2556	0.5 (0.32)	68.5 (99.16)	0.8 (0.51)	0.8 (0.51)
Butter (g) ^b	250	2334	0.1 (0.07)	63.0 (99.86)	0.1 (0.07)	0.1 (0.07)
French dressing ^b	250	660	0.9 (2.33)	13.5 (78.74)	7.3 (18.92)	6.2 (16.07)
Cream cheese (g) ^b	200	1807	3.1 (2.82)	47.4 (97.18)	0.0 (0.00)	0.0 (0.00)
Salad cream (g) ^b	425	1440	1.5 (1.71)	31.0 (79.31)	16.7 (18.99)	16.7 (18.99)
Mayonnaise (ml) ^b	340	2843	1.1 (0.64)	75.6 (98.38)	1.7 (0.98)	1.3 (0.75)
Vegetable soup (ml)	500	135	0.9 (11.29)	0.7 (19.75)	5.5 (68.97)	0.9 (11.29)
Coca Cola™ (ml) ^b	1250	174	0.0 (0.00)	0.0 (0.00)	10.9 (100.00)	10.9 (100.00)
Diet Coca Cola™ (ml) ^b	1250	2	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Sprite™ (ml) ^b	1250	93	0.0 (0.00)	0.0 (0.00)	5.8 (100.00)	5.8 (100.00)
Water (ml) ^b	2000	0	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)	0.0 (0.00)
Blackcurrant cordial (ml) ^b	1000	975	0.1 (0.16)	0.0 (0.00)	60.8 (99.84)	59.1 (97.04)
Orange cordial (ml) ^b	1000	456	0.0 (0.00)	0.0 (0.00)	28.5 (100.00)	28.5 (100.00)
Tea (ml)	260/190	28	0.5 (30.30)	0.2 (27.27)	0.7 (42.42)	0.7 (42.42)
Coffee (ml)	260/190	29	0.6 (34.29)	0.2 (25.71)	0.7 (40.00)	0.7 (40.00)

Abbreviations: CHO, carbohydrate.

^aIndicates foods that were served in the centre of the dining tables.

^bIndicates foods that were reused throughout the study, replaced when quantity may have influenced choice of food; values reported are unopened weight of food.