

# Fabules<sup>TM</sup>

## short term trial bulletin



a **DSM** Product

### Summaries of short term clinical trials with Fabules<sup>TM</sup>

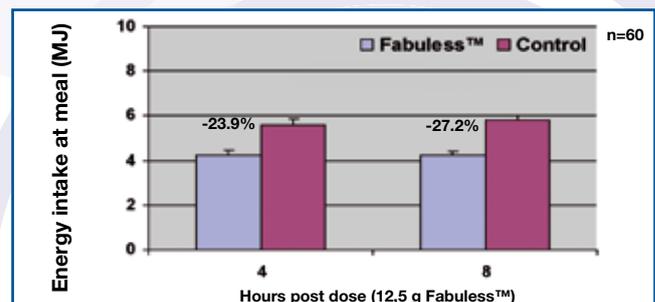
**Five different published studies have been performed at the Northern Ireland Centre for Diet and Health at the University of Ulster in order to substantiate the effect of Fabules<sup>TM</sup> on the feeling of satiety and calorie intake.**

Most studies were double-blind, randomized, placebo-controlled and included within-subject crossover. Healthy volunteers were recruited and every individual participated on two or more occasions, with exactly 7 days interval between crossover. The test products in the studies were identical yogurts except for the replacement of normal dairy fat by Fabules<sup>TM</sup> fat. In tests 1, 2 and 3 the total energy value of the yogurts was 800 kJ, corresponding to 8% of the total daily calorie intake. The content of the control and test products in study 4 had been modified with double cream to achieve the same energy content as the level in the yogurt with the highest dose of Fabules<sup>TM</sup>. The total energy in test 4 products was 1165 kJ.

Studies 1 and 2 were identical and non-obese healthy volunteers participated. They had eaten a standard breakfast and thereafter lunch was replaced by a yogurt containing either Fabules<sup>TM</sup> or dairy fat. Four hours after lunch the participants had free access to a buffet meal. The intake was properly recorded since the food was weighed prior to the meal and all uneaten food including leftovers was weighed when the participants had left. For the remainder of the day subjects were permitted to eat and drink as they wished,

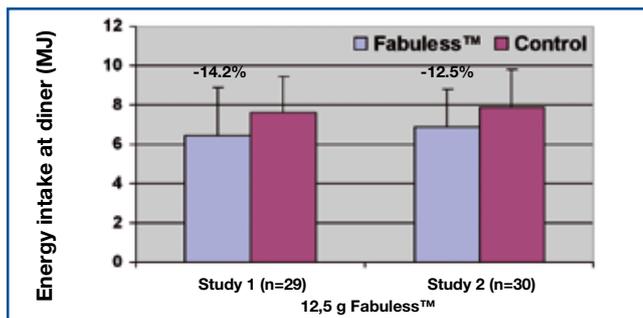
but were instructed to keep a weighed record of all food and beverages consumed.

In study 3 non-obese, overweight and obese subjects were recruited. Breakfast was replaced by yogurt containing Fabules<sup>TM</sup> or dairy fat. The participants had free access to buffet meals four and eight hours after breakfast and all food intakes were recorded as in studies 1 and 2. Each individual kept a weighed record of all food and beverage consumed during the remainder of the day and day two.

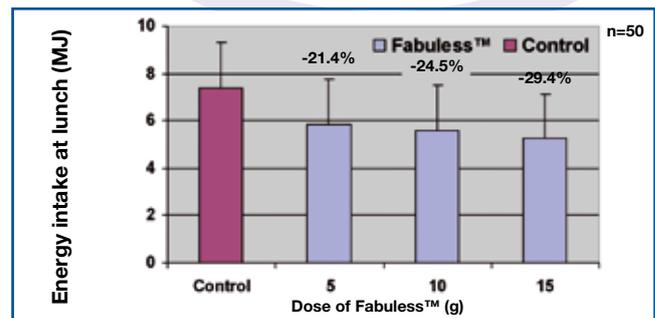


Study 3.

A dose-response effect was investigated in study 4 in non-obese subjects. The design of the study was the same as in study 3, but each participant was tested 4 times (with 7 days between crossover) and received three doses of Fabules<sup>TM</sup> and placebo in randomised order. The doses used in the study were 0, 2, 4 and 6 grams of Fabules<sup>TM</sup> fat in 200 grams of yogurt, which was adjusted to the same fat content with double cream. This corresponds to 5, 10 and 15 grams of Fabules<sup>TM</sup> emulsion.



Study 1 and 2.



Study 4.

### The results

The results showed a significant decrease in food intake at the subsequent meal four hours after consumption of yogurt containing Fabuleless™. In studies 3 and 4, a significant reduction was also observed after eight hours as well as in the following period of self-reporting of food and beverage intake. Overweight and obese subjects responded in a similar manner to their non-overweight counterparts. A dose-response effect was also demonstrated by this study.

The reduction in food intake seemed to be larger in studies 3 and 4 than in studies 1 and 2, which could be explained by a difference in study design. Lunch was replaced by yogurt in studies 1 and 2, whereas breakfast was replaced by yogurt in studies 3 and 4. This larger effect might be due to the fact that the satiety effect lasts for more than 4 hours, better results are obtained with a yogurt earlier in the day at breakfast. An overview is given of the results of the 4 studies.

The fifth short term study (Logan et al.) was performed to determine possible short-term adaptations of the satiety effect. A different study design was used as compared to

earlier published studies. The results showed no statistically significant difference in food consumption between Fabuleless™ and control. According to the authors, this result may be explained by the different study design and/or by the fact that the eating environment was much more sociable as compared to previous studies. To ascertain the efficacy of Fabuleless™ under real life conditions, long term studies were designed. See the 'Long Term Trial Bulletin'.

### Conclusion

Based on these studies it can be concluded that the energy intake at subsequent meals can be significantly reduced by eating yogurt containing Fabuleless™. The short term results have not always been reproducible, possibly due to trial conditions, and further research focuses on the long term effects of Fabuleless™.

### Publications

- International Journal of Obesity (2000) 24, 1419-1425
- International Journal of Obesity (2001) 25, 1487-1496
- European Journal of Clinical Nutrition (2002) 56, 368-377
- European Journal of Clinical Nutrition (2006) 60, 1081-1091

	Study 1	Study 2	Study 3	Study 4		
	Yogurt @ lunch 12,5g Fabuleless™	Yogurt @ lunch 12,5g Fabuleless™	Yogurt @ breakfast 12,5g Fabuleless™	Yogurt @ breakfast 5g Fabuleless™	10g Fabuleless™	15g Fabuleless™
Energy intake (MJ)	(n=29)	(n=30)	(n=60)	(n=50)	(n=50)	(n=50)
<b>4 hrs after intake</b>						
test	6,45 ± 2,4	6,90 ± 1,9	4,26 ± 0,21	5,83 ± 1,91	5,60 ± 1,89	5,24 ± 1,91
control	7,62 ± 1,8	7,89 ± 1,9	5,60 ± 0,28	7,42 ± 1,89	7,42 ± 1,89	7,42 ± 1,89
decrease (%)	14.2%	12.5%	23.9%	21.4%	24.5%	29.4%
<b>8 hrs after intake</b>						
test			4,23 ± 0,18			
control			5,81 ± 0,21			
decrease (%)			27.2%			
<b>during the evening (self reported)</b>						
test	0,70 ± 0,2	0,5 ± 0,1	0,49 ± 0,1			
control	1,1 ± 0,3	0,9 ± 0,2	0,96 ± 0,2			
decrease (%)	36.4%	44.4%	17.0%			
<b>during day 2 (self reported)</b>						
test			6,35 ± 0,4			
control			7,7 ± 0,3			
decrease (%)			17.5%			

Table 1: Summary of data from four studies with Fabuleless™.

All test results represent a statically significant decrease compared to placebo of p<0.01 with the exception of the self-reported results of study 1 and 2 with p<0.05.