

SUPPLEMENTARY DATA

Methods of Statistical Analysis

1. Sample-size calculation

Based on data from a previous study (16) using a different, less powerful design (i.e., a parallel-group rather than a crossover design), we considered that an improvement in serum total cholesterol of about 18 mg/dL with a standard deviation of 31 mg/dL would be expected in subjects administered enriched pasta compared with conventional pasta. We conservatively used these results as the basis for the sample-size calculations for the present study, under the null hypothesis that the mean individual differences in cholesterol levels detectable between administrations of the two types of pasta will be zero. Assuming a risk of a type I error of 0.05 (one-sided), we calculated that to attain a power of 0.80 in detecting the hypothesized change we would need to enroll at least 20 subjects. To allow for possible dropouts or non-compliance 26 patients were targeted for enrolment.

2. Data Analysis

Data obtained from continuous variables pertinent to the crossover study were analyzed according to Hills and Armitage (25). Patients' response to diet intervention was the difference between the values obtained at the end and at the beginning of the diet intervention period.

Lack of treatment by period interactions (sequence effects) was preliminarily addressed by testing equality of the mean response during both periods between the two groups defined by sequence of diets (i.e., between the group who received soy-enriched pasta in the first period followed by the conventional pasta in the second period, and the group fed the two pasta types in the reverse order). A significance level of $p=0.10$ was conservatively used for that test. If a significant sequence effect was detected, treatment effect was estimated from the first period only, and the second period was disregarded, i.e., data were analyzed within the framework of a parallel-group design. If no evidence of interaction emerged, the subsequent analysis was carried out according to the original crossover design. Mann-Whitney tests were used to assess significance of the interaction, period, and treatment effects.

The Wilcoxon signed-rank test was used for paired comparisons between values of continuous variables. Differences in proportions were tested using Fisher's exact test or chi-square statistics.

Statistical analyses were two-sided and performed using Stata Statistical Software (Version 11, Stata Corporation, College Station, TX).

Study data were visually displayed in the figures using the box plot technique. Briefly, the line in the middle of the box represents the median or 50th percentile of the data, and the box extends from the 25th to the 75th percentile, an interval referred to as the interquartile range. The lines emerging from the box extend to the upper and lower adjacent values, i.e., the largest data point less or equal to the 75th percentile plus 1.5 times the interquartile range, and the smallest data point greater or equal to the 25th percentile minus 1.5 times the interquartile range, respectively. If the examined data come from a normal distribution, one would expect the interval between the adjacent values to include 99.3% of the data. Observed points more extreme than the upper or lower adjacent values, if any, are plotted individually.

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Supplementary Table 1. Changes induced in Type-2 diabetic patients (n=20) by dietary inclusion of one-serving per day for 8 consecutive weeks of a soy germ isoflavone-enriched pasta (*Pasta +*), or a conventional pasta lacking isoflavones (*Pasta -*)

	Type of pasta	Baseline values	Change ^(a)	<i>P</i> value
HbA1c (%)	<i>Pasta +</i>	6.9 ± 0.6	- 0.1 ± 0.3	0.254
	<i>Pasta -</i>	6.9 ± 0.6	+ 0.1 ± 0.4	
Total cholesterol (mg/dL)	<i>Pasta +</i>	204.5 ± 43.9	- 4.9 ± 21.4	0.025
	<i>Pasta -</i>	202.4 ± 43.5	+ 8.2 ± 20.6	
LDL cholesterol (mg/dL)	<i>Pasta +</i>	131.6 ± 38.5	- 2.0 ± 23.4	0.119
	<i>Pasta -</i>	131.6 ± 36.2	+ 5.8 ± 28.5	
HDL cholesterol (mg/dL) ^(b)	<i>Pasta +</i>	46.0 ± 11.0	+ 0.6 ± 4.2	0.760
	<i>Pasta -</i>	46.6 ± 11.9	+ 0.2 ± 7.0	
Triglycerides (mg/dL)	<i>Pasta +</i>	167.3 ± 116.0	- 44.0 ± 55.9	0.119
	<i>Pasta -</i>	156.7 ± 128.5	- 27.5 ± 87.8	
Systolic blood pressure (mm Hg)	<i>Pasta +</i>	133 ± 15	- 7.0 ± 17.0	0.026
	<i>Pasta -</i>	123 ± 16	+ 7.0 ± 13.0	
Diastolic blood pressure (mm Hg)	<i>Pasta +</i>	79 ± 9	- 5.0 ± 10.0	0.017
	<i>Pasta -</i>	72 ± 12	+ 5.0 ± 12.0	
Flow-mediated vasodilation (%)	<i>Pasta +</i>	5.4 ± 4.8	+ 4.7 ± 4.9	0.0005
	<i>Pasta -</i>	7.7 ± 4.9	- 1.5 ± 4.1	
Oxidized LDL (U/mL) ^(b)	<i>Pasta +</i>	6.5 ± 4.8	- 1.60 ± 2.09	0.009
	<i>Pasta -</i>	5.6 ± 2.7	+ 0.83 ± 1.12	
8-iso-PGF2α (pg/mL) ^(b)	<i>Pasta +</i>	202 ± 200	- 123.8 ± 180.4	0.001
	<i>Pasta -</i>	115 ± 41	+ 71.9 ± 134.6	
Total Antioxidant Capacity (mmol/L)	<i>Pasta +</i>	874 ± 185	+ 79 ± 69	0.0002
	<i>Pasta -</i>	915 ± 173	- 44 ± 89	
GSH (mmol/L) ^(b)	<i>Pasta +</i>	2.8 ± 1.1	+ 5.0 ± 2.0	0.0003
	<i>Pasta -</i>	3.8 ± 2.3	+ 0.57 ± 0.93	
Cysteine (mmol/L) ^(b)	<i>Pasta +</i>	195 ± 42	+ 31.1 ± 30.2	0.138
	<i>Pasta -</i>	208 ± 41	+ 1.8 ± 39.0	
Homocysteine (mmol/L)	<i>Pasta +</i>	9.2 ± 3.0	- 1.47 ± 1.67	0.017
	<i>Pasta -</i>	8.8 ± 3.5	+ 0.34 ± 2.22	
Interleukin-6 (pg/mL) ^(b)	<i>Pasta +</i>	2.6 ± 1.9	+ 0.19 ± 0.85	0.087
	<i>Pasta -</i>	2.1 ± 1.0	+ 0.98 ± 0.93	

Data are means ± SD

^(a) Changes are the difference between values measured after 8 weeks and baseline values

^(b) Only data concerning Period 1 were considered due to presence of a sequence effect (*p*=0.057 for HDL cholesterol; *p*=0.001 for Oxidized LDL; *p*=0.037 for 8-iso-PGF2α; *p*=0.048 for GSH; *p*=0.063 for Cysteine; *p*=0.087 for Interleukin-6).

If data from both periods had been considered for these variables, i.e., the original crossover design had been followed, analysis of the treatment effect on these variables would give *p*=0.063 for HDL cholesterol, *p*=0.009 for Oxidized LDL; *p*=0.001 for 8-iso-PGF2a, *p*=0.002 for GSH; *p*=0.239 for Cysteine; *p*=0.086 for Interleukin-6