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The role of a gluten free diet in 'lifestylers'? The first double blind randomized study

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Introduction: A gluten free diet (GFD) is essential in the management of coeliac disease, as well as several studies demonstrating its utility as a dietary therapy in patients with irritable bowel syndrome. The aim of this double-blind placebo controlled study was to assess the role of a GFD in a healthy population who take a GFD as a lifestyle choice ('lifestylers').
Methods: Subjects were recruited via an advert, following exclusion criteria including coeliac disease. Following selection, subjects were commenced on a 2 week GFD following evaluation by a dietitian. Participants were then randomized to receive either organic gluten (Group A, Vital Gluten 14g gluten protein/day) or gluten free flour (Group B) in pre-made bags, over a 2 week period. These were sprinkled on their food twice daily. Gastrointestinal Symptom Rating Scale (GSRS) scores were assessed at baseline (following 2 weeks GFD) and after 2 weeks of randomization. Data was analyzed using SPSS version 22.
Results: 45 subjects were identified with 28 participants recruited into the trial (Group A; n=14, Group B; n=14) following exclusion criteria. Median age was 36.5 years (range: 19-63) and 21 (75%) were female. There was no significant difference in baseline demographics between both groups (p=0.54). Over a 2 week period there was no significant difference in gastrointestinal symptoms or fatigue in either group, as seen in Table 1.

Table 1

GSRS	Group A (Baseline)	Group A (End of Intervention)		Group B (Baseline)	Group B (End of Intervention)	
	Mean +/- SD	Mean +/- SD	Difference from Baseline (Paired T-test), p-value	Mean +/- SD	Mean +/- SD	Difference from Baseline (Paired T-test), p-value
Abdo Pain	2.50 +/- 1.40	2.14 +/- 1.70	0.504	2.35+/- 1.33	2.07+/- 0.99	0.486
Reflux	1.71 +/- 1.13	1.64 +/- 1.15	0.72	2.50 +/- 2.20	2.57 +/- 1.95	0.895
Indigestion	2.14 +/- 1.35	2.07 +/- 1.32	0.876	2.14 +/- 1.35	1.79 +/- 0.97	0.336
Diarrhoea	2.71 +/- 1.93	1.64 +/- 0.92	0.03	1.85 +/- 1.46	1.86 +/- 1.35	1
Constipation	2.50 +/- 1.82	2.46 +/- 1.81	0.697	1.92 +/- 1.54	2.50 +/- 1.65	0.179
Fatigue Score	6.61 +/- 2.36	6.00 +/-2.98	0.585	6.57 +/-2.44	5.36 +/-2.27	0.232

Conclusion: This study demonstrates that gluten is unlikely to be the culprit agent for gastrointestinal symptoms or fatigue in healthy individuals. A GFD has no evidence base in individuals who do not have coeliac disease or IBS. The public should be discouraged from considering a GFD of their own volition.