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## The Effects of a Gluten-free Diet Versus a Hypocaloric Diet Among Patients With Fibromyalgia Experiencing Gluten Sensitivity-like Symptoms: A Pilot, Open-Label Randomized Clinical Trial.

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### Abstract

**BACKGROUND AND AIMS:** Patients with fibromyalgia frequently present with symptoms similar to those experienced by patients with gluten-related disorders, raising the possibility that a subgroup of these patients could be experiencing underlying gluten sensitivity. This study aimed to evaluate the effects of a gluten-free diet (GFD) compared with a hypocaloric diet (HCD) among patients with fibromyalgia.

**METHODS:** Adult patients diagnosed with fibromyalgia were randomly allocated to receive a GFD or a HCD over a 24-week period. The primary outcome measure was the change in the number of gluten sensitivity symptoms. The following secondary outcomes were evaluated: body mass index, Revised Fibromyalgia Impact Questionnaire, Pittsburgh Sleep Quality Index, Brief Pain Inventory, Beck Depression Inventory-II, State-Trait Anxiety Inventory, Short-Form Health Survey, Patient Global Impression Scale of Severity, Patient Global Impression Scale of Improvement, and adverse events.

**RESULTS:** Seventy-five subjects were randomly allocated to receive either a GFD (n=35) or an HCD (n=40). The least squares mean change in the total number of gluten sensitivity symptoms from baseline did not differ significantly between the GFD and HCD groups ( $-2.44 \pm 0.40$  for the GFD;  $-2.10 \pm 0.37$  for the HCD;  $P=0.343$ ). Similarly, the 2 dietary interventions did not differ in any of the remaining measured secondary outcomes. Both dietary interventions were well tolerated.

**CONCLUSIONS:** Both dietary interventions were associated with similar beneficial outcomes in reducing gluten sensitivity symptoms and other secondary outcomes. However, despite its specificity, GFD was not superior to HCD in reducing the number of gluten sensitivity symptoms or secondary outcomes.

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