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# **Efficacy and safety of honey based formulation of *Nigella sativa* seed oil in functional dyspepsia: A double blind randomized controlled clinical trial.**

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## **Author information**

### **Abstract**

#### **ETHNOPHARMACOLOGICAL RELEVANCE:**

A honey based formulation from *Nigella sativa* L. (*N. sativa*) has been used in Traditional Persian Medicine for upper gastrointestinal symptoms. Considering the traditional use of this formulation and its ingredients known pharmacologic effects, this study aimed to evaluate the efficacy and safety of *N. sativa* seed oil mixed with honey in treatment of patients with functional dyspepsia.

#### **METHODS AND MATERIALS:**

Seventy patients diagnosed with functional dyspepsia according to ROME III criteria and confirmed by upper gastrointestinal endoscopy were selected to receive a traditional honey based formulation of *N. sativa* (5ml *N. sativa* oil orally daily) or placebo for 8 weeks in a double-blind randomized placebo-controlled clinical trial using a parallel design with a 1:1 allocation ratio. Patients were evaluated prior to and following 8 weeks of the intervention in terms of the Hong Kong index of dyspepsia severity, presence of *Helicobacter pylori* infection based on urease test, scores in different domains of short form (SF-36) health survey, and any observed adverse events.

#### **RESULTS:**

The mean scores of Hong Kong index of dyspepsia severity sores and the rate of *H. pylori* infection were significantly lower in the *N. sativa* group comparing the placebo group after the intervention ( $P < 0.001$ ). No serious adverse event was reported.

#### **CONCLUSION:**

This study showed that adjuvant supplementation of honey based formulation of *N. sativa* can cause significant symptomatic improvement of patients with functional dyspepsia whom received the standard anti-secretory therapy. The results should be investigated further in studies with longer duration and larger sample size.

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**KEYWORDS:**

Functional dyspepsia; Honey; *Nigella sativa*; Traditional Persian Medicine