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Treatment of irritable bowel syndrome with Chinese herbal medicine: a randomized controlled trial.

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CONTEXT: Irritable bowel syndrome (IBS) is a common functional bowel disorder for which there is no reliable medical treatment. **OBJECTIVE:** To determine whether Chinese herbal medicine (CHM) is of any benefit in the treatment of IBS. **DESIGN:** Randomized, double-blind, placebo-controlled trial conducted during 1996 through 1997. **SETTING:** Patients were recruited through 2 teaching hospitals and 5 private practices of gastroenterologists, and received CHM in 3 Chinese herbal clinics. **PATIENTS:** A total of 116 patients who fulfilled the Rome criteria, an established standard for diagnosis of IBS. **INTERVENTION:** Patients were randomly allocated to 1 of 3 treatment groups: individualized Chinese herbal formulations (n = 38), a standard Chinese herbal formulation (n = 43), or placebo (n = 35). Patients received 5 capsules 3 times daily for 16 weeks and were evaluated regularly by a traditional Chinese herbalist and by a gastroenterologist. Patients, gastroenterologists, and herbalists were all blinded to treatment group. **MAIN OUTCOME MEASURES:** Change in total bowel symptom scale scores and global improvement assessed by patients and gastroenterologists and change in the degree of interference in life caused by IBS symptoms assessed by patients. **RESULTS:** Compared with patients in the placebo group, patients in the active treatment groups (standard and individualized CHM) had significant improvement in bowel symptom scores as rated by patients (P=.03) and by gastroenterologists (P=.001), and significant global improvement as rated by patients (P=.007) and by gastroenterologists (P=.002). Patients reported that treatment significantly reduced the degree of interference with life caused by IBS symptoms (P=.03). Chinese herbal formulations individually tailored to the patient proved no more effective than standard CHM treatment. On follow-up 14 weeks after completion of treatment, only the individualized CHM treatment group maintained improvement. **CONCLUSION:** Chinese herbal formulations appear to offer improvement in symptoms for some patients with IBS.

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