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**FILE: ■Smooth Move® Tea
■Constipation
■Elderly**

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RE: Small Study Shows Smooth Move® Tea Effective in Treatment of Chronic Constipation for Elderly Adults

Bub S, Brinckmann J, Cicconetti G, Valentine B. Efficacy of an herbal dietary supplement (Smooth Move) in the management of constipation in nursing home residents: a randomized, double-blind, placebo-controlled study. *J Am Med Dir Assoc.* 2006; 1-6.

Elderly nursing home residents are at a high risk of developing chronic constipation. This is due to several factors including constipation-causing medication, chronic medical conditions, immobility, dietary changes, and dementia. Chronic constipation can lead to impaction, considered to be a serious event meriting investigation when it is reported in nursing homes. For this reason, chronic constipation is aggressively managed by nursing home staff. This randomized, double-blind, placebo-controlled clinical trial examines the effect of treating chronic constipation with Smooth Move® herbal tea (Traditional Medicinals®, Sebastapol, California) as an addition to constipation treatments that the patients were already receiving.

The single study center is the "real-life situation" of the County Nursing Home in Allentown, Pennsylvania, where all of the patients were residents at the time of the study. In keeping with the focus on "real-life situation," patients continued to receive their regular diets, medications, and constipation treatments throughout the study period, with the exception of any patients already receiving Smooth Move tea, who were subject to a wash-out period. Patients received either daily laxatives or the "bowel routine protocol" to manage their chronic constipation. Constipation treatments used include milk of magnesia, rectal suppositories, and enemas. Patients' bowel movements were monitored for 28 days; this was followed by a 28-day study period in which the patients received 1 cup of either a placebo tea or Smooth Move tea daily at lunchtime.

The primary outcome measure was the difference in the average number of bowel movements between the 2 periods (the study and the prior wash-out period). Secondary outcome measures were the differences in the average number of standard treatments and the average treatment costs between the 2 periods.

Each single serving of Smooth Move tea is 2,000 mg and contains 1,080 mg of senna leaf (*Senna alexandrina* syn. *Cassia angustifolia*), providing 20 mg of sennosides A and B per cup of tea when prepared as directed. Other ingredients in Smooth Move tea include licorice (*Glycyrrhiza glabra*)

root, fennel (*Foeniculum vulgare* var. *vulgare*) fruit (normally called fennel seed), sweet orange (*Citrus sinensis*) peel, cassia (*Cinnamomum aromaticum* syn. *C. cassia*) bark, coriander (*Coriandrum sativum*) fruit (commonly referred to as seed), ginger (*Zingiber officinale*) rhizome, and essential oil of sweet orange peel dried on acacia gum (*Acacia senegal*). The authors write that these other herbs "are traditionally combined with senna leaf." Fennel fruit and coriander fruit are included for their carminative and spasmolytic properties. Licorice root is included "as an antispasmodic component" and because it potentiates the actions of senna leaf (thus lowering the dose needed for an effect).

The placebo tea was packaged identically to the Smooth Move tea and was designed to be similar in taste, smell, and appearance to Smooth Move tea, without a laxative component. The placebo tea included 2,000 mg of the following herbs: roasted carob (*Ceratonia siliqua*) fruit, fennel fruit, sweet orange peel, Saigon cinnamon (*Cinnamomum loureirii*) bark, coriander fruit, ginger rhizome, and "orange flavor."

A total of 92 patients with chronic constipation were randomized using a statistical software package (MINITAB v14) to receive Smooth Move tea ($n=45$) or the placebo tea ($n=47$). Of the patients that started the study, 1 died and 2 dropped out of each group. A total of 42 patients from the Smooth Move group and 44 patients from the placebo group were included in the final data analysis. A total of 4 patients experienced 5 adverse effects: 0 patients from the Smooth Move group and 4 patients from the placebo group. The adverse effects were determined to be unrelated to the study.

Patients who received Smooth Move tea had an average of 4.14 more bowel movements during the treatment period than during the pre-treatment wash-out period, when compared with the placebo group ($P=0.017$). There were no significant differences between the 2 groups in terms of the differences in treatment costs and the number of standard treatments; although a difference in total costs was observed (total cost was reduced in the Smooth Move group).

The authors conclude that the results show that Smooth Move herbal tea is superior to a placebo in the treatment of chronic constipation. No significant adverse effects due to the tea were observed; however, the authors warn that it "should be used no more than 3 times per week when bulk or osmotic laxatives fail." The authors write that the results of this clinical trial warrant a follow-up multicenter clinical trial "to further assess efficacy and cost-effectiveness." In addition to assessing the number of bowel movements, data on stool consistency, stool weight, and ease of defecation would enhance future trials.

—Marissa Oppel, MS

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