

Efficacy of an Herbal Dietary Supplement (Smooth Move) in the Management of Constipation in Nursing Home Residents: A Randomized, Double-Blind, Placebo-Controlled Study

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Objective: To investigate the efficacy and cost effectiveness of an herbal tea, Smooth Move, in nursing home residents with chronic constipation.

Design: Double-blind, placebo-controlled, 2-armed, parallel-group clinical trial.

Setting: A 483-bed nursing home in Allentown, Pennsylvania, operated by Lehigh County Government.

Participants: A total of 86 nursing home residents with chronic constipation.

Interventions: Participants (n = 86) were randomly assigned to receive Smooth Move (n = 42) or a placebo (n = 44), once daily, in addition to standard treatment for chronic constipation. The study period was 28 days.

Measurements: The primary efficacy parameter was the difference in total number of bowel movements. Secondary parameters included the difference in aver-

age number of standard treatment doses dispensed, and the difference in total medication costs.

Results: Compared to placebo, in the intention to treat (ITT analysis) there was a statistically significant increase in the number of bowel movements in the Smooth Move group. The Smooth Move group (n = 42) compared with the placebo group (n = 44) experienced an average of 4.14 more bowel movements during the 28-day study period versus the 28-day pre-study period ($P = .017$).

Conclusion: Smooth Move herbal tea, when added to the standard treatment regimen for nursing home residents with chronic constipation, increased the average number of bowel movements compared to the addition of a placebo tea. (*J Am Med Dir Assoc* 2006; 7: 556–561)

Keywords: Constipation; elderly; herbal tea; laxatives; randomized clinical trial senna

Constipation is a significant problem in the elderly.¹ The prevalence of constipation and the impact on quality of life are greatest in the elderly,² with a reported incidence among ambulatory adults 65 years of age and older of 26% in men and 34% in women.³ Constipation in elderly people living in nursing homes and hospitals is generally considered to be higher than those living in the community. Once admitted, other factors may contribute to constipation (eg, changes in diet and activity; loss of privacy).² More than 80% of nursing home and/or extended-care facility residents are reported to suffer from constipation.³ This population includes persons

with the highest frequency of risk factors (eg, immobility, polypharmacy, and chronic medical conditions).⁴ Volicer et al⁵ reported that dementia is a risk factor for constipation, and residents may be more difficult to manage than cognitively intact patients. Risk factors for constipation include the use of certain drugs (eg, anticholinergic antidepressants, opioid analgesics, and nonsteroidal anti-inflammatory drugs [NSAIDs] including aspirin). In clinical practice, however, the drug(s) that may be causing the constipation may need to be continued in spite of their negative effects on bowel function. In a constipation care study by Frank et al,⁶ it was concluded that nursing staff performance of constipation care-related tasks is time consuming and costly in the long-term care setting.

In this study, 54.65% of the resident population were dementia/Alzheimer's patients (26 in the placebo group and 21 in the Smooth Move group) routinely receiving constipation-causing medications plus a range of interventions to relieve constipation including orally ingested liquids, powders, and tablets; supposi-

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tories; and enemas. The aim of this study was to investigate the effects of introducing an herbal dietary supplement, Smooth Move herbal tea, into the daily regimen of elderly long-term care facility residents.

METHODS

Study Design

The study was designed as a randomized, double-blind, placebo-controlled, single center study. The participants were randomly assigned to receive either Smooth Move tea or placebo tea. Residents continued to be administered their existing laxative medications and/or enemas in addition to the investigational product. At the discretion of the nursing staff and physician, the dosage of the laxatives could be adjusted according to bowel function. For all residents already using Smooth Move, there was an initial 28-day washout period before resuming Smooth Move at start of study. This design enabled the analysis of differences in total bowel movements, for each group, in the 28-day pre-study period versus the 28-day study period, and an analysis of those differences comparing the Smooth Move group against the placebo group.

This study was designed to assess, in the real-life situation of a busy nursing home with elderly residents receiving numerous medications, including constipation-causing medications, the effects of introducing an herbal dietary supplement (Smooth Move herbal tea) in the regimen of residents suffering from chronic constipation, the dispensing of standard treatment by nursing home staff, and on costs of care and medications. Subjects with chronic constipation were defined as residents who used laxatives at least once a week. This included residents who received a daily laxative and/or those who used the bowel routine protocol once a week. The following describes the bowel routine protocol: If no bowel movement (BM) by day 2, evening nurse gives a laxative on day 2 (1700 h): Milk of Magnesia (MOM) 30 mL orally; if no BM by day 3, evening nurse gives a laxative on day 3 (1700 h): MOM 30 mL orally; if no BM by the morning of day 4, day nurse gives a suppository that morning: Dulcolax rectal suppository; if no BM within 3 to 5 hours of suppository insertion, give an enema.

In this design, even if nursing staff did not adjust standard treatment interventions, the addition of Smooth Move provides a measurable variable for differences in total number of bowel movements.

The study protocol and the informed consent form were reviewed and approved by the local Institutional Review Board (IRB) of Sacred Heart Hospital, Allentown, Pennsylvania, on July 12, 2004. Each resident, or his or her legal guardian, was informed both orally and in writing. Written informed consent was obtained from all residents, or from their legal guardians, before study participation.

Subjects and nursing home staff were not compensated for participating. This study was investigator-initiated research, and the lead investigator approached the sponsor about cooperating on the study. Expenses related to the development of the study were assumed by the study sponsor. The principal

investigator has no equity interest or intellectual property rights in the investigational product, however a small stipend was paid by the sponsor for some labor and expenses in the development of this study.

Patients

Residents were recruited at the County Nursing Home in Allentown, Pennsylvania. Evaluated for enrolment were male and female nursing home residents with chronic constipation, who had been living at the center for at least 1 month, and were presently receiving laxative medications (eg, Dulcolax, Metamucil, Milk of Magnesia, and Senokot). Because a significant number of the study participants were nursing home residents with dementia, it was not feasible in all cases to require a diagnosis according to "Rome II" criteria for functional constipation as a prerequisite for the inclusion criteria. Such a diagnosis would require a level of communication with the patient that was not usually possible. Exclusion criteria were patients on feeding tube, thickened liquids, currently on Smooth Move herbal tea, diarrhea, patients with ileus, renal failure, dialysis, Crohn's disease, ulcerative colitis, chronic abdominal pain, and patients at the facility for less than 1 month.

Treatment

Residents with chronic constipation were randomized to receive either placebo tea or Smooth Move tea (Traditional Medicinals, Sebastopol, CA) at a serving of 1 cup each afternoon. The tea was dispensed by the day shift, usually with lunch, because the night shift had fewer staff and there would be better compliance if given by the day shift.

The investigational products were supplied as homogeneous mixtures of dried botanicals packaged in unbleached double-pouch filter tea bags, individually sealed in plain white tamper-evident envelopes. Each single serving of Smooth Move contained 2000 mg of pharmacopeial-grade ingredients including 1080 mg of the stimulant laxative active ingredient senna leaf PhEur (*Cassia angustifolia* Vahl). Prepared as directed, one cup of the herbal tea contains 20 mg sennosides A and B (± 4.0 mg per cup), as determined by high performance liquid chromatography (HPLC).

While the risks of laxative abuse have been overemphasized,⁷ senna leaf teas are nonetheless contraindicated in cases of ileus, acute intestinal inflammation (eg, Crohn's disease, colitis ulcerosa, appendicitis), abdominal pain of unknown origin, and severe dehydration states with water and electrolyte depletion. In case of overdose, symptoms of intoxication may include diarrhea with excessive dehydration and loss of electrolytes, especially potassium. Emergency measures for overdose include electrolyte and fluid-regulating measures. Potential drug interactions for senna teas, with chronic use or abuse, include potassium depletion, which may potentiate the action of cardiac glycosides and may also lead to a possible interaction with antiarrhythmic agents. Potassium deficiency can be intensified by concomitant ingestion of saluretics, adrenal corticosteroids, or licorice root. Possible side effects of senna teas, in individual cases, may include cramp-like discomforts of the gastrointestinal tract, particularly in patients

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