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Clinical Study

Randomized clinical trial assessing whether additional massage treatments for chronic neck pain improve 12- and 26-week outcomes

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Abstract

BACKGROUND CONTEXT: This is the first study to systematically evaluate the value of a longer treatment period for massage. We provide a framework of how to conceptualize an optimal dose in this challenging setting of nonpharmacologic treatments.

PURPOSE: The aim was to determine the optimal dose of massage for neck pain.

STUDY DESIGN/SETTING: Two-phase randomized trial for persons with chronic nonspecific neck pain. Primary randomization to one of five groups receiving 4 weeks of massage (30 minutes 2x/or 3x/wk or 60 minutes 1x, 2x, or 3x/wk). Booster randomization of participants to receive an additional six massages, 60 minutes 1x/wk, or no additional massage.

PATIENT SAMPLE: A total of 179 participants from Group Health and the general population of Seattle, WA, USA recruited between June 2010 and August 2011 were included.

OUTCOME MEASURES: Primary outcomes self-reported neck-related dysfunction (Neck Disability Index) and pain (0–10 scale) were assessed at baseline, 12, and 26 weeks. Clinically meaningful improvement was defined as greater than or equal to 5-point decrease in dysfunction and greater than or equal to 30% decrease in pain from baseline.

METHODS: Clinically meaningful improvement for each primary outcome with both follow-up times was analyzed using adjusted modified Poisson generalized estimating equations (GEEs). Secondary analyses for the continuous outcomes used linear GEEs.

RESULTS: There were no observed differences by primary treatment group at 12 or 26 weeks. Those receiving booster dose had improvements in both dysfunction and pain at 12 weeks (dysfunction: relative risk [RR]=1.56 [1.08–2.25], p=.018; pain: RR=1.25 [0.98-1.61], p=.077), but those were nonsignificant at 26 weeks (dysfunction: RR=1.22 [0.85–1.74]; pain: RR=1.09 [0.82–1.43]). Subgroup analysis by primary and booster treatments found the booster dose only effective among those initially randomized to one of the 60-minute massage groups.

CONCLUSIONS: "Booster" doses for those initially receiving 60 minutes of massage should be incorporated into future trials of massage for chronic neck pain.

Keywords: Chronic neck pain; Dosing; Massage; Randomized clinical trial; Complementary medicine; Clinical trial methods

FDA device/drug status: Not applicable.

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The disclosure key can be found on the Table of Contents and at www.TheSpineJournalOnline.com.

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Trial Registration: NCT01122836 (ClinicalTrials.gov).

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Introduction

One challenge in evaluating the efficacy of nonpharmacologic treatments for spinal pain is the paucity of data available on the optimal dose of the treatment [1]. Without this information, researchers and clinicians cannot be sure that research findings capture the potential for the therapy to improve pain and function. In fact, several Cochrane reviews of massage for neck pain have noted that previous studies used such different types and doses of massage that the optimum dose for practice and clinical trials is unknown [2,3]. These reviews called for studies to explicitly remedy this deficit. Moreover, for massage, there are a variety of elements that go into dosing, including the length of each treatment session, the weekly frequency of treatments, and the number of weeks of treatment.

To address the lack of knowledge regarding the optimal dose of massage for chronic neck pain, we designed a study to look at the optimal combination of treatment frequency and session duration for massage over a 4-week period and to determine whether an additional 6 weeks of massage extended the benefits of the initial month of treatment. We have previously reported the outcomes of the initial 4-week treatment period [4], and in this article, we report on the effects of an additional 6 weeks of treatment.

EVIDENCE & METHODS

Context
The authors present results of what they maintain to be the first study to consider the value of longer treatment periods of massotherapy for the treatment of chronic nonspecific neck pain. This was a two-phased randomized trial of 179 patients.

Contribution
Patients randomized to the booster dose of massage therapy had significantly superior short-term outcomes in terms of pain and dysfunction. Outcomes were no longer significant, however, at six-month follow-up.

Implications
The idealized setting of a randomized trial and the inclusion criteria for participation in this study may impair the generalization of the findings. Further research must address the clinical utility of a ''booster dose'' of massage therapy in the treatment of chronic neck pain and its efficacy in the general population with chronic nonspecific neck pain.

—*The Editors*

Materials and methods

Design

We conducted a two-phase individually randomized clinical trial to assess the optimal dose of massage for chronic neck pain that would be evaluated in future full-scale effectiveness studies. In the first phase (the ''primary treatment'' period), participants were randomly assigned to receive 4 weeks of one of five different doses of massage or to a wait-list control group. Those receiving massage during the primary treatment period were then randomized to receive an additional six weekly 60-minute massages (booster treatment) or to stop having massage.

The Group Health Research Institute (Seattle, WA, USA) institutional review board approved the trial protocol and all study procedures. Prospective participants giving oral consent by telephone were screened for eligibility, and those found eligible were asked to provide written consent before their in-person examination and study enrollment. The published study protocol [5] is summarized in the following sections. Results from the primary treatment period have been previously published [4]. This article presents the effects of the 6-week booster treatment after 12 and 26 weeks.

Study participants

We recruited study participants from Group Health, an integrated health-care system serving about 600,000 members, and from the general population of Seattle. We recruited prospective participants between June 2010 and August 2011 using mailed invitations to Group Health members, those with neck pain–related visits to primary care providers, advertisements in the health plan's magazine, posters, a study Web site, neighborhood blogs, and direct mail postcards. Persons aged 20 to 64 with chronic nonspecific neck pain who were able and willing to attend treatments at our clinic and give informed consent were potentially eligible.

We excluded persons whose neck pain had a pathologically identifiable cause (eg, vertebral fracture, metastatic cancer) was complex (eg, cervical radiculopathy, recent automobile accident) or too mild (<4 on an 11-point pain intensity scale and <5 on the 0–50 Neck Disability Index [6,7]). We also excluded those with potential contraindications for massage (eg, hypersensitivity to touch), any massage within the last 3 months, massage for neck pain within the last year, an inability to give informed consent or speak English, or with medicolegal issues related to neck or back pain.

Randomization

After completing the baseline interview, a research assistant randomized participants using a computer-assisted telephone interviewing program, to one of the six groups in the primary treatment randomization. Treatment assignments were generated by a statistician (AJC) using R (version 2.11.0; R Core Team (2013), Vienna, Austria. http://www.