Retention of Blinding at Follow-Up in a Randomized Clinical Study Using a Sham-Control Cervical Manipulation Procedure for Neck Pain: Secondary Analyses From a Randomized Clinical Study

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Abstract

Objective: Participants in clinical trials of spinal manipulation have not been rigorously blinded to group assignment. This study reports on secondary analyses of the retention of participant blinding beyond the immediate posttreatment time frame following a single-session, randomized clinical study. A novel control cervical manipulation procedure that has previously been shown to be therapeutically inert was contrasted with a typical manipulation procedure.

Methods: A randomized clinical study of a single session of typical vs sham-control manipulation in patients with chronic neck pain was conducted. Findings of self-reported group registration at 24 to 48 hours posttreatment were computed. The Blinding Index (BI) of Bang et al was then applied to both the immediate and post–24- to 48-hour results.

Results: Twenty-four to 48 hours after treatment, 94% and 22% of participants in the typical and control groups, respectively, correctly identified their group assignment. When analyzed with the BI of Bang et al, the immediate posttreatment BI for the group receiving a typical manipulation was 0.22 (95% confidence interval [CI], −0.03 to 0.47); for the group receiving a control manipulation, it was 0.19 (95% CI, −0.06 to 0.43). The BI at post-24 hours was as follows: typical = 0.75 (95% CI, 0.59-0.91) and control = −0.34 (95% CI, −0.58 to −0.11).

Conclusions: This study found that the novel sham-control cervical manipulation procedure may be effective in blinding sham group allocation up to 48 hours posttreatment. It appears that, at 48 hours posttreatment, the modified form of the typical cervical manipulation was not. The sham-control procedure appears to be a promising procedure for future clinical trials. (J Manipulative Physiol Ther 2013;36:522-526)

Key indexing terms: *Neck Pain; Clinical Trial; Manipulation, Spinal; Placebo*

Rigorous clinical trials of spinal manipulation for neck pain (NP)–related complaints require a valid sham manipulative procedure to blind participants with respect to treatment group allocation. Allocation concealment and participant blinding form 2 of the strongest tools to minimize selection bias and confounding of study outcomes.[1] These are particularly important for efficacy trials that are explanatory, attempting to differentiate active from inactive components of the treatment experience. Physical treatments pose serious obstacles to effective blinding. Assessor blinding to group allocation and clinical status of participants has been the main alternative strategy to avoid biasing of outcomes during trials of manual therapies. Participants, on the other hand, can readily form suspicions as to their group assignment. Those who perceive they may be receiving an experimental treatment or a placebo may harbor increased apprehension or unrealistic expectations.

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Paper submitted October 26, 2012; in revised form June 25, 2013; accepted June 27, 2013.
0161-4754/$36.00

http://dx.doi.org/10.1016/j.jmpt.2013.06.005

Absent an effective control/sham/placebo, nonspecific effects of a treatment cannot readily be separated from potentially beneficial therapeutic effects during pragmatic randomized comparative trials[2-5] that are reported in the literature. Some study methods have attempted to offset this limitation by using control treatment procedures for a single session of manipulation. The review of Vernon et al[6] of these trials identified lack of control for bias as a major weakness in these studies. As well, the generalizability of results beyond the immediate short-term outcomes is questionable, as there are no reports of retention of blinding effects from control/sham/placebo beyond the immediate timeframe.

Vernon et al[7] reported a novel sham-control cervical manipulation procedure that showed promise in blinding patients with NP who were naive to manipulation as to whether the treatment procedure used was a "real treatment." Recent modifications of this method have been tested in a larger sample of participants with NP who were randomly assigned to receive either the sham-control or a real cervical spine manipulation.[8] Findings included near-equal proportions of participants in each group mistaking their group allocation (53% in the "real manipulation" group; 50% in the "sham manipulation" group); there were no significant decreases in pain scores or tenderness in both groups, with no differences between groups.[8] However, these findings again are relevant only to the immediate postintervention results.

The purpose of this study was to examine the longitudinal validity of the sham-control procedure by evaluating the retention of blinding effects 24 to 48 hours following the immediate response involving a single treatment session by using the Blinding Index (BI) of Bang et al.[9]

Methods

Study Design

A randomized, single-blind (participant) clinical study was conducted involving patients with chronic mechanical NP. The details of the project are reported elsewhere[8] and are briefly reviewed to provide context for the evaluation of retention of blinding beyond the immediate outcome measure after treatment. This study's methods and consent processes were approved by the Research Ethics Board of the Canadian Memorial Chiropractic College (#0902B02).

Participants

Participants were recruited from the population of patients consulting for care of chronic mechanical NP at an outpatient teaching clinic and by local area advertisements. Table 1 summarizes the inclusion criteria. Patients both with and without prior experience with manipulation intentionally were enrolled in the study, as compared with only naive participants in the 2005 study.[7] Those with evidence of any pathology, any reported arm pain, or NP score (visual analog scale) greater than 7/10 were excluded. After completing informed consent, participants were evaluated and randomly assigned to a single-session treatment using either a typical or a sham-control manipulation procedure. Randomization was accomplished prospectively using block allocation to ensure equal numbers in each group. The random allocation was concealed using sealed individual numbered envelopes sequestered from the assessors in the study. The assessors for both the physical outcomes and the primary outcome pertinent to the current study were blinded to group allocation. Pain and tenderness scores were not included in this study.

Table 1. *Inclusion criteria*

Variable	Criterion
Age	18-60
Pain	Visual analog scale ≥ 3.0
Duration	8 wk or longer
Symptom distribution	Bounded by: nuchal ridge of occiput inferiorly to spine of the scapula, bilaterally.
Origin	Cervical segment by IASP criteria[10]

IASP, International Association for the Study of Pain.

Interventions

In previous studies, the terms *sham* and *real* have been used to describe the 2 interventions delivered in this study. For the current study, the terms *control* and *typical* are used, respectively, as these terms have a more neutral connotation for all readers. However, when referring to the choices given to the participants for their response to the question by which the primary data were obtained, the term *real* will still be used. The clinician performing the treatment conducted his own mechanical assessment of the neck, determining the cervical segment to which treatment should be applied following the International Association for the Study of Pain[10] criteria. The control procedure was engineered to provide the sensory input similar to that experienced by patients receiving typical manipulation treatment[11] while avoiding any thrust directly to the neck. Each procedure consisted of 2 maneuvers, emulating the common application of treatment to more than 1 site in an individual session. The control group participants received 2 control maneuvers, 1 to each side of the neck. In the typical manipulation group, participants received, first, 1 typical thrust manipulation on the side previously determined to be clinically relevant, followed by 1 control maneuver on the other side. No other interaction was permitted between the treatment provider and the participant.

Following treatment, the participant was independently assessed including a scripted question designed to allow the patient to register his/her response to the question, "Was the procedure you just received a real chiropractic treatment?" This was repeated by phone contact with the patient 24 to 48 hours following treatment.