

SHORT-TERM EFFECT OF SPINAL MANIPULATION ON THE MAGNITUDE OF EXOPHORIA
IN ADULTS WHO ARE ASYMPTOMATIC: A RANDOMIZED CONTROLLED TRIAL

Running head: Cervical manipulation in exophoria

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ABSTRACT

Objective: This study aimed to assess the immediate and short-term effects of cervical spinal manipulation, compared with a placebo, on the magnitude of near and distance exophoria in adults with asymptomatic exophoria.

Methods: In this single-blind, randomized controlled trial, individuals with a clinical diagnosis of horizontal exophoria confirmed with the prism alternating cover test (PACT) were allocated to a single intervention session using a high-velocity, low-amplitude cervical spinal manipulation technique or a sham intervention (manual contact under the head). Outcomes were the magnitude of horizontal heterophoria, as a measure of binocular vision efficiency at near (40 cm) or distance (4 m) fixation, using the PACT. Evaluations were made at baseline, immediately after intervention, and at a 1-week follow-up.

Results: From May to September 2021, 44 volunteers (23 women), with a mean age of 35 (SD = 9.5) years, were recruited and equally distributed into the study groups. All participants completed follow-up assessments, and no adverse events were reported. There was a significant time x group interaction for exophoria at near vision, but not at distance fixation. The spinal manipulation group showed a significant decrease of near exophoria compared to the control group at the 1-week follow-up (mean difference = -1.09 prism diopters; 95% CI = -0.20 to -1.98 prism diopters).

Conclusion: The use of cervical spinal manipulation therapy resulted in a significant reduction of the magnitude of horizontal exophoria at near vision (medium effect size), compared with the placebo, in young adults who are asymptomatic. However, these effects were not observed at distance fixation and should be considered cautiously due to the pre-post design with a single intervention session and the short-term follow-up.

Impact: The findings suggest short-term benefits of spinal manipulation therapy can manage undiagnosed ocular convergence disorders, although changes were not clinically relevant.

Key Words: exophoria, binocular vision, spinal manipulation, vision screening

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Introduction

Binocular vision depends on effective neural integration of sensorimotor information that results in convergence of the visual axes¹. Heterophoria, defined as a relative misalignment of the eyes in absence of fusional convergence², can start during early childhood³, and it is frequent in young and older adults^{4,5}. Special attention should be given to those with high visual demands, e.g., using near vision in front of a visual display unit for many hours⁶.

Basic exophoria occurs when the eyes tend to diverge at near (convergence insufficiency) or distance (divergence excess)⁴. Although heterophoria is often asymptomatic, it may cause different symptoms when decompensated, e.g., blur and distorted vision, nausea, headache, ocular pain, and sore eyes⁶⁻⁸. Additionally, the sustained contraction of eye muscles may increase the activity of neck-shoulder muscles and lead to musculoskeletal complaints in this area⁹, with a negative impact on daily life activities^{10,11}. Therefore, clinical management of heterophoria can be relevant in individuals who are asymptomatic. Currently, common conservative interventions include the use of prism-lensed glasses, alone or combined with oculomotor training. However, evidence about their effectiveness is scant and unclear¹², and even the most effective approaches are only successful in some cases and require long treatment hours¹³, which may decrease adherence. Thus, there is a need for novel therapeutic protocols and new research on this topic is warranted^{12,13}.

Several studies have concluded a cross-dysfunction between the visual and musculoskeletal system in the cervical spine^{8,14,15}. This would explain the altered motor control activity of eye muscles in people with neck disorders^{14,16}. Similarly, neck pain and cervical postural changes have been observed in individuals with convergence insufficiency¹⁷. Spinal manipulation (SM) is known to modify sensorimotor integration, with proven peripheral and central neurophysiological effects¹⁸. Preliminary findings suggest that even a single SM technique may have a positive impact on oculomotor control¹⁹, intraocular pressure²⁰, eye reflexes²¹, and visual acuity²². To date, no study has investigated the efficacy of SM on the magnitude of heterophoria. It should be noted that adverse events have been occasionally reported following cervical SM²³, so these maneuvers should be used cautiously. Yet, establishing a causality remains challenging²³, serious adverse events are rare, and the occurrence of adverse events after cervical SM appears to be similar compared with other treatment modalities²⁴.

The present study aimed to assess the immediate and short-term effect of a single upper cervical SM technique, compared with placebo, on the magnitude of near and distance exophoria, in adults with asymptomatic exophoria. We hypothesized better results for participants who received SM.

METHODS

Design

A two-armed, parallel-group, and single-blinded randomized controlled trial was conducted. The study complied with the Consolidated Standards of Reporting Trials (CONSORT) statement²⁵, and the ethical principles of the Declaration of Helsinki. The research protocol was approved by the Institutional Ethics Review Board (code number: 15-F-16) and was prospectively registered at ClinicalTrials.gov (NCT04901533).

Participants

Following a convenience sampling, eligible individuals were recruited at a university setting and selected among students between 18 and 55 years. Participants were considered with a clinical diagnosis of horizontal exophoria when they were observed to deviate the eye outwards during the prism alternating cover test (PACT)²⁶. Normative physiological values for non-strabismic binocular vision disorders has been established at 3 ± 3 prism diopters (Δ) in near vision and $1 \pm 2 \Delta$ in distance vision²⁷. Exclusion criteria were: no evidence of current or treated strabismus or any abnormality beyond uncorrected refractive error³; previous severe neck trauma, e.g., cervical whiplash; having received manual therapy in the cervical spine within 4 weeks; any known contraindication to SM, e.g., rheumatic polyarthritis, or fracture²⁸; and diagnosed neurological symptoms. All participants signed a written informed consent before allocation to intervention.

Randomization and Blinding

An external staff member used Microsoft Excel to obtain a random numbers table sequence, considering a 1:1 distribution ratio. Concealment of treatment allocation was ensured using consecutively numbered sealed opaque envelopes. The outcome assessor remained blinded to allocation.

Interventions

One physiotherapist, with over 15 years of manual therapy experience, was responsible for the interventions in both groups. The SM group underwent an upper cervical SM technique. The occiput-atlas-axis (OAA) global manipulation maneuver²⁹ was conducted bilaterally to evoke the biomechanical and neurophysiological responses associated with SM³⁰. With the participant in supine, the therapist placed both hands at the head and delivered a high-velocity low-amplitude technique in a two-step process. First, the therapist performed a slight axial decompression of the cervical spine. Then, he rotated the neck to one side and searched for the joint barrier using selective pressure and small circumduction movements (figure 1). Individuals in the control group remained in comfortable supine position while the therapist kept both hands under their head. Participants were instructed to gently move to a seated position after intervention. The treatment protocol was conducted at the university laboratories and lasted for approximately 5 minutes in both groups.

Outcome measures

An experienced orthoptist, who was unaware of the study aim, completed the evaluations at baseline, immediately after intervention, and at a 1-week follow-up. The study measure was the magnitude of horizontal heterophoria, assessed with the PACT²⁶, at near (40 cm) and distance (4 m) fixation (figure 2). Prior to examination, the target distance was marked on the floor. Measures were undertaken in the same room, equipped with full illumination (>750 lx). Participants were instructed to seat upright, with their chin and head straight, and to look at an object in front of them. Then, the orthoptist covered one of the eyes with a translucent cover for 3 to 4 seconds. The cover was moved immediately to the other eye for another 3 to 4 seconds, and the same process was repeated several times, i.e., to cover one eye while uncover the other. In people with exophoria, the eye that is just uncovered will drift inwards to keep gaze at the fixated point. The examiner observed the participant's eyes movement and used a prism

bar to neutralize the eye deviation and quantify the severity of exophoria (Δ)²⁶. The examiner added base in and base out prism until eye deviation was not observed, and the midpoint of the prism measurements was then recorded^{26,31}. Participants were told to wear their usual vision correction during the test. The PACT has shown a high intra- and inter- examiner repeatability and reproducibility^{26,31}. The clinically relevant threshold for this test has been established at 2Δ ³¹, as the minimum detectable eye movement under ideal conditions ranges between 2 and 3Δ ³².

Sample Size

Sample size was estimated for 2 groups and 3 measurements. We considered an alpha value of 0.05, an 80% power, a correlation among repeated measures of 0.4, and a medium effect size ($\eta^2 \approx 0.12$) for the differences between groups in the PACT at near vision (G*power software, v 3.1.9.7, Kiel University, Kiel, Germany). A total of 42 participants, including a 10% dropout rate, were required to complete the study.

Statistical Analysis

Statistical processing was conducted with the IBM Statistics Package for Social Science® software, version 26 (IBM Corp, Armonk, NY, USA), considering an intention-to-treat analysis. Normal distribution of the data was assessed with the Shapiro-Wilk test. Results are reported as mean (standard deviation), mean (95% confidence interval) or in percentages. A repeated-measures analysis of variance (ANOVA) was used to explore the differences in the PACT at near or distance, using group (SM or placebo) as the between-subjects factor, and time as the within-subjects factor. Effect size was estimated using the partial eta squared (η^2), and the level of significance was set to a *P* value < .05.

RESULTS

From May to September 2021, a total of 44 individuals (23 females) with asymptomatic exophoria, mean age of 35.4 (9.5) years, were recruited. No participants were lost during follow-up (figure 3), and no adverse events were reported during the study protocol. Table 1 lists the baseline clinical

characteristics of the sample. There were no significant differences between groups for any of the study measures (all, $P > .05$).

The ANOVA demonstrated a significant time*group interaction (with a medium effect size) for the magnitude of horizontal heterophoria at near (40 cm) fixation ($F = 3.845$; $P = .034$; $\eta^2 = 0.084$), but not at distance (4 m) fixation ($F = 1.271$; $P = .283$; $\eta^2 = 0.029$) (Tab. 2). In the between-groups comparison, the SM group showed a higher reduction in the level of heterophoria at near vision, compared to the control group, only at the 1-week follow-up (mean difference -1.09Δ ; 95% CI = -0.20 to -1.98Δ).

DISCUSSION

We examined, for the first time, the effect of SM on modifying the magnitude of horizontal exophoria in participants who were asymptomatic. Partly in line with our hypothesis, the upper cervical SM technique was better than placebo to reduce exophoria at near distance, which seems encouraging for clinical purposes. However, current findings must be interpreted with caution based on the pre-post design with a single intervention session, the lack of clinically important changes, and the evaluation in a short follow-up period.

Assessment and treatment of binocular vision problems is important among purportedly asymptomatic visual display unit users, e.g., university students. For example, young adults tend to experience exophoria after prolonged use of digital devices³³. Similarly, reading on a smartphone can lead to eye tiredness, sleepiness, and blur sight^{34,35}, which can affect binocular convergence, especially for near vision, even in healthy individuals³⁶. Near vision tasks are often more demanding than far visual fixation, so most people become farsighted as they age³⁷. Consequently, exophoria is more prone to appear at near vision to compensate the inability of neuromuscular mechanisms to control visual convergence³⁸. The present findings showed a positive impact of the cervical SM technique on near horizontal exophoria. Although these results could seem promising, the differences **within and** between groups were below the clinically meaningful threshold (2Δ)³¹. However, it should be also acknowledged that this threshold has not been established on the grounds of diagnostic significance²,

thus its clinical accuracy still needs to be determined ²⁶. In addition, even though the PACT is a valid, widespread, and easy to use tool, the test is usually conducted using different techniques, and final measures are subjective and depend on the ability of the examiner ². All this together makes difficult to compare among studies.

In line with our results on convergence insufficiency, previous studies have shown that one treatment session with SM therapy can have a positive effect on the efficiency of binocular vision by improving the reading time in children with attention deficit disorders ¹⁹, and reducing the intraocular pressure in adults with type I diabetes ²⁰ or the edge light pupil cycle time in healthy individuals ²¹. These results could be partially explained by the alleged influence of SM on sensorimotor integration and on the prefrontal cortex ¹⁹, which is key to process visual information ³⁹. Other mechanisms may help to understand the present findings. Bilateral cervical rotation can be increased immediately after SM at the OOA complex ⁴⁰, and changes in cervical mobility are known to influence eye stabilization reflexes ⁴¹. SM therapy also influences parasympathetic activity ⁴², which may reduce the effort of eye muscles to keep convergence at near. Yet, we did not evaluate neck mobility or the response of the autonomic nervous system, so all this remains speculative.

Contrary to our findings, SM usually evoke immediate effects that may not sustain in the medium term. However, responses to SM are variable and dependent on the individual ⁴³, which could support the lack of differences between groups immediately after intervention, compared to the results at 1-week. Importantly, no adverse events were reported during the study. Cervical SM involving rotational movements has been associated with unusual ophthalmological adverse events, e.g., diplopia, or retinal hemorrhages ^{23,44}. Overall, a causal relationship between cervical SM and major adverse events is not likely ⁴⁵, and it is more prone to happen when treatment protocols include multiple sessions ⁴⁶. Still, clinical decisions to include SM techniques need to balance potential risks and proven benefits ²³. Previous research investigating the effect of conservative interventions on visual convergence is scarce. Orthoptic exercises, alone or combined with glasses, may improve near point of convergence in people with convergence insufficiency or with exophoria ^{47,48}. This positive effect can be sustained at 3 and 6 months ⁴⁹, although this latter trial lacked a control group, which detracts from its methodological quality. Wong et al. ⁵⁰ combined manual therapy, visual exercises, and vestibular rehabilitation in

patients with postconcussion symptoms and observed no impact on convergence insufficiency. The use of soft-tissue techniques, in addition to SM, achieved changes on visual acuity, but not on vertical heterophoria in individuals with vertigo⁵¹. Among children population, manual therapy has been proposed to restore visual reflexes in those with myopia⁵², whereas supervised vergence/accommodative therapy together with home reinforcement has proven effective to improve convergence insufficiency¹². In young adults, base-in prism reading glasses can reduce symptoms associated with exophoria, but do not seem to change near point of convergence or fusional vergence⁵³. The high heterogeneity among previous trials in terms of intervention techniques, treatment protocols, and tools used to evaluate binocular vision, warrants further research in the topic^{12,13}.

Study limitations

The research protocol was useful for the study aim, but does not reflect current clinical standards, where conservative interventions are often multimodal. Participants were asymptomatic and, therefore, the impact of SM therapy on exophoria related symptoms remains unknown. The design with only one treatment session may provide limited clinical information. Besides, there is no known standard for an ideal number of sessions using SM to manage a given condition⁵⁴. The PACT is an easy-to-use method to quantify visual convergence, but it may fail to represent the motor and perceptual challenges of efficient binocular vision in a real-life scenario⁵⁵. Standard normative values for binocular vision were considered in this study. However, these may differ depending on individual features, e.g., age, and race, or the specific techniques or assessment procedures⁵⁶. Finally, a risk of performance bias should be acknowledged for the therapist, who was the same for all individuals, and for participants (given the differences between treatments and the fact that they were recruited at a university setting).

CONCLUSION

Our findings suggest that an upper cervical SM technique was better than placebo to reduce the magnitude of exophoria at near distance but showed no significant effect on far vision. The lack of clinically meaningful differences between groups warrants further research to investigate the long-term impact of SM therapy on exophoria-related symptoms.

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Clinical Trial Registration

This protocol was prospectively registered at ClinicalTrials.gov (NCT04901533).

Disclosures

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Table 1. Baseline clinical and demographic features of participants in the study groups

	Spinal manipulation group n =	Placebo control group
	22	n = 22
Age, y, mean (SD)	36.7 (10.6)	34.2 (8.1)
Sex reported as female, n (%)	11 (50%)	12 (54.5%)
Height, cm, mean (SD)	171.1 (8.8)	173.0 (10.3)
Weight, kg, mean (SD)	72.5 (12.2)	71.2 (12.1)
Body mass index, kg/cm ² , mean (SD)	24.6 (2.4)	23.6 (2.1)

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Table 2. Changes in the Prism Alternating Cover Test (PACT) at Near or Distance Fixation^a

Outcomes	Within-Group Differences		Between-Group Differences
	Spinal Manipulation Group	Control Group	
PACT, 0 cm (Δ)			
Baseline (T1)	3.7 (2.4)	3.1 (2.9)	NA
Postintervention (T2)	3.4 (3.1)	2.8 (3.3)	NA
Change T1 to T2	-0.32 (-0.94 to 0.30)	-0.31 (-0.73 to 0.10)	0.00 (-0.72 to 0.72)
1 wk follow-up (T3)	2.6 (2.2)	3.1 (3.3)	
Change T1 to T3	-1.09 (-1.65 to -0.53) ^b	0.00 (-0.72 to 0.72)	-1.09 (-0.20 to -1.98) ^b
PACT, 4 m (Δ)			
Baseline (T1)	1.3 (1.8)	0.6 (1.2)	NA
Postintervention (T2)	1.1 (2.5)	0.3 (0.6)	NA
Change T1 to T2	-0.22 (-0.82 to 0.36)	-0.27 (-0.58 to 0.03)	0.04 (-0.60 to 0.69)
1 week follow-up (T3)	0.9 (1.8)	0.6 (1.2)	NA
Change T1 to T3	-0.40 (-0.83 to 0.01)	-0.04 (-0.14 to 0.04)	-0.36 (-0.78 to 0.06)

^aData are reported as mean (SD) or mean (95% CI). NA = not applicable.

^bStatistical significance (95% CI does not cross zero; $P < .05$).

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Figure 1. The occiput-atlas-axis (OAA) global manipulation technique (left neck rotation).

UNCORRECTED MANUSCRIPT



Figure 2. Prism alternating cover test at near distance (40 cm).

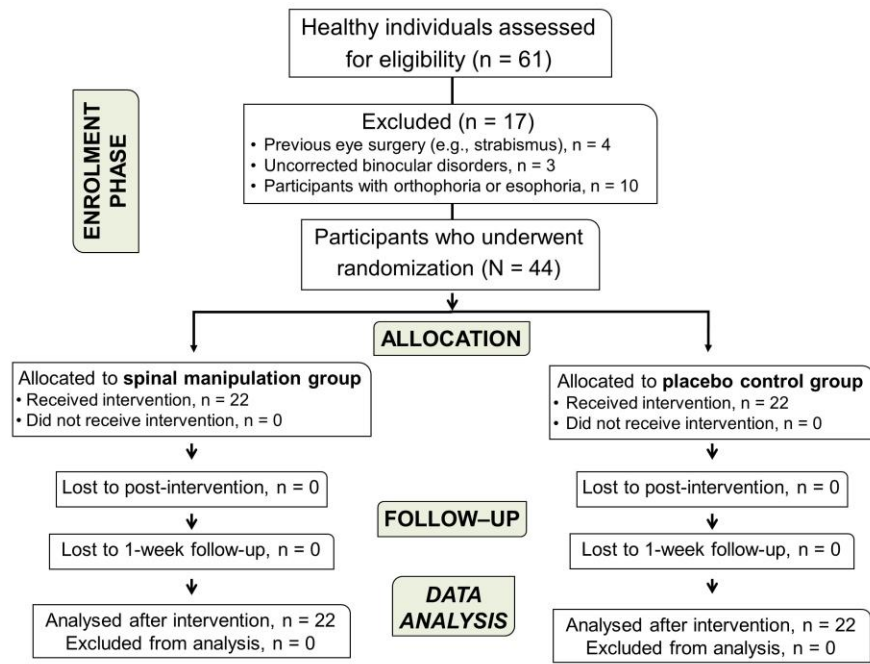


Figure 3. Flowchart diagram.