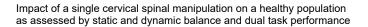


Impact of a single cervical spinal manipulation on a healthy population as assessed by static and dynamic balance and dual task performance: a feasibility study

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<u>Abstract</u>

Objective: The purpose of this study was to assess the feasibility of implementing a protocol evaluating the impact of chiropractic spinal manipulation on both static (one leg stance test) and dynamic (limits of stability test) balance assessments during regular and dual task (counting backwards by threes) conditions.

Methods: Thirty healthy participants were randomized into either a cervical spinal manipulation (n=15) or sham group (n=15). Participants completed balance assessments at pre, immediate post, and at a one-week follow-up. A survey assessing their experience was also administered at the one-week follow-up.

Results: All participants were compliant with protocols, including returning for the followup session. Group blinding and the sham procedure were not successful. Data for the balance assessments showed mixed changes in both groups, with some notable improvements in limits of stability variables following a single chiropractic cervical manipulation.

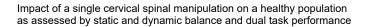
Conclusion: Further investigation into the impact of chiropractic spinal manipulation on both static and dynamic balance assessments during regular and dual task conditions appears feasible.



Maintaining proper balance is an important part of our activities of daily living. For example, unilateral postural control is important for everyday activities, such as turning, climbing stairs, walking, and dressing.¹ Individuals with reduced postural control may have difficulty with daily activities, including locomotor tasks, tasks with external perturbations, and multitasking, which could ultimately lead to falls and possible injury.²⁻⁴ Balance research using dual task paradigms can help mimic the complexity of everyday activities and can include static or dynamic assessments coupled with a cognitive or motor task.⁵

Static and dynamic dual task paradigms have been used in various balance-related research investigations; fall prevention in the elderly, implications of low back pain on postural control, and injury risk related to postural control variation are just a few examples.⁶⁻⁸ The investigation into the use of these paradigms also includes understanding more about the impact of various therapeutic interventions on balance performance during these conditions. Previous reviews have documented the positive impact of various exercise and therapeutic modalities on postural control in different populations, including younger individuals, older individuals, individuals with traumatic brain injuries, and individuals with Parkinson's disease.⁹⁻¹² Chiropractic spinal manipulation is one therapeutic intervention that has shown documented changes with postural control in healthy individuals.¹³⁻¹⁴ A randomized controlled trial by Vining et al. found a statistically significant increase in the amount of stance time in a one leg stance test with eyes closed in military personnel after four weeks of care.¹³ Another study by Malaya and colleagues found improvements in both static postural control and performance.¹⁴ Using a cross-over design and manual dual task condition, improvements were observed after upper and lower extremity adjustments in a cohort of healthy students.¹⁴

To add to this body of knowledge investigating the impact of chiropractic spinal manipulation on balance control, the purpose of this study was to assess the feasibility of implementing a protocol evaluating the impact of chiropractic spinal manipulation on both static (one leg stance test) and dynamic (limits of stability test) balance assessments during regular and dual task (counting backwards by threes) conditions. This feasibility study also evaluated the use of a previously documented movement-based procedure as a sham procedure for future studies. Information from this feasibility may help inform the design of future investigations related to the use of chiropractic spinal manipulation as a therapeutic intervention for challenges in dual-task ability and balance performance related to injury risk and activities of daily living.





METHODS

Trial Design

This study was a randomized, single blind feasibility study. Specifically, the study aimed to assess 1) acceptability and safety of study protocols; 2) participant retention; 3) effectiveness of group blinding; 4) use of a previously documented movement protocol as a sham and 5) changes in static and dynamic balance during regular and dual task conditions following a chiropractic spinal manipulation. Data collection occurred from December 2019 to April 2021. A pause in data collection occurred between March 2020 and September 2020 due to the COVID-19 pandemic.

Participants

A convenience sample of thirty individuals was recruited by word of mouth and university electronic newsletters. Individuals were eligible if they were between the ages of 18 and 50, had no injury to the spine within the last year, had no history of balance issues or dizziness, had no acute lower extremity injury, were not currently pregnant, and had not received chiropractic care within the last two weeks. Eligibility was assessed via a phone survey. All study procedures were approved by the (blinded) University Institutional Review Board, and all participants signed an informed consent form prior to any data collection or treatment. Procedures were conducted at the (blinded).

Randomization and Blinding

This study had two groups: chiropractic spinal manipulation and sham. Thirty participants were equally allocated to a group based on computer randomization using a list randomizer function (random.org). Group allocation occurred after informed consent was provided. Participants were blinded to their group allocation; however, it was not possible to blind the clinician to the allocation. Two investigators performed data collection, and neither were blinded to the group allocation.

Clinicians

Technique faculty members at (blinded) University volunteered their time for this study. To be respectful of busy schedules, three licensed chiropractors having at least 10 years of clinical experience participated. Clinicians met with study investigators during development to discuss and develop a consensus on the procedures for the physical exam and the technique to be used for the intervention and sham protocol.

Physical Exam

The clinician conducted the physical exam consistent with the standard of care according to state chiropractic board requirements. Exams consisted of range of motion testing, palpatory assessment of the spine, orthopedic testing, and neurologic testing. Because



all participants would only be receiving cervical interventions, only the cervical spine was examined through these tests, and the patient remained in a seated position throughout the entire assessment.

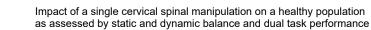
Active range of motion testing included the participant moving their own neck into flexion, extension, bilateral rotation, and bilateral lateral flexion. The palpatory assessment of C1 was completed by the clinician with their middle finger of one hand over the transverse process of the far side of the Atlas and the other hand guiding the participant's head through bilateral rotation. This procedure was repeated on the opposite side of C1 with the opposite hands of the clinician. C2 through C7 were assessed by the clinician holding the participant's forehead with one hand and contacting over the laminar pillars on the far side of the cervical spine with their middle three fingertips before switching hands and assessing the opposite side of the neck in the same manner. The fingertips of the clinician pushed in a posterior to anterior direction with slight lateral flexion over the contact point following the line of the facet joints of the cervical spine. Any soft tissue discrepancies (temperature, taut/tender muscle fibers) were noted at this point as well.

Cervical orthopedic testing included foraminal compression test, shoulder compression, Valsalva maneuver, and Spurling's test. The upper extremity neurologic testing was done in the form of bilateral reflex testing (triceps, biceps, and brachioradialis) and bilateral motor strength testing (deltoid, biceps, triceps, wrist extensors, wrist flexors, finger flexors, finger abductors, and finger adductors). Blood pressure was also assessed manually with the participant in a seated position using a manual sphygmomanometer and stethoscope on the left arm.

Intervention

The participants in the intervention group were given a chiropractic spinal manipulation by the same chiropractor who screened them. This study took a pragmatic approach, allowing the doctor to determine the most appropriate adjustment based on the static and motion palpation that occurred during the physical exam. All three doctors utilized the Diversified chiropractic technique, which consists of high velocity, low amplitude manipulations and were limited to the cervical spine. The cervical spine was chosen for its previously assessed role in postural control.¹⁵

Those in the sham group were taken through passive movements without applying pressure to any cervical segment, similar to the passive head movement intervention by Haavik-Taylor and Murphy in 2007.¹⁶ The doctor grasped the participant's parietal temporal region of their head, moving them through passive cervical rotation and passive cervical lateral flexion while in a supine position. This procedure was performed by the same clinician who had screened the participant in the physical exam. Although not originally intended as a sham procedure by Haavik-Taylor and Murphy, this study aimed to assess if the movement pattern could be used as a non-force sham protocol





considering it mimicked motion often conducted by the chiropractor during a supine spinal manipulation.¹⁷

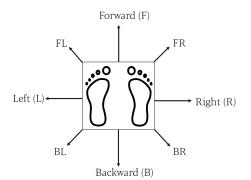
Balance Assessments

Limits of Stability

Before the assessment, each participant practiced the dual task condition of counting backwards by threes while seated. For the LOS test, participants were fitted with a safety harness attached to the frame of the NeuroCom balance system (NeuroCom Balance Manager SMART EquiTest System; Natus Medical Incorporated). They were instructed to stand on the balance plate with feet about hip width apart, hands down to the side, head erect, and facing forward towards the computer screen that was at eye level. The computer screen depicted a centre box with eight target boxes equally spaced around the centre box. Individuals were instructed to shift their centre of gravity (indicated by an icon on the screen) towards the designated direction once they heard an auditory cue; they were instructed to keep their feet flat and remain erect. Prior to the test trials, a practice run of four directions was used without the dual task (forward, right, backward, and left) to help orient the individual to the task.

The LOS test trials consisted of eight directions: forward, right forward, right, right backward, backward, left backward, left, and left forward. Figure 1. For the standard condition, individuals completed all eight directions as described. For the dual task condition, individuals began counting backwards by threes beginning at 100 the moment they began to move their body weight and were instructed to keep counting during the entire trial. Each trial lasted about ten seconds. At the start of each new trial, individuals were instructed to continue counting backwards by threes beginning with the last number from the previous trial. Once the individual reached zero, they were instructed to begin at 100 again. As an added safety measure, an investigator always stood behind the participant in the event of instability or a fall.

Figure 1 Directions for Limits of Stability Test





Limits of stability performance was measured by the following variables: directional control (DCL), endpoint excursion (EPE), movement velocity (MVL), maximum excursion, (MXE) and reaction time (RT).¹⁸ More information regarding each variable is provided in Table 1. Composite scores, which are an average of each direction, were used for the statistical analyses on all five variables.

Variable	Units	Definition
Directional Control (DCL)	%	Amount of movement in the intended direction minus the amount of off-axis movement
Endpoint Excursion (EPE)	%	Distance travelled by the centre of gravity on the primary attempt to reach the target
Movement Velocity (MVL)	deg/sec	Average speed of the centre of gravity shift toward the target
Maximum Excursion (MXE)	%	Furthest distance travelled by the centre of gravity in a given trial
Reaction Time (RT)	sec	Time from the cue to the time the centre of pressure sway exceeds the random range indicating volitional movement has begun

Table 1 Limits of Stability Variables

One-Leg Stance Test

For the OLST, participants stood on a balance plate with feet about hip width apart, hands on the iliac crest, head erect, and facing forward towards a computer screen that was at eye level (NeuroCom Balance Manager SMART EquiTest System; Natus Medical Incorporated). The safety harness remained on for testing. Individuals were instructed to balance on the designated leg under four, eyes-open conditions: left leg only, left leg only with dual task, right leg only, right leg only with dual task. Each condition consisted of three, ten-second trials. Each trial began with the participants standing on both legs, and the individual lifting the non-testing leg as soon as they heard an auditory cue. The participants returned to both legs after the ten second trial was complete. During the dual task condition, individuals were instructed to count backwards by threes as soon as they lifted their leg and continue counting until the end of the trial. Individuals were provided the same counting instructions as described earlier. As an added safety measure, an investigator always stood behind the participant in the event of instability or a fall.



One leg stance test performance was measured by the variable centre of gravity sway velocity, which is the ratio of the distance travelled by the centre of gravity to the time of the trial.¹⁹ The average of the three trials was used for statistical analyses.

Post Survey

After completing the one-week follow-up assessment, participants completed a sevenquestion survey assessing their experience. Questions assessed the participants' evaluation of the difficulty of the tests, if they knew their randomized group, and their overall experience.

Figure 2: Post Survey Questions

Completion Survey

1.	Did you find it difficult to lean in any direction?	Yes 🗆	No 🗆
2.	If so, which direction?		
3.	Did you find it difficult to stand on one leg?	Yes 🛛	No 🗆
4.	If so, which leg?		
5.	Did you think you were in the movement only or Chiropractic thrust Adjustment group?	Movement	Thrust 🛛
6.	Did you find this study to be time consuming?	Yes 🛛	No 🗆
7.	Would you be willing to participate in a study such as this at the Center for Chiropractic Research again?	Yes 🛛	No 🗆

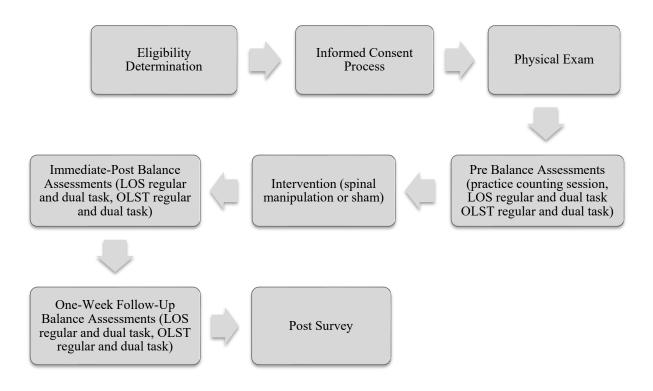
Study Protocol Flow

Balance assessments were performed at baseline, immediately after the allocated intervention, and one-week later. The one-week follow-up session served as a way to evaluate participant retention and to evaluate any short-term changes in balance performance. Responses to the post survey were collected at the one-week time point after all assessments were complete. Figure 3 provides information on the progress of the participants throughout the study.



Impact of a single cervical spinal manipulation on a healthy population as assessed by static and dynamic balance and dual task performance

Figure 3 Study Flow Chart



Data management and analysis

To maintain confidentiality, all participants were assigned a study identification number. Signed informed consent documents were stored in a secure cabinet only accessible by HIPAA trained investigators. Computerized data was saved in a password protected database.

Because this is a feasibility study, descriptive statistics were used to provide preliminary information on the relationship between group and balance performance; due to notable outliers determined from box and whisker plots, median values are reported for all balance assessment metrics.

RESULTS

Participant characteristics, unanticipated events, and retention

Participants were between the ages of 21 and 47 (mean=28.1 years; SD=6.14), had an average height of 171.78 centimeters, and included 16 females and 11 males. Three individuals in the intervention group received adjustments beyond the cervical region; therefore, their data was not included in the final analysis. One additional individual in the



intervention group did not complete the unilateral stance on the right leg at the one-week follow-up due to hurting the right foot after placing the foot down after the left leg stance test; this individual completed all other balance tests and the post survey. Another individual in the intervention group reported a migraine the day after the adjustment was performed. Both individuals recovered swiftly.

Limits of stability

Table 2 shows the median values and the inter quartile ranges for the limits of stability test for both groups. Both groups demonstrated various changes in each of the measured variables between the three time points. From pre to post, the intervention group showed improvements in DCL (+1.3%), EPE (+5.6%), MVL (+0.4deg/sec), MXE (+2.3%), and RT (-0.2sec) in the dual task condition. The sham group showed improvements in DCL (+0.3%) and MXE (+2.5%) in the regular condition and an improvement in DCL (+0.9%) in the dual task condition. From pre to one-week, the intervention group had an improvement in MVL (+0.4deg/sec) in the regular condition and an improvement in EPE (+3.9%) in the dual task condition. The sham group showed improvements in DCL (+0.1%) and MXE (+0.8%) in the regular condition and improvements in DCL (+0.5%), MVL (+0.1deg/sec), and MXE (+2.5%), and RT (-0.1sec) in the dual task condition.

		Pre	Post	One Week
DCL (%)	A-Reg	85.9 (83.6-88.5)	85.9 (83.5-89.9)	85.0 (81.8-89.2)
	A-BB3	83.6 (80.4-87.1)	84.8 (80.6-88.6)	82.6 (79.3-88.1)
	S-Reg	86.3 (85.0-88.8)	86.5 (83.3-89.7)	86.4 (83.6-87.7)
	S-BB3	84.5 (83.3-88.3)	85.4 (80.9-88.4)	85.0 (81.6-87.1)
EPE (%)	A-Reg	65.2 (57.3-76.9)	64.9 (49.5-71.9)	63.4 (49.9-75.8)
	A-BB3	60.7 (49.8-71.3)	66.3 (45.5-77.0)	64.6 (47.6-80.8)
	S-Reg	69.8 (59.7-75.5)	69.8 (66.7-75.6)	69.1 (55.6-76.1)
	S-BB3	70.1 (56.1-77.6)	64.5 (61.4-72.1)	67.9 (59.3-73.5)
MVL (deg/sec)	A-Reg A-BB3 S-Reg S-BB3	2.5 (1.9-3.1) 2.0 (1.8-2.9) 3.0 (2.4-3.5) 2.8 (2.1-3.4)	2.0 (1.8-3.1) 2.4 (1.7-2.8) 2.8 (2.5-3.3) 2.8 (1.7-3.1)	2.8 (2.1-3.8) 1.9 (1.6-2.8) 2.5 (1.9-3.5) 2.9 (2.3-3.9)
MXE (%)	A-Reg	77.1 (71.2-80.4)	73.8 (65.7-81.9)	75.5 (59.8-85.1)
	A-BB3	75.3 (67.6-82.2)	77.6 (67.4-83.0)	75.1 (62.9-86.8)
	S-Reg	74.6 (69.7-87.4)	77.1 (73.3-81.6)	75.4 (64.3-84.6)
	S-BB3	75.8 (63.2-83.6)	75.5 (71.8-83.6)	78.3 (68.4-84.1)
RT (sec)	A-Reg	1.0 (0.8-1.2)	1.1 (1.0-1.4)	1.0 (0.8-1.1)
	A-BB3	1.2 (1.0-1.3)	0.9 (0.8-1.1)	1.3 (1.1-1.5)
	S-Reg	0.8 (0.8-1.1)	0.8 (0.7-1.0)	1.1 (0.9-1.2)
	S-BB3	1.0 (0.8-1.0)	1.0 (0.8-1.3)	0.9 (0.8-1.1)

Table 2 Limits of Stability Median (IQR) Values



One leg stance test

Table 3 shows the median values and the inter quartile range for the one leg stance test for both groups. For both the left and right leg, the sham group showed improvements in the center of gravity sway velocity from pre to post in the regular condition (-0.1deg/sec). The intervention group showed a decrement in the center of gravity sway velocity for the left leg from pre to post in the regular condition (+0.1deg/sec) as well as from pre to post and pre to week for the right leg in the dual task condition (+0.1deg/sec).

Table 3 One Leg Stance Test Median (IQR) Values

		Pre	Post	One-Week
	A-Reg	0.6 (0.6-0.7)	0.7 (0.5-0.7)	0.6 (0.5-0.6)
Left Leg	A-BB3	0.6 (0.6-0.9)	0.6 (0.5-0.7)	0.6 (0.6-0.7)
(deg/sec)	S-Reg	0.6 (0.5-0.7)	0.5 (0.5-0.7)	0.6 (0.5-0.7)
	S-BB3	0.6 (0.5-0.8)	0.6 (0.5-0.7)	0.6 (0.5-0.8)
	A-Reg	0.6 (0.6-0.8)	0.6 (0.5-0.7)	0.6 (0.6-0.7)
Right Leg	A-BB3	0.6 (0.6-0.8)	0.7 (0.5-0.7)	0.7 (0.6-0.8)
(deg/sec)	S-Reg	0.6 (0.5-0.7)	0.5 (0.5-0.7)	0.6 (0.5-0.7)
	S-BB3	0.6 (0.5-0.8)	0.6 (0.5-0.7)	0.6 (0.5-0.6)

Post Survey

Table 4 shows the responses from the post survey completed by participants at the conclusion of the one-week assessment. Thirty-three percent of participants found it difficult to lean in any direction on the limits of stability test, with the most common directions being backward, left back, and left. Twenty-three percent of participants found it difficult to stand on one leg, with the right leg being the most common. Only one individual did not correctly identify which randomized group they were part of. Ninety-seven percent of participants did not find the study time-consuming and would participate in a future study.



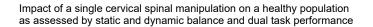
Did you find it difficult to lean in any direction?		Did you find it difficult to stand on one leg?		
Yes	N=10	Yes	N=7	
No	N=20	No	N=23	
If so, wh	ich direction?	If so, which leg?		
В	N=8	Right	N=5	
LB	N=5	Left	N=4	
L RB F R	N=5 N=4 N=2 N=2	Did you think you were in only or chiropractic thr group?		
RF	N=1	Correctly identified their group allocation Incorrectly identified their	N=29 N=1	
LF	N=1	group allocation		
Did you t	find this study to be time co	onsuming?		
	Yes	N=1		
	No	N=29		
Would you be willing to participate in a study, such as this, at the (blinded) again?				
	Yes	N=29		
	No	N=1		

Table 4 Responses of the Post Survey

DISCUSSION

Considering this was a feasibility study, a small sample size was used and therefore this discussion will focus on the pre-defined aims regarding the protocol. The first aim was to assess the acceptability and safety of the study protocols. The post survey showed that a majority of participants indicated that it was not difficult to lean in any direction on the LOS test and that it was not difficult to stand on one leg during the OLST. Ninety-seven percent of participants reported that they did not find the study time-consuming and would participate in a future study. Although safety protocols were in place, including the use of the safety harness as well as the investigator always being present behind the participant, one injury occurred during testing in which a participant placed their foot down in a painful way following a OLST trial. This resulted in a loss of data for the right foot OLST at the one-week follow-up. The participant did make a swift recovery.

To test participant retention for future studies, a one-week follow-up was implemented. The study had 100% success in all enrolled individuals returning for the follow-up data





collection session. Considering this study used a convenience sample of individuals recruited by word of mouth from the investigators and electronic newsletters on campus, there is some bias as to who would agree to participate which could result in successful retention. Future studies should include more diverse recruitment strategies to reach a more diverse population in the community. These strategies could include more traditional methods, such as recruitment through local clinics or advertisements, or virtual strategies, such as online platforms or social media.²⁰

The third specific aim was to assess the blinding protocols for the group allocation. It was impossible to blind clinicians to the group allocation due to the nature of the intervention compared to the sham; however, the participants were blinded. Considering the limited availability of individuals to assist with the study, two investigators performed all data collection and were not blinded to group allocation. Future studies should employ technicians who can be blinded. The post survey provided an opportunity to test the success of the participant blinding. The results of that question showed that 97% of individuals correctly identified which group they were allocated too. This leads to the fourth specific aim of this study, which was to assess the use of a previously documented movement protocol as a sham. Investigators determined that the movement protocol documented by Haavik-Taylor and Murphy in 2007 could be considered a non-force sham protocol because it mimicked true manipulation but was deemed by the investigators to be inactive.¹⁷ To judge the success of a sham protocol, it has been postulated that a sham procedure is successful if it provides no significant changes in clinical status and the individual perceives it to be a real manipulation.²¹ Unfortunately, the post survey responses along with the improvements noted in the balance assessments in the sham group indicate that this was not a successful sham procedure. More research is needed to determine an appropriate sham for a high velocity, low amplitude chiropractic spinal manipulation.

The fifth aim for the study was to provide a preliminary evaluation of participant responsiveness to the balance assessments following chiropractic spinal manipulation. This aim can be addressed by determining whether the intervention shows promise of being successful with this proposed healthy-subjects population.²² No improvements in the median values for the center of gravity sway velocity of the OLST were noted in the intervention group for either time comparison. For the LOS variables of the intervention group, this study found improvements in DCL, EPE, MVL, MXE, and RT in the dual task condition from pre to post, an improvement in MVL in the regular condition from pre to week. Comparison of these changes to a calculated minimal detectable change will help determine if the noted changes are greater than the test variability and therefore considered relevant.²³ Lininger and colleagues (2018) provided standard error of measure data for healthy young adults, which can be used to calculate the MDC by using the following formula where MDC is the minimal detectable change and SEM is the standard error of measure.^{18,23}



MDC95% = 1.96 × √2 SEM

Using this formula, the improvements in EPE (change: 5.6; MDC: 4.5), MXE (change: 2.3; MDC: 1.8), and RT (change: 0.2; MDC: 0.1) noted in the dual task condition from pre to post provides some promise of the intervention being successful; however, further investigation with larger sample sizes is needed to truly determine the impact of chiropractic spinal manipulation on dynamic balance.

CONCLUSION

Evaluation of the acceptability and safety of study protocols, participant retention, and preliminary evaluation of participant responsiveness to the LOS and OLST testing during a dual task condition following a chiropractic spinal manipulation indicate that the protocol chosen appears to be feasible. The sham procedure was not feasible. More research is needed to determine an appropriate sham for a high velocity, low amplitude chiropractic spinal manipulation.



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