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RESEARCH ARTICLE

The effect of chiropractic spinal manipulation on the H-reflex and muscle strength in children with cerebral palsy: A feasibility study

[version 1; peer review: 1 approved with reservations]

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Abstract

Background

Children with cerebral palsy (CP) have deficits in various aspects of motor control, including motor neuron excitability, which can affect muscle strength, gait, and ability to perform activities of daily living. Previous research on chiropractic spinal manipulation in healthy adults, athletes, and a brain-injured population has indicated improvements in motor neuron excitability, muscle strength, and various aspects of motor control. Thus, chiropractic spinal manipulation may improve motor control in children with CP.

Methods

Children with spastic diplegic CP, aged 8-13 years, were recruited for a randomized, controlled feasibility study. Feasibility was assessed in terms of recruitment strategy and rate, data collection procedures, equipment, intervention, and compliance.

Results

Three children completed the data collection comprising pre- and post-measurements of the H reflex, V-wave, and muscle strength. The recruitment strategy and rate were not feasible. The data collection

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procedures were appropriate and complied with, except for the V-wave measurements. The H-reflex threshold decreased and s50 and slope increased in the participants who received chiropractic spinal manipulation; the opposite was seen in the control group. The changes in MVC force were inconsistent between subjects.

Conclusion

This study answered some important feasibility questions regarding conducting a large-scale randomized controlled study with the same design. Some aspects proved feasible, such as H-reflex recordings, and some aspects, such as recruitment methods and V-wave recordings, need to be altered for future research in this area.

Keywords
chiropractic, cerebral palsy, spinal manipulation, muscle strength, motor neuron excitability, H reflex, recruitment methods, V wave

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1. Introduction

Cerebral palsy (CP) is an umbrella term used to describe a group of non-progressive motor disorders resulting from injury to the developing brain during pregnancy, birth, or in infants up to the age of 2 years.[1] Its prevalence is estimated at 2.1 per 1000 live births and is the most common cause of physical disability in children, which has a significant impact on the function and health-related quality of life of those affected.[2]

Injury to the brain that occurs in those with CP causes problems with motor control, and the child may develop deficits in movement, posture, balance, coordination, and muscle strength, all of which hinder their ability to perform activities of daily living.[3–5] Alongside this, there are considerable social, emotional, and economic costs to the individual and their families as they manage the lifelong consequences of the disorder.

Muscle weakness is one of the most widely recognized clinical manifestations of CP and a significant contributor to deficits in gait and function. Previous studies have noted that children with CP have significantly lower muscle strength than typically developing children of a similar age.[1,6–8] In a review of 51 articles concerning CP and muscle strength, all concluded that children with CP are weaker than their typically developed peers.[9] The hip extensors, ankle dorsiflexors, and ankle plantar flexors were found to be the weakest, with some studies reporting strength values of 24%, 46%, and 36%, respectively, in typically developed children, while others reported values as low as 18% in dorsiflexors and 23% in plantar flexors.[6] Ross and Ensberg[10] reported a high correlation between strength and Gross motor function classification system (GMFCS) score (r=.83) and stride length (r=.71) and a moderate correlation with gait speed (r=.61).

Numerous studies have assessed the effectiveness of strength or resistance training in increasing muscle strength in children with CP. Systematic reviews on this subject revealed that the evidence is strong for the efficacy of strength training, with the majority of studies reporting significant increases in strength.[9,11] However, its effect on functional outcomes and gait is not clear. Not all studies reviewed assessed the impact on function and/or gait, but those that did report small effect sizes on activity and function levels and variable results on mobility, with some studies reporting significant improvement[9] and others reporting no improvement.[11] This may be partly due to the variability in the strength training regimes, the samples assessed, and the methods used to assess gait and function. Nevertheless, there are indications that improving muscle strength could help alleviate or reduce some of the impairments seen in CP. Further research is needed to assess the impact of improved muscle strength on functional outcomes.

Current treatment of CP is based on the neuroplasticity of motor learning and the maximization of the uninjured parts of the brain.[12] Neurorehabilitation treatments aim to use the principles of neuroplasticity in that repetitive movements enhance neuronal connections in the brain. Such treatments include the use of specially designed exercise programs, robotic assisted therapies, treadmill exercises, constraint induced therapy, functional electrical muscle stimulation, spinal cord electrical stimulation and loading suits to enhance proprioceptive feedback.[4,13] These therapies have shown benefits in reducing spasticity, increasing muscle strength, and improving postural stability; however, there is limited evidence for improvement in functional outcomes and gait after the use of these therapies.[13] One of the therapies that utilizes Lokomat, which combines the use of a treadmill, lower limb unloading, orthoses, and a feedback module, is one of the few that show improvements in gait and gross motor functional measures.[13] Evidence suggests that it is likely that a combination of therapies has the best results for children.[4,13]

Over the past 20 years, a growing body of research has investigated the neuroplastic and neuromodulatory effects of chiropractic adjustments and spinal manipulation.[14–24] It is hypothesized that articular dysfunction in the spine causes altered afferent input to the brain, which affects how the CNS processes and integrates all subsequent sensory inputs.[18,25] Some studies have shown neural plastic changes such as altered sensorimotor integration and motor control after chiropractic SM.[14,15,18,20,21,24,26,27] Other studies have shown improvements in muscle strength and motor neuron excitability in healthy adults and elite athletes, as well as in an adult brain injured population (a chronic stroke population).[22,28–31]

There is limited research on the effects of spinal manipulation in children with cerebral palsy. One study assessed the effects of spinal manipulation on muscle spasticity and manual dexterity using a randomized controlled trial (RCT) design.[32] They enrolled 78 participants with cerebral palsy (age 7-18 years) and randomized them into two groups: a spinal manipulation intervention group and a control group. The researchers found a statistically significant reduction in wrist spasticity in the group that received spinal manipulation compared to the control group.[32] No significant differences were noted in manual dexterity. This is the only RCT conducted in this field to date.

Muscle weakness is correlated with gait problems and poor gross motor function in children with CP. Improving muscle strength in this population group could potentially be beneficial over time in changing gait and increasing functionality, particularly at a time when their nervous system and muscles are still developing.[9,11,33,34] The changes in motor control, muscle strength, and motor neuron excitability in both healthy and brain-injured adult populations following chiropractic SM and the previously outlined issues with muscle weakness in children with CP provide grounds for investigating the effects of chiropractic SM on muscle strength and motor neuron excitability in children with CP.

Research investigating this has not been conducted before; therefore, a feasibility study was proposed to assess aspects of the study design, recruitment, and outcome measures before a full-scale RCT was conducted. This study aimed to assess the feasibility of conducting a large-scale, randomized, controlled trial to test the hypothesis that chiropractic SM results in improvements in motor neuron excitability and muscle strength in children with CP.

2. Methods

2.1 Study design and recruitment

This study was conducted as a feasibility study utilizing a single-blinded, parallel group, randomized, controlled design. Participants were recruited through the New Zealand Cerebral Palsy Registry (NZCPR). Participants were identified in the NZCPR database that consented to being contacted for research studies. Those identified were further assessed for eligibility for this study. Potential participants were then posted a letter of invitation to participate and a flyer with information about the study. Parents were asked to contact the lead researcher with any questions and/or if they wished to participate in the study. Prior to participation in the study, written informed consent was obtained from the parents of the participants and the participants provided written informed assent. Consent was not obtained from the participants themselves as they were under the age of 16 years, which is the legal age of consent in New Zealand. Written informed assent was obtained from participants instead, as required by the Health and Disability Ethics Committee in New Zealand.

The chiropractor, who was not involved in data collection or analysis, randomized the participants into one of two groups, SM intervention or passive movement control intervention, through a coin toss in a separate room. A more rigorous randomization procedure, such as computer-generated randomization, was not used because of the small sample size, but would be used in a larger scale study to reduce group differences and potential bias.

Following pre-intervention recordings, the chiropractor then took the participant and caregiver to a separate room to perform the spinal examination and provide the SM or control intervention. Participants or caregivers were not informed of the group they were in. Following the intervention, the chiropractor brought the participant and caregiver back to the data collection room for post recordings and then left. Documentation regarding the intervention was maintained by the chiropractor until the data analysis was complete. At no time before this, the researchers involved in data collection and analysis were made aware of the group allocation.

2.2 Participants

Inclusion criteria for this study were children diagnosed with spastic diplegic CP, aged 8-13 years and classified as Level I-II on the Gross Motor Function Classification System (GMFCS). Participants were required to be proficient in English and have been able and willing to sign written informed assent. Exclusion criteria were any known contraindications to chiropractic SM (previous reaction to spinal manipulation, fracture, cancer, recent trauma, ligamentous instability, and known inflammatory or infectious arthritis). Participants who had undergone surgery, inhibiting casts, or botulinum toxin treatment in the last 6 months were also excluded from this study.

2.3 Intervention and control

After the pre-recording session was completed, participants and caregivers were collected by the chiropractor and placed in a separate room. If allocated to the intervention group, participants received chiropractic SM by a registered chiropractor. A full spine check was conducted, and SM was performed on specific segments exhibiting evidence of joint dysfunction, such as restricted intersegmental range of motion, tenderness on palpation, and intervertebral muscle tension. These are all indicators commonly used in chiropractic practice and have been shown to be reliable indicators of spinal dysfunction.[35–38] Chiropractors have specific training in pediatric care, and participants were thoroughly assessed and technique adapted to lower force applications when necessary. All SM's performed, and on which vertebral segments, were recorded by the chiropractor.

If allocated to the control group, the participants received a control intervention that involved non-specific movements of their head, spine, and body, but did not include the thrust that was given with SM. This was done to control for proprioceptive input that could have neurological consequences that occur during the procedure of checking for spinal dysfunction and placing a person into positions for SM. Following the intervention, the participants were returned to the data collection room, and post-recordings were conducted in the same manner as the pre-recordings.

2.3 Procedure

Participants and their caregivers attended one data collection session at the Health and Rehabilitation Research Institute of the Auckland University of Technology (AUT). Prior to the recording of outcome measures, the primary researcher discussed the procedures for the study, answered any questions, and obtained informed consent from the participant and caregiver. Following this, a structured interview was conducted to gather information on patients' age, sex, ethnicity, and health history. Muscle strength, H-reflex, and V-wave recordings were conducted by the primary researcher and a biomedical engineer. To assess compliance and tolerance to the data collection protocol, notes were taken on any observations or comments the participant made about tolerance of the procedures, such as discomfort, boredom, and wanting to stop. At the end of the data collection session, the participants and their families were also asked if they were okay and how they felt about it.

The muscle strength was recorded by measuring the isometric force of the plantar flexors using a custom-made force transducer. The foot of the affected leg was placed in the force transducer and strapped using Velcro fasteners. The distal thigh was also fixed in place using Velcro fasteners to reduce leg movements during plantar flexion. Once the leg was fixed, the knee angle was measured again post intervention/control to maintain the same conditions. The participant was instructed to push down with their foot as hard as possible for 5 s, which was repeated a total of three times. The participants were verbally encouraged during each MVC to aid in the highest possible contraction. The force was recorded with a CED Power 1401 MK 2 Data Acquisition Board at a sample rate of 1 kHz and an isometric strain gauge (Model MLP100 transducer Techniques Tennecula, California, USA). The corresponding computation was performed using Spike software (https://ced.co.uk/products/spkovin). The strongest MVC of the three measurements was used to compute the 10% amount required as a background plantar flexion contraction during the H- and V-wave recordings.

Surface electromyography (sEMG) measures the electrical activity of a muscle by placing electrodes on the skin over the belly of the muscle.[39] The sEMG was used to record the motor response of the soleus muscle for the H, M, and V wave recordings during this experiment. The soleus muscle was identified by asking the patient to stand on the tip of their toes to produce plantar flexion and then palpate the location just lateral to the gastrocnemius muscle. To produce a clear signal and reduce skin impedance, the skin was first prepared by shaving the area, gently abrading the skin with sandpaper, wiping the skin with Nuprep gel, and cleaning the area with alcohol wipes. Subsequently, two bipolar surface electrodes were placed two cm apart along the belly of the soleus muscle, perpendicular to the muscle fibers, to record the innervation zone.[40] A ground electrode was placed on the bony prominence of the medial malleolus. The electrodes were then connected via cables to a custom-built amplifier with a built-in stimulus artifact suppressor and a high-pass filter (20 Hz), and the signals were recorded using the SIGNAL software (https://ced.co.uk/products/sigovin).

The H reflex and Mmax and V waves of the soleus muscle were elicited via electrical stimulation of the tibial nerve. After explaining the procedure to the participant and caregiver, a stimulating electrode (cathode) was placed in the popliteal fossa and the anode electrode was placed just proximal to the patella. This positioning ensures that the H-reflex can be elicited at the lowest possible threshold as the current passes transversely through the tibial nerve. The knee was then bandaged to apply pressure on the cathode for ease of stimulation. Electrical stimulation was delivered by using a Digitimer-isolated stimulator (Digitimer DS7AH, Digitimer Ltd, Hertfordshire, UK). The position of the electrodes was altered accordingly to provide the lowest stimulation intensity while ensuring the activation of the entire soleus muscle.

2.4 Data recording

The M wave recording was elicited by electrical stimulation of the tibial nerve starting at 5mA and was progressively increased in 5mA increments until the M wave appeared in the sEMG. M-max, which represents the recruitment of all motor axons, is reached when the motor response does not increase with further increases in electrical stimulation, and the H reflex response has disappeared. This value was then recorded as M-max, 10% of which was calculated and used in the H-reflex recording.

For the H-reflex recording, the participant was asked to push down their foot gently to maintain a contraction at 10% of M-max (as determined above in section 3.2.4.1). This was displayed on a computer screen directly in front of the patient, as a line for visual feedback. The purpose of this low-level constant contraction is to allow for some stable background electrical activity throughout the stimulation protocol so that any changes in the H-reflex can be determined to be due to other test conditions.[40] The H-reflex is then elicited via electrical stimulation of the tibial nerve. The participants received 48 stimulations at different intensities, and each stimulation was given at 0.5 ms intervals. Equally dividing the M-max into 16 determined the intensity levels, and then three stimulations per level were applied. The levels were randomly stimulated to reduce the predictability of the participants' responses.

The V-wave was then recorded using sEMG and force measurements. Participants were asked to perform three separate MVC's by pushing down their feet as hard as possible while being verbally encouraged by the researcher. During each of these MVC's they were given three electrical stimulations at a supra-maximal intensity (110%) of M-max.

2.5 Data processing

Variations can be seen in the H reflex due to changes in subject position during recording, alterations in electrode positioning or contact, and/or alterations in the muscle itself, which can affect study results if adequate H-reflex curve analysis is not performed.[40,41] Furthermore, thresholds to elicit the H reflex and M wave can differ not only between subjects but also within subjects, even if tested on the same day.[41] In order to account for these changes, to obtain results that reflect genuine H reflex changes from the intervention and to determine the H reflex and V wave at different intensities along the recruitment curve, it is necessary to perform curve fitting and normalization on the raw H reflex data.[41] This was performed using the procedure described by Brinkworth[41] and used in previous H-reflex studies with chiropractic SM as the intervention.[22,28]

First, the peak-to-peak amplitudes of the H, M, and V waves were obtained from the EMG signals. Normalization was then performed to compare the results between subjects, with M-Max recorded in the pre-assessment used as a normalization factor in that particular session. For each participant in both the pre- and post-sessions, M-max was used for the corresponding H-reflex, M-wave, and V-waves to provide H/Mmax and V/Mmax ratios for each participant. Having this normalized to the specific H-reflex or V-wave stimuli, for each subject and each session allows for a more accurate assessment of the changes in the H-reflex and V-wave represent.[22,41] Once normalization was performed, these values were modeled for curve fit analysis with a hyperbolic function for the M wave and a Gaussian equation for the H and V waves.[41]

After curve fitting and normalization were performed, the H-reflex was analyzed for threshold levels by identifying the intensity when the H-reflex curve started to rise. MATLAB code was used as an automatized procedure; however, the time windows for each data set were also manually inspected to ensure the accuracy of this level. The results of each session were then superimposed and post intervention/control results were compared with the intervention/control results. Parameters extracted from the curve-fitted H reflex data were the H reflex threshold, s50, and slope.

After curve fitting and normalization, the V wave was analyzed using peak-to-peak amplitudes, which were then superimposed and averaged to produce a mean value difference between the pre- and post sessions.

To determine the difference in force measurements of maximum voluntary contractions, the EMG signal was manually inspected and analyzed using peak-to-peak amplitude calculations. This was done by placing one cursor at the baseline immediately before the contraction started and placing a second cursor at the end of the contraction immediately before the return to baseline, and then calculating the difference. These values were then compared pre- and post-intervention/control.

3. Results

3.1 Feasibility

3.1.1 Recruitment

The participants in this study were recruited through NZCPR. At the time of this study, NZCPR was newly established, and this was the first study to use it for recruitment. Consequently, it took considerable time to set up the process to recruit through them, from the first contact in May 2016 until the first flyers were sent out in July 2017. In addition, because they were a new organization, they were still in the process of approving the registrations that they had on their system, which meant that only the approved registrations could be contacted for this study.

In total, 50 families that were registered in the Auckland region with a GMFCS of I-II and aged between 8-13 years old were sent the study information over a six-week recruitment period. From this 50, five parents (10%) made contact via email inquiring about participating in the study. Of these, three met the inclusion criteria and were included in the study. The two participants that were not included were excluded because one had athetoid dyskinetic CP and the other was only going to turn eight years old in December, after the study period had finished. This resulted in a recruitment rate of only 6%.

There was a 100% retention rate for every participant who completed the session. The characteristics of the sample are listed in Table 1. Due to the small and unequal sample sizes, the intervention and control groups were inevitably not equally distributed. Interestingly, although this was not an inclusion criterion, all the participants had previous experience with chiropractic SM.

The recruitment period was set at 6 weeks, both for timely purposes of completing the study and to have a set limit in place in order to assess the recruitment rate. With three people successfully recruited into the study over a 6-week period, this gives an average of one participant every two weeks.

For a large scale RCT, an estimated sample size of 128 participants is predicted based on a calculation with a given effect size (d) of 0.5, type 1 error probability (α) of 0.05 and a power of 0.8 (minimally acceptable). Based on this recruitment strategy and a rate of one participant every two weeks, it would take 256 weeks or almost five years to recruit enough people. With a recruitment rate of 6 %, more than 2000 families/potential participants would need to be contacted.

3.1.2 Data collection procedure

All data collection took place at the Health Research and Rehabilitation Institute of the AUT. This was well received by all participants and had ease of access to disability carparks; families were also familiar with the location due to the gait analysis clinic for children being in the same area. All consent and child assent forms were received and reported to the researcher to be understood by the parent and child. Participants were advised that the sessions would take approximately two hours for the pre- and post-combined. This was fairly accurate for sessions between 90 minutes and two hours.

In general, the data collection procedure was well tolerated. Owing to the nature of the measurement protocol using electrical stimulation, participants were advised at the beginning of the session that if they did not want to continue, they could ask us to stop at any time. One participant reported feeling bored, had difficulty concentrating, and sat in a chair for the required amount of time, and the parent had to give her a smartphone to play a game to distract her. This participant did not want to do the final part of the pre-session recording, which was the V-wave recording, so this was omitted from the post-session data collection. This was the only indication of poor compliance with the recording protocol. The other two participants had no issues, fully accepted the protocol, and did not complain.

3.1.3 Equipment

There were some issues with the custom-made force transducers. The one that was initially planned to be used was in use in another study at the time of the first data-collection session and could not be moved. Therefore, the older version that used the same measurement was used for the first participant. The participant reported this as being uncomfortable, which was the same participant who had difficulty accepting the full H, M, and V wave protocols, and it is possible that this was partly due to the discomfort from the force transducer. The second and third participants used the new version, originally planned for use in this study. There have been no reports of discomfort or problems associated with this condition.

All other equipment worked well and had no issues.

3.1.4 Intervention

The chiropractic SM and passive control interventions were well tolerated by all participants. No issues were reported by the chiropractor or participants, and all movements were well tolerated. No serious or minor adverse events were reported due to intervention or passive control. All participants had previously received chiropractic care more than one year prior to this study, which may have alleviated any potential concerns.

3.2 H-reflex, V wave and force

Due to the small sample size of the three participants and group variation, statistical analysis was not performed on the data obtained for the H reflex, V wave, and force. Therefore, no conclusions will be drawn regarding the efficacy of the intervention versus passive control. The following section will present the results and trends identified, with the aim of determining whether changes can be detected using this protocol and intervention in children with CP in future research studies.

3.2.1 H-reflex

Results from the H-reflex recording showed that both participants in the intervention group had a shift in the H-reflex threshold towards the left, or a lowered threshold, post intervention. This contrasts with the control participant, which had a shift in the H-reflex threshold towards the right, or a higher threshold, post-passive control intervention. Results of the s50 parameter showed that participants in the intervention group both had an increase in s50, suggesting a trend towards a greater number of motor neurons being recruited after chiropractic SM intervention at 50% stimulus compared to pre-intervention. Control participants showed a decrease in s50. Changes in slope showed similar trends with a slope gradient

Table 1. **H reflex results.**

Subject No.	Control/ Intervention	H Reflex threshold Pre	H Reflex threshold Post	% change	S50 Pre	S50 Post	Slope Pre	Slope Post
1	Intervention	7	6.574	-6%	12.87	13.29	0.43	0.63
2	Control	5	5.432	6.8%	10.04	9.701	0.81	0.62
3	Intervention	4	2.017	-49.6%	6.97	7.95	0.44	0.57

Table 2. **V wave results.**

Subject No.	Control/Intervention	V/M wave Pre Mean (SD)	V/M wave Post Mean (SD)	% change
2	Control	0.363 (0.057)	0.361 (0.121)	-0.39
3	Intervention	0.555 (0.066)	0.207 (0.375)	-62.7

Table 3. **MVC Force results.**

Subject no.	Control/Intervention	Force (Fraction change from baseline) Pre	Force (Fraction change from baseline) Post	% change
1	Intervention	0.656	0.750	14.3
2	Control	0.690	0.555	-19.5
3	Intervention	0.727	0.371	-48.9

increase after chiropractic SM intervention, suggesting the ability to recruit motor neurons faster. This is in contrast to the passive control intervention, which resulted in a decreased slope gradient. The numerical data for these results are listed in Table 1.

3.2.2 V wave

As mentioned above, the first participant did not wish to continue with the protocol at that time; therefore, the V wave was only recorded in two participants, one control, and one intervention. The participant who received the passive control intervention showed a mean reduction in the V-wave amplitude post intervention of 0.39%, so there was no real change. The participants who received chiropractic SM intervention showed a mean reduction in V-wave amplitude post intervention of 62.6%. The results are presented in Table 2.

3.2.3 Force

Changes in MVC force were variable between participants.

The passive control participants had a 19.5% reduction in MVC force post intervention. In the chiropractic SM intervention group, one participant had a 14.3% increase in MVC force, and the other participant had a 48.9% decrease in MVC force. The results are presented in Table 3.

4. Discussion

This study aimed to answer specific feasibility questions to determine whether a full-scale RCT using the same design would be appropriate. Feasibility was assessed in the following areas: recruitment rate and method, equipment, tolerance, and compliance with the intervention and data collection protocol, and to determine whether it is possible to obtain changes in outcome measures. This feasibility study suggests that a full-scale RCT assessing the effects of chiropractic SM on motor neuron excitability and muscle strength in children with CP using the same recruitment methods would not be feasible because of a low recruitment rate that would make recruitment in a timely manner for a larger-scale RCT difficult. However, the results of other aspects of the study indicate positive feasibility, and thus, with alterations to the recruitment methodology, a full-scale RCT could be conducted.

All recruitment for this study was conducted using NZCPR. The NZCPR is a new organization that was still in its operational stage when this study was conducted; this was not known by the researcher until well into the recruitment setup. Consequently, all recruitment procedures were new and the registry had a limited number of registered and approved families. Contact was made by mailing out study flyers and information sheets to all eligible and registered families, and then parents/caregivers were required to contact the researcher to be involved. This is an example of convenience or availability sampling, and has potential issues.[42] First, any results only represent a small sample population; second, it is possible that there are a large number of children with CP in the Auckland region that were not yet on the registry and so were not made aware of the study, both of which introduce sampling bias.[42] To alleviate this potential bias and increase recruitment numbers, other sources of potential participants could be used, such as recruiting through CP associations or schools that have specialty programs for CP or high numbers of students with CP. These are potential methods for future research.

It is also possible that the age range was too small and could have affected the recruitment rate. All participants were aged 12 years; the higher limit of the range was 13, and perhaps having a higher limit may improve recruitment. One parent contacted the researcher about participating, but their child was only turning 8 in December, two months after completion, so perhaps also having a lower limit may have been beneficial. Previous studies assessing the H reflex in children with CP have used age ranges of 5-15 years,[43] 5-12 years[44] and 4-6 years.[45] However, as only children aged 12 years were assessed for tolerance and compliance with the data collection protocol and intervention, decreasing the age limit is not recommended, as it is not tested in the younger age group. The possible amended age range could be 8-14 years.

A GMFCS of I-II was set as an inclusion criterion, and participants were only contacted for participation that met this criterion for the NZCPR. This was chosen because GMFCS levels III-V have significantly more mobility impairments and it was thought, as others have suggested, that this would introduce too much variability into the sample set.[46] However, it was noted by the NZCPR that there was a low number of children meeting this criterion in the lower socioeconomic regions of Auckland, which had predominately GMFCS levels of III-IV, which may have affected adequate population representation and recruitment rate.

Based on the calculations, a sample size of 128 participants (64 in each group) was estimated for a large-scale study. Based on the recruitment rate found in this feasibility study, this would mean the need to contact more than 2000 families. Exact epidemiological data on the number of children with CP living in Auckland are not available; however, estimates can be made based on population statistics and CP birth rates. In the greater Auckland region (including Counties Manukau and Waitemata), there are an estimated 440,000 people living under the age of 19 with diagnosed CP.[47] Based on the birth rate for CP being 2.5 in 1000 live births, this gives an estimated 1100 people living with CP in the greater Auckland region under the age of 19 years. As this does not consider the age range, GMFCS, and other inclusion/exclusion criteria for this study, it may not be possible to contact enough families based on this recruitment strategy.

As mentioned previously, the results of this study are not intended to be used to make any claims regarding intervention effects. However, it is noted that both participants in the intervention group demonstrated changes in the H-reflex recordings consistent with those observed in previous studies assessing the effects of chiropractic SM on motor neuron excitability.[22,28,29] Interestingly, the results of the V wave are not consistent with previous studies that have found an increase in the V wave and force post-chiropractic SM.[22,28,29] The V-wave represents volitional drive, which is the amount of voluntary drive during muscle contraction.[48] The V-wave amplitude depends on the density of action potentials sent down from the supraspinal centers, which block the antidromic action potentials caused by supramaximal stimulation of the tibial nerve. Thus, if maximal effort is not made during the data collection of the V-waves, their amplitude will be smaller, and the maximum force will be smaller. Therefore, in light of the changes in the H-reflex that are consistent with increased corticospinal excitability after chiropractic SM intervention, and considering that the H-reflex recording protocol did not require any voluntary effort on the child's behalf, the V-wave and strength results of the one-child post-chiropractic SM showing a 62% decrease in the V-wave and 48.9% decrease in MVC force, is likely due to the child simply not trying to maximally contract their muscle after the chiropractic SM intervention. The V-wave measure and the maximum force output rely on the child trying to contract their muscle as much as they can, and with an almost 50% decrease in force produced after the chiropractic SM intervention, it is unlikely that this child made a maximum effort, especially considering that their H-reflex results indicate an increased corticospinal excitability with a lower H-reflex threshold, increased s50, and increased H-reflex slope. The idea that this child most likely did not try during the V wave and strength data collection post chiropractic SM is also further supported by the fact that one of the other participants would not do the V wave part of the protocol due to fatigue and discomfort. This suggests that if further studies are to be conducted on this population group, the V-wave part of the protocol may need to be omitted or performed earlier in the post-intervention data-recording session.

A lower H-reflex threshold, as has been seen previously in post-chiropractic SM[22] would suggest that spinal manipulation lowers the recruitment threshold of motoneurons to Ia afferent input. In other words, the low threshold motoneurons have become more excitable, or the synapses of the Ia primary afferents have become more efficient, since a lower stimulus intensity can now recruit the same motoneurons compared to baseline recordings. The increase in the s50 parameter suggests that a greater number of motor neurons are recruited after chiropractic SM intervention at 50% stimulus compared with pre-intervention.[40] A steeper H-reflex slope post-chiropractic SM suggests that motor neurons can be recruited at a faster rate.[40] Thus, these three measures that did not require voluntary participation or maximum effort suggest that chiropractic SM intervention resulted in increased corticospinal excitability. These findings could have important implications, as it is thought that those with CP have problems activating available motor units and increasing motor unit firing rates.[7] Again, it is important to note that this study was not designed to test efficacy, nor did we have sufficient subjects to make any such claims. Larger-scale studies are needed to further investigate this.

The feasibility of the data collection protocol is questionable. The acceptability of the protocol was not measured formally; for example, with a post-study questionnaire, tolerance and compliance were assessed as an informal discussion with the participants and parents/caregivers and through observations of the researchers. Consequently, tolerance and compliance of the protocol needs to be viewed with the potential for bias from the researchers in mind, and results interpreted with caution. Of note, one participant was unable to complete the full protocol and did not want to do the V-wave part, which was at the end of each data recording session. This child reported feeling tired and did not want to stay sitting or strapped into the force transducer any longer. This participant had apparent attention deficits and needed to play games on the phone to keep her distracted. There were no exclusion criteria set for comorbid conditions, such as attention-deficit-hyperactivity disorder or autism spectrum disorders, which could potentially be added in future studies, although this would further reduce the potential sample population. Environmental distractors and changes during H-reflex recordings are thought to have an impact on the H-reflex results, so these need to be minimized in future studies.[41]

No adverse events due to the intervention were reported by the participants or their families. The chiropractor informed the researcher that all the intervention procedures were well tolerated. Again, this was not formally assessed and poses the potential for bias from the chiropractor.

This study was conducted using a single-blind approach, in which the researchers were blinded to the group allocation during data collection and analysis. The chiropractor could not be blinded because they had to provide the intervention. Participants were also not told which group they were in, and the control involved the same physical examination, interaction, movement, time, and setup as the SM intervention (but no thrust). This helps to reduce some of the bias that can occur from doctor-patient interaction, proprioceptive input from cutaneous receptors, vestibular input, and mechanoreceptors, and time between pre- and post-data collection sessions, which are arguable issues with manual therapy studies.[49] However, it must be noted that in this study, all three participants had chiropractic SM before; thus, participants may have been able to guess which group they were in. However, this was not a variable assessed in the present study.

No study has assessed changes in muscle strength and motor neuron excitability in children with CP following chiropractic SM; therefore, the role of prior chiropractic care is poorly understood. It is possible that previous chiropractic care could have altered the baseline recordings; however, as none of the participants were new to chiropractic care, this is difficult to assess. However, for all the participants, it had been a minimum of one year since they last had chiropractic SM, so it is unlikely that any effects significantly altered baseline measurements.

This study has provided valuable insight and knowledge on issues pertaining to conducting research in a population group of children with CP and a chiropractic intervention. Learning from this study can help guide future research, not only using these specific outcome measures but also on recruitment ability for any study involving children with CP. It is evident that there is a strong basis for further assessment of the effects of chiropractic SM on children with CP. Future trials may consider including more ‘low-effort’ functional outcomes, such as gait, quality of life and ability to perform activities of daily living. Recommendations for any future research include recruiting from more sources, such as CP associations or schools, using a multi-tiered recruitment strategy with follow-up phone calls and emails, changing inclusion criteria by extending the age range to 8-14 years, using only the new model force transducer for data collection, and omitting V wave recordings or conducting them earlier in the protocol.

Limitations

This study was designed to answer specific feasibility questions, which it has done so adequately. The small sample size (n=3), change in equipment between participants, sampling bias, and uneven sample characteristics are factors that limit any further interpretation of results, efficacy of intervention, and generalizability.

There was also no formal assessment of tolerance of the data collection protocol or intervention, such as a post-study questionnaire assessing acceptability. This is a limitation of this feasibility study as it introduces bias from the researchers in their observations and questioning of the participants and from the chiropractor in assessing the tolerance of the intervention. The researcher also provided consent and asked if the participant and caregiver understood the consent and assent forms. This could have influenced the responses and introduced bias.

Another limitation of this study is that all participants had received chiropractic SM before, which means that there is a chance that they were able to guess which intervention they received, and conclusions cannot be made about the tolerance of chiropractic SM intervention in those who had not had SM before.

5. Conclusions

In conclusion, the results of this study provide valuable knowledge on the feasibility of a protocol to measure changes in H, V, and MVC forces in children with CP following chiropractic SM intervention. This is the first study of its kind to address gaps in the current literature on the feasibility of assessing changes in muscle strength and motor neuron excitability in children with CP following chiropractic SM. Much has been learned about adequate recruitment methods, changes that need to be made to the protocol, and tolerance of chiropractic SM as an intervention. The idea to undertake research in this population group was first to investigate a treatment modality, chiropractic, which is noninvasive and has a growing body of evidence to suggest improvements in neurological function, and whether this would allow children with CP to have an improved quality of life and function.

This feasibility study has shown that modifications to the recruitment method would have to be performed to run a full-scale RCT in this population in the future. Such a full-scale RCT appears to be feasible and should adhere to the recommendations of this thesis, such as modifications in recruitment methods, widening the age range, using only the best equipment, and recording V waves earlier in the collection protocol.

Author contributions

Conceptualization, J.D., D.T., I.K.N., and H.H.; methodology, J.D., D.T., H.H., I.K.N., and R.W.N.; software, I.K.N. and R.W.N.; validation, J. D., D. T., and H.H.; formal analysis, I.K.N and R.W.N.; resources, D.T. and H.H.; data curation, J.D., R.W.N.; writing—original draft preparation, J.D.; writing—review and editing, J.D., D.T.,H.H., I.K.N.; visualization, J.D.; supervision, D.T. and H.H.; project administration, J.D.; funding acquisition, J.D., and H.H. All authors have read and agreed to the published version of the manuscript.

Institutional review board statement

The study was conducted in accordance with the guidelines of the Declaration of Helsinki and approved by the Health and Disability Ethics Committee of New Zealand (16/NTA/158, 16/11/2016). The date of ethical approval is 16th November 2016.

Informed consent statement

Informed consent was obtained from all the subjects involved in the study. Prior to participation in the study, written informed consent was obtained from the parents of the participants and the participants provided written informed assent. Consent was not obtained from the participants themselves as they were under the age of 16 years, which is the legal age of consent in New Zealand. Written informed assent was obtained from participants instead as required by the Health and Disability Ethics Committee in New Zealand.

Data availability statement

The data are not publicly available because of ethics committee restrictions on data related to vulnerable populations. Readers and reviewers can request to view the data by emailing the corresponding author jenna.duehr@nzchiro.co.nz. The data will be released after approval from the Health and Disability Ethics Committee of New Zealand.

Software availability statement

The tasks mentioned in the manuscript, such as data analysis and processing, can be performed using custom-written scripts in open-source languages like Python, R, or Octave. These provide a flexible and open-access alternative to proprietary software. We have ensured that any required software can be replicated with freely available tools, and no proprietary software is essential for the project's execution.

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This article explores the feasibility of studying the effects of chiropractic spinal manipulation (SM) on CP-related motor neuron excitability and muscle strength. While it provides valuable insights into logistical challenges and methodological considerations, its small sample size, limited data accessibility due to ethical concerns have reduced its interpretation and generalizability.

Below are the serial-wise answers of questions being asked in the report.
2. The study employs a randomized controlled design, which is appropriate for a feasibility study. However, the small sample size (n=3) limits the strengths of the findings and raises concerns about generalizability.
3. The rationale for using specific parameters (e.g., s50, slope) is not fully explained for this population, leaving room for interpretation errors in replication attempts.
4. Due to the very small sample size, statistical analysis was not performed, and thus, there are no interpretations of statistical significance. While this is acceptable in such a small scale feasibility study, it limits the depth of interpretation and validation of trends observed in the results.
5. The data are not publicly available due to ethical restrictions related to vulnerable populations. However, the authors indicate that data can be requested under certain conditions.
6. The conclusions regarding feasibility are supported by the results, particularly concerning recruitment challenges and data collection procedures. However, claims about the effects of chiropractic spinal manipulation on muscle strength and motor neuron excitability are not sufficiently substantiated due to the small sample size and lack of statistical analysis.

Additionally, there are minor grammatical issues which have been advised corrections via reviewing suggestions, comments have been embedded within the manuscript so that author can answer and adjust those changes within the manuscript. Few of those suggestions are reproduced here for ease of reference.
a. Table of demographic and baseline characteristics of the study population is missing. This table

can be added in the manuscript before Table-1.
b. It is better to use the key words in alphabetic order, so alphabetize these words.
c. In some paragraphs, author has used abbreviation for spinal manipulation as SM, while in others, this abbreviation was not used. Therefore, it is better to have uniform approach of using abbreviation of any word in whole of the manuscript. Principle is that when any word comes first time, write full word along its abbreviation in the bracket. Later only abbreviation can be used.
d. Instead of using "non-specific movements of their head, spine, and body", use proper and specific term as passive range of motion.
e. Author has mentioned contact with families in May 2016 and sending flyer in 2017, but when actually this study was conducted. This is missing. Actual dates when the intervention applied and data collected should be mentioned.
f. Author stated that for a large scale RCT with sample size of 128, it may take 256 weeks and 2000 families to be contacted in future which seems overestimation due to a specific time and location situation. Participation depends upon many known and un-known factors. Even in one geographical location, responses of same participants may differ at two different timepoints. Moreover, as the sample size is to small, so predication based on it, does not seem justified. Author should be cautious in such interpretations as it may promote de-motivation among future researchers.
g. Author reported about a participant which did not complete the assigned task that perhaps that child had apparent attention deficiency issue. But this attention deficiency might be temporary response in some un-wanted scenario. Have the author checked with medical record that whether the child was a diagnosed case of such disorder. If this was just clinical observation, then such claim is not justified. Many children want to move and play instead of being tied to one place. This is normal and natural behavior. Author may amend the sentence.

Additional comments mentioned in this attached file link:
https://f1000research.s3.amazonaws.com/linked/691601.ID_155618-Reviewer_comment_file-FRES.docx

Is the work clearly and accurately presented and does it cite the current literature?
Yes

Is the study design appropriate and is the work technically sound?
Partly

Are sufficient details of methods and analysis provided to allow replication by others?
Partly

If applicable, is the statistical analysis and its interpretation appropriate?
Not applicable

Are all the source data underlying the results available to ensure full reproducibility?
Partly

Are the conclusions drawn adequately supported by the results?
Partly

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: I have PhD Rehabilitation sciences at my credit. Moreover, I have more than 34 years of academic and clinical experience in the management of children with Cerebral Palsy.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.