Chiropractic Intervention and the Control of Eye Movement in Children with Attention Deficit Hyperactivity Disorder: A Pilot Study.

Alice Cade
9615405

Project Supervisors: Dr Kelly Jones,
Dr Kelly Holt & Dr Heidi Haavik.

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Abstract

Background: Attention Deficit Hyperactivity Disorder (ADHD) is a multifaceted brain-based disorder that is often associated with adverse changes in the capacity to control eye movements when tracking visual stimuli, otherwise referred to as oculomotor function. Sensorimotor integration, defined as the capability of the central nervous system to integrate different sources of stimuli in parallel and to transform such inputs into appropriate motor actions, is essential for proper oculomotor function. Previous research has shown chiropractic care alters sensorimotor integration in brain areas also thought to be responsible for some of the cognitive and oculomotor deficits exhibited by those with ADHD.

Objectives: This study tested the implementation of all study processes. Secondary aims were to examine the preliminary efficacy of a chiropractic intervention, aimed at improving spinal function, on oculomotor outcomes in children with ADHD.

Methods: Thirty children between 8-15 years were recruited for a randomised controlled crossover pilot study to test all study processes, including recruitment, data collection, and general study management. The study also investigated chiropractic intervention versus an active control intervention on measures of oculomotor outcomes. Oculomotor function was tested before and after each intervention using a computerised eye tracker that measured target acquisition, reading speed, fixation time, and saccade length.

Results: The study proved successful in its procedural testing; participant recruitment was completed in eleven weeks, with 100% retention and zero drop-outs, the outcomes measured were a reliable indicator of oculomotor function, and not susceptible to participant's effort, researcher influence or parental reporting bias. Additionally, 85-100% of participants and guardians agreed or strongly agreed with statements evaluating the study, an overwhelmingly positive response. However, 40% of participants were unable

to complete some part of the pre or post intervention outcome measures due to equipment calibration issues. Future research or clinical trials are recommended, with some modification of the study's processes (for example improved eye tracking equipment and study settings).

Secondary findings revealed a significant reduction ($p = .034$) was observed in the total reading time post chiropractic intervention (mean reduction: 646.87ms) compared to post control intervention (mean reduction: 108.35ms). No significant group differences pre or post chiropractic or control intervention in target acquisition time or number of distractions off-target ($p > .05$).

Conclusions: This study is a successful pilot for further research in the area of chiropractic and oculomotor outcomes, proving feasible in terms of recruitment, data collection, outcome measurements used, and ease of testing procedures**.** Additionally, this study's secondary findings open up the possibility that chiropractic care may have a role in improving reading ability and oculomotor function.

Keywords: ADHD, chiropractic, oculomotor, eye tracking, child outcomes, reading, saccades, target acquisition, fixations.

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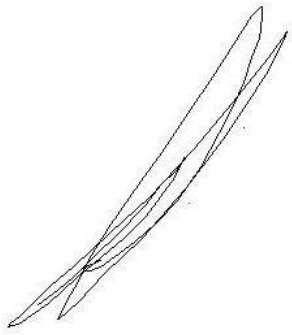
Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signed:



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Ethics Approval

Ethics approval for this study was gained from the Health and Disability Ethics Committee (HDEC 16/NTA/56) and the Auckland University of Technology Ethics Committee (AUTEC 16/311). An amendment to the original ethics approval was made to allow data collection in sites other than the New Zealand College of Chiropractic laboratory (HDEC 16/NTA/56/AM01).

Chapter 1: Introduction

Attention deficit/hyperactivity disorder (ADHD) is a neurodevelopmental disorder associated with significant alterations in brain development and function (Dunn & Kronenberger, 2005). Approximately 75,000 New Zealand (NZ) children suffer from ADHD (Thomas, Sanders, Doust, Beller, & Glasziou, 2015) and rates are increasing (Willcutt, 2012). This increase is possibly due to improved detection or increasing child poverty rates (Akinbami, Liu, Pastor, & Reuben, 2011). Parental reports show a strong negative impact on a child's daily life, school and social life (Caci et al., 2014).

Many children with ADHD struggle with school work (Orfield, Basa, & Yun, 2001) and have lower educational achievement (Harpin, 2005). Poor academic ability common amongst children with ADHD may stem from difficulties with reading (Munoz, Armstrong, Hampton, & Moore, 2003; Orfield et al., 2001; Willcutt et al., 2010). It was previously thought that children overcome ADHD as they mature, however recent studies suggest that 30–60% of affected individuals continue to show significant symptoms of the disorder in adulthood. Adults with ADHD report a significant decrease in their perceived quality of life from the lifetime impact of the disorder (Caci et al., 2015). These poor outcomes highlight the need to identify effective treatments to address the underlying mechanisms contributing to the adverse consequences of ADHD in childhood.

Children with ADHD have morphologically and functionally different brains than children without ADHD, exhibiting difficulty with top-down neural control of eye movements (Dunn & Kronenberger, 2005). Disordered eye movements during reading have been identified as one of the primary culprits responsible for the reading difficulties sometimes observed in children with ADHD (Damyanovich, Baziyan, Sagalov, & Kumskova, 2013). Reading difficulties are identified as having literacy levels consistently below that of age and developmentally

matched peers (Torgesen, 2002; Yang, 2006). Eye tracking, otherwise known as oculomotor control, is the ability of the extra-ocular muscles to control and coordinate eye movements accurately (Kandel, Schwartz, & Jessell, 2000). Poor control of eye tracking in children with ADHD may be due in part to alterations in brain function that affect oculomotor control (Damyanovich et al., 2013).

Oculomotor changes can lead to a compromised ability to suppress unwanted saccades (short jumps of eye movement off the intended target and not under conscious control (Brysbaert, Drieghe, & Vitu, 2005)) and reduced control of steady fixation (for cognitive processing of visual information), making simple reading tasks challenging (Dunn & Kronenberger, 2005). These alterations in oculomotor control stem from poor processing speed, sensory filtering, working memory, sensorimotor integration, and executive function difficulties likely related to dysfunction in the prefrontal cortex (Funahashi & Andreau, 2013; Willcutt et al., 2010). In children with ADHD these deficits present themselves clinically as longer fixations, more regressive saccades, and slower, less accurate word recognition and identification (Hayhoe & Ballard, 2005; Irwin, 1998; Munoz et al., 2003; Tseng et al., 2013) making their reading challenging, slower and less comprehensible.

Interventions aimed at improving oculomotor control offer some promise in improving or retraining impaired eye movements, leading to improvements in reading and comprehension (Fischer & Hartnegg, 2000; Solan, Shelley-Tremblay, Ficarra, Silverman, & Larson, 2003). For example, Solan et al. (2001) showed significant improvement in eye movement and reading comprehension following 12 hours of computer-based reading and oculomotor training. However, a systematic review (Cade, 2016) revealed several well-studied oculomotor interventions for children with ADHD, and all studies reviewed had significant methodological flaws. For example, previous studies have tended to use small sample sizes (Sigler & Wylie, 1994) with inadequate description of demographic data (Fischer & Hartnegg, 2000; Sigler & Wylie, 1994; Solan, Larson, Shelley-

Tremblay, Ficarra, & Silverman, 2001), poor blinding and no control group (Fischer & Hartnegg, 2000; Solan et al., 2001), no description of randomisation processes (Fischer & Hartnegg, 2000; Solan et al., 2001), non-specific description of interventions (Sigler & Wylie, 1994), and flawed study designs such as case studies misrepresented as experimental trials (Sigler & Wylie, 1994).

Anecdotally chiropractors report (C. Fairest, personal communication, May 2015) noticing changes in oculomotor control post treatment in children with ADHD but this has never been scientifically assessed. Recent evidence suggests that chiropractic interventions have the capacity to alter brain function in areas responsible for eye movement, executive function, working memory, and attention (Funahashi & Andreau, 2013; Inami et al., 2017; Lelic et al., 2016). For example, Lelic et al. (2016) examined somatosensory evoked potential peak amplitudes following spinal manipulation (chiropractic adjustments) of dysfunctional spinal segments and found changes in somatosensory processing at the cortical level, particularly within the prefrontal cortex, of those who received spinal manipulation. These areas, especially the prefrontal cortex, have been identified as generating some of the symptoms of ADHD (Dickstein, Bannon, Xavier Castellanos, & Milham, 2006; Dirlikov et al., 2015; Valera, Faraone, Murray, & Seidman, 2007).

Oculomotor function has long been known as a symptom of spinal dysfunction (Storaci et al., 2006; Treleaven, 2008b; Treleaven, Jull, & LowChoy, 2006; Treleaven & Takasaki, 2014) with the offender likely being abnormal neck proprioceptive activity (Falla, Elliot, & Jull, 2011; Gimse, Tjell, Bjôrgen, & Saunte, 1996). Palmgren, Sandström, Lundqvist, and Heikkilä (2006) have shown that spinal manipulation can improve neck proprioception, as measured by improved improve sensorimotor integration and improve eye-tracking control, it may assist in improving academic performance and even overall quality of life for children with ADHD.

Attention-Deficit/Hyperactivity Disorder

Aetiology and clinical presentation

ADHD is a chronic neurodevelopmental disorder, characterised by inattention and/or hyperactivity-impulsivity reaching past normal developmental stages (American Psychiatric Association, 2013). It can affect an individual's academic performance, social interactions, and interpersonal relationships (Harpin, 2005). It is characterised by impulsiveness, hyperactivity, and inattention that interferes with the development or functioning of an individual (Munoz et al., 2003). Key symptoms of ADHD include inability to sustain focused attention; lack of control over impulsive behaviour; and general over-activity (American Psychiatric Association, 2013; Reebye, 2008). Symptoms must be present in two or more settings (e.g. at school, home, work, recreation activities or with friends/relatives), be present for six months (in those under 12 years), and negatively affect academic, social, or occupational functioning (American Psychiatric Association, 2013). Worldwide, the prevalence of ADHD is estimated at 5.9-7.1% of the child population (Caci et al., 2014; Willcutt, 2012), making it the most common childhood neurobehavioral disorder (Steinau, 2013). ADHD is more prevalent among boys (Lara et al., 2009; Murphy & Barkley, 1996; Willcutt, 2012), who are 2.3 times more likely be diagnosed with ADHD than girls (Bauermeister et al., 2007).

The exact cause of ADHD remains unknown (Barkley, 2014). Environmental (pre and perinatal), social, and genetic factors (Rapport, Chung, Shore, & Isaacs, 2001) are thought to contribute to both the development and/or the expression of symptoms of ADHD (Biederman et al., 1995; Lou, 1996; Mayes, Bagwell, & Erkulwater, 2008; Neuman et al., 2007). Barkley (2014) argues that neurological changes are a major contributing factor to the development of ADHD. Evidence points to a combination of structural (Davenport, Karatekin, White, & Lim, 2010; Kobel et al., 2010), functional (Cortese et al., 2012), and chemical (Economidou, Theobald, Robbins, Everitt, & Dalley, 2012; Volkow et al., 2009) differences in the

brains of those with ADHD (Hart, Radua, Nakao, Mataix-Cols, & Rubia, 2013; Hoogman et al., 2012; Makris et al., 2013) compared to those without.

Oculomotor control of the eye.

The ability to coordinate the eye's tracking path via close oculomotor control is important in an individual's sensory processing as it allows piecemeal scanning of the environment to be integrated into a coherent whole (Brysbaert et al., 2005). Small portions of the field of view are brought into the field of highest resolution (the fovea) to be investigated in detail (Duchowski, 2007). Eye movement differs with the expectation of the viewer and progression in scanning can be task-dependant (Brysbaert et al., 2005; Hayhoe & Ballard, 2005). Put more simply; what we see is dependent on how our brain chooses to scan an image (Duchowski, 2007). This indicates that visual processing is not only a bottom-up model of visual attention, but also relies on top-down control where higher-level functions drive the eye's scanning pathway (Duchowski, 2007).

This piecemeal scanning of the environment is particularly important during reading, a task that is made up of fixations, saccades and regressions (Kristjansson, 2007). Fixations are when the eye is somewhat still and focused on a target, typically lasting an average of 200-300 milliseconds (Brysbaert et al., 2005). With normal readers, when a target is presented on a screen, the length of time it takes a person to fixate on the target is approximately 220 milliseconds (Brysbaert et al., 2005). Saccades are rapid movements or jumps moving the eyes from one point to another while scanning and processing information between the points (Deans, 2010). Saccades are variable but are typically 7-9 letter spaces (Kristjansson, 2007). Reverse or regressive saccades are small, left moving saccades used to re-read a section of text (Hayhoe & Ballard, 2005; Yang, 2006). Regressions can occur when a forward saccade is too fast or covers more words than the individual can process. Around 10-15% of all saccades are regressions (Hayhoe & Ballard, 2005; Yang, 2006).

Control of saccades can be volitional or involuntary, but once 'in-flight' they cannot be altered (Duchowski, 2007). There has been debate over the exact neural system that drives saccades, but it seems the brain retains a copy or memory of eye, head and target position in space to guide the eye while the saccade takes place (Duchowski, 2007). Thus, somatosensory processing and sensorimotor integration are likely to be important in guiding saccade paths.

As text becomes more difficult, even neuro-typical (non-ADHD) readers exhibit an increase in fixation numbers and regressions, and a decrease in saccade length (Rayner, 1998b; Yang, 2006). One of the features of oculomotor control in children with ADHD is the inability to suppress moving their visual field off a chosen target when distracting stimuli are present (Munoz et al., 2003). The pre-frontal cortex drives the decision-making process of where to move the eyes next, however the disordered top-down control that children with ADHD display may interfere with tight regulation of eye control (Damyanovich et al., 2013). This allows intrusive stimuli to 'hijack' oculomotor control via the lack of top-down inhibition of premature 'distraction' saccades away from target (Tseng et al., 2013). In fact, Tseng et al. (2013) refers to children with ADHD as having stimulus-driven oculomotor control as opposed to the normal top-down or cortex-driven oculomotor system.

These changes in oculomotor control present clinically in the form of reduced ability to suppress unwanted saccades, and reduced control of steady fixation on a target (Munoz et al., 2003). Children with ADHD present clinically with longer fixations and more regressive saccades, and slower and less accurate word recognition and identification (Irwin, 1998; Tseng et al., 2013), making their oculomotor patterns diagnostic of ADHD (Tseng et al., 2013). Damyanovich et al. (2013) and Tseng et al. (2013) have shown that the oculomotor abilities of children with ADHD resemble readers of difficult text (even when reading simple sentences) and show more distraction saccades away from the target in comparison to neuro-typical controls.

Reading and oculomotor control.

Oculomotor control is vitally important for children's academic development and learning, and a breakdown in oculomotor control may be responsible for the reading difficulties that are often seen in children with ADHD (Damyanovich et al., 2013). It is thought that by improving oculomotor control it is possible to improve reading ability (Hayhoe & Ballard, 2005; Yang, 2006). Interventions aimed at improving oculomotor control have resulted in improved reading ability in other populations (Thiagarajan, Ciuffreda, Capo-Aponte, Ludlam, & Kapoor, 2014). If oculomotor control can be improved in children with ADHD this could make it easier for them to focus on and follow text, leading to subsequent improvements in their reading abilities, and possibly their academic performance.

While oculomotor interventions focus on retraining eye muscles, Medland, Walter, and Margaret Woodhouse (2010) remind us that eye movement difficulties are an effect, likely of dysfunctional cortical processes, rather than a cause of reading difficulties. The use of oculomotor control in the investigation and diagnosis of ADHD is relatively new, and research aimed at improving oculomotor control in ADHD is sparse. However, oculomotor control is a clinically relevant outcome measure for the ADHD population and appears to be amenable to rehabilitative interventions (Ciuffreda, Han, Kapoor, & Ficarra, 2006; Thiagarajan et al., 2014). Some research has already been undertaken in those with reading difficulties and dyslexia, both common comorbidities to ADHD (Damyanovich et al., 2013).

Munoz et al. (2003) showed that changes in eye movement control include reduced ability to control fixations, and to suppress saccades away from the target. These oculomotor alterations have been associated with reading delay and poor reading ability (Lampe, Turova, Blumenstein, & Alves-Pinto, 2014;

Rayner, 1998b; Uppal et al., 2011). It is thought that these changes in eye movement are responsible for the reading difficulties in children with ADHD (Damyanovich et al., 2013). Similarly, oculomotor abnormalities have been shown in those with reading difficulties (Tseng et al., 2013) and autistim spectrum disorders (Wagner, Hirsch, Vogel-Farley, Redcay, & Nelson, 2013) as well.

Willcutt et al. (2010) proposed a model involving a number of deficits to explain the comorbidity of reading difficulties and ADHD. These deficits include difficulties with in sound awareness, verbal reasoning, processing speed, and working memory deficits (for reading difficulties) and dysfunctional inhibitory controls plus poor processing speed (for ADHD) (Willcutt et al., 2010). According to Willcutt et al. (2010) both reading difficulties and ADHD share a cognitive marker of poor processing speed implicating the prefrontal cortex as an area of possible dysfunction (Funahashi & Andreau, 2013).

Little is known about what drives eye movement forward from one word to the next, but higher-level cognitive processes are thought to be involved. Sereno and Rayner (2003) suggest that fixation length is related to the cognitive processing of the written word plus sufficient time to programme an eye movement (oculomotor latency), and that fixation varies with processing complexity. As those with ADHD are known to have problems with executive functions (Funahashi & Andreau, 2013) and slow word processing ability (Willcutt et al., 2010) it would seem reasonable that those with ADHD may have longer fixations and more regressive saccades (Tseng et al., 2013). Previous research has shown that short saccadic eye movements were associated with slower and less accurate word recognition and/or identification (Brysbaert et al., 2005; Hayhoe & Ballard, 2005; Yang, 2006). These findings suggest that any eye movement has a concomitant dual-task cost. Simply put, the more the eyes move around the harder it is to read. As those with ADHD have eyes that do 'move around' more, it follows that children with ADHD may struggle with reading comprehension.

Chiropractic and its potential relationship with oculomotor control.

Current research (Group, 2017) suggests that the spinal adjustments (a specific manual thrust delivered to a dysfunctional spinal joint segment (Haavik-Taylor & Murphy, 2007b)) applied to areas of spinal dysfunction, known as vertebral subluxations, , can alter central neural functions that in turn alter sensorimotor control, resulting in improved clinical outcomes (Henderson, 2012; Taylor, Holt, & Murphy, 2010). The spine, particularly the cervical area, has a significant impact on oculomotor control (Treleaven, 2008a). Proprioceptive inputs from muscle spindles interact at the level of the vestibular nucleus, which is the common central processor for orientating motor responses to the eyes and body (Kandel et al., 2000; Kristjansson; & Treleaven, 2009; Treleaven et al., 2006). Cervical afferents are also involved in reflexes influencing head, eye and postural stability that interact with the extra-ocular muscles, allowing smoothly coordinated eye movements to occur (Treleaven, 2008b).

Altered cervical somatosensory activity and disturbance of sensorimotor function can be caused by trauma, fatigue, psychosocial pressures, spinal degeneration, and pain (Elliott et al., 2006; Falla, 2004; Flor, 2003; Kristjansson; & Treleaven, 2009; Le Pera et al., 2001; Loescher, Holland, & Robinson, 1993; Passatore & Roatta, 2006). These experiences can change muscle spindle sensitivity and mechanoreceptor function, altering the cortical representation and modulation of cervical afferent input (Flor, 2003; Le Pera et al., 2001; Passatore & Roatta, 2006). Treleaven (2008a) suggests these processes combine to alter somatosensory integration from the cervical spine, which can affect oculomotor control. This concept has been studied in whiplash-associated disorders (Storaci et al., 2006; Treleaven & Takasaki, 2014).

As discussed above, proprioceptive inputs from muscle spindles (particularly from the cervical spine (Treleaven, 2008a)) interact at the level of the vestibular nucleus, which is the common central processor for orientating motor responses

to the eyes and body (Kandel et al., 2000; E. Kristjansson & Treleaven, 2009). The cervical afferents are also involved in reflexes influencing head, eye and postural stability that interact with the extra-ocular muscles allowing smooth eye movements to occur (Treleaven, 2008a).

Altered cervical somatosensory activity can result in disturbances of sensorimotor function (Hinoki & Niki, 1975), which can occur in a number of ways. Cervical mechanoreceptor function can change due to direct trauma (Chen, Lu, Kallakuri, Patwardhan, & Cavanaugh, 2006; Loescher et al., 1993), fatigue (D. Falla, 2004) or degenerative changes (Elliott et al., 2006; E. Kristjansson, Hardardottir, Asmundardottir, & Gudmundsson, 2004; McPartland, Brodeur, & Hallgren, 1997; Uhlig, Weber, Grob, & Müntener, 1995). Additionally, pain can change muscle spindle sensitivity and alter the cortical representation and modulation of cervical afferent input (Flor, 2003; Le Pera et al., 2001). Even psychosocial stresses may alter muscle spindle activity via activation of the sympathetic nervous system (Passatore & Roatta, 2006). Treleaven (2008a) suggests that these processes combine to alter somatosensory integration from the cervical spine, which can affect eye movement control. This concept has been studied in whiplash-associated disorders (Heikkilä & Wenngren, 1998; Hildingsson, Wenngren, & Toolanen, 1993; Treleaven, 2008b). Interestingly, chiropractic intervention, when used in the cervical spine, has been shown to improve proprioceptive function in the body (Haavik & Murphy, 2011) and to alter sensorimotor integration (Haavik & Murphy, 2012; Taylor et al., 2010).

Over the last 15 years research has tested the hypothesis that the articular dysfunction component of the vertebral subluxation results in altered afferent input to the central nervous system (CNS), modifying the way the CNS processes and integrates all following sensory input (Haavik-Taylor & Murphy, 2010; Holt, Haavik, Lee, Murphy, & Elley, 2016). This sensorimotor processing appears most susceptible to altered inputs (Haavik-Taylor & Murphy, 2007a, 2007b, 2007c, 2010; Haavik & Murphy, 2011, 2012; Niazi et al., 2015). A series of experiments

(Haavik-Taylor & Murphy, 2007a, 2007b, 2007c) were designed to test the effects of altering peripheral input on sensorimotor integration with two specific tasks (20 minutes of motor training and spinal manipulation). Manipulation of dysfunctional spinal joints showed an altered ability to filter somatosensory information. As joint dysfunction can lead to altered afferent input to the brain (Bolton & Holland, 1998) dysfunctional spinal joints may alter the way in which new sensory input is received and processed. Haavik-Taylor and Murphy (2007b) showed this was so after demonstrating somatosensory processing, sensorimotor integration, and motor control was changed for 20-30 minutes after manipulation of cervical spine joints. As oculomotor control relies on adept sensory processing (Irwin, 1998; Sereno & Rayner, 2003) it is possible that aberrant input, from dysfunctional spinal joints, may change somatosensory processing enough to alter sensorimotor control of the eyes

Recent studies have shown that chiropractic care alters sensorimotor filtering (Haavik-Taylor & Murphy, 2010), cortical, and cerebellar motor processing (Daligadu, Haavik, Yielder, Baarbe, & Murphy, 2013), all of which are known to be important in the neurodevelopment of ADHD (Dunn & Kronenberger, 2005; Sable et al., 2012). More studies have also shown that chiropractic care can lead to changes in multimodal integration involving visual and auditory inputs (Holt et al., 2016), suggesting chiropractic may well alter visual processing and central oculomotor control. Chiropractic intervention, when used in the cervical spine, has been shown to improve proprioceptive function of not only the spine itself (Palmgren et al., 2006) but also of the upper (Haavik & Murphy, 2011) and lower limbs (Holt et al., 2016), as well as altering central sensorimotor integration (Haavik & Murphy, 2012; Taylor et al., 2010). Collectively, these studies add evidentiary weight to the hypothesis above.

A recent study using whole head electroencephalography and source localisation techniques demonstrated that chiropractic adjustments alter sensorimotor integration in the prefrontal cortex (Lelic et al., 2016). The prefrontal cortex is

involved in attention, working memory, and the control of eye movements (Funahashi & Andreau, 2013). Prefrontal cortex function influences reaction times, responses to stimuli, and inhibition of irrelevant distraction, all of which are necessary for reading and comprehension (Rayner, 1998a). The prefrontal cortex contains the frontal eye fields that are essential for the control of eye movements (Fukushima, Yamanobe, Shinmei, Fukushima, & Kurkin, 2004). This area of the brain is morphologically altered in children with ADHD (Dickstein et al., 2006; Dirlikov et al., 2015; Valera et al., 2007). For example, A meta-analysis by Valera et al. (2007) identified a number of brain areas that differed in volume between ADHD and normal controls; total cerebral volume, frontal and prefrontal areas (Valera et al., 2007). The hypoactive frontal areas described are thought to be associated with deficits in executive function that those with ADHD exhibit (Dirlikov et al., 2015; Kobel et al., 2010). Dunn and Kronenberger (2005) implicate changes in fronto-striatal pathways that can lead to difficulties with "top-down" attentional control. These neurological changes are associated with alterations to sensory filtering, sensorimotor gating, and sensorimotor control of eye movements (Munoz et al., 2003; Sable et al., 2012). It is, therefore plausible that adjusting subluxations in children with ADHD may alter their prefrontal cortical function and influence oculomotor control, altering their eye movements. This is something that can be measured with eye tracking equipment (Damyanovich et al., 2013; Tseng et al., 2013).

There are neurophysiological explanations that can implicate the spine in oculomotor dysfunction (Fukushima et al., 2004; Funahashi & Andreau, 2013; Holt et al., 2016; Lelic et al., 2016) making it possible to posit that treatment of dysfunctional spinal areas may improve oculomotor control. However, there are only a few published papers or case studies involving chiropractic intervention for visual problems (Gilman & Bergstrand, 1990; Schutte, Teese, & Jamison, 1989; Stephens & Gorman, 1995; Terrett & Gorman, 1995; Zhang et al., 1984). All are adult case studies, except Terrett and Gorman (1995) which describes changes in visual fields in a 9 year old girl after chiropractic intervention. Specifically, Terrett and Gorman (1995) found bilateral narrowing of the visual

fields a nine-year-old female which normalised after a single application of spinal manipulation. Following this, the same child returned one year later with monocular visual loss, after being struck in the head by a ball, which again resolved after a single spinal manipulation. Further, a large experimental study of 500 individuals described improvements in the blind spot of participants visual fields after chiropractic adjustments; researchers noted a cervical spine adjustment opposite the side of the enlarged blind spot seemed to most effectively reduce the blind spot (Carrick, 1997). They suggested that altered afferent inputs from the spine change an individual's sensory integration and processing of visual information. A later study, using upper extremity manipulation to affect afferent input to the brain, seems to support the concept that altered sensorimotor input can affect visual field blind spots (Daubeny, Carrick, Melillo, & Leisman, 2010). The above studies describe improvements in a specific outcome such as visual acuity, visual fields, oculomotor function, intraocular pressure, and pupillary size after chiropractic intervention.

Zhang et al. (1984) reported on 114 cases of adults with cervical degeneration and associated visual disorders that were not specified. Visual improvement following manipulative treatment was reported in 83%. In 54 of the cases followed up for six months, 91% showed a stable visual change. Treleaven (2008b) also reported four case studies detailing various training exercises (gaze stability, balance, cervical joint position exercises, and eye-head coordination exercises) on oculomotor function in patients with neck disorders and associated sensorimotor dysfunction of the eye.

Unfortunately, all of these studies, except those by Carrick (1997), Daubeny (2010), and Treleaven (2008) have provided minimal or no description of their interventions. Furthermore, few details have been provided around outcome measurement, resulting in weak evidence to support the neurophysiological theory of spinal or chiropractic intervention affecting oculomotor control.

Summary

It is clear that those with ADHD have significant differences in oculomotor control compared to neuro-typical individuals (Damyanovich et al., 2013; Deans, 2010; Karatekin, 2007; Munoz et al., 2003; Tseng et al., 2013). These changes may stem from altered cortical functioning and can have significant short and long-term effects on schooling, employment, and overall quality of life (Caci et al., 2015; Caci et al., 2014; Harpin, 2005). Oculomotor control is dependent on coherent sensorimotor control and attentional processes (Duchowski, 2007; Zeki, 1993) for functionally useful eye movements. As chiropractic intervention alters sensorimotor integration (Haavik-Taylor & Murphy, 2007b, 2010; Taylor et al., 2010) and and affects processing in the prefrontal regions known to be important for accurate oculomotor control (Lelic et al., 2016). Hence, adjustment of joint dysfunction via chiropractic care may have some application in improving oculomotor function for children with ADHD.

Aims

In response to these gaps identified in knowledge, the primary aim of this study was to **t**est all study processes, and identify any barriers to adherence to study protocol. Specifically, the study tested processes relating to participant randomisation, recruitment and retention, eligibility criteria, data collection, and equipment. Acceptability or how participants felt about the chiropractic intervention intervention was also assessed. Secondary aims were to compare the visual target acquisition time, number of off-target distractions and oculomotor control via reading (reading time, number, time and length of forward and reverse fixations and saccades) of children with ADHD following a single chiropractic intervention with a comparison session following a control intervention.

Chapter 2: Methods

Design

This was an experimental randomised controlled pilot study that utilised a cross over design with a one-week washout period. A crossover design was chosen to 1) allow participants to act as their own control in an effort to manage confounding variables such as sex or age differences (Wellek & Blettner, 2012), and 2) to reduce the required sample size to confirm the presence of a treatment effect (Wellek & Blettner, 2012). A one-week washout period was chosen as it has been successfully used in previous trials featuring a single chiropractic intervention (Haavik-Taylor & Murphy, 2007a, 2007c, 2010).

Ethical Approvals.

Ethics approval for this study was gained from the Health and Disability Ethics Committee (HDEC 16/NTA/56) and the Auckland University of Technology Ethics Committee (AUTEC 16/311). An amendment to the original ethics approval was made to allow data collection at sites other than the write in full New Zealand College of Chiropractic laboratory (HDEC 16/NTA/56/AM01).

Participants

Inclusion criteria were a parent-reported medical diagnosis of ADHD in a child aged 8-15 years. Given this study's focus on ADHD, children who had been medically diagnosed with comorbid conditions that seriously altered their reading ability (major visual disabilities or reading deficits from sources other than ADHD) were excluded from this study.

A sample size of 30 participants for this pilot study was used to enable assessment of qualitative aspects of feasibility, based on the samples used in similar studies (Tseng et al., 2013). 30 participants also allowed for estimation of potential effect sizes for use in sample size calculations to determine the sample size for future clinical trials. Additionally, regarding the participant

sample, a convenience or availability sampling method (the sample was made up of those participants who are easy to reach, who respond to study invitations first and are willing to participate (Acharya, Prakash, Saxena, & Nigam, 2013)) was used for this study, as there is a very small, but possible, potential for harm with a chiropractic intervention: 1% of children may experience a mild, transient negative side effects (i.e. muscle soreness)(Miller & Benfield, 2008). Thus, using a convenience sampling method allowed participants entry to the study only if they wish to receive chiropractic care.

Demographic information was collected for the following reasons. Age, as the younger child may exhibit oculomotor behaviours similar to that of an older child who has difficulty reading (Duchowski, 2007; Tseng et al., 2013). Gender information was collected as boys and girls exhibit symptoms of ADHD differently (Bauermeister et al., 2007). But, as yet, there seems to be no research relating describing sex-related differences in oculomotor function in children with ADHD. Medication use was important to collect as commonly used ADHD medication, such as Ritalin (Barkley, 2014), can affect oculomotor metrics (Fried et al., 2014). Medication data was collected as yes, no, or not on the day of testing. The addition the latter demographic was because some ADHD medication is short-acting, with a duration of one to four hours (Kimko, Cross, & Abernethy, 1999) with many parents taking weekend 'holidays' from medication (Martins et al., 2004). Only those participants who did not take medication at either session were coded as 'medication not taken on day of testing'. As this study investigates chiropractic adjustments related to oculomotor outcomes it was prudent to also collect data on participants having previous chiropractic care. Finally, data on comorbid conditions was collected as some have similar areas of brain dysfunction (Damyanovich et al., 2013) and may affect oculomotor function (Thiagarajan et al., 2014).

Procedures

Participants were recruited via advertising (see Appendix 4) through participating chiropractic practices in the greater Auckland area. Recruitment efforts were primarily focused on family and friends of patients of participating practices. Since study participants were required to be between 8-15 years the flyers asked if current patients knew of any child (or adult with children) who had ADHD and may be interested in participating in the study. If so, the flyer requested they pass on the contact details of the principal investigator to any potential participants or their guardians and suggested they make contact if interested in learning more about the study. Chiropractors were also encouraged to post the flyer on their Facebook pages, websites, email it to their patients (if prior consent to email them had been obtained), and to discuss the study with patients, potential patients and in other networking activities.

Children and their guardians interested in participating in this study registered their interest with their respective advertisers. They were then sent (by email or regular post) the child and parent versions of the study information sheet. If they agreed, via email or phone call, to be part of this study they were then invited, by phone or email, to ask any questions they may have had regarding the study. If, after screening, both the child and guardian agreed to participate in the study they were booked in for their first appointment. First appointments included; further discussion about the study, seeking of written caregiver consent and child assent, and the collection of demographic information and contact details (Appendix 6 and 7).

This study was carried out at the New Zealand College of Chiropractic or at participants' homes. Upon arrival at the New Zealand College of Chiropractic laboratory, participants and guardians were greeted then taken to the testing area. All participants examined and tested at the New Zealand College of Chiropractic were situated in a chiropractic examination room, which was set up in the same configuration for every participant. The setting was designed to

minimise distraction and maximise uniformity for every individual. For participants tested outside the New Zealand College of Chiropractic, the setting configuration was approximated to the best of the abilities of the investigator present.

Before proceeding with any data collection, guardians and children were given the opportunity to ask further questions regarding the study and were reminded of their right to withdraw from the study at any point in time. If they were then willing to continue both participants and guardians were presented with a copy of the appropriate information and consent/assent forms, and given sufficient time to re-familiarise themselves with the forms. As participants for this study were unable to give informed consent, due to their age, their guardians were asked to give informed consent for the study. Participants were asked for informed assent, as per the New Zealand Health and Disability guidelines. A copy of guardian consent and child participation assent sheets is attached in appendices 1 and 2. Guardians/participants were then given a second chance to ask any questions they may have regarding the study. If all questions were answered to the satisfaction of the guardians/participants they were asked to name and sign the consent/assent forms. On completion of consent/assent forms a basic health history was taken from each participant (see appendices 1 and 2), and baseline oculomotor data was collected.

All consenting and eligible participants undertook their first baseline outcome testing and were then randomised to either the chiropractic intervention or the control intervention. Participants were randomised for the order of intervention (chiropractic first or control first), and balanced for age and gender, using a computer-generated block randomisation sequence using a free, online program known as QMinim (Saghaei & Saghaei, 2011). The attending chiropractor (also outcomes assessor and data analyst) performed the randomisation (after baseline information and pre-intervention outcome measurements were taken) and was the only person who knew which intervention children were allocated to. Once allocated to either the experimental or control intervention children

underwent their appropriate intervention with the attending chiropractor. Participants were not told in advance which group they were assigned to and completed their baseline assessment blinded to the upcoming type of intervention. Intervention or control movements are described below and were estimated to take approximately 5 minutes. Due to the nature of the control and chiropractic intervention and to the fact that child participants were required to have a guardian present during either intervention, complete blinding of participants was not possible. Similarly, the attending chiropractor performed the randomisation and was the outcomes assessor, thus was also not fully blinded. To accommodate for incomplete blinding at the time of intervention, all the data was analysed fully blinded. This was achieved by firstly recording data with an associated participant identification code, then replacing the participant code with an unrelated numerical code before analysis, thereby removing any associated participant identifiers.

Finally, post intervention/control oculomotor data was collected and participants/guardians were invited to ask any further questions they may have. At the close of the first session, both participants and guardians were thanked for their involvement in this study and a follow-up session was scheduled. Guardians/participants were also asked if they would like a reminder call, text or email prior to their follow-up appointment.

Chiropractic Intervention.

Children allocated to the chiropractic intervention had a single session of chiropractic care. Full spine chiropractic assessment and intervention was carried out as part of the chiropractic intervention. All interventions were performed by an experienced, registered chiropractor with at least ten years practising experience and a Diplomate in Clinical Chiropractic Paediatrics (the attending chiropractor). The entire spine and sacroiliac joints were assessed for segmental dysfunction and adjusted where deemed necessary. The clinical indicators that were used to assess the function of the spine included; joint tenderness to palpation, restricted inter-segmental range of motion, asymmetric

intervertebral muscle tension, and abnormal spinal joint play. All of these are known clinical indicators of spinal dysfunction (Cooperstein, Haneline, & Young, 2010; Cooperstein, Young, & Haneline, 2013; Fryer, Morris, & Gibbons, 2004; Hestœk & Leboeuf-Yde, 2000). The spinal adjustments carried out were high-velocity, low-amplitude thrusts to the spine or pelvic joints, a standard spinal manipulation technique used by chiropractors. This manipulation technique has also been previously used in studies that have investigated neurophysiological effects of spinal manipulation (for review see; Haavik & Murphy, 2012).

Control Intervention.

Children underwent a series of passive and active movements of the head, spine and body carried out by the same chiropractor that assessed the chiropractic intervention group. This involved the participants being moved into spinal manipulation setup positions but without delivering an adjustment thrust or loading tension into any spinal joints. Pre-loading a joint, as is normal prior to spinal manipulation has been shown to alter paraspinal proprioceptive firing in anesthetised cats (Pickar & Wheeler, 2001). No spinal manipulation was performed during any control. This active control was not intended to act as a sham for manipulation but to be a physiological control for any possible changes that may occur due to cutaneous, muscular or vestibular input (Kandel et al., 2000) from the passive and active movements used in preparing for a spinal manipulation.

Follow-up assessment.

At a minimum seven days after the initial randomisation and intervention, all participants' outcome measures were retested after which they received the alternative intervention. Procedures for the follow-up assessment was similar to the initial assessment; excepting consent/assent, randomisation, demographic and health history data was not performed/taken a second time. For example, if a participant had received the control intervention first, after the washout period they received the chiropractic intervention. After the appropriate intervention

was applied, according to the outline provided above (except for the initial baseline demographic and health history information), participants' were then reassessed following the intervention. Finally, a short 10-minute questionnaire followed the intervention to gather feedback from children and guardians around their impressions of the study and included activities.

Safety Monitoring

Any serious adverse events identified were to be reported to the primary contact person/investigator, who updated the Data and Safety Monitoring Committee concerning identified events on a weekly basis, or as they happened. Information regarding any adverse events was to be recorded whether they were felt to be associated with the study or not. The primary contact person/investigator updated the Data and Safety Monitoring Committee, weekly regarding the progression of the trial, data auditing, and integrity.

Outcome Measures

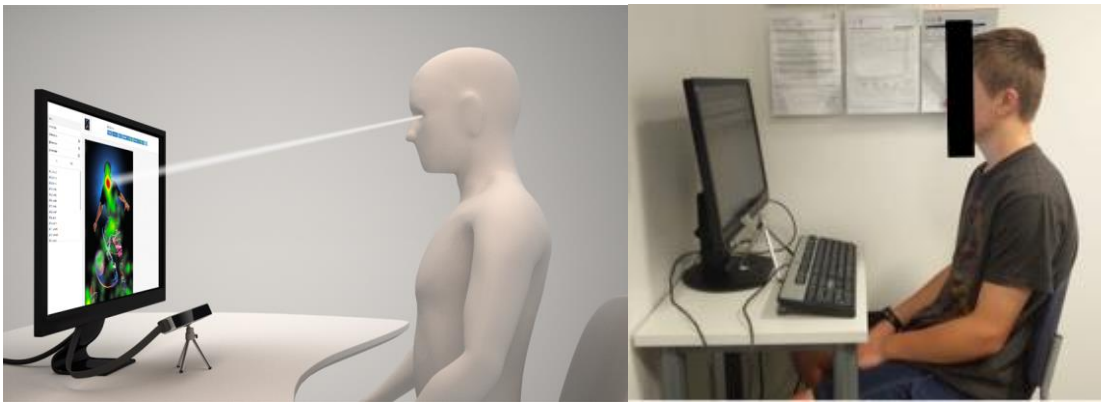
Feasibility Measures: participant and guardian impressions

All participant and guardians were asked to complete a study-specific evaluation questionnaire to gather their impressions of the study (i.e., duration, intervention, satisfaction). Free text and Likert scale responses were gathered. Example questions include: 'I/we feel the difficulty of the eye-tracking test was appropriate for me/my child'; 'the instructions and explanations by the research team alone provided me/my child with enough information to understand the study procedures and expectations'. Likert scale responses were denoted from 1-7, 1 being 'strongly disagree' and 7 being 'strongly agree'. Data collected from this questionnaire will be used to help drive any procedural changes necessary for a larger clinical trial. See Appendix 5 for a copy of the child and parent questionnaires.

Secondary Measures: The Eye Tribe eye tracker.

The Eye Tribe tracker is a computerised measure of target acquisition time, fixations, reading time and forward or reverse saccades (see figure 1). It calculates the location gaze by information extracted from participants face and eyes. The eye and gaze coordinates are calculated in relation to a screen the participant is looking at, and are represented by a pair of (x, y) coordinates (Tribe, 2014).

Figure 1 The Eye Tribe eye tracker set up



Left represents the recommended Eye Tribe set up (Tribe, 2014) and right, the study set up.

The Eye Tribe tracker is calibrated for collecting usable data to an average accuracy of around 0.5 to 1º of visual angle when the participant sits approximately 600 mm away from the tracker (Tribe, 2014). The eye tracker operating distance is 450-800 mm allowing for free head movements when the participant's head is within the viewing area; the shape of a truncated cone extending out from the eye tracker (Gibaldi, Vanegas, Bex, & Maiello, 2016). This allows horizontal and vertical head movements of 240mm left or right and 195mm up or down, essentially forgiving the tiny, natural movements an individual makes even when sitting "still" (Gibaldi et al., 2016). The eye tracker has an accuracy corresponding to an on-screen average error of 0.5 to 1 cm

(Tribe, 2014). Perfect calibration gives a less than 0.5° level of accuracy and a moderate (still useful) calibration is less than 1° (Ooms, Dupont, Lapon, & Popelka, 2015; Tribe, 2014). Lower ranges of accuracy can create some variance in fixation points or saccade length measurements (Tribe, 2014). All outcomes measures were taken with a calibration of 'perfect' or 'moderate', with 'moderate' calibration being used only when the participant failed to attain 'perfect' calibration after multiple attempts.

Previous research is divided around the accuracy and precision on the Eye Tribe tracker, some suggesting it is useful for fixation checking, gaze analyses, and pupilometry but, it is not accurate enough for specific saccade metrics (Dalmaijer, 2014). Others argue that with careful set-up the Eye Tribe tracker can be a useful, accurate tool (Gibaldi et al., 2016; Ooms et al., 2015). The Eye Tribe tracker has been previously used in both experimental research projects involving children (Morgante, Zolfaghari, & Johnson, 2012) and adults (Duchowski, 2007; Elsabbagh et al., 2012; Hepach, Vaish, & Tomasello, 2012) and studies successfully testing its methodological value in data collection from non-neurotypical children (Sasson & Elison, 2012).

Sasson & Elison (2012) suggest a number of protocols around the eye tracking in non-neurotypical children as part of best practice procedures. Firstly, the tracker must account for head movement and be as unobtrusive as possible to avoid distracting the participant. The Eye Tribe tracker satisfies both these suggestions (Tribe, 2014). Sparsely decorated rooms should be used, guardians should be present and, if possible, the researcher should not be visible to the participant (Sasson & Elison, 2012). This last suggestion was not possible, but the attending researcher aimed to minimise their presence by not speaking (except in the two trial runs) or moving excessively when testing took place. Finally, tasks should be short, designed for passive viewing (such as the target task) or as minimally demanding - as possible as the simple sentences of the reading task were (Sasson & Elison, 2012).

Eye tracking tasks.

All secondary outcome measures were collected using the Eye Tribe tracker. Time was measured in milliseconds and saccades were measured in pixel length. For both the target acquisition task and reading task there were two test-run tasks, where the attending researcher verbalised a standardised set of instructions to the participant, then ten further tasks that the participant completed without concurrent verbal instructions. Only the ten tasks completed without verbal instructions were used in the analysis.

Target acquisition task.

This task required participants to locate a visual target flashed on a computer screen. The task required fixating their gaze on the green "GO" button to start the task, then to fixate their gaze on the target (orange dot) as soon as it appeared. Participants were further instructed to ignore the purple distractor dot after their fixation on the orange target dot.

As part of the eye tracker target acquisition assessment, the following measures were collected -

Visual target acquisition time. Any fixations longer than 300 milliseconds (Duchowski, 2007) onto the purple distractor dot were recorded. Past research has shown that children with ADHD show longer reaction times in response to presentation of a new target, greater variation in their responses, and increased time in moving their gaze from one target to another (Munoz et al., 2003).

Number of distractions. As described above, participants were directed to fixate their gaze on a particular target on the screen and ignore any distracting stimuli (purple dot) that appeared on the screen. Any fixations longer than 300ms (Duchowski, 2007) onto the purple distractor dot were recorded.

Reading task.

Participants were directed to read a short sentence on a computer screen. This task required fixating their gaze on the green "GO" button to start the task, then

to read the sentence as soon as it appeared. Once participants had read the sentence they were instructed to press the space bar, indicating they had finished reading. As soon as the space bar was pressed a question related to the sentence appeared on the screen. The attending researcher read the question to the participant and asked them to answer it to the best of their abilities. The purpose of the question was to prime the participant to the importance of reading and processing the question and to avoid them simply looking at the screen and pushing the space bar. Post the intervention the reading task was re-tested and a slightly different set of sentences was used to avoid participants relying on memory to recognise the sentence. Post intervention sentences were similar in length, content and difficulty (Stockmeyer, 2009). All sentences were adapted from the Woodcock-Johnson III Tests of Achievement (Schrank, Mather, & McGrew, 2014). A full list of pre and post sentences and questions is given in Appendix 8. The Flesch-Kincaid Grade (a measure of reading ability (Stockmeyer, 2009)) ranges from 0.0 (easiest question) to 5.8 (hardest question) with an average of 2.2. The average 8-year-old reader should be able to read a question with a Flesch-Kincaid Grade of 3.0 easily (Stockmeyer, 2009). The ten test questions were presented in a random order of difficulty.

As part of the reading task, the following measures were recorded, each of which is associated with reading ability (Tseng et al., 2013).

Number of forward and reverse fixations. Fixations are when the eye is relatively still and focused on a target, typically lasting an average of 220ms for a normal reader (Yang, 2006). Fixation threshold was set at 300ms for this study to control for any micro saccadic movement (has no associated cognitive processing) that may be present (Fried et al., 2014). Increasing numbers of reverse fixations are associated with more complex reading tasks or more difficulty with reading (Brysbaert et al., 2005; Yang, 2006).

Time of forward and reverse fixations. Measured in milliseconds. Increasing fixation time is associated with more cognitive processing of words and

sentences and time increases with complex reading tasks (Brysbaert et al., 2005; Yang, 2006).

Number and length of forward and reverse saccades. Measured in pixels. Increasing length for forward saccades indicates a faster, more advanced reader (Brysbaert et al., 2005; Yang, 2006). Similarly, an increase in reverse saccade length indicates difficulty making sense of the information in the sentence, requiring the reader to skip backwards in order to re-read and re-process the information content of the sentence (Brysbaert et al., 2005; Yang, 2006).

Data Management

Electronic data were entered, stored and backed-up in a secure manner on the New Zealand College of Chiropractic research department server. Hard copies of essential written documents and records were securely stored in the New Zealand College of Chiropractic research offices. Data entry checking procedures were utilised to improve data quality and reduce the chance of outliers occurring due to data entry errors in accordance with recommendations made by Büchele, Och, Bolte, and Weiland (2005). Participant data were de-identified by ensuring all identifying material was kept separate from confidential study material. Consent forms and demographic forms, which included participant names, did not also include the participants study ID, and were secured separately to participant data. All documentation will remain secured at the New Zealand College of Chiropractic or approved archive) for a minimum 10 years following the study's closure, in accordance with New Zealand Health and Disability Ethics Committee regulations.

The three supervisors of this study formed the Data and Safety Monitoring Committee, to oversee data auditing, verify the integrity and validity of data, and to safeguard participants during the trial. They met regularly throughout the course of the study. Participants were encouraged to report any issues or adverse events at any stage of the study.

Data Analysis

Feasibility data was analysed using a qualitative descriptive methodology (Sandelowski, 2000), specifically content analysis (Crowe, Inder, & Porter, 2015; Vaismoradi, Turunen, & Bondas, 2013). Content analysis was undertaken by categorising participant responses into clusters (Crowe et al., 2015), then organising and interpreting the data to identify commonalities and dissimilarities (common themes) reported in the post study questionnaire (Vaismoradi et al., 2013). Participant and guardian written responses from the post study evaluation questionnaire were sorted into groups of similar data items and analysed for initial codes. These initial codes were then re-analysed to produce a final code (see appendix C) (Elo & Kyngäs, 2008). Findings from the post study evaluation questionnaire have been presented as a summary of central themes and (if any) sub themes (Elo & Kyngäs, 2008) with participant quotes to assist in substantiating the conclusions drawn from the data. All coding was performed by hand and not by an automated method.

Descriptive statistics (unadjusted means, standard deviations, and counts) were used to describe the characteristics of the study sample. . Multifactorial repeated measure analysis of variance (ANOVA) tests were used to assess for within subject differences (Pallant, 2013). Shapiro-Wilk tests (Pallant, 2013) were used to assess the data collected for all tasks and they revealed data were not normally distributed. Accordingly, all data not normally distributed were subjected to a Logarithmic or two-step rank-transformation (Osborne, 2010; Templeton, 2011) in order to normalise data before analysis, as there is no non-parametric alternative to the Multifactorial repeated measure analysis of variance (ANOVA) (Pallant, 2013). After the data were normalised a multifactorial repeated measures ANOVA was performed to assess the impact of both interventions (chiropractic and control) on participants' scores of total time to acquire the target, across two time periods (pre-intervention and post-intervention). Pre and post intervention measures (target acquisition time, number of distractors, reading time, number, time and length of forward and reverse fixations and saccades) for each dependent variable and intervention (chiropractic versus control) were used as factors

when assessing main effects or interaction effects. An a priori pairwise comparison of the pre and post intervention data was carried out when an interactive effect was significant (set at $P \leq .05$). Confidence intervals were given at a two-sided 95% level. No adjustments to p-values were planned or made due to the use of multiple outcome measures, as recommended by Feise (2002) and Perneger (1998). Data were also evaluated to assess for any statistically significant differences between groups. All analyses were performed on the intention-to-treat (ITT) principle, insomuch as participants were analysed according to the intervention they were randomised to first, regardless of order of intervention. An ITT analysis was adopted to avoid over-optimistic estimation of the intervention's efficacy due to the removal of non-completers, as it accepts patient non-compliance of some kind is likely to occur in actual clinical practice (Gupta, 2011). All available data were used and no missing data imputation was performed.

Chapter 3: Results

Feasibility.

Recruitment and Retention.

The majority of participants were recruited by ADHD support groups (57%), private chiropractic practices (23%) and Facebook (10%). The remaining 3 (10%) participants were identified through the New Zealand College of Chiropractic Chiropractic Centre. Sixty-four individuals responded to advertising material posted asking for more information. Of these individuals two children aged six and seven years did not meet inclusion criteria and two

were non-consenting, giving travel time as their reason for declining involvement. The remaining thirty individuals were non-responsive after study information they requested was sent to them.

Participant recruitment was timely (eleven weeks); there were no dropouts, complaints or other non-compliance issues. Overall, sixty-four people expressed interest in participating in this study. All interested parties contacted the research team via email, preferring this method of communication. There were thirty people (46.88%) who contacted the research team expressing interest in the study, but failed to respond again until after recruitment closed. Five (16.67%) of these 30 non-responders contacted the research team after recruitment closed asking to join the study.

Participant recruitment and data collection spanned mid-October 2016 to early January 2017 (eleven weeks); a relatively small window of time given it covered the Christmas period. The shortest first contact to final data collection period was eight days and the longest was sixty-one days; a timeframe that was unlikely to place an undue burden on participants. Study participants reported no complaints regarding paperwork or testing procedures and all information, consent and assent information forms were well received and appeared to be well understood. Computerised collection of outcome measures made consolidating collected data simple, so a single researcher was able to manage participants' communications, paperwork and data collection processing. Each study assessment was expected to take between 30-45 minutes; however, in reality each session took around 60 minutes to complete due to participants and guardians further questions regarding the study and related subject matter.

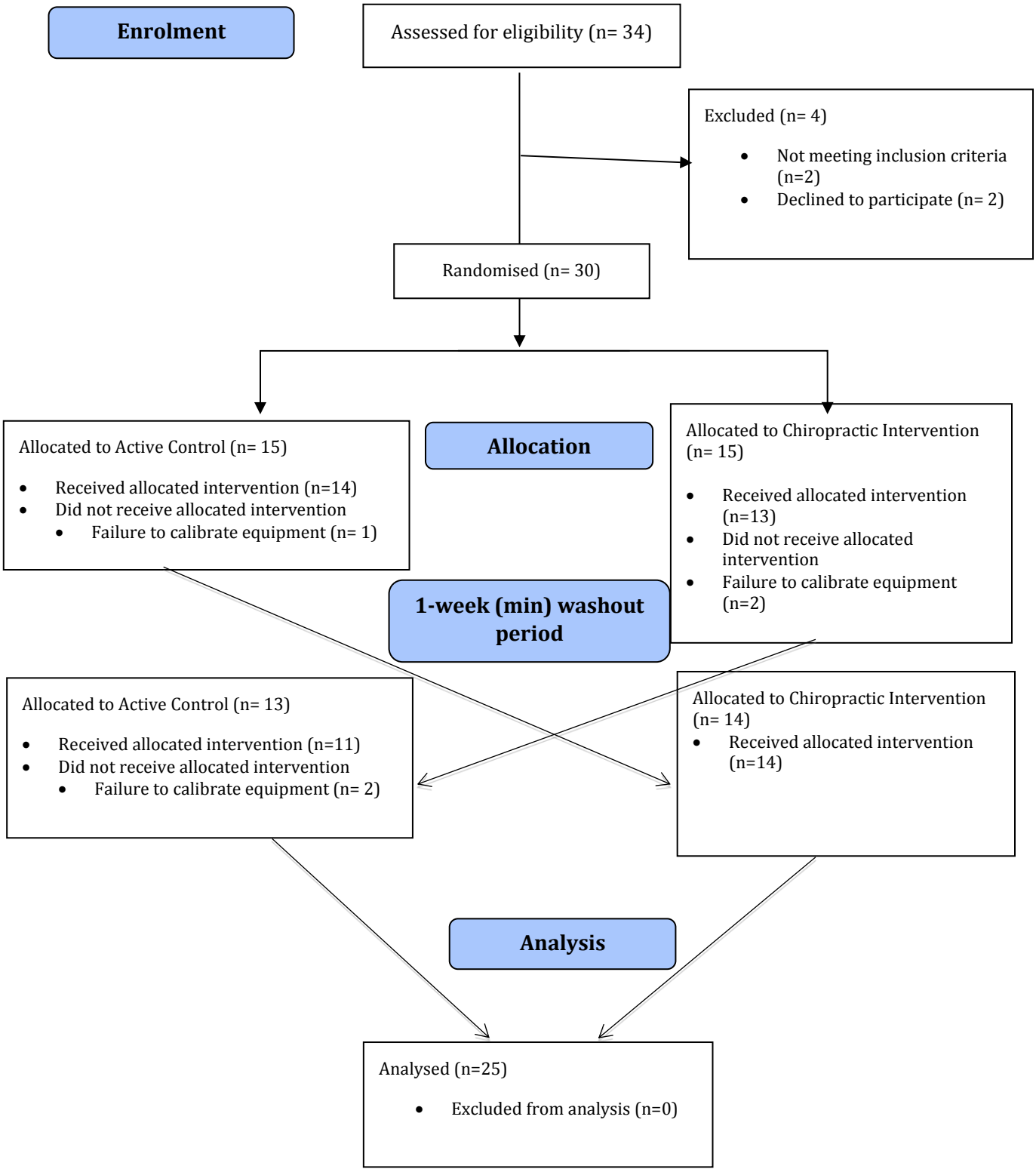
Twenty-three (76.6%) participants were assessed in the New Zealand College of Chiropractic laboratory setting and seven (23.3%) were assessed in their homes. There were three participants (10.0%) assessed at home in the chiropractic intervention first group and four (13.3%) in the control intervention first group.

For all study sessions (at home or in the New Zealand College of Chiropractic) it was noted that there was difficulty in predicting or removing participant sibling or guardian interruptions or "helping" instructions from guardians. Interruptions occurred even though every participant and their family was carefully instructed not to interrupt or distract the participant during the testing procedures.

Figure 2 shows the flow of participants through the study. Thirty-four participants were screened for eligibility, with two being ineligible, as they did not meet age requirements. A further two declined to participate citing travel time as their reason for refusal. The participants were randomised to either receive the control intervention first (n=15) or the chiropractic intervention first (n=15). Twenty-seven (90%) participants completed the study (n=13) who received the chiropractic intervention first and n=14 who received the control intervention first). Three participants (10%) were not included in the analysis after being unable to complete calibration with the eye tracker for any outcome measure. Those children not included in the current analysis (due to an inability to calibrate at all) had no significant baseline differences to those included in the analysis.

There was a 100% retention rate with no drop-outs in this study for any reason. Two participants rescheduled their follow up appointments due to conflicting events but they completed their second data collection session without further problems. The maximum window between the baseline and follow-up was 4 weeks with an average of 10 days between sessions.

Figure 2 - Consort diagram of study sample ADHD



Sample characteristics

Baseline demographic information and medical history are summarised in Table 1. Baseline values for outcome measures are included in Tables 4 and 5. Randomisation resulted in similar groups. However, some group differences occurred in gender distribution, medication use, prior chiropractic care and comorbid conditions.

Table 1 Sample Characteristics

Sample Characteristics	*Total N=30*		*Control First N=15*		*Chiropractic first N=15*		*P value*
Mean (SD) Age (Years) at assessment	11.3 (2.29)		11.4 (2.23)		11.1 (2.42)		0.72
Grouped age, n (%)							
8-11yrs	17	(56.67)	9	(60.00)	9	(60.00)	
12-15yrs	13	(43.33)	6	(40.00)	7	(46.67)	
Gender, n (%)							0.72
Female	9	(30.00)	5	(33.33)	4	(26.67)	
Male	21	(70.00)	10	(66.67)	11	(73.33)	
Medication Use, n (%)							0.08
Yes	16	(53.33)	8	(53.33)	8	(53.33)	
No	9	(30.00)	6	(40.00)	3	(20.00)	
Not taken on day of data collection	5	(16.67)	1	(6.67)	4	(26.67)	
Prior Chiropractic Care, n (%)							0.04*
Yes	12	(40.00)	8	(53.33)	4	(26.67)	
No	18	(60.00)	7	(46.67)	11	(73.33)	
Comorbid Conditions, n (%)	16	(53.33)	10	(66.67)	6	(40.00)	0.04*
ASD	3	(10.00)	2	(13.33)	1	(6.67)	
Other Behavioural Disorders (NOS*)	1	(3.33)	1	(6.67)	0	(0.00)	
Dyspraxia	1	(3.33)	0	(0.00)	1	(6.67)	
Dyslexia	5	(16.67)	4	(26.67)	1	(6.67)	
Other Learning Difficulties (NOS*)	6	(20.00)	3	(20.00)	3	(20.00)	

Note: Data are presented as n (%), unless stated otherwise.*NOS = Not Otherwise Specified. *Significant p <.05.

Due to the smaller sample size used in this study, some baseline characteristic differences were inevitable. The most obvious difference in characteristics was participant gender. Of the total sample 70% were male (n=21) and 30% female (n=9). Differences also existed in medication use in the sample population. Over half (53.33%) of participants involved in this study were on medication at the time of data collection. A further 17% were medicated, but not on the day of data collection. Additionally, of the thirty children who participated in this trial, 27% had received chiropractic care either recently or in past years. The most recent chiropractic session was two weeks prior, the next most recent was over three months prior. 66.67% of the chiropractic first participants had a comorbid condition, while 40.00% of the control first had a comorbid condition. Of the demographic differences only the previous chiropractic and comorbid conditions showed significant difference between the control intervention first and the chiropractic intervention first participants (p=0.040 and p=0.040 respectively)

Randomisation

Randomisation resulted in fifteen (50%) receiving the chiropractic intervention first and fifteen participants (50%) receiving the control intervention first. The participants and attending chiropractor were blind to intervention allocation until after the first data collection was performed. No participant or guardian expressed any discontent with the randomisation procedure or the intervention allocation.

Equipment.

The equipment was problematic as the Eye Tribe Tracker had some technical drawbacks. The Eye Tribe Tracker was challenging to calibrate with some children and appeared to be somewhat unstable in its software platform, requiring many computer restarts, wasting time and frustrating participants and researchers alike (See section 4.2.10). Overall, twelve (40%) participants were unable to complete some parts of the assessment due to difficulties with

equipment calibration. For the three children who could not calibrate at all (the eye tracker could not capture any data from the participant) the process for randomisation was thus: the pre intervention calibration was attempted and after it was deemed unsuccessful the participant was still randomised using the QMinum program. The participant then received the intervention that was appropriate for their randomisation and post intervention calibration was attempted. As post calibration intervention was also unsuccessful these three participants were not included in data analysis.

Details of the calibration failures per task, excepting the three participants unable to calibrate for any task were:

Target: Two participants were unable to calibrate with the eye tracker pre or post control and one post control only. One participant could calibrate, but their post control data was not included in the analysis as their mother was holding their head still. This resulted in capturing all data for twenty-three (85.82%) participants, and partial data for another two (7.4%). For the chiropractic intervention, one participant was unable to calibrate pre or post-intervention, one pre chiropractic intervention only and two were unable post chiropractic intervention. This resulted in twenty-three participants (85.82%) with complete data collection pre and post chiropractic intervention and three participants (11.11%) with partial data collection. Those children with partial data sets were included in the analysis, but three children were excluded, as they were unable to calibrate for any session.

Reading: Thee participants were unable to calibrate with the eye tracker pre or post control and one pre control only. This resulted in capturing all data for twenty-four (88.89%) participants, and partial data for another one (3.7%). For the chiropractic intervention, all participants were able to calibrate for some part. Two participants were unable to calibrate pre intervention and four post chiropractic intervention. This resulted in twenty-one participants (77.78%) with complete data collection pre and post chiropractic intervention and six participants (22.22%) with partial data collection. Those children with partial

data sets were included in the analysis, but three children were excluded, as they were unable to calibrate for any session.

Interventions

For the chiropractic interventions one child expressed some reluctance to receiving a neck adjustment, so to accommodate his desires one segment in his cervical spine was adjusted with instrument assistance. Overall, the chiropractic intervention was well tolerated by guardians and children, some stating it "…was the best part…" of the study (see **Post study evaluation questionnaire**). There were no problems or issues arising from the control intervention. All participants engaged in the full series of movements with no concerns raised. No serious adverse events were reported related to the study interventions or assessments. Nor were any minor adverse events reported by participants relating to the provision of the chiropractic care, the control intervention or the testing of outcome measures.

Feasibility measures

Post-study evaluation questionnaire

All participants elected to take the post-study evaluation questionnaire home with them. All participants were emailed after data collection concluded (with a questionnaire attached) and asked to complete and return the questionnaire. According to Auckland University of Technology guidelines only one communication in this manner should be attempted. Of the twenty-seven participants and guardians able to fully participate in this study (those able to calibrate with the equipment), only seven (25.93%) sets of participants and guardians completed the post-study evaluation questionnaire. This percentage changes to a 30.4% return rate as some of the participants were siblings, meaning twenty-three not twenty-seven family groups were involved. However, the responses of those returned were overwhelmingly positive. The results below reflect the anecdotal impressions collected by the attending chiropractor and primary researcher during the course of the study.

Section one of the post-study evaluation questionnaire included questions 1-7 grading responses on a seven point Likert scale to capture participants' impressions of the study (1 being 'strongly disagree', 7 being 'strongly agree'; see Appendix 5). Table 2 describes their collaborative responses. As shown in table 2, overall responses were positive with 85.7-100% of participants strongly agreeing with statements. There were no Likert scores below a six given to any of the questions.

Table 2 Participants and guardians impression of the study

Post study question	Response given (*N*=7)	
	6 (agree)	7 (strongly agree)
1. The study was clearly explained to my child and I. N (%)	1 (14.3)	6 (85.7)
2. The study tasks were easy to understand and realistic to perform for my child and I.	1 (14.3)	6 (85.7)
3. I found it easy to communicate with the research staff.	1 (14.3)	6 (85.7)
4. I felt comfortable with the study's expectations of my child.	1 (14.3)	6 (85.7)
5. My child and I were happy with the care provided by the staff and chiropractor.	1 (14.3)	6 (85.7)
6. The research staff and chiropractor were responsive to my/my child's questions.	0 (0.00)	7 (100.00)
7. The time required to complete this study is reasonable for my child and I.	0 (0.00)	7 (100.00)

All Data are reported as n (%). Note: Scores of 1-5 are not shown as none of the questionnaires reported these values

A qualitative descriptive content analysis of participants' responses (Grove, Burns, & Gray, 2012; Sandelowski, 2000, 2010) revealed a number of themes (Elo & Kyngäs, 2008) running through participants' responses. Themes suggested from participant and guardians' responses are shown in table 3. 28.57% of responses recognised the difficulty some participants had with calibration and suggested better equipment would improve their experience.

The same number (28.57%) found the travel time arduous and a need for more locations from which to perform the study was identified. Children and guardians (57.14%) reported improvements in how they or their child felt after receiving the chiropractic intervention. These included; "…amazed at the [positive] difference between test sessions…" and "…able to fully complete a timed math's test for the first time ever…" and, that the attending chiropractor made the experience of the study enjoyable. Three questionnaires (42.86%) reported nothing the participants and guardians' did not like about the study. 57.14% reported the study procedures were described as "quick and easy". Finally, 42.86% of respondents reported that the researcher was willing to give information on many aspects of ADHD and involved the child participant in said discussions at a level they could understand and interpret. Also, one respondent (14.29%) noticed that after the study and the information gained from it, their child had "…a greater willingness to self-manage their own ADHD". Participation in the study revealed a need, by guardians and participants for more information regarding chiropractic and ADHD.

Table 3: Themes suggested from participant and guardian responses to the post study evaluation questionnaire.

Theme	*# Responses*	*% of returned evaluations (N = 7)*
Equipment difficulty	2	28.57
Travel	2	28.57
Enjoyment	4	57.14
Ease of use	4	57.14
Information	3	42.86

Secondary Outcome Measures

The following sections describe the results recorded for the outcome measures. The results of the mixed model repeated measure ANOVAs that tested for a group effect or a group by time interaction effect. Table 4 presents the outcome measure results of study participants' pre and post chiropractic intervention versus active control for the reading task.

Target Task

Visual target acquisition time. No significant interaction was found between intervention type and time, Wilks' Lambda = .997, F (1, 438) = 1.47, p = .23, partial eta squared = .003. Nor was there a main effect for time, Wilks' Lambda = 1.0, F (1, 438) = 0.020, p < .887, partial eta squared = .000, even though the chiropractic group experienced a large decrease in time to fixation and the control group a small increase in time (see table 4). The main effect comparing the two types of intervention was also not significant, F (1, 438) = 1.47, p = .23, partial eta squared = .003, suggesting no significant difference in the two interventions. However, as both groups started with large differences in their pre-intervention scores further investigation of this finding should be considered.

Target acquisition task: Number of distractions. Table 4 shows changes in the mean number of distractor target fixations for both group's pre and post-intervention. A multifactorial repeated measures ANOVA was not attempted, as the data set was not normally distributed and resistant to transformation. However, basic data description shows some interesting trends. The time to acquire a target reduced by 643.37ms in the chiropractic group, and increased by 1.43ms in the control group. The chiropractic group also exhibited a mean decrease of 1.47 distractor fixations while the control group increased their number of distractor fixations post-intervention by 0.64.

Table 4 Target task outcome measure results of study participant's pre and post chiropractic intervention versus active control

	Intervention								*Significance*	
	Chiropractic				Control					
Outcome	*N*	Pre	*N*	Post	*N*	Pre	*N*	Post	Group effect P value	Group by time interaction P Value
Visual target acquisition time (ms) *M (SD)*	25†	1550.00 (3583.84)	24†	906.63 (1502.63)	25†	981.95 (1437.58)	24†	983.29 (2047.83)	0.23	0.23
Number of distractions *M (SD)*	10*	4.2 (2.76)	8*	2.73 (1.68)	9*	3.82 (2.75)	7*	4.46 (3.01)	^	^

Note: N† are participants able to calibrate, N* are participants who exhibited a distractor behaviour. P value significance set at 0.05 ^= unable to perform group effect or group by time analysis as data was not normally distributed even after attempted data transformation to a normal distribution

Reading task.

Table 5 shows the outcome measure results of a participant's pre and post chiropractic intervention versus active control for the reading task. There was showed a significant interaction between intervention type and time, Wilks' Lambda = .988, F (4.5, 383) = 4.52, p = .035, partial eta squared = .012. There was a significant main effect for time, Wilks' Lambda = .986, F (5.5, 384) = 5.53, p < .019, partial eta squared = .014, with both groups showing a reduction in total reading time across the pre/post intervention periods (see Table 3.4). The main effect comparing the two types of intervention was also significant, F (1, 384) = 4.42, p = .034, partial eta squared = .012, suggesting a significant difference in the effectiveness of the two interventions.

Forward and reverse fixations and Saccades. Table 5, below, shows the changes in mean fixation time and number, and saccade length (both forward and reverse) pre and post either the chiropractic intervention or the active control. Overall the chiropractic group had shorter forward fixation time, post chiropractic decreasing by 76.78ms and the control increasing by 30.81ms, indicating faster processing time after the chiropractic intervention. Post chiropractic intervention there were 0.24 fewer forward saccades and post control 0.06 fewer. There was a reduction in reverse saccades (0.17 fewer) and reverse fixation time (reduction of 111.76ms) compared to 0.05 fewer reverse saccades and an increase of 48.38ms in reverse fixation time after the control intervention. The post control intervention showed a smaller decrease in overall reading time (108.35ms) compared to the post chiropractic intervention (646.87ms) Interestingly, both interventions showed a slight decrease in forward saccade length (chiropractic=6.75 pixels, control=5.64 pixels), however, the faster fixation/processing time exhibited by the chiropractic group countered this leading to a faster overall reading time.

Table 5 Reading task: Outcome measure results of study participant's pre and post chiropractic intervention versus active control

		Intervention								*Significance*	
		Chiropractic Intervention				Control Intervention					
Outcome+		*N*	Pre	*N*	Post	*N*	Pre	*N*	Post	Group effect P value	Group by time interaction P Value
Reading time	*M (SD)*	25†	4016.93 (1894.50)	23†	3370.06 (1508.91)	23†	3548.76 (1637.85)	24†	3440.41 (1971.01)	0.034	0.035
Number of forward fixations	*M (SD)*	25†	2.37 (1.14)	23†	2.13 (0.96)	23†	2.24 (1.15)	24†	2.18 (1.00)	^	^
Forward fixation time	*M (SD)*	25†	970.94 (645.49)	23†	894.16 (514.45)	23†	854.42 (469.52)	24†	885.23 (604.58)	^	^
Number reverse fixations	*M (SD)*	18*	1.21 (0.45)	20*	1.04 (0.21)	16*	1.22 (0.46)	19*	1.17 (0.59)	^	^
Reverse fixation time	*M (SD)*	18*	867.15 (672.2)	20*	755.39 (555.85)	16*	678.89 (506.73)	19*	727.23 (559.7)	^	^
Forward saccade length	*M (SD)*	25†	407.61 (135.41)	23†	400.86 (117.50)	23†	398.41 (96.74)	24†	392.77 (88.19)	^	^
Reverse saccade length	*M (SD)*	18*	284.24 (280.78)	20*	223.12 (150.09)	16*	253.37 (191.97)	19*	223.76 (142.95)	^	^

Note: + = per sentence. N† are participants able to calibrate, N* are participants who exhibited a reverse reading behaviour. Time is milliseconds and length in pixels. P value significance set at 0.05. ^= unable to perform group effect or group by time analysis as data was not normally distributed after attempted data transformation to a normal distribution

Post-hoc testing.

Due to the unexpected large group differences in the chiropractic and control pre intervention measures, post-hoc testing was undertaken to investigate any possible effects of intervention order. Tabulated data detailing outcome measure changes from order intervention is available in Appendix 9. Figures 3a, 3b, 4a and 4b show the outcome measures by which order they were delivered in. For both the number of distractions (in the target task) and total reading time (in the reading task), having the chiropractic intervention first seems to alter the data collected in the control intervention session. In both the target acquisition and reading tasks, the participants receiving the chiropractic intervention first show a different pattern of findings to the control-first control measures.

Figure 3a shows the number of distractions for the chiropractic first and control first interventions. Both pre-intervention measures start relatively similarly (4.14 and 4.5 distractions for control and chiropractic interventions respectively). Post-intervention, the participants who received the control intervention show more distractions (5.57 distractions), while those who received the chiropractic intervention showed less (3.0 distractions).

Figure 3b shows the number of distractions for the chiropractic second and control second interventions. The pre-intervention measures for those who received the chiropractic intervention second (figure 3b: dashed line (4.14 distractions)) are similar to the pre-intervention values for the chiropractic first and control first measures, as was expected. However, the pre-intervention measures of those who received the control second (figure 3b: solid line (3.25 distractions)) are different than expected. The pre-intervention values for the control second (3.25 distractions) are closer to the post-intervention chiropractic first (3.0 distractions) values, rather than the pre-intervention chiropractic and control first measures (4.14-4.5 distractions).

Figure 3a: Number of target distractions for the chiropractic first and control first interventions.

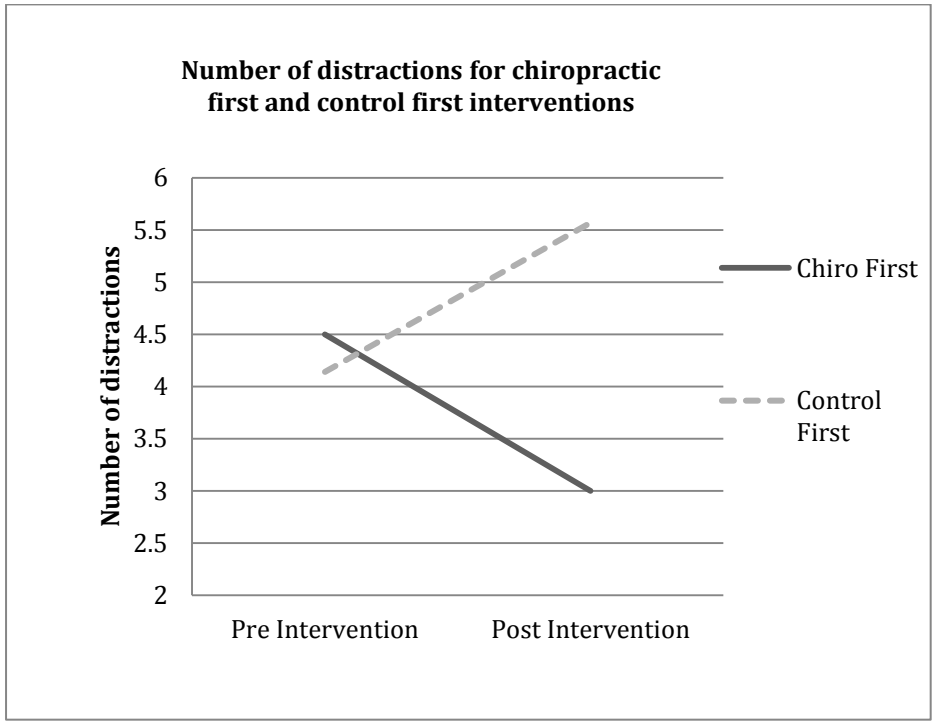


Figure 3a: The number of distractions for the chiropractic first and control first interventions. Both pre-intervention measures start relatively similarly (4.14 and 4.5 distractions for control and chiropractic interventions respectively). Post-intervention, the participants who received the control intervention show more distractions (5.57 distractions), while those who received the chiropractic intervention showed less (3.0 distractions).

Figure 3b: Number of target distractions for the chiropractic second and control second interventions.

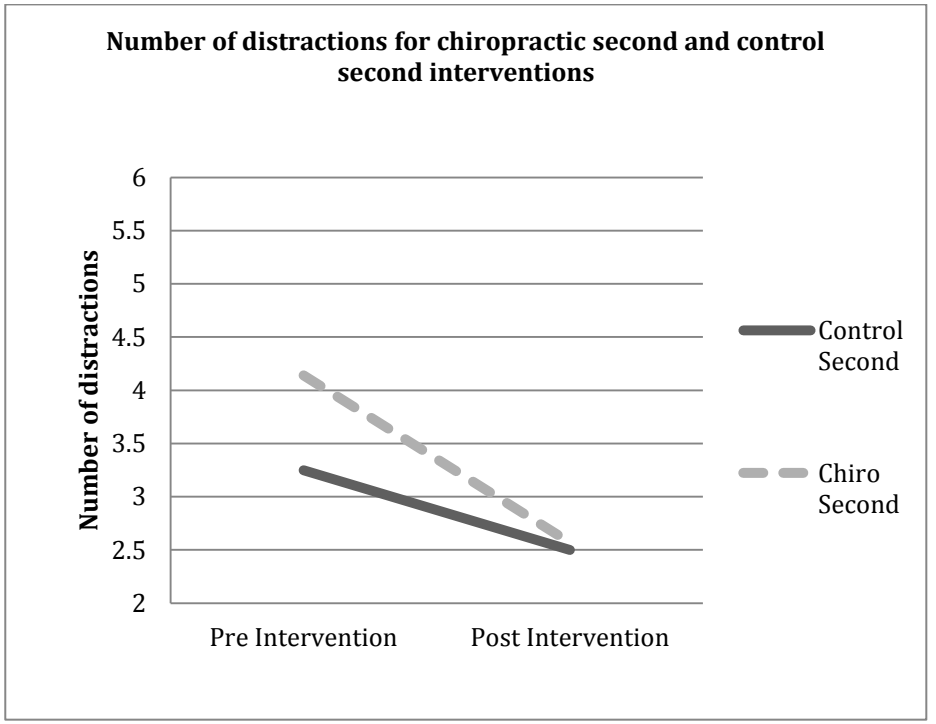


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Figure 4a shows the reading time for the chiropractic first (4208.89ms) and control first (3809.75ms) interventions. Post-intervention the participants who received the control intervention showed a longer reading time (3977.46ms), while those who received the chiropractic intervention showed a shorter reading time (3620.73ms).

Figure 4b shows reading time for the chiropractic second and control second interventions. The pre-intervention measures for both the control second and chiropractic second start lower (faster reading time of 3327.38ms and 3708.12ms respectively), which was expected as participants were reading similar sentences in close time proximity to their first reading time. The pre intervention measures for the control first (figure 4a: dashed line (3809.75ms)) and chiropractic second (figure 4b: solid line (3708.12ms)) are also similar, another expected result. What was not expected was those who received the control second (figure 4b: red line) to have such low values measured (3327.38ms) at their pre-intervention control second session. These pre-intervention values are lower than any of the chiropractic or control first values, either pre or post-intervention. These data for the target and reading tasks seem to show undergoing the chiropractic intervention before the control intervention affects the control outcome measures.

Figure 4a: Order effect in the reading task: chiropractic first and control first interventions

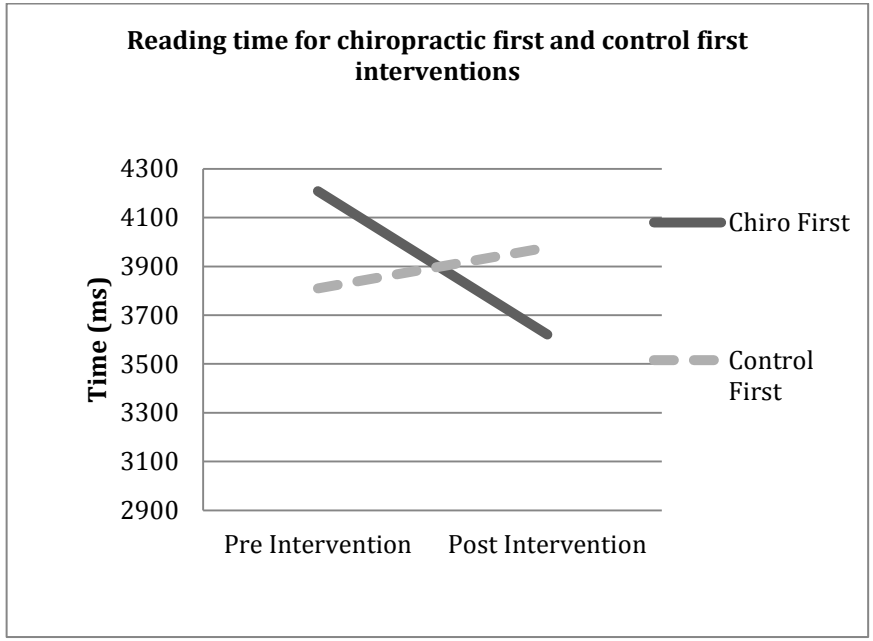

Figure 4a. The reading time for the chiropractic first (4208.89ms) and control first (3809.75ms) interventions. Post-intervention the participants who received the control intervention showed a longer reading time (3977.46ms), while those who received the chiropractic intervention showed a shorter reading time (3620.73ms).

Figure 4b: Order effect in the reading task: chiropractic second and control second interventions

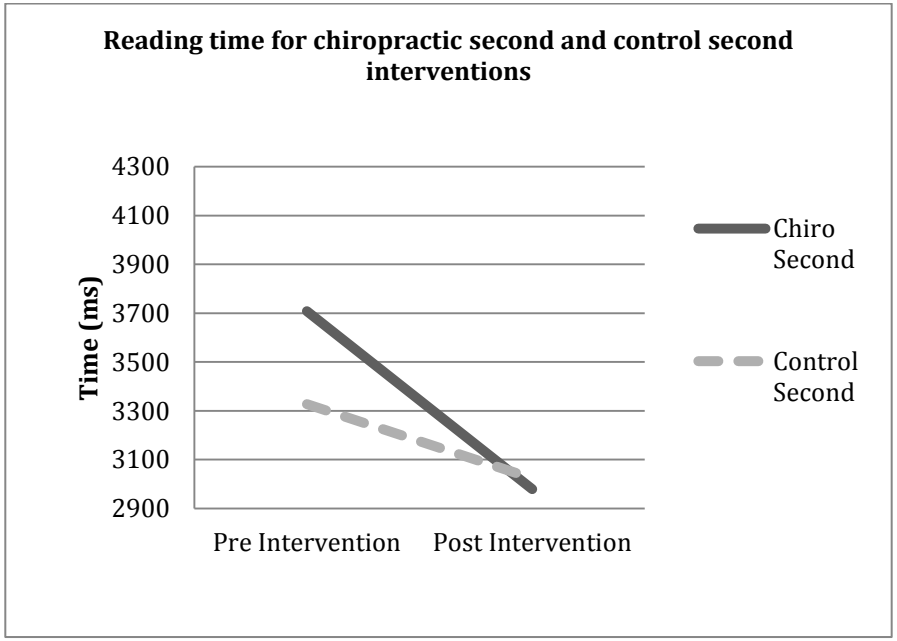

Figure 4b. Reading time for the chiropractic second and control second interventions. The pre-intervention measures for both the control second and chiropractic second start lower (faster reading time of 3327.38ms and 3708.12ms respectively). The pre intervention measures for the control first (figure 4a: dashed line (3809.75ms)) and chiropractic second (figure 4b: solid line (3708.12ms)) are also similar. What was not expected was those who received the control second (figure 4b: red line) to have such low values measured (3327.38ms) at their pre-intervention control second session.

Chapter 4: Discussion

Key findings

This pilot study was designed with specific feasibility aims, in order to test all aspects of its processes for future studies. The first goal of this study was to evaluate specific feasibility areas and to identify any barriers to adherence to the study protocol. The areas assessed were; participant randomisation, researchers' recruiting ability, the number of eligible participants available, how participant characteristics may have affected the proposed outcome measures, equipment, retention rates, evaluation questionnaire response rates and intervention acceptability. This study suggests that a future randomized clinical trial comparing the efficacy of a chiropractic intervention with that of an active control intervention on oculomotor function in children with ADHD is feasible - with modifications to some study processes. The recommended amendments to some aspects of this study's processes will enhance the likelihood of gaining more accurate and appropriate outcomes in future work.

The secondary scientific findings of this study were that of statistically significant improvements in total sentence task reading time post the chiropractic intervention as compared to post control. These findings provide some support for the hypothesis that a single chiropractic intervention improves oculomotor control in children with ADHD. The remaining outcome data, not related to reading time, shows trends towards improvements post chiropractic intervention, but is not statistically significant. Nearly all of the reading and target outcomes improved post chiropractic invention, indicating better reading ability and decreased distractibility (Damyanovich et al., 2013; Duchowski, 2007; Yang, 2006). One important issue regarding the secondary findings of this study was that of order of intervention. Post-hoc analysis of data for the target and

reading tasks seems to show undergoing the chiropractic intervention first, before the control intervention affects control-second outcome measures.

Feasibility.

As is described above most of the participants recruited to this study were members of an Auckland ADHD support group, who were contacted by emailed, courtesy of the group manager. Any future studies would be well placed to continue advertising in this way, as it proved to be a successful recruitment relationship. Of note regarding the recruitment phase a number of guardians missed out on their children being involved due to responding only after recruitment had closed. This was likely due to the fact that recruitment and data collection took place around the end of the school term, and close to the Christmas break. Those who missed out on participation expressed disappointment and the desire to be involved in any future, similar studies. This seems to speak positively for recruitment to future research studies. Perhaps, as the data collection for a larger study is likely to take longer, non-participation from failure to respond may be lessened. However, the reason for non-response to communication is largely unknown.

Additionally, regarding participant recruitment, a convenience or availability sampling method was used for this study, which may have resulted in sampling bias (Acharya et al., 2013). There is a very small, but possible, potential for negative side effects with chiropractic intervention (Miller & Benfield, 2008; Todd, Carroll, Robinson, & Mitchell, 2015), thus, using a convenience sampling method allows participants entry to the study only if they wish to receive chiropractic care. The study's inclusion criteria were also very open and non-restrictive, but the exclusion criteria, while useful for defining participant age, but was not specific enough regarding reading. The exclusion criteria were: any child who had been medically diagnosed with comorbid conditions that seriously altered their reading ability (major visual disabilities or reading deficits from sources other than ADHD). This did not exclude illiterate children who had no

medical explanation for their inability to read, or children who were non-verbal (the reading task required answering a question). A future prudent addendum to eligibility would require participant's to be verbal and able to read in some manner. As well as limited exclusion criteria the attending chiropractor was the freedom to use their judgement on where in the spine to deliver an adjustive thrust to the participant, as would happen in normal practice. These factors, while enhancing the external validity and potential generalisation of the study, did provide a trade-off with internal validity as the chiropractic adjustments differed in vertebral level from participant to participant.

In a pilot study, such as this one, some baseline characteristic differences were inevitable due to the small sample size used in this study. Of the baseline characteristics between the chiropractic intervention first and the control intervention first participants only previous chiropractic care and comorbid conditions were statistically significant ($p=0.04$ for both). Of the thirty children who participated in this trial, 27% had received chiropractic care, either recently or in past years. The most recent chiropractic session was two weeks prior, the next most recent over three months prior. No study has yet aimed to record changes from a single chiropractic intervention past 30 minutes, so it is possible that previous chiropractic care may have altered the baseline secondary outcome measures collected. Post-hoc analysis of data from this study seems to show undergoing the chiropractic intervention before the control intervention affects the control outcome measures, suggesting previous chiropractic care may have affected the outcomes measured. That said, only one participant received chiropractic care two weeks beforehand, the next most recent being three months before the trial, so while possible, it seems unlikely previous chiropractic care could have significantly affected this study's data collected.

The presence of comorbid disorders could have affected the baseline data for the chiropractic or control first interventions also. While disorders comorbid to ADHD (dyslexia, dyspraxia, ASD) share characteristics to ADHD, they differ in

their aetiology and slightly in their areas of brain dysfunction (Vidyasagar & Pammer, 2010). However, these disorders do seem to also affect oculomotor function (Deans, 2010; Fletcher-Watson, Leekam, Benson, Frank, & Findlay, 2009; Garcia Dominguez, Stieben, Perez Velazquez, & Shanker, 2013; Tseng et al., 2013; Vidyasagar & Pammer, 2010; Wagner et al., 2013) and some can respond to oculomotor retraining (Fischer & Hartnegg, 2000; Solan et al., 2001; Solan et al., 2003). But there appears to be a vast gap in the literature regarding these outcomes in the ADHD population. The most difficult issue in relating these findings to previous research is the minimal amount of published research available to appraise (Cade, 2016). In light of the participants' baseline differences, additional statistical analyses were originally planned to investigate if they could have affected participants' outcomes. However, as the entire sample was relatively small further breaking it down (via comorbidities or past chiropractic care) would likely lead to flawed conclusions (S. Taylor, personal communication, 23rd January 2017). Thus, at this point in time care it is not possible to say whether baseline differences for each intervention had an effect on oculomotor outcomes.

While baseline differences for the chiropractic or control first interventions did exist in this study, one of its strengths were the use of an unpredictable randomisation sequencer QMinum (Saghaei, 2011), and the maintenance of group allocation concealment until after the participant's baseline assessment was performed (Grimes & Schulz, 2002; Schulz & Grimes, 2002). The random approach to allocation meant the attending researcher was unable to predict which group participants would be assigned to, disallowing any chance to influence baseline data collection or bias reporting test results. Randomisation was balanced by age and sex only, so this (along with the relatively small sample size) was likely another reason baseline differences appeared between the intervention allocation groups. Another reason for baseline gender differences in the participants studies is that ADHD is a more common diagnosis in boys compare to girls (Barkley, 2014).

Staying in the subject of group allocation and feasibility issues comes that of blinding. Unlike drug trials, where different medication can be disguised to look the same, the difference between a manual therapy, like chiropractic, and a control is often clear. Trials like this one cannot effectively blind either the participants or their guardians (Rosner, 2012). Previous studies (Alcantara, Alcantara, & Alcantara, 2011) have suggested that participants who know their allocation may alter their behaviour due to an internal bias, or that guardians may report more changes in their children when they know their child has been allocated to the treatment group. However, follow-up studies to Alcantara et al. (2011) showed parental bias seemed to have minimal effects on outcomes (Miller, Newell, & Bolton, 2012). For this study, parental reports were limited to the post-study evaluation questionnaire and used for feasibility aspects, not for evaluating intervention effects. Also, due to the nature and type of outcome measures tested (computerised recording of oculomotor behaviour) unconscious reporting bias would likely have been minimised as oculomotor outcomes such as these are not collected via participant, guardian or researcher reporting, only via computerised recording. This is because oculomotor outcomes are instinctive in nature and there is no evidence that humans can easily change the length, timing, and direction of their saccades and fixations at will (Mahone, 2012; Medland et al., 2010; Yang, 2006). Only with consistent up-skilling over a long period of time, such as moving from a novice to experienced reader, can these outcome measures be changed (Hayhoe & Ballard, 2005; Tseng et al., 2013)

Other chiropractic-based studies (Holt et al., 2016) raise the possibility that the extra attention given by the practitioner during the chiropractic intervention may affect participants' outcomes, as the participant may feel they are required to 'repay' the practitioner for their attention and try harder to concentrate on testing. This study attempted to negate this type participant-chiropractor interaction effect by using an active control that had physical touch and attention. Also, as above, short-term bursts of will power or concentration does not seem to alter oculomotor outcomes (Damyanovich et al., 2013; Hayhoe & Ballard, 2005; Tseng et al., 2013; Yang, 2006).

The physical examination prior to chiropractic intervention may have also affected post-intervention outcomes. For those patients a chiropractor has not adjusted before a physical examination of the patient is required. This includes, but is not limited to, appropriate range of movement, orthopaedic and neurological testing, plus an examination of inter-segmental vertebral motion. All of these affect input to the patients vestibular system (Kandel et al., 2000), possibly affecting their oculomotor abilities (Treleaven, 2008a; Treleaven & Takasaki, 2014). To reduce any possible effects of additional vestibular or proprioceptive input an abbreviated, but patient-appropriate, physical examination was performed, palpation of the spine was kept to a minimum and an active control was used so each participant received similar attention, touch and vestibular input (Kandel et al., 2000).

Many researchers previously also suggested that any changes following chiropractic care would likely be due to the placebo effect from the chiropractor's attention, manual palpation and enthusiasm (Ernst & Harkness, 2001; Kaptchuk, 2002; Vernon et al., 2012). It is certainly possible that two interactions with the attending chiropractor may have influenced the participants to put more effort into their assessment and to attend to the test more. However, Hróbjartsson and Gøtzsche (2001) found little evidence that placebos, in general, have powerful clinical effects after conducting a systematic review of clinical trials. They compared placebo with no treatment and revealed no significant effects of a placebo on objectively measured outcomes (Hróbjartsson & Gøtzsche, 2001). This would seem to suggest that a placebo effect would be unlikely to affect objective outcome measures like those used in this study. However, as a sham or placebo treatment was not used in this study, placebo effects cannot be totally discounted as a possible source of outcome measure changes (Hróbjartsson & Gøtzsche, 2001). Again, as is discussed above, participants' extra focus or attention is unlikely to affect oculomotor outcomes (Damyanovich et al., 2013; Hayhoe & Ballard, 2005; Tseng et al., 2013; Yang, 2006).

The post-study evaluation questionnaire responses and anecdotal evidence suggest participants found it to be a positive experience, further reinforced by positive feedback from their guardians (see below for further discussion). Reflecting this enjoyment was that all participants (100%) attended their second session, and there were zero dropouts during the study. These attrition and attendance rates are exceptional when compared to rates reported by others (Karlson & Rapoff, 2009). A systematic review by Karlson and Rapoff (2009) reporting mean attrition rates of 20% (0-54%) for initial follow-ups for randomised controlled trials involving children with chronic conditions. A minor issue regarding attendance was that each of the face-to-face sessions with participants (consent/assent, data collection and intervention) was expected to take between 30-45 minutes to complete. In actuality, each session took between 30-60 minutes to complete due to the participants and guardians interest in discussing the study and its associated research. Future studies should modify their advertising and information sheets to reflect this, as the extra time used in discussion with those involved in this study seemed to be one of its more appreciated features.

A procedural issue that affecting this study's feasibility was one sentence in the reading task seemed to confuse many participants. It read; "A fish has two arms and legs" in the pre-intervention testing and "A fish has six arms and legs" in the post-intervention testing. Clearly, this is a factually incorrect statement and it seemed to give participants pause, lengthening the time needed to read the sentence. Some participants even stopped and looked at their parent or the researcher for confirmation they were reading the sentence correctly. At least five participants commented during the testing procedure that it was a "silly" or "dumb" question, possibly creating a confounding factor in the data.

Despite the above procedural issues, guardian and participant response to this study was positive. All attendees reported (verbally or in the evaluation

questionnaire) that they would be happy to be involved in future research of this kind. While attendance was exceptional for this study, only seven of thirty possible questionnaires were returned making an in depth investigation of all participants' and a guardians' thoughts in the study difficult. A possible reason for the low return rate is that some participants were siblings; meaning twenty-three (not thirty) family groups were involved. In effect meaning there was a 30.4% response rate. Previous research shows the response rates to email based questionnaires ranges from 25-30% without a second, follow-up email (Yun & Trumbo, 2000), thus return rates for this study's evaluation questionnaire are not abnormal. Other possible issues with the low return rate were; many guardians gave formative feedback during the sessions, possibly leading them to think that feedback was adequate; study protocol stating that the questionnaire was voluntary and finally, the fact that many guardians took the questionnaire home and failed to return it. All study participants were contacted after the second session had concluded, via email (which included an electronic copy of the questionnaire), and asked to complete and return the questionnaire. A second, reminder email, may have improved questionnaire return rate (Yun & Trumbo, 2000). While participant responses to this study were positive, the fact remains that only seven participants gave feedback, thus their results cannot be generalised to the remainder of the study participants.

The main negative feedback collected was around the computerised eye tracker and its calibration difficulties. Future studies would be wise to use a more reliably calibrating eye tracker to help correct this issue. The remaining issue uncovered by the questionnaire was of travel distance, which presents a problem given the size of the greater Auckland area and its continual traffic issues. Even moving to a practice-based method similar to that used by Holt (2016) where interventions were given over a number of weeks by chiropractors in different areas does not solve this issue completely as all participants came to the New Zealand College of Chiropractic laboratory three times for data collection during the study. It is possible, due to the portable nature of the eye tracker, that data collection could be performed in various locations. However, this does raise the

issue of inter-setting variability and how this may affect any participant's concentration and attention to the tasks involved in data collection.

After data collection and preliminary analyses, a methodological query also arose concerning the order of intervention, which speaks to the primary feasibility of the study. After post-hoc analyses reviewed outcome measurements by which intervention came first, data appear to show if the chiropractic intervention came first it had an effect on the control-second baseline values (see figures 3a, 3b, 4a and 4b). These analyses would suggest that a one-week washout period was not enough to remove the effects of a single session of chiropractic care. For this study the average time between sessions was 10 days, meaning that this time period may not have been long enough either. In light of this, any future studies would be recommended to either move to a parallel study design, or extend the washout time period. Prior to that, it would be worth conducting other studies relating to the length of time changes can be seen after a single chiropractic adjusting session before moving forward with another cross-over design study. This would be true for any cross over study design involving the application of a physical treatment in that unless the dose-dependent effects of the treatment are well known a parallel design would be better suited (Redmond & Colton, 2001).

Secondary Endpoints.

As discussed above, there were no dropouts, but some participants could not complete all assessments. Three of the thirty participants were unable to calibrate at all with equipment at all, five participants had calibration difficulty with the target task, and six with the reading task leading to incomplete data sets. Nonetheless, all participants, including those with calibration issues, returned for their follow-up session. The use of a multifactorial repeated measures ANOVA approach to the statistical analysis meant that participant's results, even with missing data sets, still contributed to the intention-to-treat statistical analysis

(ITT). ITT Also minimises allows for the greatest general applicability of results (Gupta, 2011).

In terms of scientific aims, as the sample size was small Type II errors are possible (Gurusamy, Gluud, Nikolova, & Davidson, 2011). However, the significant changes seen in total reading time suggest not all of the data is at risk of a Type II errors, but more to do with the order of the intervention. Data entry checking procedures were utilised to improve data quality and reduce the chance of outliers occurring due to data entry errors, in accordance with recommendations made by Büchele et al. (2005).

A strength of this study is that the outcome measures used have been previously well studied (Deans, 2010; Mahone, 2012; Tseng et al., 2013). So much so that previous researchers were able to infer diagnosis for ADHD in the without using any other type of examination procedures (Deans, 2010; Mahone, 2012; Tseng et al., 2013). But, there are procedural issues in this study that may have affected its measured outcomes. A normal reader takes approximately 220ms to fixate on a target presented on a screen (Yang, 2006). This study set fixation thresholds at 300ms as a precautionary buffer to weed out micro-saccadic movements that can be confused with fixations involving information processing (Fried et al., 2014). Other research suggests setting a lower threshold, 100ms, for fixation may be more appropriate (Inhoff, Eiter, Radach, & Juhasz, 2003; Jacob & Karn, 2003; Radach, 1998). It is possible this study missed out on collecting pertinent data as the threshold for fixation was set at 300ms. Future studies could collect data on short fixations also, to investigate whether any type of intervention changes smaller fixation times.

Reaction time may also be a confounding factor in this study. As part of the reading task participants were instructed to press the space bar as soon as they had finished reading the sentence displayed. Clearly, the cortical processing involved in pressing the space bar is more than is required for reading and

processing the sentence displayed. It brings into play the possibility of changes in reaction time. It is possible to argue that some of the changes seen in this study related to improved reaction speed and changes in sensorimotor processing, as seen in previous studies (Holt et al., 2016; Kelly, Murphy, & Backhouse, 2000). To remove reaction time as a confounding factor, sentence-reading time was taken from the first fixation after the green "GO" button disappeared, to the second-to-last fixation before the participant pressed the space bar.

While not statistically significant, possibly due to the effect of order of intervention, preliminary data suggests post the chiropractic intervention participants had shorter forward fixations, fewer forward saccades and a reduction in reverse saccades and fixation time. These findings suggest faster basic cognitive processing of information and better decision making on where to shift gaze to next (Brysbaert et al., 2005; Hayhoe & Ballard, 2005; Yang, 2006). Post the control intervention there was a smaller decrease in overall reading time and a mildly reduced number of forward saccades, but participants increased both their forward and reverse fixation time – indicating basic cognitive processing of where to move the eye to next was taking longer (Brysbaert et al., 2005; Hayhoe & Ballard, 2005; Yang, 2006). Interestingly, both groups showed a slight decrease in forward saccade length, usually an indicator of poorer reading behaviour (Brysbaert et al., 2005; Hayhoe & Ballard, 2005; Yang, 2006), however, the reduced fixation/processing time experienced after the chiropractic intervention would counter this leading to the faster overall reading time. The caveat of this discussion is that, excepting reading time, none of the data was statistically significant, thus it can only be said to show trends or possibilities in the data, warranting further investigation.

Another concept to note is that none of the outcomes tested were strict measures of cognitive ability (Hayhoe & Ballard, 2005; Tseng et al., 2013). Improvements in oculomotor function can only infer improvements in reading and cognitive

ability (Duchowski, 2007). An additional step in the reading task, for future studies, could be to add a 'correct/incorrect' metric to each question asked in the sentence-reading task. This may allow a better inference of cognitive processing regarding the sentence content (Duchowski, 2007), i.e. did the participants actually read the sentence and, and more importantly, did they understand the content.

To date, the effects of chiropractic care on the neurological function of children diagnosed with ADHD have not been investigated thoroughly and are limited mostly to case studies and retrospective case reviews (Karpouzis, Pollard, & Bonello, 2009). This study shows that chiropractic intervention does influence oculomotor control and reading speed. What is still unclear at this time is how this happens and if this translates to an improvement in reading ability. All that can be shown, regarding the secondary endpoints of this study, is that adjusting the spine does seem to result in improvements in oculomotor control. There are a number of possible mechanisms that may have contributed to and help explain the significant differences observed in this study. They include chiropractic affecting sensorimotor integration (within the CNS) through altered proprioceptive input from spinal origins, and possible placebo effects. Dysfunctional spinal input has been shown to affect oculomotor function in a variety of settings (Treleaven, 2008a; Treleaven & Takasaki, 2014). Altered afferent inputs from dysfunctional spinal joints might affect oculomotor control via altered sensorimotor integration also (Bolton & Holland, 1998). Manipulation of dysfunctional spinal joints can alter somatosensory filtering of afferent inputs (Haavik-Taylor & Murphy, 2007a, 2007b, 2007c). Haavik-Taylor and Murphy (2007b) showed altered somatosensory processing, sensorimotor integration, and motor control after manipulation of cervical spine joints. Multiple previous studies show that adjusting the spine leads to changes in somatosensory processing, sensorimotor integration, and motor control of both upper and lower limb muscles (Haavik & Murphy, 2011, 2012; Holt et al., 2016; Niazi et al., 2015; Palmgren et al., 2006; Taylor et al., 2010). As oculomotor control relies on accurate sensory processing (Irwin, 1998; Sereno & Rayner,

2003), it is possible that aberrant afferent input could change somatosensory processing enough to alter oculomotor control.

A further step in understanding the puzzle associating spinal and also chiropractic's role in oculomotor control is the Lelic et al. (2016) study showing alterations in the prefrontal cortex with chiropractic adjustments to the spine. The prefrontal cortex is the 'decision-making' area of the brain that unconsciously decides where to make the next saccade move the eye (Hung, Driver, & Walsh, 2011). According to Willcutt et al. (2010) those with ADHD show a cognitive marker of poor processing speed implicating the prefrontal cortex as an area of dysfunction (Funahashi & Andreau, 2013). It is currently unknown what drives eye movement forward from one word to the next, but higher-level cognitive processes and executive functioning are thought to be involved. Those with ADHD are known to have problems with executive functions, word processing ability and decision making ability, which are functions associated with the prefrontal cortex (Hart et al., 2013; Hung et al., 2011; Willcutt et al., 2010)The prefrontal cortex function also influences reaction times, responses to stimuli, and inhibition of irrelevant distraction, all of which are necessary for reading and comprehension (Deans, 2010; Dirlikov et al., 2015; Inhoff et al., 2003; Rayner, 1998b; Vidyasagar & Pammer, 2010). The prefrontal cortex contains the frontal eye fields that are essential for the control of eye movements (Fukushima et al., 2004). As this area of the brain is morphologically altered in children with ADHD (Dickstein et al., 2006; Dirlikov et al., 2015; Valera et al., 2007) it is plausible that adjusting subluxations in children with ADHD may alter their prefrontal function, in turn altering oculomotor function.

More studies have shown that chiropractic care can also lead to changes in multimodal integration involving visual and auditory inputs (Holt et al., 2016), suggesting chiropractic may well alter visual processing and central oculomotor control. Holt et al. (2016) reported changes in sensorimotor integration in older

adults who received chiropractic care. The greatest gains in their sensory and motor outcome tests were recorded after 4 weeks of consistent chiropractic care (Holt, 2016). This suggests further studies into the effects of chiropractic on oculomotor control may be wise to use repeated intervention sessions over a number of weeks. In other studies a repeated application, of different types of intervention, has shown promise for improving oculomotor function in children (Fischer & Hartnegg, 2000; Solan et al., 2001; Solan et al., 2003).

What is particularly interesting is that the function of the spine has a significant impact on the control of eye movements (Treleaven, 2008a). If chiropractic care enhances oculomotor control in children with ADHD it may also potentially enhance their reading performance and academic performance as well. With more sensitive technology oculomotor outcomes could be tracked in longitudinal studies to investigate whether chiropractic care influences reading behaviour and target acquisition in a way that affects reading comprehension in children with ADHD. This study (and previous others in the area of oculomotor control) have shown that it is possible to alter oculomotor function positively (Fischer & Hartnegg, 2000; Solan et al., 2001; Treleaven, 2008a, 2008b; Treleaven & Takasaki, 2014). What should be the most important driver of future research is how serious the long-term effects of poor oculomotor control can be for a child with ADHD. Combined with the lack of well-researched interventions available it is clear that more targeted, methodologically sound research must be performed in this area in the near future. Further research is needed to provide clarity on which mechanisms are involved in the improvements observed in this trial and to substantiate the findings. Further research should also attempt to investigate whether the improvements in oculomotor outcomes shown relate to an overall improvement in reading ability.

Study Limitations

This study shows promise in investigating chiropractic's effects on oculomotor control and reading behaviour in children with ADHD. However, the design of the study limits what conclusions can be made due to issues like specificity and accuracy with eye tracker itself, setting interruptions and the effect of the intervention order.

One of the more significant limitations to this study was the eye tracker itself. The Eye Tribe tracker is calibrated when the participant sits approximately 60cm (a range of 45-80cm) away from the tracker. Its best accuracy (a 'perfect' score) corresponds to an on-screen average error of 0.5 to 1cm (Tribe, 2014). 'Perfect' calibration gives a less than 0.5° level of accuracy and a 'moderate' (still usable (Ooms et al., 2015)) calibration is less than 1° (Ooms et al., 2015; Tribe, 2014). This study accepted only 'perfect' and 'moderate' calibration. Undoubtedly, utilising calibration over a range of accuracies would create some variance in fixation points or saccade length measurements.

Previous research is also divided around the accuracy and precision on the Eye Tribe eye tracker, suggesting it is useful for specific oculomotor metrics (Dalmaijer, 2014) but only with carefully maintained set-up (Ooms et al., 2015). As this study's testing set-up had some issues (distance, potential to be bumped) accuracy may have been unwittingly compromised during data collection. Furthermore, some participants mentioned they could "see the whole screen [display]" without actually having to move their eyes. Even though all participants were all similarly instructed to move their eyes to read or acquire targets, the possibility of participants' not actively moving their eyes remains an issue. Perhaps as the target dots do not require cognitive processing for information, this confounding factor was made more likely. In future trials, an alteration to the process may include asking participants to acquire a target that requires simple cognitive processing for content recognition. Such as, finding the target letter 'A' in a field of distractor '4's'.

The eye tracker used was not a fixed system; rather it sat on a tripod in front of the screen (see figure 1). Thus, any movement of the table, or knocks to the tracker required time-consuming re-calibration of the tracker. Lastly, this particular eye tracker set-up relies on the participant staying between 45-80cm away (Tribe, 2014) from the tracker and screen. As expected in a child with ADHD, some exhibited enthusiastic and frequent movements of their head, even when seated. Unless the researchers were to fix the participants heads to the chair eye tracker calibration distance would be difficult to maintain, especially in younger, more active children. To work around this issue, children were instructed to lean back into the chair provided and their heads were propped with pillows to minimise movement but, understandably, this did not negate all movement out of the eye trackers range.

A procedural issue, and limitation, that became obvious in the execution of this study was that of parental interruptions. Children were examined in a variety of settings, either the New Zealand College of Chiropractic laboratory or their homes. Most guardians chose to utilise weekends to attend the study, and many bought siblings with them, or siblings were present at home. While great care was taken to instruct all participants and guardians in a similar way, there were a number of interruptions from excited siblings, participants wanting to speak to guardians and the occasional guardian interruption of the study (to "help" with instructions). If future studies in this vein were undertaken perhaps providing a moveable screen between the participant and their family would be of help, or to have a separate waiting/play area for other children. This, however, would be more difficult to apply in a home-based setting. Fully separating participants and guardians would not be advisable as New Zealand Health and Disabilities law requires the presence of a guardian when a child under the age of medical consent is being adjusted by a chiropractor (King, 2000). On a more anecdotal note, and in the author's clinical experience, separating children from their guardians in a novel environment may cause more distraction and non-compliance than having the occasional guardian interruption.

Just as participant effort and concentration may affect a study, investigator efforts may do the same as well. As the primary investigator, also the attending chiropractor and using this study to complete a Master's thesis, the author had a number of motivators to complete this study and show "good" or promising results: a risk of examiner bias. These influences could have shaped the study and the communication of its findings, no matter how much objectivity was aimed for. This, while possible, is unlikely as the oculomotor outcomes measured seem to only respond to persistent training over time (Deans, 2010; Mahone, 2012; Tseng et al., 2013) or, as this study suggests, to chiropractic intervention. Due to the small number of evaluation questionnaires returned it is not possible to ascertain if evaluation reports were influenced in any way. But, any future studies could avoid any suggestion of bias by having another researcher with less personal involvement collect the data.

Lastly, the choice of study design limits the interpretation of this study's data. Post-hoc analysis of the outcome measures collected suggests that the effects of a single chiropractic adjustment may have lasted over the washout period used. In effect, receiving the chiropractic intervention first seemed to affect the control values recorded, suggesting a parallel group design would have been a better choice for this study.

The results of this study should not yet be generalised to the population. This study was designed, first and foremost, to test study feasibility not to show a treatment effect. While it is true that this study does show a small (though significant) effect of a single chiropractic adjustment on oculomotor function it should be viewed as a proof-of-concept design (Thabane et al., 2010). While the sample studied has similar baseline characteristics (previous chiropractic care and comorbidities) to that of the general ADHD population (American Psychiatric Association, 2013; Barkley, 2014; Barkley et al., 2002; Bauermeister et al., 2007; Brown et al., 2001) issues with eye tracking equipment, study

settings, and data collection parameters make it prudent to commit to further similar studies before generalising the results of this one study. Correcting these issues for future studies would increase their robustness and possibly generate findings that could be used to drive clinical treatment changes for the ADHD population.

Recommendations for future research.

This study succeeded in its primary aims to provide a useful platform from which to build further research. It allowed real-world testing of procedures, equipment, and recruitment strategies for testing a novel combination of intervention and outcome measures. Future studies can use the experience gained from this pilot to alter some of its execution (settings and equipment) to improve their reliability, validity, and general applicability. This study has provided some thought-provoking learning regarding methodology, processing, and experience, and has resulted in many procedures being reviewed that will improve future research. Two important revelations have come from completing this study; Firstly, that a more advanced eye tracker should be used to assist in recording specific oculomotor metrics (Sasson & Elison, 2012; Uppal et al., 2011). Secondly, that a parallel design study would be recommended, instead of a cross over design, as receiving chiropractic first seemed to alter control outcome measures.

Other changes could include chiropractic care over a number of weeks, as has been previously trialled for other types of intervention (Fischer & Hartnegg, 2000; Solan et al., 2001; Solan et al., 2003). Also, alteration in testing procedures might include reducing intrusions into testing times or adding a cognitive element to target acquisition or to the reading task. For instance, requiring the participant to identify a target A in a field of 4's, or rating a participant's responses to questions asked (about the content of each sentence) as correct or incorrect. Further to this removing factually incorrect questions that confuse participants would be wise. In future studies having two different sentence sets

(with similar difficulty) for each intervention session would also be wise, to better control for participants learning or remembering sentences from their first session. With longer-term trials other outcomes could be recorded and included, such as parent or teacher-reported changes in behaviour or learning ability, changes in reading comprehension over time or other quality of life changes. Additionally, future research could include another therapy to form a comparative effectiveness study.

As it stands and from a scientific viewpoint, this pilot study adds to the growing body of evidence that suggests chiropractic care influences neurological function (Haavik-Taylor & Murphy, 2010; Haavik & Murphy, 2012; Lelic et al., 2016; Niazi et al., 2015). It is possible that chiropractors may play a role in enhancing the neurological and oculomotor function of individuals with ADHD. This study noted that total sentence reading time improved in children with ADHD after a single session of chiropractic care when compared to an active control. This is an outcome measure associated with improved oculomotor function and the ability to read well (Yang, 2006). These preliminary findings open up the possibility that chiropractic care may have a role in improving reading ability and oculomotor function. While reading speed has long been associated with 'better' reading (Brysbaert et al., 2005; Hayhoe & Ballard, 2005; Yang, 2006) this study does not assess for improvements in cognitive processing. It can at best infer them. Other outcome measures from this study show promising possible improvements, but further study into these is required before any lasting conclusions can be drawn. Additional studies must also investigate changes in the other outcome measures (saccades, fixations, distractors) that are also used to infer changes in cognitive abilities. Most importantly, it should be recognised that until the results of the study are repeated and additional research conducted into the effect of chiropractic care on oculomotor function in children with ADHD, these results cannot be used to inform changes in treatment profiles or public health policy.

Conclusions

In conclusion, the current study addresses gaps in the literature by adding new, if exploratory, insights into chiropractic's effects on oculomotor control. However, most importantly, this research provides knowledge that can support the formation of new research studies in the same field. It has provided greater clarification surrounding the study procedures, equipment and management, likely leading to future research outputs that will be more reliable and generally applicable to the greater ADHD population.

This study's findings are also beneficial to the wider research community as it contributes to knowledge of oculomotor control. It has the potential, if further studies are undertaken with the above recommendation, to open the door to better management and, possibly to improve the quality of life of children with ADHD.

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Appendices

Appendix A: Ethics Approval

1. Full HDEC approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

02 August 2016

Dr Kelly Jones
Faculty of Health & Environmental Sciences
National Institute for Stroke and Applied Neurosciences
AUT University
Private Bag 92006
Auckland 1142

Dear Dr Jones

Re:	Ethics ref:	16/NTA/56
	Study title:	Chiropractic intervention and the control of eye movement in children with attention deficit hyperactivity disorder: A pilot study.

I am pleased to advise that this application has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern A Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **01 August 2017**.

Participant access to ACC

The Northern A Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
CV for CI: CV for CI	pdf	27 February 2016
Protocol: Study Protocol	pdf	27 February 2016
CVs for other Investigators: CV Holt	1	19 March 2016
CVs for other Investigators: CV Cade	1	19 March 2016
Evidence of scientific review: AUT review	1	19 March 2016
Survey/questionnaire: Participant baseline info	1	11 April 2016
Survey/questionnaire: Post study Questionnaire	1	11 April 2016
Investigator's Brochure: Child info sheet	1	11 April 2016
Investigator's Brochure: Guardian info sheet and consent	1	11 April 2016
Investigator's Brochure: Flyer	1	11 April 2016
Child assent	1	11 April 2016
PIS/CF: Guardian Consent	1	11 April 2016
PIS/CF for persons interested in welfare of non-consenting participant: Child assent	1	11 April 2016
Application		
Survey/questionnaire: Post study questionnaire Version 2	V2	09 June 2016
PIS/CF: PIF Version 2	V2	09 June 2016
PIS/CF for persons interested in welfare of non-consenting participant: CIF Version 2	V2	09 June 2016
Investigator's Brochure: Flyer Version 2	V2	09 June 2016
Covering Letter: Response to HDEC queries.	V2	09 June 2016
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Ms Rosemary Abbott	Lay (the law)	15/03/2016	15/03/2019
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Charis Brown	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Susan Buckland	Lay (consumer/community perspectives)	11/11/2015	11/11/2016
Ms Shamim Chagani	Non-lay (health/disability service provision)	11/11/2015	11/11/2016
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

2. HDEC amendment

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

04 816 3985
hdecs@moh.govt.nz

23 November 2016

Dr Kelly Jones
Faculty of Health & Environmental Sciences
National Institute for Stroke and Applied Neurosciences
AUT University
Private Bag 92006
Auckland 1142

Dear Dr Jones

Re:	Ethics ref:	16/NTA/56/AM01
	Study title:	Chiropractic intervention and the control of eye movement in children with attention deficit hyperactivity disorder: A pilot study.

I am pleased to advise that this amendment has been *approved* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

BJ Fergus

Dr Brian Fergus
Chairperson
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted and approved

Document	Version	Date
Post Approval Form	1	-
PIS/CF for persons interested in welfare of non-consenting participant: arent guardian Participation Information Sheet Alt V3.pdf	3.0	09 June 2016
Protocol: Research Protocols Appendix 1 V2.pdf	2.0	-

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Dr Charis Brown	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

Appendix B: Tools

1: Parent or Guardian Information and Consent Sheet

Parent or Guardian Information and Consent Sheet

Study title:	Chiropractic intervention and the control of eye movement in children with attention deficit hyperactivity disorder: A pilot study.	
Locality:	Auckland	Ethics committee ref: 16/NTA/56
Lead investigator:	Dr. Kelly Jones	Contact phone number: Alice Cade (co-investigator)09 526 6789

Your child is invited to take part in a study, as part of a Master's thesis being undertaken at the Auckland University of Technology (AUT), on the effect chiropractic adjustments on eye tracking ability in children with ADHD. Whether or not your child takes part is your choice and also theirs. If you don't want them to take part, you don't have to give a reason, and it won't affect the care they receive. If you do want to take part now, but change your mind later, you can stop your child's participation at any time.

This Parent/Legal Guardian Participant Information Sheet will help you decide if you'd like your child to take part. It sets out why we are doing the study, what your child's participation will involve, what the benefits and risks to your child might be, and what will happen after the study ends. We will go through this information with you and answer any questions you, or your child, may have by phone and/or when you come in to participate in the study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this and we can arrange for your child to complete the test at a later date within the study timeframe. We will also send you the Child Participation and Assent form for you to look over

If you agree for your child to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Parent/Legal Guardian Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

This study will investigate the effects of chiropractic adjustments on eye tracking in children with ADHD and it is being undertaken by a joint research team from AUT University and the New Zealand College of Chiropractic Centre for Research. Please read this information carefully and keep it for your records. If you would like further information, please contact the researchers.

Background: Eye tracking refers to the ability of a person to smoothly and accurately move their eyes when reading or looking around. Eye tracking can be examined using a computer-based test that measures the time taken to see an image, and the way your child's eyes move when they read words.

The purpose of this study is to investigate whether chiropractic treatment alters eye tracking ability in healthy children, from 8-15 years old, who have ADHD. However, the researchers would like you to understand that this is not a treatment for eye-tracking problems or ADHD This project is an investigation to see if there is a relationship between ADHD, eye tracking and chiropractic. Past studies have showed us that brain changes may be present up to 30 minutes after a chiropractic session, if they are present for longer than that, we don't yet know.

The practical significance of the findings from this study will mean we can better understand how a chiropractic adjustment can affect a child's brain function. More specifically how to accurately and smoothly move the eyes. These skills are very useful in reading ability and reading comprehension.

This study is funded by the Auckland University of Technology and the New Zealand College of Chiropractic.

Ethics for this study has been provided by the Health and Disability Ethics Committee of New Zealand and the AUT University Health Research Ethics Committee in Auckland.

The researcher conducting the tests will be available to answer any questions you or your child has about the study on the day of the testing. The Chief Investigator and co-investigators from the New Zealand Centre for Chiropractic Research can be contacted to answer any questions.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

Children aged 8-15 years attending participating chiropractic practices or child health care clinics in the Auckland Region of New Zealand are being invited to participate in a study by completing four short eye tracking tests on a computer. It is estimated that each test will take approximately 5 minutes to complete. Each pair of tests will be at least a week apart.

The computer will automatically collect information on the accuracy and speed of each child's eye tracking ability both before and after a chiropractic adjustment.

Children will be randomly allocated into either a treatment or control group when they see the chiropractor. This means they will either adjusted (treatment) or have their spine palpated/touched (control) in between doing the test two times. It is anticipated that the children participating in this study will take approximately 30-45 minutes to complete both tests, including the control and adjustment group. A minimum of a week later each child will return to take the eye test again, but this time they will be in the opposite treatment or control group.

The study will take place at the New Zealand College of Chiropractic, your local child health care clinic or your home. If your child participates in this study, they will complete the study once during the length of the project.

Details about your child's age, gender and health history will be recorded along with their test results.

The research assistant/chiropractor will be present to explain the test to your child and you, as a parent will be present as well. The eye test is designed for this age group; and research assistant will help them to understand what to do and give out instructions for them.

Should your child become distressed during the test the research assistant will immediately stop the test.

Neither you nor your child are expected or required to pay for participation in this trial.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Possible Benefits: This project will help us to understand what, if any, effects there are on eye tracking function in children with ADHD as a result of a chiropractic adjustment. Therefore, this project will help to strengthen the understanding of the effect of chiropractic care on improving eye tracking and brain function in children with ADHD.

Possible Risks: There are no foreseeable risks resulting from participation in this project. However, in the unlikely event that your child becomes distressed, or is hurt, as a result of completing this study, your chiropractor will be informed and provide the necessary health care or referral as required.

WHO PAYS FOR THE STUDY?

There is no cost to the participants or guardians to be involved in this study.

We appreciate that you and your child have volunteered an extra 30-45 minutes of time to become involved in this study.

WHAT IF SOMETHING GOES WRONG?

If your child were injured in this study, which is unlikely, you may be eligible for compensation from ACC just as you would be if you were injured in an accident at work, school or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your child's recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Participation is Voluntary: Being in this study is voluntary and you and your child are under no obligation to agree to take part. If you let us know that you do not wish to take part in the study, we will make sure that you are not contacted by the study team again.

What if I change my mind: If you decide that your child may participate and later change your mind, you are free to withdraw your child from the project at any

stage. Your decision to take part or not, or to take part and then withdraw from the study, will not impact upon your relationship with your child's chiropractor or health care provider. Should you choose for your child not to continue your participation their results will be withdrawn.

Results of the Project: Group findings of this project will be communicated via a written summary report and neither you nor your child will be identified and no personal information will be revealed in any presentation or publication of the findings.

Privacy, Confidentiality and Disclosure of Information: If you choose to participate in the Chiropractic intervention and the control of eye movement in children with attention deficit hyperactivity disorder: A pilot study, de-identified information may be shared with other researchers involved in the study research program, to better understand the impact of the chiropractic adjustments, eye and brain function.

Printed eye test results and consent forms will be stored in a locked filing cabinet and electronic data will be in a password protected file, accessible only by the researchers, for a period of at least ten years following your child turning 16 years old. Eye test results and consent forms will be shredded prior to their disposal. Data may be used for future research purposes; however, all data will be de-identified.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Name: Dr. Kelly Jones Researcher

Position: (Lead Investigator)

Telephone number: 07 838 4257

Email: kejones@aut.ac.nz

Name: Dr. Alice Cade

Position: Co-Investigator

Telephone number: +64 21 400739

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Maori Cultural Advisor: Morehu McDonald

Phone: 0800 355 553

Email: morehum@xtra.co.nz

Parent/Legal Guardian Participant Consent Form

Guardian Name:

Childs name:

	Yes
I have read, or have had read to me in my first language, and I understand the Parent/Legal Guardian Participant Information Sheet.	☐
I have been given sufficient time to consider whether or not to participate in this study.	☐
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	☐
I understand that taking part in this study is voluntary (my choice) and that I may withdraw my child from the study at any time without this affecting their chiropractic/health care.	☐
I confirm that to the best of my knowledge, my child does not have any major visual impairment, reading disability or any physical reason why they should not be receiving chiropractic care.	☐
If I decide to withdraw my child from the study, I agree that the information collected about my child up to the point when they withdraw may continue to be processed.	☐
I understand that my child's participation in this study is confidential and that no material, which could identify me or my child personally, will be used in any reports on this study.	☐
I understand the ACC compensation provisions in case of injury during the study.	☐
I know who to contact if I have any questions about the study in general.	☐
I understand my responsibilities as parent or guardian, of a study participant.	☐

I wish to receive a summary of the results from the study.

If yes, please write your email: Yes ☐ No ☐ (Email address:_____)

Consent for Chiropractic Care

As with all health care professionals the law now requires practitioners who adjust the spine to inform patients of material risk. Chiropractic adjustments of the spine are internationally recognised as being safer in dealing with neck and low back pain than medication and many other alternatives. (A risk assessment cervical of manipulation, JMPT, 1995.Magna Report, Ontario Ministry of Health, 1993). In extremely rare circumstances some treatments of the neck may damage a blood vessel and give rise to a stroke or stroke like symptoms. This is extremely rare occurring in approx. 1 in 5.85 million (Haldeman, et al. Spine, 1999, Vol 24-8). Whilst this has never occurred at the NEW ZEALAND COLLEGE OF CHIROPRACTIC to any child in New Zealand, we are still required to impart this information. Before you receive any adjustments you will be tested to minimise risk, as has always been our practice. If you have any questions related to the care you are about to receive please speak to the chiropractor.

Declaration by participant's parent or legal guardian who takes care of them:

I hereby consent for my child to take part in this study and to be checked and adjusted by the chiropractor as deemed appropriate.

Parent or legal guardian who cares for participant name:

Parent or legal guardian who cares for participant phone number:

Signature: Date:

Child's name:

Child's Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Researcher's Signature: Date:

2: Child Information and Assent Sheet.

NEW ZEALAND COLLEGE OF CHIROPRACTIC
graduating hands, hearts & minds

AUT

Child Participant Information Sheet (8-15yrs)

Study title:	Chiropractic intervention and the control of eye movement in children with attention deficit hyperactivity disorder: A pilot study.	
Locality:	Auckland	Ethics committee ref: 16/NTA/56
Lead investigator:	Dr. Kelly Jones 07 838 4257	Contact phone number: Alice Cade (co-investigator) 09 526 6789

WHY AM I HERE TODAY?

This information sheet was written for you to tell you about a project we are doing. It is part of a Master's degree for Alice Cade. Please read this information sheet carefully. You can ask any questions you like about the project if you come to visit us.

We are researchers from AUT University and the New Zealand College of Chiropractic. We would like you and other children your age to do a short 5-minute eye game on a computer both before and after you have a spine check by a chiropractor.

The reason we are doing this, is so we can measure if chiropractic care changes how your brain or eyes work, so we want you to do your best on the word game. This is not a treatment for ADHD or for your eyes, we just want to see if or how ADHD, eyes and chiropractic are related. Other studies have shown us that chiropractic can change how your brain works for about 30 minutes, but we are not sure how much longer these changes can last.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

The person who looks after you has said that it is ok for you to take part. However, we also want to make sure that you are happy to do the word game.

You will be given a word game on a computer where you will be asked to look at a dot or read some words. The researcher and the person who looks after you will be in the room with you. The researcher will help you understand what to do before each game. It takes about 5 minutes to do the game. You will do it two times, once now and once in a week or so.

All of your answers will go onto the computer so we can look at the results without your name being on it.

We will not tell anyone apart from other researchers involved in the study about your results.

During the game you will be asked to look at a dot on the computer screen and to read some words.

You don't need to worry about practicing for this game, we want to see just how good you are!

After you have the game a chiropractor will check your back and spine. This means a chiropractor will use their hands to feel your back to see how it moves. If they need to the chiropractor will give small, gentle pushes to your back to help it work better. Neither you nor your guardians will need to pay for doing the game or for getting chiropractic.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

It is up to you if you want to do the game or not. We will not get upset and you will not be in trouble if you do not want to do any of the game, or if you change your mind and do not want to finish the game, even if you're part way through it.

Child Assent Form 8-15 years

If you need some help understanding this form and what it means, please ask the research assistant to help you. This form explains about the game and asks for your permission to take part.

Study ID No: **Child's Name:** **DOB: / /**

Gender: F M **Contact No:**

Address:

	Yes
I understand what the test is about and want to do it.	☐
I have read and understand the information sheet.	☐
I have had a chance to speak to my mum, dad or adult who takes care of me, about doing this test and I feel happy to do the test.	☐
I understand that I can stop doing the test at any time	☐
I understand that the chiropractor will treat me after I have finished the test	☐
I understand that no one will tell anyone about my test results, including my caregiver and my chiropractor	☐
I know who to contact if I have any questions about the test or the study.	☐
I understand what I need to do to go ahead with the test.	☐

Declaration by child participant:

I give my permission to take part in this study.

Child Participant's name:

Child Signature or name here: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it. I believe that the participant understands the study and has given informed consent to participate.

Research Assistants name:

Research Assistant's Signature: Date:

3: Study Protocol

Each participant underwent the same protocols and procedures as described below:

1. Registration of interest with participating advertising practice.
2. Receipt of participant information sheets
3. Phone contact with research assistant to discuss interest, study protocol and requirements.
4. Booking of initial assessment and assent/consent appointment
5. Face to face discussion of the study protocol and requirements with research assistant.
6. Explanation of assent and consent forms to child and parent
7. Agreement to and signing of assent and consent forms by child and parent
8. Allocation to group by attending chiropractor
9. Demographic data taken from child participant
10. Baseline oculomotor assessment taken (see below)
11. Intervention or control given by attending chiropractor (see below)
12. Post intervention/control oculomotor assessment given.
13. Parent and child dismissed for minimum one week wash out period
14. Parent and child return for second baseline oculomotor assessment
15. Child receives required intervention or control (opposite to initial intervention/control)
16. Post intervention/control oculomotor assessment given.
17. Parent and child are asked to fill out a voluntary post-study questionnaire
18. Guardians and children are thanked for their participation and leave.
19. Parent and child receive a summary of the study's results after data analysis has taken place.
20. Parent and child's participation in study ends.

Baseline assessment. Following screening, each participating parent and child will complete a baseline assessment. This will include collection of demographic (child age, sex, and health history) and oculomotor data (number and length (millimetres) for forward and reverse saccade, number and length (milliseconds) for fixations, total reading time, level of reading ability, as per the Woodcock-Johnson III Tests of Achievement (Woodcock et. Al., 2001), length of time for target acquisitions, ability to ignore intrusive visual stimuli.). Each baseline assessment will be completed immediately prior to the intervention session, at the New Zealand College of Chiropractic, and is estimated to take approximately 30-60 minutes.

Oculomotor assessment was as follows:

Test 1: Target Acquisition

Instructions: I want you to look for the dot on the screen. We will start by looking at the green "GO" sign at the top of the screen. When that "GO" sign disappears the test will start. I want you to find the dot on the screen as quickly as you can. The dot might be anywhere on the screen. I will tell you when you don't have to look at the dot anymore. Let's have a practice? Look at the screen.

Sample test of target acquisition

If the child is unable to find the target, then discontinue the task. Otherwise say "Now we are ready to begin".

Instructions: I want you to look for the dot on the screen. We will start by looking at the green "GO" sign at the top of the screen. When that "GO" sign

disappears the test will start. I want you to find the dot on the screen as quickly as you can. I will tell you when you don't have to look at the dot anymore. The dot might be anywhere on the screen. Look at the screen.

Target Distractions

Instructions: I want you to look at the dot on the screen. This time another dot will appear, anywhere one the screen but I want you to completely ignore it and not look at it. The other dot might be anywhere on the screen. I will tell you when you don't have to look at the dot anymore. Let's have a practice? Look at the screen.

Sample test of intrusive stimuli

If the child is unable to find the first target, then discontinue the task. Otherwise say "Now we are ready to begin".

Instructions: I want you to look at the dot on the screen. This time another dot will appear, anywhere one the screen but I want you to completely ignore it and not look at it. The other dot might be anywhere on the screen. I will tell you when you don't have to look at the dot anymore. Let's have a Look at the screen.

Test 3: Reading

As part of standardized eye-tracking data (Duchowski, 2007) collection 20 separate reading tasks were used. The first ten reading tasks were arranged in an order of ascending complexity. For example; the simplest reading task was displayed first, the most complex was tenth. In order to collect statistically

significant data an additional ten reading tasks followed, however these final ten reading tasks were mid-range in their complexity.

In order to control for any post-intervention changes in reaction time (Kelly, Murphy et al. 2000; Holt, 2014) total reading time is taken from the start of the task (after the 'GO' button disappears) to the beginning of the final fixation.

Instructions: I want you to read some sentences. Each sentence will be followed by a question on the screen, which I want you to answer, if you can. We will start by looking at the green "GO" sign at the top of the screen. When that "GO" sign disappears the test will start. When you have finished reading the sentence I want you to press the mouse button.

Sample Item: Look at this sentence. It says, 'A cow is an animal'. Here is your question – What animal is mentioned in the sentence? A cow is mentioned in the sentence so you would answer "cow".

Practice Exercises: Now you can have a practice. Look at the green "GO" on the screen, when it disappears read the sentence. Once you have finished press the mouse button, and read the question. Once you have read the question click on the right answer

Practice Item 1: A man has two legs

Question: In this sentence, what has two legs?

If the child is unable to read the sentences, then discontinue the task. Otherwise say; "Now we are ready to begin".

Instructions:

“Look at the green “GO” on the screen, when it disappears read the sentence. Read each sentence when it appears on the screen. Once you have finished press the mouse button, and read the question. Once you have read the question click on the right answer. Try to get as many questions right as you can. There will be up to twenty sentences.”

Let’s have another practice.

Practice item 2: A fish lives in water.

Question: In this sentence, where does a fish live?

OK, now let’s start the real questions. Ready?

Test items

Pre-Intervention Statements

"You can eat an apple and an orange.",
"A hat goes on your head and keeps you warm.",
"A book has pages and a cover.",
"A fish has two arms and legs.",
"A phone book has many numbers and addresses.",
"The moon and stars hang in the sky.",
"A spoon and fork can be used for eating noodles.",
"People may listen to music on a radio in their car.",
"A roof is at the top of a house, the floor on the bottom.",
"A key may open the lock on a door to let you inside."

Pre-Intervention Questions

"What can you eat?",
"What goes on your head?",
"What does a book have?",
"What has two arms and legs?",

"What book has many numbers in it?",
"The moon is where?",
"What can you use for eating?",
"What can people listen to music on?",
"What is at the top of the house?",
"What might open the lock?"

Post-Intervention Statements

"You can eat a pear and a banana.",
"A shoe goes on your foot and keeps you safe.",
"A book has words and a name.",
"A fish has six arms and legs.",
"A maths book has many numbers and equations.",
"The sun and planets are in the sky.",
"A knife and scissor can be used for cutting.",
"People may listen to music on an iPod in their pocket.",
"A lawn is at the front of a house, the deck at the back.",
"A code may open the lock on a door to let you inside."

Post-Intervention Questions

"What can you eat?",
"What goes on your foot?",
"What does a book have?",
"What has six arms and legs?",
"What book has many numbers in it?",
"The planets are where?",
"What can you use for cutting?",
"What can people listen to music on?",
"What is at the front of the house?",
"What might open the lock?"

4: Study Flyer

NEW ZEALAND COLLEGE OF

VOLUNTEERS NEEDED FOR A CHIROPRACTIC RESEARCH STUDY

At NEW ZEALAND COLLEGE OF CHIROPRACTIC Centre for Chiropractic Research we are involved in a research project that is being run as part of a Master's thesis by AUT University in collaboration with the New Zealand College of Chiropractic. This study investigates if there are any changes in eye tracking abilities before and after getting a chiropractic adjustment, in children with ADHD. This study is not a treatment for ADHD or eye tracking problems. It's both fun and interesting and will only take two sessions (around 30mins each) over a week apart at the New Zealand College of Chiropractic

To be eligible to participate, kids need to be:

- 8 – 15 years of age
- Have a previous diagnosis of ADHD
- Not have any major visual disability (seriously impaired vision, cataracts or eye trauma)

Please contact us at alice.cade@nzchiro.co.nz if you or your child would like to participate or would like more information.

Chief Investigator: Dr Kelly Jones

Co investigators: Dr Kelly Holt & Dr Alice Cade

CONTACT: alice.cade@nzchiro.co.nz or 021 400739

5: Post Study Questionnaire

Participant ID # _____

Todays Date: _____

Visit Two Information & Follow Up Questionnaire

Visit One (strike out which intervention is not used at this visit)

Chiropractic Examination (record: date, spinal segments manipulated & chiropractic indicators such as; muscle tension, edema, joint play, active motion, point tenderness)

_____
_____
_____
_____
_____
_____
_____
_____
_____

Active control movements (date)

_____
_____
_____

Data relevant to study

	Time to complete task (ms)	Fixations		Forward Saccades		Reverse Saccades	
Pre Intervention		Total #	Ave time (ms)	Total #	Ave time (ms)	Total #	Ave time (ms)

Post Intervention	Total #	Ave time (ms)	Total #	Ave time (ms)	Total #	Ave time (ms)

As a final voluntary step, please complete this questionnaire with your child. The questions ask you about how you both felt about participating in this study and the care you received from your chiropractor. Your answers will remain confidential and will not be shared. Your feedback will be used to help improve our processes for future studies.

Please note: Completion of this questionnaire is VOLUNTARY.

Section One:

Please indicate how strongly you agree or disagree with the following statements by circling the appropriate number for each question below.

1= Strongly Disagree

2= Disagree

3= Slightly Disagree

4= Neutral

5= Slightly Agree

6 = Agree

7= Strongly Agree

		Strongly Disagree		Neutral				Strongly Agree
1	The study was clearly explained to my child and I.	1	2	3	4	5	6	7
2	The study tasks were easy to understand and realistic to perform for my child and I.	1	2	3	4	5	6	7
3	I found it easy to communicate with the research staff.	1	2	3	4	5	6	7
4	I felt comfortable with the study's expectations of my child.	1	2	3	4	5	6	7
5	My child and I were happy with the care provided by the staff and chiropractor.	1	2	3	4	5	6	7
6	The research staff and chiropractor were responsive to my/my child's questions.	1	2	3	4	5	6	7
7	The time required to complete this study is reasonable for my child and I.	1	2	3	4	5	6	7

Section Two:

1: What procedures, if any, do you think could be improved in future studies?

_____

_____

_____

_____

_____

_____

_____

_____

_____

2: What did you and child like least about this study?

_____

_____

_____

_____

_____

_____

_____

3: What did you and child like best about this study?

_____

_____

_____

_____

_____

_____

_____

_____

4: Is their anything else you would like to add about your experiences on this study?

_____

_____

_____

_____

_____

6: Participant Baseline Information Form/Visit One Form

Today's date: / /

Participant ID: _____

Past History:

Previous Chiropractic Care: Y/N If yes, from whom?_____

Approx date last visit:_____

Do you have any current complaints? (Pain, headaches or injuries?)

☐ Yes ☐ No If 'yes' please give details and dates:

_____
_____
_____
_____
_____
_____

Have you ever had any trauma to your body? (e.g. Sporting injuries, falls, motor vehicle accidents etc)

☐ Yes ☐ No If 'yes' please give details and dates:

_____
_____
_____

Have you ever broken any bones? ☐ Yes ☐ No if 'yes' please state what and when:

_____
_____
_____

Have you had any surgeries/operations? ☐ Yes ☐ No if 'yes' please state what and when:

_____

_____
_____

Are you on any medications? ☐ Yes ☐ No if 'yes' please state what they are:

_____
_____
_____

Have you ever had any major illnesses, learning problems or vision problems? ☐ Yes ☐ No if 'yes' please state what and when:

_____
_____
_____

Chiropractic Examination

Vertebrobasilar Insufficiency test:

_____

Cervical
ROM:_____

Lumbar
ROM:_____

Orthopedic Examination (if required, note test names and outcomes)

_____
_____
_____

Neurological Examination (if required, note test names and outcomes)

_____
_____
_____

Visit One (strike out which intervention is not used at this visit)

Chiropractic Examination (record: date, spinal segments manipulated & chiropractic indicators such as; muscle tension, edema, joint play, active motion, point tenderness)

_____
_____
_____
_____

_____
_____
_____
_____

Active control movements (date)

_____
_____
_____

Data relevant to study

	Time to complete task (ms)	Fixations		Forward Saccades		Reverse Saccades	
Pre Intervention		Total #	Ave time (ms)	Total #	Ave time (ms)	Total #	Ave time (ms)
Post Intervention		Total #	Ave time (ms)	Total #	Ave time (ms)	Total #	Ave time (ms)

7: Child Contact Information Form

Today's date: / /

Name: _____ I prefer to be called:_____

Study ID: _____

Guardians Name: _____

DOB: / / Gender: F M

Address:_____

_____

Contact No:_____

Alternative Contact No (ie; grandparent) :_____

Previous Chiropractic Care: Y/N If yes, from whom?_____

Approx date last visit:_____

Your GP:_____

8: Reading test questions with Flesch-Kincaid Grade.

3

You can eat an apple and an orange.

You can eat a pear and a banana.

Flesch reading ease: 92.2

Flesch-Kincaid Grade: 2.2

4

A hat goes on your head and keeps you warm.

A shoe goes on your foot and keeps you safe.

Flesch reading ease: 100

Flesch-Kincaid Grade: 0.1

5

A book has pages and a cover.

A book has words and a name.

Flesch reading ease: 100

Flesch-Kincaid Grade: 0.6

6

A fish has two arms and legs.

A fish has six arms and legs.

Flesch reading ease: 100

Flesch-Kincaid Grade: 0.0

7

A phone book has many numbers and addresses.

A maths book has many numbers and equations.

Flesch reading ease: 71.8

Flesch-Kincaid Grade: 5.2

8

The moon and stars hang in the sky.

The sun and planets are in the sky.

Flesch reading ease: 100

Flesch-Kincaid Grade: 0.0

9

A spoon and fork can be used for eating noodles.

A knife and scissor can be used for cutting.

Flesch reading ease: 94.7

Flesch-Kincaid Grade: 2.3

10

People may listen to music on a radio in their car.

People may listen to music on an iPod in their pocket.

Flesch reading ease: 72.6

Flesch-Kincaid Grade: 5.8

11

A roof is at the top of a house, the floor on the bottom.

A lawn is at the front of a house, the deck at the back.

Flesch reading ease: 100

Flesch-Kincaid Grade: 2.0

12

A key may open the lock on a door to let you inside.

A code may open the lock on a door to let you inside.

Flesch reading ease: 96

Flesch-Kincaid Grade: 3.0

9: Tabulated data of order effect on outcome measures

Order effect of Intervention: Target task								
	Chiropractic				Control			
Outcome	*N*	Pre Intervention	*N*	Post Intervention	*N*	Pre Intervention	*N*	Post Intervention
Time to Fixation of Target (ms) *M (SD)*	25†	1550.00 (3583.84)	24†	906.63 (1502.63)	25†	981.95 (1437.58)	24†	983.29 (2047.83)
Control First	11	1864.64 (4509.22)	11	1014.06 (1682.06)	12	981.14 (1592.50)	12	986.68 (2502.54)
Chiro First	14	1550.11 (3583.84)	13	906.63 (1502.63)	13	981.95 (1437.58)	12	983.29 (2047.83)
Average number of Distraction Fixations *M (SD)*	10*	4.27 (2.76)	8*	2.73 (1.68)	9*	3.82 (2.75)	7*	4.46 (3.01)
Control First	4	4.14 (2.27)	4	2.57 (1.72)	7	4.14 (2.97)	5	5.57 (3.10)
Chiro First	6	4.50 (3.87)	4	3.00 (1.72)	2	3.25 (2.63)	2	2.50 (1.73)

Time to Acquire Distractor Target (ms) *M (SD)*	10*	931.72 (699.47)	8*	635.80 (393.75)	9*	958.32 (585.387)	7*	705.96 (492.85)
Control First	4	1236.07 (825.36)	4	698.80 (452.05)	7	1065.56 (594.70)	5	716.33 (511.36)
Chiro First	6	931.72 (699.47)	4	635.80 (393.75)	2	958.32 (585.387)	2	705.96 (492.85)

Note: N† are participants able to calibrate, N* are participants who exhibited a distractor behaviour. P value significance set at 0.05

Order effect of *Intervention: Reading task*

		Chiropractic Intervention				Active Control			
Outcome		*N*	Pre Intervention	*N*	Post Intervention	*N*	Pre Intervention	*N*	Post Intervention
Mean sentence reading time	*M (SD)*	25†	4016.93 (1894.50)	23†	3370.06 (1508.91)	23†	3548.76 (1637.85)	24†	3440.41 (1971.01)
Chiro first		13	4208.89 (1936.96)	12	3620.73 (1572.55)	11	3327.38 (1495.81)	12	3023.65 (1397.46)
Control first		12	3708.12 (1791.48)	11	2979.13 (1320.33)	12	3809.75 (1763.67)	12	3977.46 (2429.65)
Average number Forward Fixations	*M (SD)*	25†	2.37 (1.14)	23†	2.13 (0.96)	23†	2.24 (1.15)	24†	2.18(1.00)
Chiro first		13	2.39 (1.15)	12	2.18 (0.92)	11	2.00 (1.30)	12	1.95 (0.83)
Control first		12	2.33 (1.14)	11	2.05 (1.00)	12	2.53 (1.22)	12	2.46 (1.13)
Average Forward Fixation Time	*M (SD)*	25†	970.94 (645.49)	23†	894.16 (514.45)	23†	854.42 (469.52)	24†	885.23 (604.58)
Chiro first		13	975.41 (579.26)	12	975.95 (560.00)	11	887.51 (518.85)	12	863.65 (542.78)
Control first		12	963.74 (743.09)	11	767.58 (406.32)	12	815.42 (402.97)	12	913.03 (677.89)
Average Forward Saccade Length	*M (SD)*	25†	407.61 (135.41)	23†	400.86 (117.50)	23†	398.41 (96.74)	24†	392.77 (88.19)

Chiro first		13	410.93 (145.09)	12	388.84 (114.90)	11	390.24 (78.45)	12	386.33 (73.59)
Control first		12	402.27 (118.76)	11	419.45 (119.73)	12	408.03 (114.32)	12	401.06 (103.86)
Average number Reverse Fixations	*M (SD)*	19*	1.21 (0.45)	20*	1.04 (0.21)	16*	1.22 (0.46)	19*	1.17(0.59)
Chiro first		11	1.21 (0.41)	10	1.00 (0.00)	7	1.14 (0.35)	9	1.07 (0.26)
Control first		8	1.22 (0.52)	10	1.11 (0.32)	9	1.28 (0.52)	10	1.26 (0.77)
Average Reverse Fixation Time	*M (SD)*	19*	867.15 (672.2)	20*	755.39 (555.85)	16*	678.89 (506.73)	19*	727.23 (559.7)
Chiro first		11	940.34 (723.84)	10	786.56 (664.26)	7	750.68 (712.46)	9	652.29 (533.47)
Control first		8	746.22 (571.50)	10	708.64 (347.85)	9	624.43 (265.91)	10	797.34 (583.06)
Average Reverse Saccade Length	*M (SD)*	19*	284.24 (280.78)	20*	223.12 (150.09)	16*	253.37 (191.97)	19*	223.76 (142.95)
Chiro first		11	291.80 (305.47)	10	199.78 (125.76	7	323.86 (218.65)	9	251.14 (141.69)

Control first	8	271.75 (240.44)	10	258.14 (178.78)	9	199.90 (151.94)	10	198.15 (141.60)

Appendix C: Sample of coding or sample of thematic analysis

Data item	Initial Codes	Final Code
"The only aspect that could be improved was the eye-tracking device. It seemed to cause Dr. Cade difficulty."	Equipment Calibration	Equipment difficulty
"The long drive to get there" *"Location – Have various locations across Auckland to allow for participants' ease of access."*	Long drive More locations	Travel