TITLE

Is device guided training targeted to the craniocervical flexor and extensor muscles efficacious? A preliminary randomized controlled trial in a cervicogenic headache population

ABSTRACT

Background: Specific neck exercise is effective in the management of cervicogenic headache (CH). The Spinertial device was designed to facilitate craniocervical flexion and extension training, but its efficacy, judged on change in headache impact, has not been tested.

Objective: To compare guided and progressive resisted specific neck exercise targeted to the craniocervical flexors and extensors (SNE-fe) performed with Spinertial device to progressive SNE-fe without the device in a cohort with CH.

Design: Randomised controlled trial

Methods: Twenty-eight participants with CH were randomly allocated to the Spinertial group (SG) or SNE-fe exercise group without the device (EG). Both groups performed 12 sessions of SNE-fe over six-weeks. The primary outcome was headache impact (HIT-6). Secondary outcomes were the craniocervical flexion test (CCFT), upper cervical (UCS) and lower cervical range of movement, flexion rotation test (FRT) analysed as more or less restricted side (MRS, LRS), the self-reported global rating of change (GROC-scale) and satisfaction with the exercise program (PACES). Outcomes were measured at baseline, post-intervention (T1) and after 1-month (T2).

Results: Significant between-groups differences were found favouring the SG for HIT-6 (T1 $p=0.010$, $d=0.5$; T2 $p<0.004$, $d=0.4$), CCFT, UCS ROM, FRT MRS, FRT LRS, PACES and GROC-scale (T1: all $p<0.01$; T2: all $p<0.01$). Effects sizes were large (>0.8) at T1 and T2. No between-groups differences were found for lower cervical ROM.

Conclusion: Training with the Spinertial was more effective than SNE without the device for improving the impact of headache, the endurance of deep neck flexors and UCS ROM in participants with CH.

Keywords: Exercises, Neck muscle, Cervical Spine, Headaches.

INTRODUCTION

The Global Burden of Disease study reported that headache disorders are a major public health concern worldwide (GBD 2019 Diseases and Injuries Collaborators). Headaches are a common cause of disability, incurring both high societal and personal costs. They can have a profound impact on quality of life regardless of their cause (Ashina et al., 2021; Shimizu et al., 2021; Van Suijlekom et al., 2003). Research to improve outcomes of treatment is needed to reduce the impact of headaches on a person's daily life.

Current evidence suggests that specific exercise for the deep craniocervical flexors can be effective in the reducing the impact and disability of cervicogenic headache (CH) and other neck disorders (Becher et al., 2023.; Jull et al., 2002; Uthaikhup et al., 2017). A recent systematic review of exercise in the management of cervicogenic headache (Becher et al., 2023) noted that while exercise interventions appeared effective, the certainty of evidence was marred by several trial features among which was the heterogeneity in exercise protocols. We propose that the exercise method could be enhanced as well as better standardized in three ways by; (i) using a device to guide performance of correct movement, (ii) training targeted to both the craniocervical flexor and extensor muscles and (iii) providing a method to add progressive resistance. This could improve on the current method where patients perform self-guided, active craniocervical movements where it is possible that inappropriate substitution movements may mar the effectiveness of training (Jull et al., 2019). To this end, we have developed a novel device, patented as Spinertial (Carrasco-Uribarren et al., 2023) (see supplementary material 1).

The Spinertial uses a sliding system to guide head movement so that patients perform craniocervical flexion and extension movements accurately to avoid, for example, unwanted chin retraction (Jull et al., 2019). It permits head movement throughout the entire range of craniocervical flexion and extension motion, and caters to each person´s individual range. Progression of training is possible as resistance can be applied to both craniocervical flexion and extension movements by adding elastic bands to the device (Carrasco-Uribarren et al., 2023). We designed a randomised controlled trial (RCT) to test the hypothesis that guided specific neck exercise to target the craniocervical flexors and extensors (SNE-fe) with progressive resistance using the Spinertial device would be more effective in improving the impact of headache on daily functions than progressive SNE-fe without the device. We chose to study a cohort with CH. Persons with

CH have been shown to have impaired craniocervical flexor activation and upper cervical spine movement restrictions and respond to SNE-fe (Jull et al., 2002, 2007; Uthaikhup et al., 2017). Thus, the aim of this study was to compare guided and progressive SNE-fe with the Spinertial to progressive SNE-fe without the guiding device for improving headache impact, muscle function and cervical ROM in patients with CH. If superior outcomes are attained in headache impact and cervical muscle performance, it would contribute to development of a research informed exercise protocol and justify further research into physiological effects of training with the Spinertial device.

MATERIALS AND METHODS

Trial design

This study was a double blind randomised controlled trial in which participants and examiners were blinded. The study was conducted in accordance with the Declaration of Helsinki for controlled clinical trials and approved by the local ethics committee (XXXXX: XXXX/XXX). All participants provided written informed consent. The study was developed according to CONSORT guidelines and was registered on clinical trials.gov: XXXXXXXX.

Participants

Thirty-five participants diagnosed with CH by a neurologist on the basis of the International Classification of Headaches Disorders 3rd edition (ICDH-3) (Headache Classification Committee of the International Headache Society, 2018) were included. The ICDH-3 criteria implemented were that headache was usually but not invariably accompanied by neck pain, cervical ROM was restricted, provocative neck manoeuvres made the headache significantly worse, and the headache improved as the cervical disorder improved (Headache Classification Committee of the International Headache Society, 2018).

Participants were initially diagnosed by a neurologist and then assessed by a physical therapist for the following clinical features as inclusion criteria: aged >18 years, a score > 50 on the HIT-6 questionnaire (Kosinski et al., 2003; Sauro et al., 2010); a craniocervical flexor contractile deficit (a failure to pass stage 2, 24 mmHg) in CCFT (Jull et al., 2008) and a restriction in upper cervical motion measured by the flexion rotation test (FRT). The FRT was considered positive when there was an asymmetry of 10º between sides or when rotation range was less than 32º (Hall & Robinson, 2004; Ogince et al., 2007). Exclusion criteria were any treatment to the neck during the previous 6 months, any red flags (vertebral fracture, malignancy, or infection), neurological or cognitive impairment, a history of head/cervical trauma or surgery during the previous year, an inability to attain the flexion position to undertake the FRT and any changes to pharmacological therapy during the study period or the month preceding the study (Buyukturan et al., 2017; Kang, 2015).

Randomisation, allocation concealment and blinding

Following referral by the neurologist, examiner A conducted a phone screening for all inclusion/exclusion criteria and 30 of 35 participants met the inclusion criteria. Examiner B ensured that participants met the physical inclusion criteria (CCFT and FRT) and had signed the informed consent statement. Examiner B then performed the first evaluation at a private clinic located in XXXXX, XXXX. This examiner was blinded to group allocation at all assessment times and documented the outcome variables at baseline (T0), immediately after the intervention (T1), and at the 1-month follow-up (T2). To ensure random allocation concealment, an independent researcher, who was not involved in the study, randomised each participant to one of two interventions with a ratio 1:1 using www.random.org for generating random numbers. The researcher assigned the participant to a group without knowledge of baseline assessments and simply handed the participant an opaque sealed envelope. The physiotherapist who applied the intervention according to the randomly assigned group was the only person who (after opening the opaque envelope) knew the group in which each participant had been assigned.

Interventions

There were two interventional groups: (i) the Spinertial exercise group (SG) used the Spinertial device to perform the specific neck exercise intervention targeting the craniocervical flexors and extensors (SNE-fe), and (ii) the exercise group (EG) performed the SNE without the device. The SNE-fe programme for both intervention groups was undertaken with 4–5 participants simultaneously. All participants received 12 sessions, 2 times a week for 6 weeks with a duration of 30 min for each session (Sremakaew et al., 2023). The first session for participants in each group was a face-to face session and the subsequent sessions were delivered on-line. The SNE-fe programme was guided by a physical therapist with more than 10 years of experience in manual therapy and therapeutic exercise.

Both exercise programs were designed as face-to-face interventions but given the situation of COVID-19 at the time of the study, the protocol was adapted to conduct the SNE-fe program by telerehabilitation (Figure 1). Nevertheless, the first session in both programs was carried out in person, to ensure personalized instruction for correct performance of the exercises.

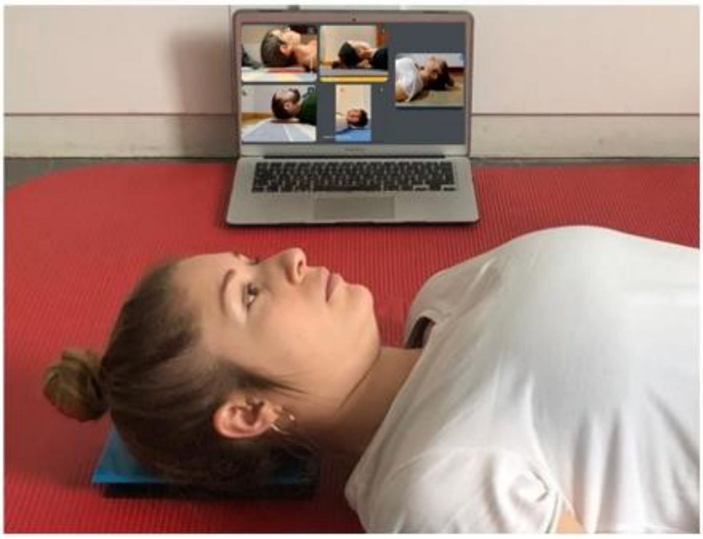

Figure 1. SNE-fe Telerehabilitation program with the Spinertial.

The SNE-fe programme in the SG: The exercise programme was divided into craniocervical flexor and extensor muscle progressive resistance exercises. The participants were placed in a supine position with the occiput resting on the Spinertial (Figure 2). First, the exercise focused on the craniocervical extensor muscles. To exercise these muscles, participants were asked to move the sliding platform of the Spinertial down to perform maximal painless craniocervical extension and to maintain it. Second, craniocervical flexor muscle exercises were performed, and participants were asked to move the surface up, performing painless maximal craniocervical flexion and sustaining the position as an endurance component to the exercise. Each participant was supplied with a Spinertial to perform the exercise program at home.

Figure 2. The SNE-fe in the SG A) craniocervical extension position. a) elastic band during craniocervical

extension. B) craniocervical neutral position. C) craniocervical flexion position. c) elastic during craniocervical flexion.

The SNE-fe in the EG: Participants trained the craniocervical flexor and extensor muscles by performing the craniocervical flexion and extension movements without any external device guidance. The exercise programme commenced with exercise for the craniocervical extensor muscles. The participant lay in a supine position and was asked to lift their chin to move upper cervical spine (UCS) into extension, maintaining this position without feeling pain (Schomacher et al., 2012). For the second phase, the participants, positioned in supine with the head and neck in a neutral position, were taught to perform the craniocervical flexion movement in a slow and controlled way facilitated with downward eye movement and again to maintain the craniocervical flexion as an endurance component to the exercise (Jull et al., 2019).

The volume and intensity were the same for both protocols. Three sets of 10 repetitions were performed; each repetition had a duration of 10 seconds, 2 seconds of movement in flexion or extension until the final position, maintained the final position for 6 seconds and 2 seconds back to the starting point. A 30-second break was applied between sets, and a 3-second break was allowed after each repetition. For both groups, the intensity of SNE-fe was increased by adding progressive resistance elastic bands. For the SG, the elastic resistance bands were fixed within the Spinertial. In the EG, progressive resistance was provided by hand-held elastic resistance bands placed behind the head to provide resistance to occipital movement as occurs with the Spinertial. Participants were instructed to keep their head in contact with the support surface at all times during the exercise. In the neutral craniocervical starting position, the elastic bands were held taut and angled slightly above eye level. For craniocervical extension, the participant rotated their head into extension against the resistance of the band, angling it slightly caudally during the movement to maintain the resistance through range. For craniocervical flexion, the opposite occurred with the band being angled slightly in a cephalad direction as the movement progressed through range. In the face-to-face session, participants received a full explanation and demonstration of the exercise and practiced applying the resistance with the band (Figure 3). The elastic band was changed weekly for one with higher resistance (Uchida et al., 2016). Each subject trained according to the baseline assessment of capability, the load was progressively increased each week (Corp et al., 2021).

Figure 3. Placement of elastic bands to perform SNE-fe in EG A) craniocervical extension position. B) craniocervical neutral position. C) craniocervical flexion position.

Outcome measures

The primary outcome was headache impact, measured with the HIT-6 questionnaire (Martin et al., 2004). The secondary outcomes were CCFT, neck flexor endurance test, ROM, PACES, and GROC scale. The outcome measures were recorded at T0, T1 and T2.

Head impact test, HIT-6.

The assessment of headache impact was measured using the HIT-6 questionnaire, whose score range is between 36 to 78 points. A higher value shows a more severe headache impact. The HIT-6 is considered one of the most useful tools to assess the effectiveness of non-pharmacological interventions for headache disorders (Pradela et al., 2021). The HIT-6 has excellent reliability (ICC = 0.95)(Pradela et al., 2021).

Muscle function assessments, cranio-cervical flexion test (CCFT) and cervical flexor endurance test.

The activation of the deep craniocervical flexor muscles was tested with the CCFT as described by Jull et al. (Jull et al., 2008). The CCFT requires participants to perform five test stages of progressively inner range craniocervical flexion, using a sagittal rotation movement rather than an incorrect retraction action, Participants are guided to each position by the output from a pressure biofeedback unit positioned behind the neck and inflated to a baseline of 20mmHg. The linear relationship between range of craniocervical flexion and the five, 2 mmHg pressure incremental stages of the test has been established (Falla et al., 2003). For this study, subjects performed three repetitions for each 2mmHg stage of the test, starting at 22mmHg and ending at 30mmHg, holding each position for 10s and resting for 30s between each stage. The stage considered for analysis was the one at which the participant performed the 3 sets of 10s correctly without substitution strategies (e.g. a retraction movement). The reliability of the CCFT is excellent when tested in both an asymptomatic population (ICC = 0.98) (Kotwani et al., 2018) and a population containing neck pain patients (ICC = 0.85)(Juul et al., 2013).

To assess the strength and endurance of the cervical flexor muscles, the head lift test was used as previously described (Cleland et al., 2006; Lourenço et al., 2016). Subjects performed and held a craniocervical flexion position and then lifted their head to clear the bed. The time the subject was able to hold the chin and head position was recorded in seconds. This test has good reliability in a cohort with subclinical neck pain (ICC = 0.76)(Alahmari et al., 2019).

Range of movement, ROM.

Craniocervical flexion and extension were measured with the CROM device with participants in the standing position with their backs against a wall. Three repetitions were performed. The average of the total UCS flexion and extension ROM was used for the statistical analysis (Satpute et al., 2023).

Craniocervical rotation was measured with a CROM device in the FRT following the protocol of Hall et al.(Hall et al., 2008; Takasaki et al., 2011). Three repetitions were performed. This test has excellent reliability in patients with CH (ICC = 0.93) (Hall et al., 2008). The test results were recorded as the average degrees of motion on the more restricted side (MRS) and on the less restricted side (LRS).

Cervical flexion, extension, left and right rotation, and left and right-side bending ROM were measured with the CROM device. The protocol used has shown excellent reliability in asymptomatic subjects (ICC > 0.80)(Tousignant et al., 2006). Participants performed movements three times in each direction. For the statistical analysis the average of the total ROM in each plane (cervical ROM flexion-extension, cervical ROM rotation and cervical ROM side-bending) was used.

Physical activity enjoyment scale, PACES.

Patients` perception and satisfaction are important variables to consider with an intervention as exercise, as it can influence compliance. The assessment of satisfaction with cervical training was assessed with the PACES-16 questionnaire. This questionnaire has been validated for evaluating the enjoyment of physical activity (Mullen et al., 2011). Higher PACES scores reflect greater levels of enjoyment (Motl et al., 2001; Teques et al., 2020). This test has good reliability (ICC = 0.76) (Jekauc et al., 2013).

Self-reported global rating of change, GROC scale.

Participants rated their perceived recovery on the GROC scale at T1 and T2 follow-ups, according to the question "Compared to before your inclusion in the study, how much has your headache problem changed?" on a 14-point Likert scale. The Minimal Clinically Important Change Difference (MCID) in persons with upper-cervical dysfunction is ±3 point which guided the formation of three categories for analysis: without clinical change, with clinical worsening, and clinical improvement (Friscia et al., 2014). The GROC has excellent reliability (ICC = 0.90)(Kamper et al., 2009).

Sample Size

The sample size was calculated based on HIT-6 using the GRANMO 7.12 program, conceptualized as a superiority study, with a α risk of 0.05, a two-sided test, and a β risk of 0.20. For HIT-6, an estimated common standard deviation of 7.1 (Petersen et al., 2019) and MCID of 8 were used (Castien et al., 2012). For this preliminary study the sample size required was 14 participants per group, giving a total sample size of at least 28 participants.

Statistical Analysis

Statistical analysis was conducted with the SPSS 20.0 package (IBM, Armonk, New York). Means and standard deviations were calculated for each variable. The Shapiro-Wilk test was used to determine the normal distribution of quantitative data.

Linear mixed-model with repeated-measures analysis was used to investigate the differences in outcomes in terms of time (baseline, postintervention, and one-month follow-up) and group (SG and EG). Analysis was performed on an intention-to-treat principle (Chakraborty et al., 2009). Change scores from baseline were calculated for post-intervention and one-month follow up. A p-value < 0.05 was considered statistically significant. The Chi-square was used to analyse between-group differences of the GROC scale and CCFT in T1 and T2 follow-ups. The effect sizes for the between group analysis of the quantitative variables were calculated using Cohen's d coefficient. The effect size >0.8 was considered large; about 0.5, moderate; and <0.2, small.

RESULTS

After telephone screening, 30 participants met the criteria and were selected for face-to-face screening. After the physical examination screening, 28 participants met the selection criteria (24 women and 4 men; 35.2 years ± 10.4). Participants were randomly assigned to the SG or to the EG. All participants completed the study, attending to all 12 sessions. There were no missing data (Figure 4). Table 1 presents the sociodemographic characteristics of both groups and the baseline values for the HIT-6, CCFT and FRT. The means and standard deviations for all primary and secondary outcomes at baseline, T1 and T2 are presented in Appendix 1.

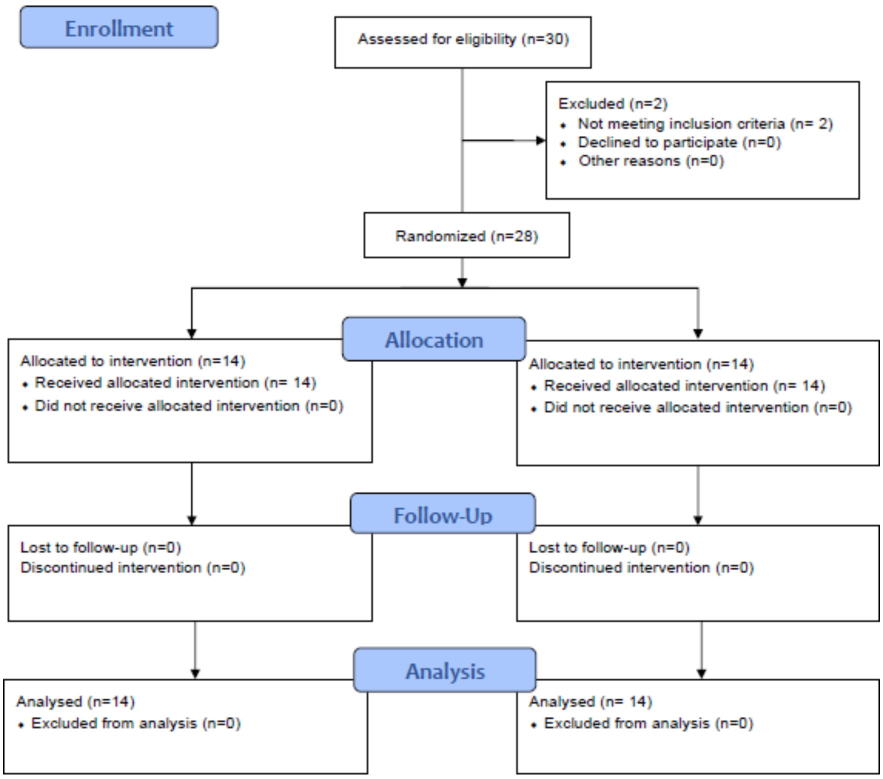

Figure 4. Flow diagram of participants throughout the course of the study.

Table 1 Sociodemographic characteristics of each group

	Spinertial group (n = 14)	Exercise group (n = 14)
Sex (% women)	12 (85.7%)	12 (85.7%)

Age (years)	35.3 ± 9.2	35.1 ± 11.8
BMI (kg/m^2)	24.0 ± 3.5	22.2 ± 2.5
Physical activity (hours/week)	3.7 ± 3.3	3.9 ± 3.0
HIT 6	56.5 ± 6.6	52.8 ± 5.7
CCFT (mmHg)	22.4 ± 0.8	22.4 ± 0.8
FRT MRS (°)	19.0 ±7.6	21.8 ± 6.0
FRT LRS (°)	26.2 ± 8.0	31.1 ± 7.3

Data are mean ± standard deviation. BMI - body max index; HIT 6 - headache impact test; CCFT - craniocervical flexion test; FRT - flexion rotation text; MRS - more restricted side; LRS - less restricted side.

Primary outcome: The changes scores of the HIT-6 for the SG and EG groups were –10.6 ± 7.1 and –3.4 ± 6.6 respectively at T1 and – 11.6 ± 5.3 and – 4.9 ± 6.0 respectively at T2. Analysis confirmed statistically significant between-groups changes at T1 (p = 0.010, d = 0.5), and T2 (p < 0.004, d = 0.4) in favour the SG.

Secondary outcomes: Statistically significant between-group changes were found in CCFT at T1 (p < 0.001; d = 2.1) and at T2 (p < 0.001; d = 2.7) in favour the SG. The change scores in the CCFT are depicted in Figure 5.

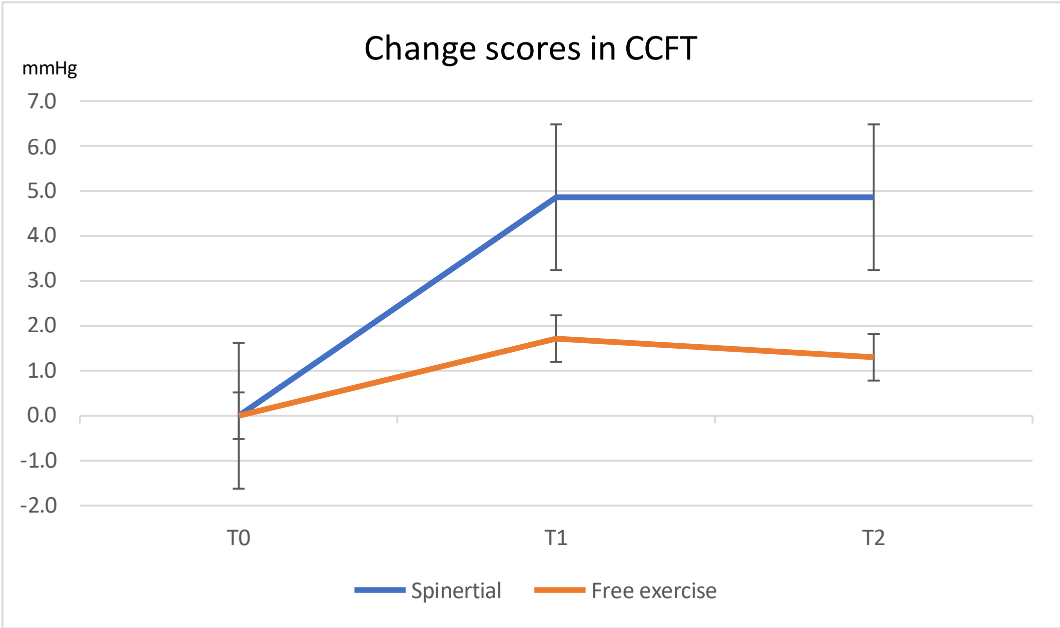

Figure 5. Change scores for the improvement in performance in CCFT (gains in mmHg) for the Spinertial and exercise groups at each timepoint.

Baseline, post-intervention changes scores, and follow-up change scores of the secondary outcomes are shown in the Table 2. Statistically significant differences were found for cervical flexor endurance test, UCS ROM, FRT MRS, and FRT LRS.

Table 2. The baseline and change scores the Spinertial and exercise groups at post-treatment and follow-up.

Outcome	Spinertial group (*n* = 14)	Exercise group (*n* = 14)	*Between group-difference in change score*	
Craniocervical flexion test (mmHg)				
Baseline	22.4 ± 0.8	22.4 ± 0.8		
T1 change score	4.9 ± 1.3	1.7 ± 1.5	3.2 (2.0, 4.2)‡	2.1
T2 change score	4.9 ± 1.2	1.3 ± 1.5	3.6 (2.5, 4.6)‡	2.7
Cervical flexor endurance (secs)				
Baseline	13.7 ± 5.8	19.7 ± 11.5		
T1 change score	16.3 ± 8.9	0.3 ± 10.4	16.0 (8.3, 23.4)‡	0.8
T2 change score	14.7 ± 13.8	-3.7 ± 10.0	18.4 (9.0, 27.8)‡	0.9
Total UCS ROM (°)				
Baseline	33.8 ± 6.3	34.5 ± 6.2		
T1 change score	8.7 ± 5.1	2.2 ± 6.3	6.5 (2.0, 11.0)*	1.3
T2 change score	7.6 ± 5.3	1.5 ± 7.6	6.1 (1.0, 11.2)§	0.8
FRT MRS (°)				
Baseline	19.0 ± 7.6	21.8 ± 6.0		
T1 change score	15.9 ± 7.2	0.5 ± 10.5	15.4 (8.4, 22.4)‡	1.5
T2 change score	14.5 ± 6.8	4.0 ± 8.2	10.5 (4.6, 16.3)‡	1.0
FRT LRS (°)				
Baseline	26.2 ± 7.9	31.0 ± 7.3		
T1 change score	14.4 ± 8.5	0.2 ± 9.3	14.2 (7.4, 21.0)‡	1.1
T2 change score	12.5 ± 6.9	2.0 ± 12.7	10.5 (2.6, 18.4)§	0.7
LCS flexion-extension (°)				
Baseline	105.7 ± 11.6	107.8 ± 7.2		
T1 change score	15.4 ± 13.0	4.9 ± 10.2	10.5 (1.4, 19.6)§	0.6
T2 change score	10.2 ± 9.6	4.2 ± 10.3	6.0 (-1.7, 13.8)	0.3
LCS rotation (°)				
Baseline	126.3 ± 10.2	132.2 ± 8.6		
T1 change score	7.7 ± 8.6	6.3 ± 10.4	1.4 (-6.0, 8.8)	0.3
T2 change score	5.1 ± 12.5	4.9 ± 7.5	0.2 (-7.7, 8.1)	0.5
LCS side-bending (°)				
Baseline	67.8 ± 11.4	68.0 ± 9.3		
T1 change score	10.3 ± 9.5	3.2 ± 13.9	7.1 (-2.1, 16.4)	0.5
T2 change score	7.9 ±10.9	4.7 ± 9.4	3.2 (-4.7, 11.1)	0.2

UCS - upper cervical spine; FRT - flexion-rotation test; MRS - most restricted side; LRS - less restricted side. ROM - range of motion; LCS - lower cervical spine. § $p < 0.05$; * $p < 0.01$; ‡ $p < 0.001$

PACES

After the intervention, the enjoyment of SNE-fe (PACES outcome) with and without Spinertial showed a mean value of 76.4 ± 3.2 in the SG and 68.5 ± 7.9 in the EG. The SG had statistically significant higher enjoyment than the EG ($p < 0.001$, $d = 1.3$).

GROC scale

A perception of improvement was reported by 13 participants in the SG and 9 in the EG at T1 ($p = 0.165$). However at T2, a difference emerged. Thirteen participants in the SG continued to report improvement but reported improvement reduced to 3 participants in the EG ($p<0.001$)

DISCUSSION

The present study showed that the program based on the SNE-fe with the Spinertial device reduced headache disability (HIT-6) and improved the outcomes of the CCFT, cervical flexor endurance test, UCS ROM and FRT to a greater extent than the progressive SNE-fe without the device (EG) in patients with CH both post-treatment and at the one-month follow-up.

The reduction in headache disability (HIT-6) scores could be expected as craniocervical flexion training as a single intervention or part of a combined intervention has shown to be effective in the management of CH (Becher et al., 2023.; Jull et al., 2002; Uthaikhup et al., 2017). The effect size of the difference in improvements in the HIT-6 with SG were moderate. The SG was also more effective than EG in the CCFT, the cervical flexor endurance test, and UCS ROM. Effect sizes were large at all timepoints for all outcomes. Only LCS ROM showed no relevant differences between groups, which could be expected as the intervention was directed at the craniocervical region.

It is proposed that this study provides evidence, based on the physical performance outcomes, that the Spinertial is potentially superior as an exercise method compared to progressive SNE-fe without the device for training the craniocervical muscles. Impaired craniocervical flexor activation, cervical flexor and extensor muscle strength and endurance and restricted cervical ROM are common impairments presenting in patients with CH (Hall & Robinson, 2004; Jull et al., 2007; Ogince et al., 2007). In accordance with the inclusion criteria, participants in this study had poor performance in the CCFT (SG: 22.4 ± 0.8; EG: SG: 22.4± 0.8), and restricted craniocervical rotation measured FRT (SG: 19.0 ± 7.6; EG: 21.8 ± 6.0).

The improvement in activation of the craniocervical flexors in the CCFT in the SG (4.9 ± 1.3 mmHg) was higher than the established minimal detectable change (change of 2mmHg)(Jørgensen et al., 2017) which was established from conventional methods of craniocervical flexor training. One of the novel features of Spinertial is the provision to add increasingly higher resistance elastic bands to progressively increase the load in the exercise intervention which was undertaken weekly in this study. This may explain the improvements in the CCFT in the SG. Our regime in the EG of adding handheld resistance to the craniocervical exercise proved unsuccessful.

Another finding of note was the improvement in cervical flexor endurance in the head lift test in the SG group, which did not occur in the EG with hand-held resistance. The head lift test requires the participant to hold a craniocervical flexion position and then lift and hold their head off the bed (Cleland et al., 2006; Lourenço et al., 2016). Holding the weight of the head in this position tests the strength and endurance of all cervical flexors (craniocervical and cervical e.g. sternocleidomastoid, anterior scalenes). The strength training afforded by the Spinertial device, even though not directly resisting the cervical flexors, improved performance in the head lift test, probably by improving the contribution of the craniocervical flexor strength to this synergistic action.

There is evidence from MRI studies that the sub-occipital muscles atrophy with neck pain and headache (Hallgren et al., 1994) and have significant fatty infiltrate in whiplash associated disorders (Elliott et al., 2006). The Spinertial device facilitates training of the craniocervical extensor muscles but the efficacy of training was not assessed. Currently, although there are laboratory-based force measurement devices for testing the craniocervical extensors (Etemadi et al., 2018), there is currently no established clinical method of measurement.

In relation to cervical movement, improvement in the FRT was superior in the SG, with mobility returning to within normal limits at the post-treatment and one-month follow-ups (Hall et al., 2010). The Spinertial guidance system assists the participant to perform repetitive movements of craniocervical segments accurately and easily (Carrasco-Uribarren et al., 2023). This would explain the improvements in UCS movement while not producing changes in the cervical (LCS) ROM and at least partly explain the improvement in craniocervical rotation in the FRT. The Spinertial permits movement throughout the individual's entire range of craniocervical flexion and extension, which may explain the far greater improvement in movement in the SG as compared to the EG.

The SG and EG participants rated their perceived recovery (GROC-scale) similarly after the intervention but this was only maintained in the SG at T2. Participants enjoyed both exercise methods (PACES), though exercise with the Spinertial was rated slightly higher. Thus, the SG showed better clinical benefits, maintained greater perceived recovery and was enjoyable, an important factor for compliance with exercise.

CH is a disabling and recurrent disorder (Headache Classification Committee of the International Headache Society, 2018). Optimization of the dose and the type of exercise is needed to restore muscle function and to help prevent the recurrence. The results of this preliminary RCT demonstrated that Spinertial is a promising device. Exercising with the device reduced the impact of headache on patients' quality of life. It allows patients to perform SNE-fe in a simple and accurate way with a facility to increase progressively the load.

This RCT has several limitations. First, the sample size is small and only patients with CH were included, so the results should be interpreted with caution and cannot be extrapolated to other neck pain populations at this time. Second, the craniocervical extensor muscles were trained but not measured, so any physical effects derived from this intervention could not be quantified. Third, given the pandemic period, the SNE-fe program was carried out online. It should be verified if the effects are different with face-to-face classes.

Nevertheless, the results provide a basis to explore the physiological mechanism of exercising with Spinertial. Future studies might investigate the morphological and physiological gains using imaging techniques such as ultrasonography or magnetic resonance imaging to overcome the challenges in accessibility of these deep cervical muscles with electromyography (Falla et al., 2003) These methods would allow comparison of gains of exercising with Spinertial to those of SNE-fe without the device and correlate muscle activation to that in the current gold standard clinical test, the CCFT.

CONCLUSION

Twelve sessions of SNE-fe with the Spinertial improved headache disability, performance in the CCFT, cervical flexor endurance, total UCS ROM and range in the FRT compared to progressive neck exercise without the device in participants with CH. Results were maintained at one-month follow-up. These results justify further research into physiological gains using the Spinertial device.

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Highlights

- Craniocervical flexor training is effective in reducing pain and disability in cervical disorders
- The Spinertial device facilitates guided and progressive resisted craniocervical muscle training
- Training with the Spinertial is more effective for cervicogenic headache impact than unguided exercise
- Training with the Spinertial better improves upper cervical range of motion and muscles endurance
- Training with the Spinertial had no superior effect on lower cervical rotation and side bending

TITLE

Is device guided craniocervical flexor and extensor training efficacious? A randomized controlled trial in a cervicogenic headache population

ABSTRACT

Background: Specific neck exercise is effective in the management of cervicogenic headache (CH). The Spinertial device designed to facilitate correct craniocervical flexion/extension movement and exercise progression, but its efficacy has not been tested.

Objective: To compare guided and progressive resisted specific neck exercise for the craniocervical flexors and extensors (SNE-fe) performed with Spinertial device to progressive SNE-fe without the device in a cohort with CH.

Design: Randomised controlled trial

Methods: Twenty-four participants with CH were randomly allocated to the Spinertial group (SG) or SNE-fe exercise group without the device (EG). Both groups performed 12 sessions of SNE-fe over six-weeks. The primary outcome was headache impact (HIT-6). Secondary outcomes were performance in the craniocervical flexion test (CCFT), upper cervical (UCS) and lower cervical range of movement, flexion rotation test (FRT) analysed as more or less or less restricted side (MRS, LRS), the self-reported global rating of change (GROC-scale) and satisfaction with the exercise program (PACES). Outcomes were measured at baseline, post-intervention (T1) and after 1-month (T2).

Results: Significant between-groups differences were found favouring the SG for HIT-6 (T1 $p=0.010$, $d=0.5$; T2 $p<0.004$, $d=0.4$), CCFT, UCS ROM, FRT MRS, FRT LRS, PACES and GROC-scale (T1: all $p<0.01$; T2: all $p<0.01$). Effects sizes were large (>0.8) at T1 and T2. No between-groups differences were found for lower cervical ROM.

Conclusion: Training with the Spinertial was more effective than SNE without the device for improving the impact of headache, the endurance of deep neck flexors and UCS ROM in participants with CH.

Keywords: Exercises, Neck muscle, Cervical Spine, Headaches.

TITTLE

Is device guided craniocervical flexor and extensor training more efficacious that free exercise. A preliminary randomised controlled trial in a cervicogenic headache population.

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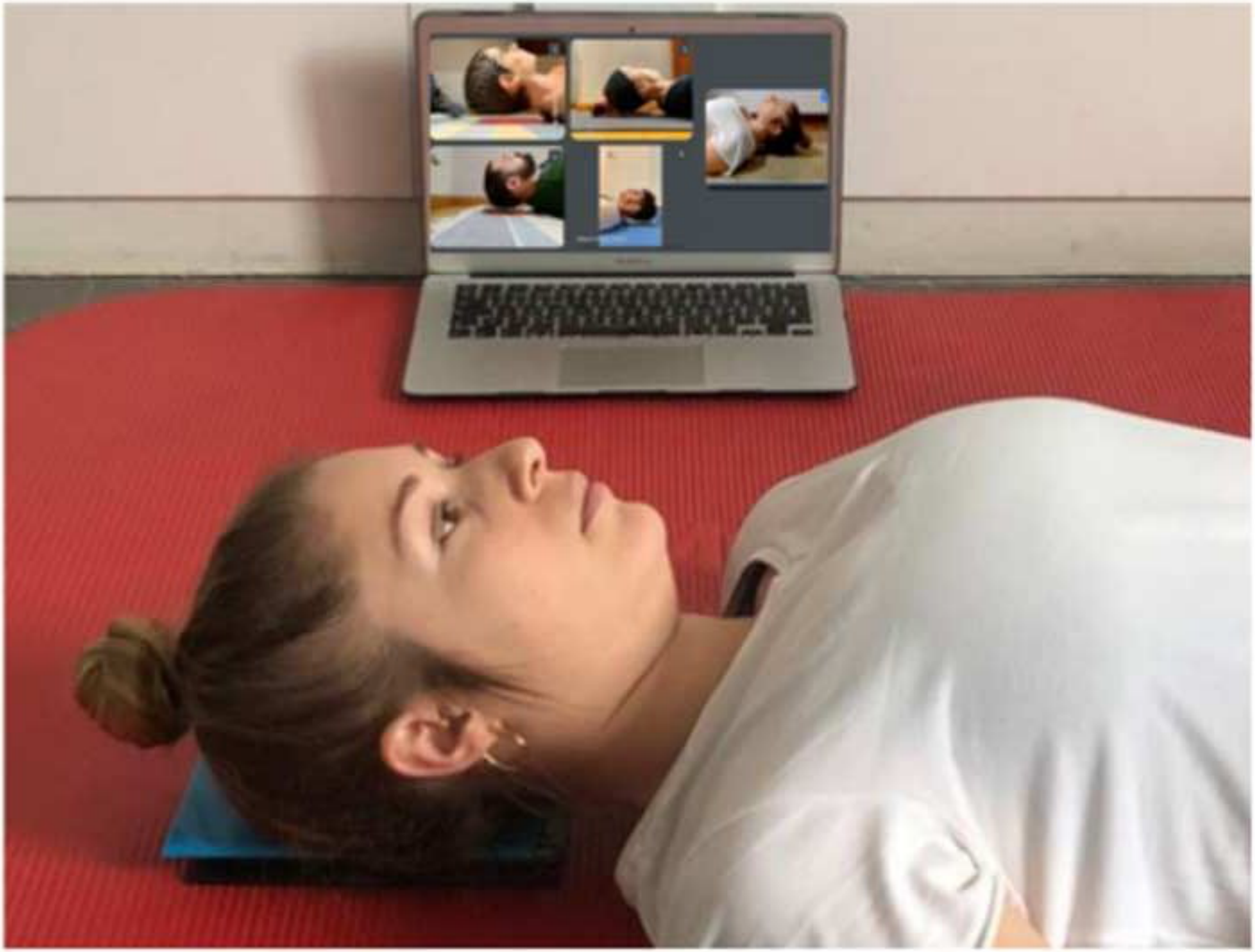

Figure 2

Figure 3

Click here to access/download;Figure;Figura 3.tif

Figure 4

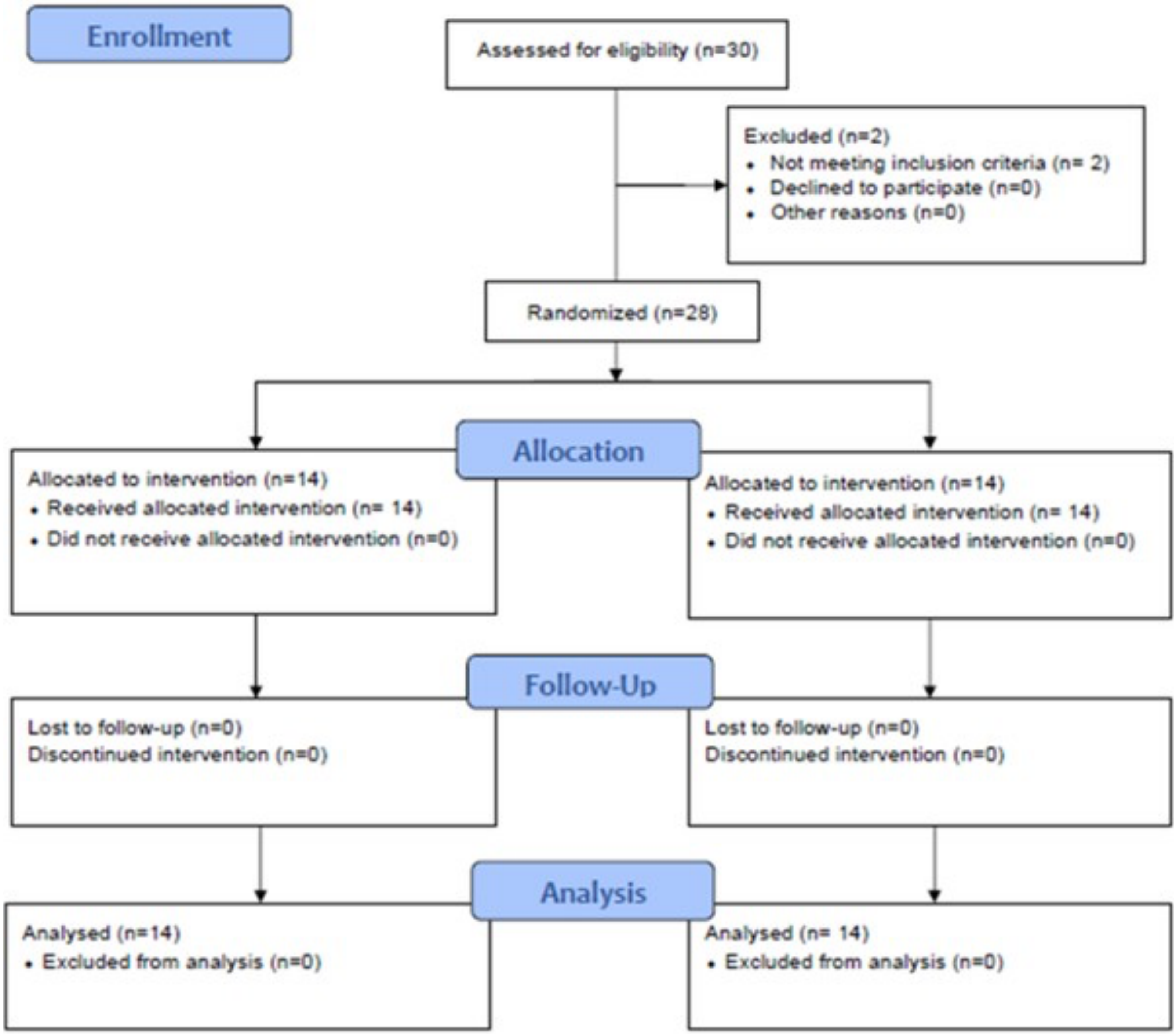
Enrollment
Assessed for eligibility (n=30)
Excluded (n=2)
• Not meeting inclusion criteria (n= 2)
• Declined to participate (n=0)
• Other reasons (n=0)
Randomized (n=28)
Allocation
Allocated to intervention (n=14)
• Received allocated intervention (n= 14)
• Did not receive allocated intervention (n=0)
Allocated to intervention (n=14)
• Received allocated intervention (n= 14)
• Did not receive allocated intervention (n=0)
Follow-Up
Lost to follow-up (n=0)
Discontinued intervention (n=0)
Lost to follow-up (n=0)
Discontinued intervention (n=0)
Analysis
Analysed (n=14)
• Excluded from analysis (n=0)
Analysed (n= 14)
• Excluded from analysis (n=0)

Figure 5


Change scores
mmHg
7,0
6,0
5,0
4,0
3,0
2,0
1,0
0,0
-1,0
-2,0
T0
T1
T2
Spinertial
Free exercise

Table 1 Sociodemographic characteristics of each group

	Spinertial group (*n* = 14)	Exercise group (*n* = 14)
Sex (% women)	12 (85.7%)	12 (85.7%)
Age (years)	35.3 ± 9.2	35.1 ± 11.8
BMI (kg/m^2)	24.0 ± 3.5	22.2 ± 2.5
Physical activity (hours/week)	3.7 ± 3.3	3.9 ± 3.0
HIT 6	56.5 ± 6.6	52.8 ± 5.7
CCFT (mmHg)	22.4 ± 0.8	22.4 ± 0.8
FRT MRS (°)	19.0 ±7.6	21.8 ± 6.0
FRT LRS (°)	26.2 ± 8.0	31.1 ± 7.3

Data are mean ± standard deviation. BMI - body max index; HIT 6 - headache impact test; CCFT - craniocervical flexion test; FRT - flexion rotation text; MRS - more restricted side; LRS - less restricted side.

Table 2. The baseline and change scores the Spinertial and exercise groups at post-treatment and follow-up.

Outcome	Spinertial group (*n* = 14)	Exercise group (*n* = 14)	*Between group-difference in change score*	
Craniocervical flexion test (mmHg)				
Baseline	22.4 ± 0.8	22.4 ± 0.8		
T1 change score	4.9 ± 1.3	1.7 ± 1.5	3.2 (2.0, 4.2)‡	2.1
T2 change score	4.9 ± 1.2	1.3 ± 1.5	3.6 (2.5, 4.6)‡	2.7
Cervical flexor endurance (secs)				
Baseline	13.7 ± 5.8	19.7 ± 11.5		
T1 change score	16.3 ± 8.9	0.3 ± 10.4	16.0 (8.3, 23.4)‡	0.8
T2 change score	14.7 ± 13.8	-3.7 ± 10.0	18.4 (9.0, 27.8)‡	0.9
Total UCS ROM (°)				
Baseline	33.8 ± 6.3	34.5 ± 6.2		
T1 change score	8.7 ± 5.1	2.2 ± 6.3	6.5 (2.0, 11.0)*	1.3
T2 change score	7.6 ± 5.3	1.5 ± 7.6	6.1 (1.0, 11.2)§	0.8
FRT MRS (°)				
Baseline	19.0 ± 7.6	21.8 ± 6.0		
T1 change score	15.9 ± 7.2	0.5 ± 10.5	15.4 (8.4, 22.4)‡	1.5
T2 change score	14.5 ± 6.8	4.0 ± 8.2	10.5 (4.6, 16.3)‡	1.0
FRT LRS (°)				
Baseline	26.2 ± 7.9	31.0 ± 7.3		
T1 change score	14.4 ± 8.5	0.2 ± 9.3	14.2 (7.4, 21.0)‡	1.1
T2 change score	12.5 ± 6.9	2.0 ± 12.7	10.5 (2.6, 18.4)§	0.7
LCS flexion-extension (°)				
Baseline	105.7 ± 11.6	107.8 ± 7.2		
T1 change score	15.4 ± 13.0	4.9 ± 10.2	10.5 (1.4, 19.6)§	0.6
T2 change score	10.2 ± 9.6	4.2 ± 10.3	6.0 (-1.7, 13.8)	0.3
LCS rotation (°)				
Baseline	126.3 ± 10.2	132.2 ± 8.6		
T1 change score	7.7 ± 8.6	6.3 ± 10.4	1.4 (-6.0, 8.8)	0.3
T2 change score	5.1 ± 12.5	4.9 ± 7.5	0.2 (-7.7, 8.1)	0.5
LCS side-bending (°)				
Baseline	67.8 ± 11.4	68.0 ± 9.3		
T1 change score	10.3 ± 9.5	3.2 ± 13.9	7.1 (-2.1, 16.4)	0.5
T2 change score	7.9 ±10.9	4.7 ± 9.4	3.2 (-4.7, 11.1)	0.2

UCS - upper cervical spine; FRT - flexion-rotation test; MRS - most restricted side; LRS - less restricted side. ROM - range of motion; LCS - lower cervical spine. § $p < 0.05$; * $p < 0.01$; ‡ $p < 0.001$

Supplementary Material 1

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TIDier Checklist

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