



## Research article

## Does restoration of sagittal cervical alignment improve cervicogenic headache pain and disability: A 2-year pilot randomized controlled trial

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## ABSTRACT

**Background:** To investigate the feasibility and effect of a multimodal program for improving chronic cervicogenic headache (CGH) via the addition of sagittal cervical spine alignment correction.**Design:** Pilot, parallel-group, randomized controlled trial.**Participants:** 60 patients with CGH, straightening of the cervical lordosis, and forward head posture (FHP) were randomly assigned using permuted-block randomization either to a control (n = 30) or an experimental group (n = 30).**Interventions:** Subjects in both groups received a multimodal program where the denneroll cervical spine extension traction orthotic was added to the experimental group only. Feasibility was assessed through recruitment rate, compliance rate, adherence rate, safety, and global satisfaction in addition to clinical outcome measures: FHP distance, cervical lordosis, headache frequency, headache disability inventory (HDI), headache impact test-6 (HIT-6), and daily defined dose (DDD). Evaluations were performed at: baseline, 10 weeks, 1 year follow up, and 2-year follow up. The assessor was blind to group allocation for all measured outcomes.**Results:** The recruitment rate was 60%, 78 % out of them completed the entire study. The recruited participants complied with 98% of the required visits. No adverse events were recorded and greater overall satisfaction with the interventions was reported. Greater improvements were found for the experimental group's cervical lordosis (f = 259.9, P < .001) and FHP (f = 142.5, P < .001). At 10 weeks, both groups showed equal improvements in CGH outcomes: headache frequency (P = 0.07), HDI (P = 0.07), HIT-6 (P = .2), and DDD (P = .3). In contrast, at the 1-year and 2-year follow up, between group differences were found for all CGH outcomes, P < .00, indicating greater improvement in the experimental group.**Conclusion:** The results indicated feasibility for recruitment rate, compliance rate, exercise session adherence, safety, and global satisfaction. At 1-year and 2-year follow-up, the addition of the denneroll orthotic device revealed positive influence on CGH management outcomes.**Trial registration:** The trial was retrospectively registered with the Pan African Clinical Trial Registry (PACTR201605001650300).

## 1. Introduction

According to the International Headache Society (HIS), Cervicogenic headache (CGH) is defined "as a secondary type of headache caused by disorders of the cervical spine or any of its components" [1]. In general, CGH is also accompanied by neck pain. The prevalence of CGH has been reported to be between 0.17% and 2.5% [2] and might be as high as 26.73% for Dentists [3] and as high as 53% whiplash injured persons [4]. CGH is aggravated by sustained and/or unusual movements of the

cervical spine [1, 2] Problematically, no universally accepted treatment protocol for the management of CGH exists, especially when considering long-term follow up of patient outcomes [5]. While many noninvasive treatment options exist for this condition [6, 7] only a few controlled trials of multimodal management of CGH have been conducted; where most of these studies have looked at relatively short term effectiveness [8]. Specifically, only one study looked at the medium range follow-up of 12 months, however it was limited to a combination of two conservative

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approaches: manipulative therapy and therapeutic exercise intervention [9].

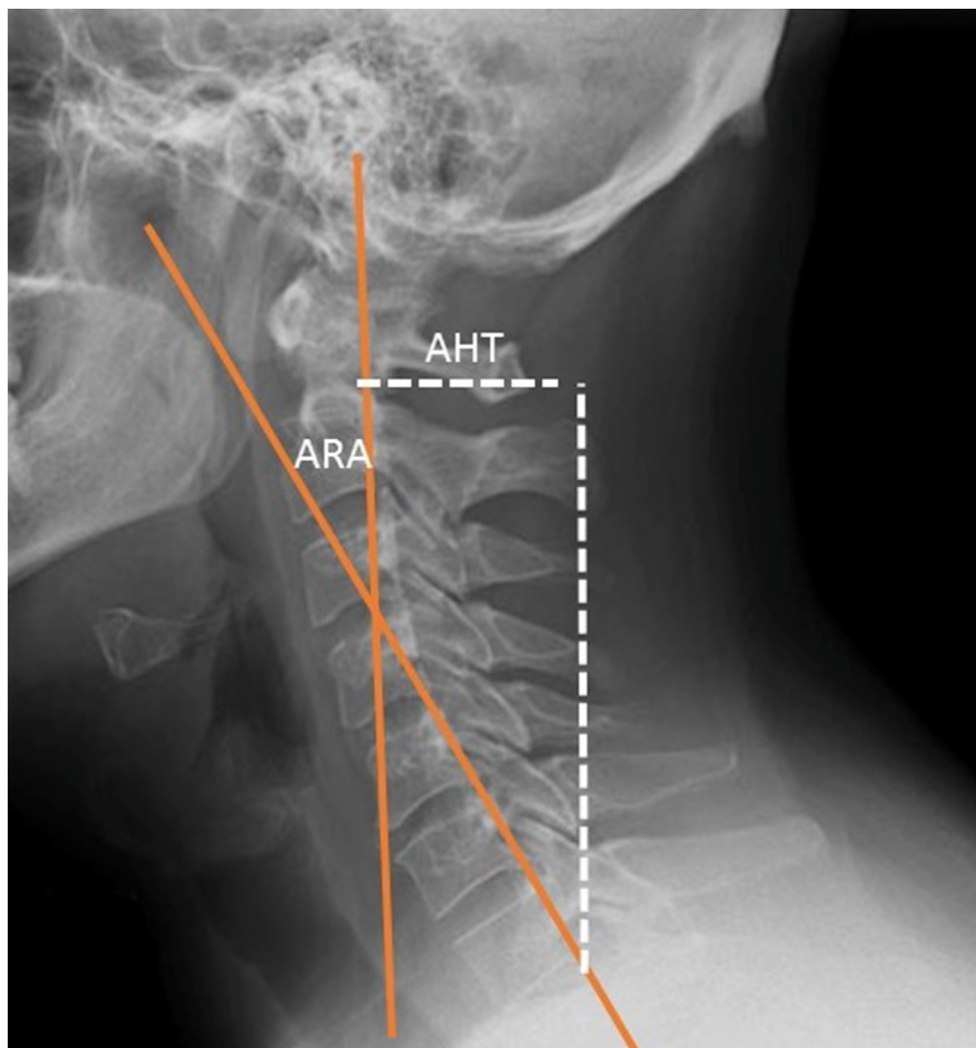
Although cervical abnormal posture has been linked to CGH [10], further research is still needed to investigate the possibility that abnormal posture is a cause of headache [11]. In this regard, little attention has been devoted to evidence-based rehabilitation of altered sagittal cervical posture and lordosis in CGH patients. To our knowledge, there are no investigations clearly demonstrating that correction of the altered sagittal cervical alignment aids in the treatment of CGH. Specifically, while the potential association between altered sagittal alignment and headache has some preliminary evidence in different headache types [12, 13] the question of whether cervical biomechanical dysfunction represented in reduced cervical lordosis and anterior head translation (AHT) can give rise to CGH has not been answered yet.

To our knowledge, this would be the first study to look at 2-year outcomes in CGH cases treated with cervical lordosis and posture correction. Accordingly, the primary objective was to evaluate the process of recruitment, adherence rate, home program adherence, safety, and patient satisfaction. The secondary aim was to investigate preliminary evidence for the hypothesis that the combination of a postural corrective orthosis, aimed at restoring the normal cervical sagittal alignment, to a multimodal program will have a lasting impact on CGH management outcomes.

## 2. Methods

A prospective, parallel randomized, pilot-controlled study was performed at Cairo University. Following Ethics Committee approval, participant recruitment began 2008 to 2015. The trial was registered with the Pan African Clinical Trial Registry (PACTR201605001650300) where the full protocol can be accessed (<https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=1650>). In order to assess a new study's research and intervention procedures, it is recommended that feasibility studies should be conducted first, then pilot studies examining the outcomes of the intervention, can be initiated (British National Institute for Health Research's (NIHR)). We registered our protocol as a pilot to investigate the effectiveness first because performing a second feasibility study before a full scale RCT would prolong the research process; thus we measured the feasibility and outcomes of the intervention concurrently in the current study following approval of Ethics Committee. The study received ethical approval from the Research Ethics Committee-Faculty of Physical Therapy-Cairo University. All participants signed an informed consent form before entering the study. Written consent to publish the content of this report along with the accompanying images was obtained from all patients.

Recruitment of participants was obtained using both printed advertisements and social media. These advertisement were directed only to the university-related communities, such as the employees, alumni and/



**Figure 1.** Illustrative figure for absolute rotation angle (ARA C2–C7) for measurement of cervical lordosis and anterior head translation (AHT) C2–C7.

or the students' parents. All the advertisements were written in English as our study require participants to be fluent in English to ensure accuracy in capturing the correct meaning of questionnaires which were originally written in English.

A phone screening protocol was used as an initial inclusion. After obtaining the informed consent, all potential participants with suspected CGH were evaluated by a neurologist where other causes of headache were. Additionally, radiographic cutoff points were used to determine hypo-cervical lordosis (intersection of posterior body tangent lines of C2–C7) and a measurement of anterior head translation (AHT) (the horizontal offset of the posterior superior body corner of C2 relative to a vertical line originating at the posterior inferior body corner of C7). [Figure 1](#). These methods of measurement have excellent reliability (ICC's > 0.90) and minimal standard errors of measurement (SEM); SEM ≈ 2° and SEM ≈ 2 mm [14].

Concerning a participants AHT on x-ray, we used the distance of greater than 15 mm [15]. Hypo-lordosis of the cervical spine was defined as C2–C7 being less than 25° or 1 standard deviation below the average asymptomatic population as reported by Harrison et al. [15].

For CGH inclusion, participants had to present with the following: 1) pain primarily localized to the neck and base of the skull, 2) pain referring to the locations of the forehead, orbital region, temples, and vertex, 3) decreased cervical range of motion, 4) moderate point tenderness on pressure palpation of cervical musculature, 5) same side headache with neck pain, 6) pain that is initiated or exacerbated by movements of the cervical spine or pressure, 7) same side pain into the shoulder or arm pain, 8) increased stiffness in the cervical spine, 9) a frequency of headache occurrence at least 1-x per week with a minimum duration in the previous 3-month period, and 10) patients whom are 40–55 years of age [16].

A physical therapist with at least 15 years clinical experience, assessed all participants. With the participant prone, the therapist applied moderate pressure to each of the cervical spine spinous processes and then to the articular processes. For participant eligibility we used the Cervicogenic Headache International Study Group criteria of pain reproduced or similar to that produced with moderate pressure palpation.

Participants were excluded for the following reasons: headaches other than CGH, any cervical spine surgery, any identified vascular disorders, pain that shifted from side to side, pain that was not improved by NSAID'S and other analgesics, sever or constant pain, any recent acute musculoskeletal injuries to the cervical spine, and degenerative arthritides.

### 2.1. Randomization and blinding

Participants were assigned at random to a treatment group (n = 30) or the control group (n = 30). We followed a previously published protocol for randomization of our participants by Moustafa et al. [5]; we refer the interested reader here for brevity herein [5]. Both the control and intervention groups received a multimodal program consisting of the following: 1) cervical spine mobilization, 2) Cervical-thoracic myofascial release, and 3) a functional exercise protocol. The treatment provider was not blinded to the treatment allocation while the outcome assessments were carried out with the assessor blind to group allocation.

### 2.2. Control group

Intervention for the control group involved myofascial release, cervical mobilization, and therapeutic exercises.

### 2.3. Myofascial release technique

The patient was in the supine position, the therapist used both hands to contact the inferior aspect of the occiput with the tips of the fingers to gently lift the patient's head anteriorly, as the patient's sub-occipital

muscles relax, continued pressure was applied in that direction. Distraction may continue for up to 3–5 min until a notable relaxation of the myofascial tissue was felt [17]. This technique was performed three times weekly for a total of 30 sessions.

### 2.4. Mobilization

The patients received low-velocity cervical mobilization techniques according to Maitland concept. The application of mobilization involved the use of a postero-anterior central oscillatory pressure; unilateral and bilateral poster anterior vertebral mobilization [18].

### 2.5. Therapeutic exercise intervention

The functional exercise protocol included endurance training of the deep cervical flexors, retraction exercises for the scapula, postural re-education, and low-load resistive training for cervical flexion and extension movements [9]. This exercise program was performed three times weekly for a total of 30 sessions.

### 2.6. Experimental group

Intervention for the experimental group involved the same multimodal program but with the addition of an extension cervical traction orthotic called the denneroll.

### 2.7. Denneroll cervical extension traction

The experimental group were treated with the denneroll cervical extension orthotic which is a patented EVA foam orthotic designed by Denneroll Industries International Pty Ltd, Wheeler Heights NSW, Australia ([www.denneroll.com](http://www.denneroll.com)). As the participant assumes a lying position, the therapist adjusts the apex of the denneroll orthotic to be placed in either the mid or lower cervical region determined by the specific cervical curve abnormality of each participant's x-ray. See [Figure 2](#). The duration of time on the denneroll started at 3 min per session and increased by 1–3 additional minutes per each consecutive session, at participant tolerance, until the patient could perform 15–20 min of sustained denneroll traction per session. The 15–20 min time frame was used as the goal and maximum time on denneroll to achieve adequate creep deformation in the soft tissues of the cervical spine [19]. This traction was performed three times weekly for a total of 30 sessions.

### 2.8. Outcome measures

As we were not intended to measure the feasibility at the beginning, the feasibility outcomes were not included in the trial registry.

Feasibility outcomes related to recruitment (time to complete enrollment, Recruitment rate), participant retention or completion rate, adherence to treatment allocation, safety and global satisfaction were assessed.

Recruitment rate was a simple ratio of the number of identified participants vs. those who actually agreed [20]. Whereas the completion rate was indicated by the number of participants that completed the entire study [21]. In our investigation, loss to follow-up was determined as the number of participants self-terminating during different parts of the study. Adherence rate was quantified by the number of treatments made vs. the total recommended.

For safety assessment, the number and nature of adverse events were recorded on weekly basis during the intervention period, and at every three months during the follow up period.

Global Satisfaction was measured by answering the question “Over the course of treatment for your cervicogenic headache in this study, how would you rate your overall medical care?” Answers to the acceptability questions were scored on a 5-point Likert scale ranging from very dissatisfied to very satisfied (5 - Very Satisfied 4 - Somewhat Satisfied 3 -



**Figure 2.** The dennerroll traction. Here a mid-cervical region (C4–C5) placement of the apex of the dennerroll orthotic is depicted. This position allows extension bending of the mid-upper cervical segments while creating a slight posterior head translation. ©Copyright CBP Seminars. Reprinted with permission.

Neither Satisfied nor Dissatisfied 2 - Somewhat Dissatisfied 1 - Very Dissatisfied).

The primary outcome tool for determining effectiveness of treatment was the Headache frequency. Frequency is the number of headaches episodes in the 2 weeks prior to beginning the evaluation [22]. Further outcome assessments included: the Headache Disability Inventory (HDI), Headache Impact Test-6 (HIT-6), Daily defined dose (DDD), and radiographic alignment variables (AHT and lordosis).

- The valid and reliable HDI was used to assess daily life impact. A decrease in the total HDI of 16 points is needed for clinically significant change [23].
- The HIT-6 was further used to assess the impact of headache on daily life, it has good to excellent internal consistency (Cronbach alpha 0.89) and test–retest reliability (ICCs ranging from 0.78 to 0.90) [23].

Daily defined dose (DDD) was used to monitor all participant medication (NSAIDs and analgesics) intake. To obtain DDD, we used a standard medication conversion from the Anatomic Therapeutic Chemical (ATC) code [24].

Cervical sagittal alignment was assessed by measuring the AHT distance and cervical lordotic angle (ARA C2–C7) [14] (representative figure of sagittal curve alignment pre and after treatment are depicted in Figure 3).

All participant outcomes were performed at baseline, ten weeks, one and two-years after the intervention period. A Physical therapist, with 15 years of clinical experience performed the evaluations before the intervention, immediately afterward, at the 10-week follow up evaluation, and at the long-term (1 and 2 years after the 10-weeks of intervention). The treatment in both groups was carried out by the same physiotherapists. The therapist received training in the required evaluation techniques prior to initiation of the study.

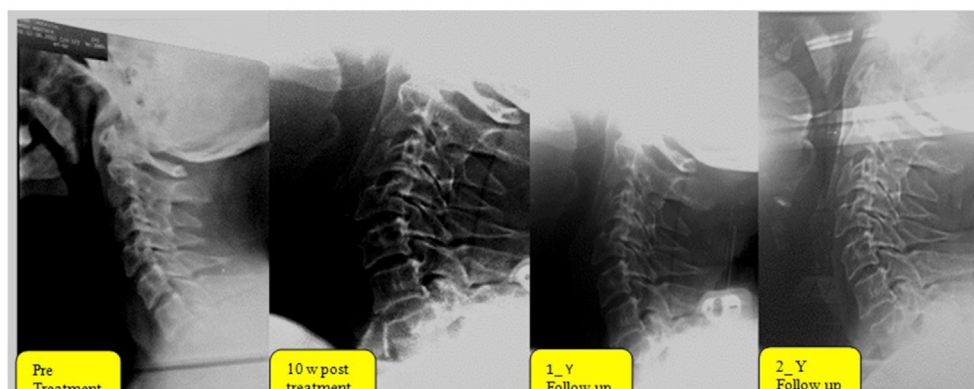
## 2.9. Sample size

A priori sample size calculation using G\*Power 3.1 indicated 60 participants in each group was required to detect a 50% reduction in headache frequency. IHS guidelines indicate that at least a 50% reduction in headache days per week is needed to identify a clinically significant difference. Using a priori power analysis (power of 0.8 and alpha of 0.05), we determined that a sample size of 50 participants in each of the two groups group was required. Estimating a dropout rate of 20%, 60 participants per each group was our target size for enrollment in a full scale future RCT. However, in the current pilot trial, we included 30 patients per group (50% of the actual study) in order to minimize the imprecision in the variance estimation.

## 2.10. Data analysis

The Kolmogorov-Smirnov test for normality of distribution was used. Equality of variance was assessed with Levene's test; attaining a 95% confidence level, p-value < 0.05. The 2-way repeated-measures analysis of covariance was used to compare between groups. The model included one independent factor (group), one repeated measure (time), and an interaction factor (group × time). A post hoc analysis using Bonferroni correction was performed if interactions were found ( $P < .05$ ). The baseline values of the outcomes were used as covariates to assess the between-group differences, to center the baseline covariates, everyone's score value was subtracted from overall mean. Pearson's correlations were used to investigate the relationships between the amount of change in cervical lordosis and anterior head translation (AHT) distance (in the study group) vs. the change in the CGH outcomes.

To impute the missing values for both groups, multiple regression models were constructed including the potentially related variables of missing data correlated with that outcome.



**Figure 3.** The representative Sample of x ray findings at the four intervals of measurement.

### 3. Results

#### 3.1. Feasibility

Recruitment: the length of time to obtain 60 participants was seven months. Our inclusion criteria removed 40% of individuals initially interested in participation. Therefore, our recruitment rate was 60%. 100 patients were initially screened and 60 subjects were eligible. In total, 60 (100%) completed the first follow-up at 10 weeks of treatment, 54 (90%) completed the second follow-up at 1 year of treatment and 47 (78 %) finished the 2-year follow up in entirety. Figure 4 shows the participant flow chart. No participants were excluded because of lack of compliance with or intolerance to either treatment regimen. The baseline

demographic and clinical characteristics per each group are shown in Table 1.

The study adherence rate was relatively consistent for both groups. Participants attained 98% of the required visits, where 80% made all study visits. Participant illness accounted for 98% and illness in a family member accounted for 2% of missed appointments.

#### 3.2. Safety

In the control group, 1 person experienced of nausea during the exercise session and was nearly done with session at the time of the incident. The incident was reported to the person's orthopedist medical management was undertaken for lack of proper nutritional daily

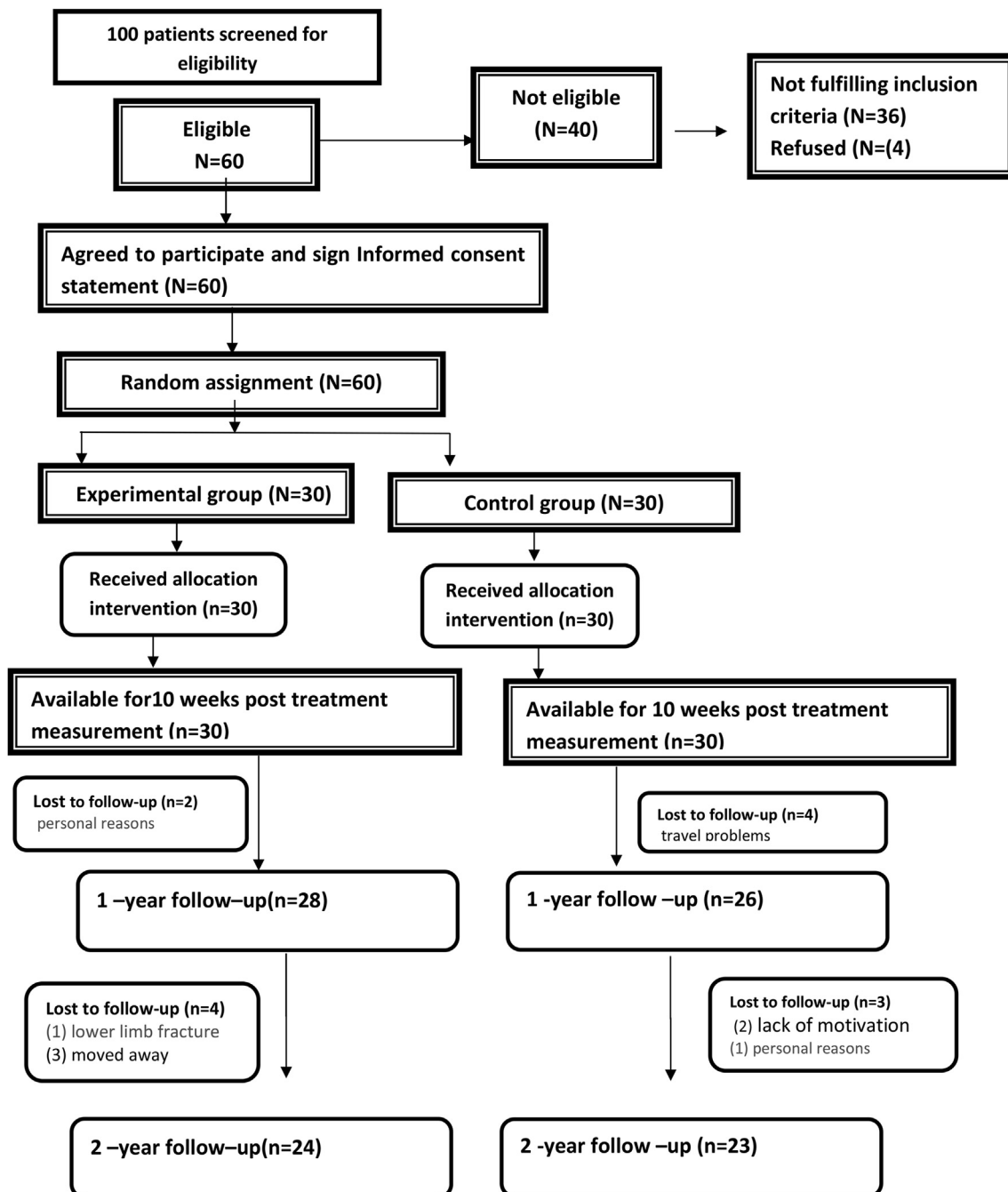


Figure 4. Participant Flow chart.



**Table 1.** Baseline participant demographics.

	Experimental group (n = 30)	Control (n = 30)	P value
Age(y)	43.1 ± 8 Range 47–65	41.9 ± 7 Range 45–64	.5
Weight (kg)	76 ± 10	78 ± 11	.4
Gender (%)			
Male	20 (67%)	18 (60%)	.5
Female	10 (33%)	12 (40%)	
Graduation			
Primary school	2 (6.7%)	1 (3.3%)	.6
Secondary school	5 (16.7%)	6 (20%)	
Advanced technical colleague	10 (33.3%)	11 (36.7%)	
University diploma	10 (33.3%)	9 (30%)	
Others	3 (10%)	3 (10%)	
Marital status			
Single	5	4	.7
Married	24	25	
Separated, divorced, or widowed	1	1	
Current use of Medications, N (%)			
Yes	28	29	.5
No	2	1	
ARA	5.5 ± 3.8	7.2 ± 3.9	0.09
AHT	25.6 ± 5.9	27.2 ± 5.6	.2
Frequency	11.7 ± 1.4	12 ± 1.5	.4
HDI	78.8 ± 7.4	79.9 ± 6.4	.5
HIT-6	65.8 ± 5.7	70.1 ± 4.7	.002*
DDD	.57 ± .14	.58 ± .12	.7

The values are presented as mean and standard deviation (SD) for age, weight, anterior head translation (AHT), absolute rotation angle (ARA), headache frequency, headache disability inventory (HDI), headache impact test-6 (HIT-6), and daily defined dose (DDD).

\* indicates statistically significant difference.

consumption and no further episodes were identified after this time. No adverse events have been recorded for the study group.

### 3.3. Satisfaction

Satisfaction with the study group intervention was high: (19 patients: 63.3% were 'Very satisfied', 10 patients 33.3% were 'somewhat satisfied', one patient: 3.3% was 'Neither Satisfied nor Dissatisfied', and 0% were 'Somewhat Dissatisfied or "Very Dissatisfied"). Less satisfaction with the control group intervention was found: 5 patients were (16.6%) 'Very satisfied', 7 patients (23.3%) were 'somewhat satisfied', 3 patients (10%) were 'Neither Satisfied nor dissatisfied', and 5 patients 16.6% were 'Somewhat dissatisfied, 10 patients (33.3.7%) were "Very Dissatisfied".

The general linear model with repeated measures indicated significant group × time effects in favor of the experimental group on measures

of cervical lordosis ( $F(3,114) = 259.9 P < 0.001$ ) and anterior head translation ( $F(3,114) = 152.7 P < 0.001$ ). Subsequent analyses identified a significant difference between both groups at all follow-up periods: at the 10-week post treatment, the 1-year follow up, and at 2-year follow up [Table 2](#).

The general linear model with repeated measures identified significant group × time effects in favor of the experimental group for the following CGH management outcomes: frequency ( $F(3,114) = 130.7 P < 0.001$ ), HDI ( $F(3,114) = 429.1 P < 0.001$ ), HIT-6 ( $F(3,114) = 408.1 P < 0.001$ ), and DDD ( $F(3,114) = 263.2 P < 0.001$ ). However, subsequent analyses indicated that, after 10 weeks of treatment, both treatments were similarly improved in the CGH management outcomes. At 10 weeks, the unpaired t test analyses found insignificant between group differences for the following parameters: frequency ( $P = .07$ ), HDI ( $P = .07$ ), HIT-6 ( $P = 0.2$ ), and DDD ( $P = 0.3$ ). [Table 3](#) shows these results.

**Table 2.** The changes in cervical sagittal alignment outcomes in experimental and control groups vs time.

		Pre treatment	Post treatment	1-year follow	2-year follow up	P		
						G	T	G Vs t
ARA	E	5.5 ± 3.8	18.9 ± 3 [3.9]	18.2 ± 3 [3.7]	17.7 ± 2.9 [3.6]	<0.001*	<0.001*	<0.001*
	C	7.2 ± 3.9	7.1 ± 3.8 [0.01]	6.9 ± 3.7 [0.07]	6.1 ± 3.6 [0.2]			
			<0.001* [9.4 13.9]	<0.001* [9.1 13.4]	<0.001* [9.4 13.6]		*	
AHT	E	25.6 ± 5.9	6.4 ± 2.2 [4.3]	6.9 ± 2.4 [4.1]	8.1 ± 2.8 [3.8]	<0.001*	<0.001*	<0.001*
	C	27.2 ± 5.6	26.9 ± 2.3 [0.07]	27.7 ± 5.5 [0.09]	28.7 ± 4.7 [.2]			
			<0.001* [-2.4, -2.3]	<0.001* [-2.1, -1.9]	<0.001* [-2.2, -1.8]			

Data are given as mean (sd) [effect size]. ARA: Absolute rotatory angle AHT: Anterior head translation E: experimental group C: control group G: group T: time G vs T: group versus time.

\* indicates statistically significant difference.

In contrast to the 10 week outcomes, the between-group analyses at long term follow-up; 1 and 2-year revealed statistically significant between group differences for all the CGH management variables (Table 4).

#### 4. Discussion

The current investigation assessed the management outcomes for participants suffering from chronic CGH in a group receiving cervical denneroll traction combined with a myofascial release, cervical mobilization, and therapeutic exercises to a group receiving myofascial release, cervical mobilization, and therapeutic exercises only. Our study indicates good feasibility in recruiting an adequate number of participants over the course of a short time for a future, planned full-scale RCT with a recruitment rate of 60%. The Adherence to treatment assignment during the 10-week intervention period and compliance with follow-up were acceptable, with no serious adverse events. Loss to follow-up was within acceptable limits, suggesting that this study design was feasible. However, the results of high recruitment rate should be interpreted with caution. This rate is different than the prevalence 0.4% and 2.5% for CGH in the general population [1, 25] However, selection was from referred patients for physiotherapy from our outpatient clinic where CGH represents the majority of all chronic headache cases; this might explain why we had a recruitment rate of 60%. Caution is also warranted for our satisfaction factor as we measured this only after the end of 2- year follow-up period and the significant decline in all outcome measures for our control group may explain, much of the significant difference between groups in favor of study group.

One of the main emphases of the current project was to assess feasibility outcomes, however, identifying possible benefits of this cervical corrective rehabilitation program was sought. We had hypothesized that denneroll traction would result in correction of the cervical curve reflected in short and long term CGH outcome benefits. The comparisons between the cervical lordotic angle and anterior head translation distance revealed significant differences at 10-weeks, 1-year, and 2-year follow up. In contrast, after 10-weeks of treatment, the results of the CGH outcomes revealed that both of the groups interventions were successful in the initial improvement of headache frequency, HDI, HIT-6, and DDD. Thus, even though the experimental group had improved lordosis and cervical posture, this did not translate into improvement in CGH as compared to the controls at 10-weeks. In contrast, at the medium range follow-up of 12 months and at long term follow up of 2 years, there were statistically significant changes where the headache denneroll group showed progressive improvement while the scores of the control

patient's regressed towards pre-treatment values (indicating a worsening). It is difficult to explain this in other than biomechanical terms. This theory was evidenced by the correlation between the improvement in cervical lordosis and AHT distance and all cervicogenic headache related outcomes.

##### 4.1. Normalizing the sagittal cervical configuration

The experimental group's results are consistent with a pilot study to evaluate the effectiveness of the denneroll traction on normalizing the sagittal cervical configuration [26]. Hypo-lordosis of the cervical spine is often attributed to muscle spasm [27], and thus, it may be speculated that the study group's increased lordosis was due to reducing spasm and tightness in the muscles. In contrast to this speculation, our study identified no differences in the control group's cervical lordosis who were subjected to myofascial release, cervical mobilization, and therapeutic exercises; which should also reduce muscle spasm and tightness. The lack of a cause and effect association between muscle spasm and hypo-lordosis in this study are consistent with a study of acute and chronic neck pain patients by Helliwell et al. [28] and the clinical investigation of et al. [29].

##### 4.2. Headache outcomes

It is interesting that both groups improved similarly in CGH outcomes at 10-weeks. It is likely that increasing the afferent input after the manual therapy in both the control and experimental groups is the explanation for decreased headaches of suspected cervical origin at the 10-week outcome interval. Increasing the afferent signals from tissue mechanoreceptors may excite inhibitory pathways in the spinal cord and can elicit cortical descending inhibitory pathways which mitigate pain. Furthermore, a reduction in activation of the suboccipital extensor muscles in the upper cervical spine driven by joint mobilization may be another possible explanation for significant improvement at the 10-week follow up point; this was also suggested by Thabe [30] Although, the role of manual therapy in the treatment of CGH is far from clear, following 10 weeks of treatment, the marked changes in CGH management outcomes in the current study is similar to those reported by Nidhi et al [31] who provided evidence that both an exercise protocol and myofascial release may be effective for CGH. Similarly, the beneficial effects of manual therapy interventions in patients with CGH were supported in a recent systematic review [32]. Although the precise content of different described treatment programs in the literature show a significant variation in, they tend to follow the same rehabilitation principles.

**Table 3.** The changes in CGH management outcomes in experimental and control groups vs time.

		Pre treatment	Post treatment	1-year follow up	2-year follow up	P		
						G	T	G Vs t
Frequency	E	11.7 ± 1.4	6.2 ± 1.6 [ 3.7]	1.3 ± 1 [ 8.5 ]	1.2 ± 1.3 [7.7 ]	<0.001*	<0.001*	<0.001*
	C	12 ± 1.5	5.7 ± .9 [5.09 ]	7.6 ± .9 [ 3.5 ]	9.1 ± 1 [2.2 ]			
			.07 [-0.04 1.09]	<0.001* [-6.7-5.9]	<0.001* [-8.3 -7.38]			
HDI	E	78.8 ± 7.4	45.8 ± 4.1 [ 5.5 ]	19.3 ± 7.1 [8.2 ]	15.6 ± 8.2 [8.09 ]	<0.001*	<0.001*	<0.001*
	C	79.9 ± 6.4	47.8 ± 6.1 [ 5.1 ]	67.4 ± 9.4 [1.5]	67.3 ± 9.4 [ 1.5]			
			.07 [-4.4 .2]	<0.001* [-51.7-44.4]	<0.001* [-55.6-47.8]			
HIT-6	E	65.8 ± 5.7	46.3 ± 5 [ 3.6 ]	38.5 ± 2.2 [6.3 ]	37.1 ± 1.9 [ 6.7]	<0.001*	<0.001*	<0.001*
	C	70.1 ± 4.7	47.4 ± 3.2 [ 5.6 ]	51.8 ± 4.3 [4]	65.4 ± 4.7 [1]			
			.2 [-2.8 0.8]	<0.001* [-14.7-11.7]	<0.001* [-29.9-26.7]			
DDD	E	.57 ± .14	.34 ± .07 [2.07 ]	.059 ± .06 [4.7 ]	.03 ± .04 [5.2 ]	<0.001*	<0.001*	<0.001*
	C	.58 ± .12	.31 ± .1 [ 2.4 ]	.52 ± .12 [ .5 ]	.57 ± .11 [0.08 ]			
			.3 [-0.03 0.07]	<0.001* [-0.5-0.41]	<0.001* [-0.61-0.50]			

Data are given as mean (sd) [effect size]. E: experimental group C: control group HDI: Headache disability inventory HIT-6: headache impact test-6 DDD: Daily defined dose G: group T: time G vs T: group versus time.

\* indicates statistically significant difference.

**Table 4.** Correlation matrix for study group.

	$\Delta$ ARA 0-10w	$\Delta$ ARA 10-1Y	$\Delta$ ARA 1Y-2Y	$\Delta$ AHT 0-10w	$\Delta$ AHT 10w-1Y	$\Delta$ AHT 1Y-2Y
$\Delta$ headache frequency 0-10w	-.41 p < 0.001			+.54 P = .000		
$\Delta$ headache frequency 10 w-1Y		-.52 <0.001			+.46 p < 0.001	
$\Delta$ headache frequency 1Y-2Y			-.64 p < 0.001			+.72 p < 0.001
$\Delta$ HDI 0-10 w	-.61 <0.001			+.57 p < 0.001		
$\Delta$ HDI 10w-1 Y		-.54 p < 0.001			+.71 p < 0.001	
$\Delta$ HDI 1Y-2Y			-.49 p < 0.001			+.65 <0.001
$\Delta$ HIT-6 0-10 w	-.52 p < 0.001			+.36 P = .000		
$\Delta$ HIT-6 10w-1 Y		-.46 P = .000			+.41 p < 0.001	
$\Delta$ HIT-6 1Y-2Y			-.64 p < 0.001			+.62 p < 0.001
$\Delta$ DDD 0-10 w	-.61 p < 0.001			+.53 p < 0.001		
$\Delta$ DDD 10w-1 Y		-.7 p < 0.001			+.43 p < 0.001	
$\Delta$ DDD 1Y-2Y			-.75 p < 0.001			+.62 p < 0.001

While the assumption that normal cervical sagittal postural position is a driver for improved afferentation is intriguing, it is surprising that restoring the normal cervical alignment did not add more significant effect in comparison with the multi-component program for all outcomes. However, no clear explanation is available, it is possible that cervical malalignment can result in abnormal stresses and strains. Once this state is established and maintained for long time, an increase in degenerative changes of the contractile, bony and neural elements exist [33]. Most important, when the abnormal load sharing is improved by way of normalizing alignment, the soft tissue degenerative and adaptive changes requires some time to be reversed. Despite no direct evidence, the delayed improvement in patient outcomes after spine correction in the experimental group at the 1 and 2 year follow ups, is supported by previous investigations [34, 35]

Our trial strengths include successful blinding of the outcome assessors, a limited loss to follow-up of 8.5%, and high compliance rate for both of our groups. Our study has several limitations. First, the lack of examiner blinding was not possible for participants receiving care and treating therapist providing the two group interventions. To account for this issue, an independent assessor who was blinded to participants group allocation was responsible for outcome assessment administration. Finally, anterior head translation greater than 15mm was chosen as a 'convenience' inclusion criteria for our investigation as this number was the mean value reported by Harrison et al. [36] Of interest, the SD in the Harrison et al. study was +/- 10 mm. Thus, we could have chosen 1 inch or 25 mm as our cut point for inclusion in our investigation. However, 1 inch of forward head translation is known to increase the axial and flexural stresses acting on the cervical vertebra and discs [33], thus we felt that this was too large of a translation as a minimum inclusion criteria. Additionally, according to Patwardhan et al. [37] Increasing forward head translation will have a kinematic effect on the quality, type, and magnitude of cervical lordosis that is driven by larger amounts of anterior head translation. Thus, inclusion of larger forward head translations as a mean value minimum would create a confounding effect on a true definition of loss of the cervical curvature that is not driven by forward head posture imbalance.

While this pilot study was inadequately powered, which might question the generalizability of the present findings to general population. In the current pilot trial, we included 30 patients per group

which represents 50% of the actual study in order to minimize the imprecision in the variance estimation. Our chosen sample size of (n = 30) per each group was based on the assumption that this would allow us sufficient data to assess the preliminary benefits of the multimodal program with the addition of denneroll cervical traction and allow some generalized extrapolation to the CGH population at large. Generalizability may be also limited by strict eligibility criteria. However, as the long term evaluation is likely to remain an important measure for gauging the impact of structural rehabilitation, we limit our sample to University-related communities to be able to monitor all participants and to decrease the dropout rate during this long term follow-up.

Notwithstanding the above limitations, this study is the first to evaluate the independent effect of sagittal cervical spine radiographic corrective care on the management outcomes and symptoms associated with CGH. To our knowledge this has not been previously reported in 1-year and 2-year follow-ups as in the current pilot project. These findings contribute to understanding the potential long-lasting effect of structural rehabilitation of the cervical spine for patients with CGH.

## 5. Conclusions

Restoring the cervical lordotic curve and improving forward head posture with a novel extension traction device is feasible and safe. At 10 weeks of treatment both the standard multi-modal program of care and the standard program with the denneroll orthotic showed comparable improvement in the clinical outcomes of participants suffering from chronic CGH. However, at 1-year and 2-year follow-up, the addition of the denneroll orthotic device identified better participant improvements for the CGH management outcomes.

## Declarations

### Author contribution statement

Ibrahim Moustafa and Aliaa Dia: Conceived and designed the experiments; Performed the experiments; Analyzed and interpreted the data.

Tamer Shousha: Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.



Deed Harrison: Conceived and designed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

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#### Data availability statement

Data will be made available on request.

#### Declaration of interests statement

The authors declare the following conflict of interests: Deed Harrison is the president of a company that distributes the cervical Denneroll product to health careproviders in North America.

#### Additional information

Supplementary content related to this article has been published online at <https://doi.org/10.1016/j.heliyon.2021.e06467>.

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