"This is the pre-peer reviewed version of the following article: [Keshavarzi F, Azadinia F, Talebian S, Khalkhali Zavieh M, Rasouli O. Effect of a semi-rigid backpack type thoracolumbar orthosis on thoracic kyphosis angle and muscle performance in older adults with hyperkyphosis: a randomized controlled trial. Disabil Rehabil. 2022 Apr 22:1-10. DOI:10.1080/09638288.2022.2065541], which has been published in final form at [https://www.tandfonline.com/doi/full/10.1080/09638288.2022.206554]. This article may be used for non-commercial purposes"

TITLE: Effect of a semi-rigid backpack type thoracolumbar orthosis on thoracic kyphosis angle and muscle performance in older adults with hyperkyphosis: a randomized controlled trial

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Ethical approval: The study protocol was approved by the Research Ethics Committee at the Iran University of Medical Sciences (IR.IUMS.REC.1398.435).

Trial registration: The trial was registered in the Iranian Registry of Clinical Trials (www.irct.ir) on 6th April 2020 as IRCT20190811044505N1.

Acknowledgments

The authors would like to thank all participants for their valuable contributions.

Competing interests

The authors declare that they have no competing interests.

Funding

The authors would like to thank the Iran University of Medical Sciences for the partial financial support of this study (grant number: 15236).

Abstract

Purpose: To investigate the effect of a semi-rigid backpack type thoracolumbar orthosis (TLO) on thoracic kyphosis angle (TKA) and potentially contributing factors of hyperkyphosis, including position sense and back muscle strength and endurance.

Method: This randomized, controlled trial was conducted on 48 older adults with hyperkyphosis, randomly allocated to an experimental or control group. The experimental group wore a semi-rigid TLO for 3 consecutive months. The control group received no external support or exercise. Thoracic kyphosis angle (TKA), joint position sense, back muscle strength and endurance were evaluated at the baseline and at the end of week 6 and week 12.

Results: The two-way (group × time) interactions were significant in terms of TKA ($F=37.88$, $p=<0.001$, $\eta_p^2=0.45$), muscle strength ($F=26.005$, $p=<0.001$, $\eta_p^2=0.36$), muscle endurance measured via load cell ($F=3.417$, $p=0.039$, $\eta_p^2=0.06$), and endurance holding time of Ito test ($F=3.629$, $p=0.045$, $\eta_p^2= 0.07$). A further analysis using one-way repeated measures of ANOVA showed that TKA, muscle strength and endurance were significantly improved in the experimental group. Also, two-way interactions were significant for absolute error and variable error of trunk neutral repositioning test from a trunk flexed and/or extended position for global components and horizontal components trunk repositioning test.

Conclusion: Wearing a semi-rigid backpack type TLO even from an unknown brand for short periods during the day (e.g., 2 – 4 hours) over 3 months not only modifies kyphotic posture but also can enhance back muscle performance in older adults with hyperkyphosis.

Keywords: Hyperkyphosis; postural deformity; spinal orthosis; back muscles; muscle strength; proprioception; position sense

Introduction

Age-related hyperkyphosis, is defined as an excessive forward curvature of the thoracic spine, affects up to 40% of people over 60 years [1-3]. Regardless of the psychologically damaging effects of this deformity and the emotional problems of dissatisfaction with appearance, hyperkyphosis is associated with adverse consequences, including decreased lung capacity, impaired physical performance, gait, and balance disturbances, and consequently increased risk of falls and mortality rates [4-6]. The progressive nature of this condition and associated health complications has recently received more attention towards the etiology, underlying causes, risk factors for kyphosis progression and related treatment options [6, 7].

Various intervention strategies, including spinal extensor strengthening exercise, postural training, Kinesio-taping, and spinal orthoses /brace, are employed to improve the posture [8-11]. Among the existing conservative management options, spinal orthoses with various designs have been widely administered to control excessive trunk flexion and promote more neutral spinal alignment [8, 12-15]. Promising evidence for the effectiveness of these orthoses in reducing pain, correcting posture, improving balance, and promoting function is available in the literature [8, 14, 16]. However, the recommendation of such orthoses for hyperkyphotic individuals still remains inconclusive, as some health practitioners have identified trunk muscle weakness and atrophy as adverse consequences of applying spinal orthoses [14, 17].

Concerns about the adverse effects of these external supportive devices on trunk muscle performance are based on the assumption that these spinal orthoses can reduce demand on back muscles; wearing them may therefore lead to atrophy of off-loaded trunk muscles [14, 17]. Such adverse effects on back extensor performance may trap the patient in a vicious circle and lead to an increase in kyphosis, as previous literature has suggested that back muscle strength significantly affects kyphotic postural changes [18].

Interestingly, some studies have reported a significant increase in trunk muscle strength, particularly in those conducted in 2004 and 2011 by scientists developing a semi-rigid backpack Thoracolumbar Orthosis (TLO) called Spinomed [12, 13]. The researchers have attributed the significant improvement in back extensor strength during the three- or six-month period of wearing Spinomed to the mechanism of action of this orthosis [12, 13]. Spinomed orthosis is based on biofeedback theory and encourages patients to use the back muscles to extend their back [15]. Therefore, it is expected that a semi-rigid backpack TLO may improve muscle strengthening by facilitating back extensor muscle activity [16] if it operates according to the biofeedback principle and is applied correctly (i.e., short periods during the day).

Participants in previous studies were individuals with painful osteoporotic vertebral fractures [12, 13, 19]. Confounding factors such as pain or pain catastrophizing may have influenced the results of muscle performance assessment in those studies [20]. Therefore, high-quality randomized clinical trials are needed to explore further the effect of semi-rigid TLO on muscle performance in older adults with thoracic hyperkyphosis. In addition, one of the other hypotheses about the underlying mechanisms of orthosis effectiveness is the increase in sensory feedback of body position and the enhancement of proprioception [21]. However, previous studies have overlooked examining this aspect of orthosis effectiveness.

The present randomized controlled trial aimed to evaluate the effect of a semi-rigid backpack type TLO on thoracic kyphosis angle (TKA) and potential contributing factors of spinal postural deformity, namely spinal position sense and back muscle strength and endurance. We hypothesized that if a semi-rigid backpack TLO is applied for short periods during the day, it would promote more neutral spinal alignment and improve muscle performance and trunk position sense.

Materials and Methods

Study design

This parallel-group, randomized controlled trial was performed from April to October 2020 at the School of Rehabilitation Sciences, Iran University of Medical Sciences. This study conforms to the recommendations in the Consolidated Standards of Reporting Trials (CONSORT) statement. The study protocol was approved by the Research Ethics Committee at Iran University of Medical Sciences (IR.IUMS.REC.1398.435) and followed the principles of the Declaration of Helsinki. The trial was registered in the Iranian Registry of Clinical Trials (www.irct.ir) on 6th April 2020 as IRCT20190811044505N1.

Participants

Using G-power software, a sample size of 36 participants (18 individuals per group for a repeated measure within-between interaction ANOVA (mixed model) with two groups over three-time points) was calculated assuming α value of 0.05, test power value of 0.8 and effect size value of 0.22 (based on the smallest η_p^2 obtained from our pilot study). However, considering the possibility of dropout, 48 community-dwelling older adults (24 individuals per group) were finally recruited for this study through public announcements, advertisements, flyers in retirement communities, and neighborhoods community centers, also via healthcare centers' databases. First, interested individuals called the main researcher and were screened by telephone to determine eligibility. Then they were invited for a baseline screening. An experienced physical therapist screened all the patients regarding the eligibility criteria before entering the study.

Inclusion criteria were age over 60 years, thoracic kyphosis angle greater than 50 degrees, ability to stand and walk without assistance, and ability to wear spinal orthosis independently. Exclusion criteria were the presence of a rigid fixed kyphotic deformity, vertebral fracture in the last six months, scoliosis, low back pain (LBP), history of spinal surgery, inflammatory diseases such as ankylosing spondylitis, rheumatoid arthritis, severe osteoporosis, neuromuscular disorders, central nervous system (CNS) disorders, and history of taking muscle relaxants and/or non-steroidal anti-inflammatory (NSAID) drugs during the study.

Randomization and Concealment

All participants signed a written consent before enrollment and were randomly assigned to the experimental or control groups. The group allocation was performed through permuted block randomization in blocks of four at an assignment ratio 1:1. For allocation concealment, the randomization codes were kept in opaque, sealed, sequentially numbered envelopes by a researcher who was not involved in the enrollment, evaluations or interventions.

Blindness

The examiner responsible for collecting outcome data was blinded to group allocation. To this end, all the participants were asked to remove the orthosis before entering the examination room, and all assessments were performed without orthoses. However, due to the obvious nature of the orthosis, it was impossible to blind participants to the intervention.

The Spinal Orthosis Group

The participants in the experimental group received a semi-rigid TLO, which consisted of two posterior aluminum bars, an abdominal pad, and shoulder straps (Figure 1). The posterior bars are shaped according to the patients' vertebral column. The abdominal pad helps to reduce the load on the spine by increasing abdominal pressure. The shoulder straps provide posterior forces for counteracting kyphotic posture. The same certified orthotist fit the orthoses for all participants and taught them how to wear and remove orthoses. The participants were asked to wear orthosis for 12 weeks, they received no other treatment, and no change was applied in their usual physical activity. In the first week, the orthosis was worn for 30 minutes daily, and throughout the second week, this period gradually increased to 2 hours per day. From the beginning of the third week to the end of week 12, the participants were asked to wear orthoses for at least 2 hours a day and allowed to wear orthoses for a maximum of 4 hours per day based on their level of physical activity. The participants were asked to record orthosis's donning and doffing hours in a daily log to monitor their adherence to our recommendations about the hours of orthosis use during the day. During the intervention period, the participants visited the orthotist each month to reset the orthosis.

The Control Group

The participants in the control group were assessed at baseline, end of week 6, and end of week 12. They were advised to maintain their daily physical activity as before and also received no external support, exercise or other interventions. However, due to ethical considerations, they received a spinal orthosis after the outcome assessment at the end of week 12.

<Figure 1 about here>

Outcome Measures

Our primary outcome was a change in thoracic kyphosis angle (TKA), and the secondary outcomes were changes in joint position sense, back muscle strength (maximal extensor force) and endurance. Since the previous literature revealed that fatigue causes a decline in proprioception [22], all participants were evaluated for position sense before other outcome measures. After measuring muscle strength, the participants rested for 30 minutes to minimize the effect of muscle fatigue on the endurance time. The same outcome examiner, who was blinded to the group allocation, performed all measurements in all participants in an orthosis-free condition three times: at baseline, end of week 6, and end of week 12.

Measurement of the Thoracic Kyphosis Angle

TKA was measured using photogrammetry examination as described in the previous literature, which is a safe, valid, and reliable technique for measuring thoracic curvature [23, 24]. Three photographs were taken by a Nikon camera (Nikon D5300, 24.2-megapixel, Nikon, Thailand) from the right side of the participants during inhalation (Figure 2). Digital photographic records were imported to AutoCAD software. The angle formed between the intersections of the straight-line extensions drawn from the markers at spinous processes of the seventh cervical (C_7) and twelfth thoracic (T_{12}) vertebrae was calculated as the thoracic kyphosis degree for each photograph, and the average of all three measures were used later.

<Figure 2 about here>

Joint Position Sense

Position sense (as one of the components of proprioception) was assessed by the active angle reproduction test, which measures a person’s ability to reproduce a predetermined target position. The participants sat on an adjustable chair in their normal upright posture (Figure 3). The participants adopted their neutral, upright posture, focused on it, and maintained it for 5 seconds. In this condition, a photograph was taken using the camera. The participants were then asked to perform maximum flexion and or extension without any pain or discomfort without detaching the lumbo-pelvic from the chair’s backrest at their preferred speed while maintaining a neutral neck position. Then, they relocated the initial neutral position as accurately as possible, informing the examiner by pressing the handheld button of the laser pointer in their left hand, and the camera captured a photograph. The participants receive no feedback on their performance. Six trials were repeated for each direction from trunk flexion to a neutral position or trunk extension to the neutral position. The order of trunk flexion or trunk extension was chosen randomly. The participants were blindfolded to remove visual clues. To minimize the effects of diurnal variation, we evaluated position sense at least three hours after waking up. In addition, the participants were asked to refrain from strenuous physical activity for 24 hours before testing and refrain from eating or drinking for 2 hours before testing.

<Figure 3 about here>

The photograph records were imported into the Paint software. The marker position in the Paint software for each photograph was extracted on the abscissa (X-axis) and ordinate (Y-axis) in pixel and then converted to centimeters. Then, a customized program developed in Excel, using these two values, the global components (i.e., the linear length extending from the reference point (i.e., C_7 in the beginning) to the marker location (i.e., C7 during laser light)) were calculated by the equation of $R = \sqrt{x^2 + y^2}$. Using trigonometric formula (degree = tangent^{-1} ${}^{R}/_{100}\,cm$), head repositioning errors were converted to degrees. Trunk position sense was assessed via computing absolute error (AE) and variable error (VE) along their horizontal (X), vertical (Y) and global (R) components. AE measures the overall accuracy of repositioning performance, which has been reported as the primary outcome measure in most previous studies [8, 25]. AE shows how close the person’s responses are to the target, which is measured by calculating the average deviation of the person’s response from the target. ’Higher AE values indicate less accurate repositioning performance. VE is a measure of the consistency (i.e., variability) of repositioning, which is the average deviation of the persons’ response from his/her own average score. Higher VE values indicate less consistent repositioning performance. The AE and VE indices along the global, horizontal, and vertical components were calculated in degrees.

Back Muscle Strength (Maximal Extensor Force)

Back extensor strength was measured by a “S” shape load cell (FG-5100, Lutron Electronic Enterprise Co., Ltd., Taiwan) in the sitting position. Our designed setup consists of a chair with a 25 cm high backrest, with two vertical bars firmly attached to the backrest, a board with a hole in the center to hold the load cell was mounted on the vertical bars, with the height of the board and the load cell via a rail bar adjusted to the vertical bars according to the height of the participants (figure 4). For the convenience of the participants and to minimize the local bony pressure, the load cell was covered with a pad of high-density foam. Prior to the test, a warm-up of the back extensor muscles was performed for 2 minutes and the load cell was calibrated before each session. After positioning the participant on the chair in the neutral, upright posture, the load cell position was adjusted on the vertical bars to align with the spinous process of the T_7 vertebra. The participants were asked to gradually increase their backward force over 1-3 seconds upon hearing a “beep” sound, and then maintain the maximum force for 5 seconds and gradually relax it over 1-3 seconds. A 30-second rest was given between the trials to prevent fatigue, and three successive trials were performed. For each trial, peak back extensor force (kg) was recorded. If the maximum trial was more than 5% higher than either of the previous two trials, an additional trial would be conducted. Participants were familiarized with the testing procedure by performing a practice trial before starting data recording. All measurements were performed by a standardized procedure. During each effort, the participants received verbal encouragement and visual feedback (displaying force output on a monitor) to achieve maximum force.

<Figure 4 about here>

Trunk Muscle Endurance Test

Trunk muscle extensor endurance time was assessed by two different methods, including designed load cell setup and Ito test.

Muscle Endurance Measured via Load Cell

After measuring the maximal extensor force, a 30-minute rest interval was considered to minimize the effect of fatigue on the outcome measure. The participants were then asked to perform a sustained contraction at 50% of their maximum force to assess back muscle endurance. After a single familiarization trial, three endurance trials with 30-second rest between trials were performed, and maximum endurance time (in seconds) was recorded. During the endurance test, the test would stop when the person could not maintain more than 40% of their maximum force (i.e., if the sustained contraction was 10% less than the target level).

Ito Test

This is a prone trunk holding test as a modification of the Biering-Sorenson method [26]. The participants were placed in a prone position with a small pillow under their lower abdomen while their arms were at their sides. They were asked to lift their sternum off the ground upon hearing the “start” command. During the test, they needed to maintain maximum flexion of the cervical spine and contract the gluteal muscles to stabilize the pelvis. They were asked to hold this position as long as they could, but not more than a 300-second limit. Duration was recorded in seconds using a handheld stopwatch.

Statistical Analysis

Data were analyzed using SPSS Version 22. All the data were encoded to prevent bias in data analysis and to blind the statistician. The normality of the distribution of the variables was evaluated using the Shapiro-Wilk test and residual plot assessment. Given that back muscle endurance time measured via both load cell and Ito test, AE, and VE in repositioning tests had a skewed distribution, and the lack of a non-parametric equivalent test for Mixed model analysis of variances (ANOVA), these variables were log-transformed to stabilize the variance. The independent t-tests or Mann-Whitney U tests were used for the between-group comparisons of the demographic characteristics depending on the normal or non-normal distribution of the variables. All participants were analyzed based on the intention-to-treat principle to avoid the overestimation of treatment efficacy resulting from the dropout of participants. For this purpose, the last measures of any dropouts were carried forward in the analysis. Dependent variables were analyzed using separate 2 (group: experimental vs. control group) × 3 (time: baseline, week 6, and week 12) mixed-model ANOVA. Where the group's interaction with time was significant, a one-way repeated-measures ANOVA was used to determine the simple main effect. Bonferroni corrections were used for multiple comparisons. The level of statistical significance was set at α=0.05.

Results

A total of 167 older adults (114 women and 53 men) were screened from April to October 2020, and 48 of them were eligible and willing to participate in the study (figure 5). Comparison of demographic and clinical characteristics between the two groups showed no significant differences at baseline ($p > 0.05$; Table 1, and Table 2). During the experiment, three patients withdrew from the experimental group-one person due to illness and two others because of personal reasons; in addition, four participants withdrew from the control group because of personal reasons (n = 2), traveling abroad (n = 1), and abdominal surgery (n = 1).

<Figure 5 about here>

<Table 1 about here>

The two-way (group × time) interactions were significant in terms of TKA (F= 37.88, p= <0.001, η_p^2= 0.45), muscle strength (F= 26.005, p=< 0.001, η_p^2= 0.36), muscle endurance measured via load cell (F= 3.417, p= 0.039, η_p^2= 0.06), endurance holding time of Ito test (F=

3.629, p= 0.045, η_p^2= 0.07). Further analysis in each group showed that TKA, muscle strength and endurance were significantly improved in the orthosis group over 3 months. Comparison between two groups showed the significant difference in TKA, and endurance holding time of Ito test at the end of week 12. However, there was no statistically significant difference between two groups in back extensor strength and endurance measured via the load cell. The two-way (group × time) interactions were significant for AE and VE of trunk neutral repositioning test from a trunk flexed position for global components (F= 7.09, p= 0.002, η_p^2= 0.13; F= 6.584, p= 0.003, η_p^2= 0.12) and horizontal components (F= 4.23, p= 0.017, η_p^2= 0.08; F= 5.011, p= 0.009 η_p^2= 0.09,) respectively. Also, two-way interactions were significant for AE and VE of trunk neutral repositioning test from a trunk extended position for global components (F=5.344, p=0.009, η_p^2=0.10; F=4.648, p=0.017, η_p^2=0.09) and horizontal components (F=4.147, p=0.023, η_p^2=0.08; F=4.876, p=0.015, η_p^2=0.09) respectively (Table 3). Further analysis in each group showed that change in AE and VE in the orthosis group was not significant. However, some AE and VE values in the control group increased significantly. Comparison between the two groups showed a significant difference in AE and VE at the end of week 12 (Table 2). It is worth noticing that re-analysis utilizing a per-protocol approach did not change the results and produced a similar conclusion to the intention-to-treat analysis (Supplementary material).

<Table 2 about here>

<Table 3 about here>

DISCUSSION

The present study aimed to investigate the effect of a semi-rigid backpack type TLO on TKA and potentially contributing factors (i.e., position sense and back muscle strength and endurance) of hyperkyphosis in older adults. According to the results of this RCT, spinal alignment, back muscle strength and endurance were significantly improved in the experimental group, which wore a semi-rigid TLO for three months, compared with the control group.

In our study, there was a significant difference between two groups regarding TKA after 3 months, favoring the orthosis group. TKA was reduced by 14.8 degrees in the orthosis group and progressed 1.2 degrees in the control group over 3 months. This value of kyphosis angle correction was greater than the 7.9 and 8.1 degree decreases reported by wearing Spinomed orthosis and Spinomed active orthosis following six months, respectively, in studies by Pfiefer et al. [12, 13], and was close to the 11.7 degree decrease reported by Hosseinabadi et al. [8]. Higher kyphotic angle correction observed in the present study may be somewhat attributable to periodic adjustment of orthosis, as it is possible to achieve an intimate fit and apply optimal corrective force through periodic adjustment. However, it is worth noting that none of the participants in the present study suffered from fixed spinal deformity; therefore, this amount of reduction in thoracic kyphosis angle may not be achieved in fixed spinal deformity.

Another issue that needs clarification is that this improvement in spinal alignment resulting from wearing this semi-rigid TLO should not occur in exchange for muscle deconditioning. Therefore, we evaluated both maximal back extensor strength and back muscle endurance by measuring holding time in the Ito test and via a designed load cell setup. The change in maximal isometric back extensor strength was 31.4% in the orthosis group, albeit with no significant difference between the two groups, after 3 months. Participants in the intervention group showed an improved back extensor strength by 7.9 kg, whereas the control group presented a decreased back extensor strength by 0.4 kg over 3 months. In the two RCTs performed by the Spinomed development team [12, 13], 73% and 64% increases in back extensor strength were reported, respectively, after six months of wearing Spinomed and Spinomed active. Valentin et al. [19] found a 50% increase in back muscle strength. Further increase in maximum muscle strength in the mentioned studies compared to the present study may be partly attributed to differences in health status and demographic characteristics. For example, Pfeifer et al. [12, 13] and Valentin et al. [19] recruited participants with a symptomatic vertebral compression fracture. They may have avoided maximum effort in the pre-treatment session due to pain or fear of unsafe or uncomfortable testing. Therefore, we excluded individuals with vertebral fracture and back pain in the present study to avoid confounding factors such as pain and/or fear-avoidance beliefs [20]. The findings of increased back extensor strength were close to the results reported by Alin et al. [27], which was an increase of approximately 27%. Alin et al. [27] recruited women with osteoporosis without acute or subacute vertebral fracture.

. In addition, we measured back muscle endurance and the intervention group had 23.9 s increases in holding time, while those in the control group had a 4.6 s increase in holding time after 3 months. Furthermore, participants in the intervention group had a 22.6 s increase in holding time of Ito test while those in the control group had a 1 s decrease in holding time of Ito test, resulting in a significant difference between two groups after 3 months, favoring the orthosis group. The study by Hosseinabadi et al. [8] has been the only one evaluating the back muscle endurance and reporting an 11-s increase in the Ito test after three months of wearing Spinomed. A significant increase in back muscle strength and endurance after a period of wearing spinal orthosis in older adults with hyperkyphosis is a promising finding which does not confirm the assumption commonly made about the side effects of spinal orthoses on muscle performance. It also shows that wearing a semi-rigid TLO for short periods during days [17], such as 2 to 4 hours during upright activities, not only does not adversely affect muscle performance but also can increase back extensor strength and endurance by facilitating the trunk muscles activity during daily activities [15]. The semi-rigid backpack TLO used in his study, like Spinomed orthosis employed in previous studies[8, 12, 13], does not provide full spinal movement restriction. Concerns about the adverse effects of wearing spinal orthosis for trunk muscle performance are rational if the orthosis provides full immobility [17]. Furthermore, improvement of muscle performance in the orthosis group can be justified by the flexion-relaxation phenomena. Some previous studies have revealed the reduced back muscle activity based on flexion-relaxation response to flexed trunk posture, which in the long run leads to deconditioning of the back musculature [28]. Correction of spinal alignment through orthotic treatment can facilitate back muscle activity and subsequently enhance capacity of muscle to produce maximal voluntary contraction force and or sustain an isometric contraction.

Sinaki et al. [21] hypothesized that one of the underlying principles of the efficacy of spinal orthoses is that the orthosis enhances proprioceptive input and increases awareness of body position. However, this notion of the efficacy of spinal orthosis remained a hypothesis and had not been tested in previous studies. Only in the study by Hosseinabadi et al. [8] the effect of Spinomed orthoses on trunk position sense was evaluated, and a decrease in AE was reported after 3 months of wearing the orthosis. Caution should be taken to compare our study with Hosseinabadi et al. [8] due to differences in predefined target position, movement direction, and instrument. For example, Hosseinabadi et al. [8] used a dual inclinometer to assess trunk position sense; additional cutaneous input may have been generated due to the need to hold the sensors on the participants' trunk and pressure applied, which may have affected the accuracy of the results. Although a trend for decreasing AE and VE in the orthosis group was found in our study, this decrease was not significant. In contrast, some AE and VE values in the control group increased significantly, resulting in a significant difference between the two groups in trunk position sense after 3 months. Increased AE and VE errors in the control group, suggesting a decrease in accuracy and an increase in inconsistency and or variability of participants' response, respectively, indicating proprioception degradation in the control group after 3 months. In other words, it seems that spinal orthosis may prevent proprioceptive deficit progression over 3 months. This decrease in spinal position sense in the control group may be partly attributable to muscle fatigue and loss of muscular endurance. There is evidence that muscle fatigue is associated with a decline in position sense [22]. The chronic kyphotic posture may increase the demand for back extensor muscles to maintain a more upright posture [29, 30], which has caused fatigue in these muscles over time as well as abnormal afferent information originating from muscle spindles about trunk posture to the CNS [31]. Another possible justification for the decline in position sense in the control group may be creep deformation of the spinal soft tissue due to prolonged kyphotic posture. The creep can cause desensitization of mechanoreceptors and less accurate estimation of trunk position [32]. In addition, we evaluated position sense, like other outcomes in conditions without orthosis. Cutaneous afferent stimulation might have increased awareness of the trunk position if the assessments were performed while the person was wearing the orthosis.

Some limitations should be considered when interpreting the results of this study. Our participants were older adults with a flexible kyphotic deformity without acute fracture or back pain. Thus, caution should be taken when generalizing these findings to individuals with symptomatic hyperkyphosis and individuals with a fixed deformity. Due to the obvious nature of the orthosis, it was impossible to blind participants to the intervention; however, all measurements were performed in an orthosis-free condition, and the outcome examiner was blinded to the group allocation. Whether the participants had worn the orthosis according to the orthotist's instructions was questionable. However, participants recorded donning and doffing their LSO daily and reported an average of 2.54 hours wearing their orthosis per day.

Conclusion

The results of this study suggest that wearing a semi-rigid backpack type TLO for 3 months, even from an unknown brand for short periods during a day (e.g., 2 – 4 hours), not only modifies kyphotic posture but also enhances back muscle performance in older adults with hyperkyphosis. The values for trunk position sense, back muscle strength and endurance at the baseline in our study were different from the normal values reported for the older adults of the same age range with normal thoracic curvature in a previous study [33]. Thus, according to our findings, it seems that the patients in the orthosis group have a chance to improve their muscle performance and reach close to normal values.

Word count: 4642

Acknowledgments

The authors would like to thank all participants for their valuable contributions.

Competing interests

The authors declare that they have no competing interests.

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Figure Legends

Figure 1. semi-rigid backpack type thoracolumbar orthosis.

Figure 1 Alt Text. A person wore a semi-rigid thoracolumbar orthosis similar to a backpack consisting of two posterior aluminum bars, an abdominal pad, and shoulder straps.

Figure 2. Measuring thoracic kyphosis using photogrammetry technique.

Spinous processes of the seventh cervical (C_7) and twelfth thoracic (T_{12}) vertebrae were detected by palpation and marked by a pencil on the skin. Then custom-made lightweight markers were adhered vertically on the skin by double-sided adhesive tape on the spinous processes of C_7 and T_{12} vertebrae. Participants stood barefoot in their habitual standing position. The legs were shoulder-width apart, the arms were flexed, and the fists were placed on the clavicle. The camera was fixed at a distance of one meter from the participant's body, but its height was adjusted according to each person's height so that the camera lens was centered on the mid-thoracic vertebrae and the whole spine length was in view.

Figure 2 Alt Text. One camera took pictures of a person from the right side while the person was standing barefoot in his habitual standing position with crossed arms. Two black markers were placed on the C_7 and T_{12}.

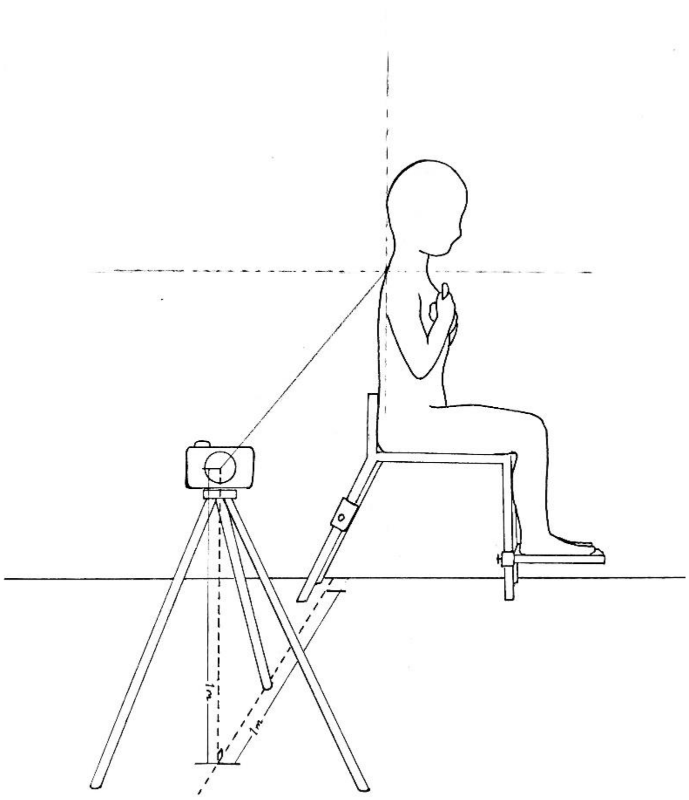

Figure 3. The experimental setup for trunk repositioning test.

The participants sat on an adjustable chair in their normal upright posture. This chair had a short backrest to limit lumbopelvic motion. The contact of the participant's lumbopelvic region to the chair's backrest was monitored by a switch mounted on the chair's backrest that turns a light. The hips and knees were at 90° flexion, the arms were crossed over the chest, and the fingertips touched the shoulder. A custom-made lightweight marker was adhered to the spinous process of C_7 by double-sided adhesive tape. The camera was located at the height of 1 meter from the ground and 1 meter from the imaginary line perpendicular to the chair's backrest. The right side of the participant's body was facing the camera.

Figure 3 Alt Text. One schematic drawing displays a person sitting straight, arms crossed over the chest, and looking forward on an adjustable chair with a backrest during the active angle reproduction test. One camera is also placed on the right side of the person.

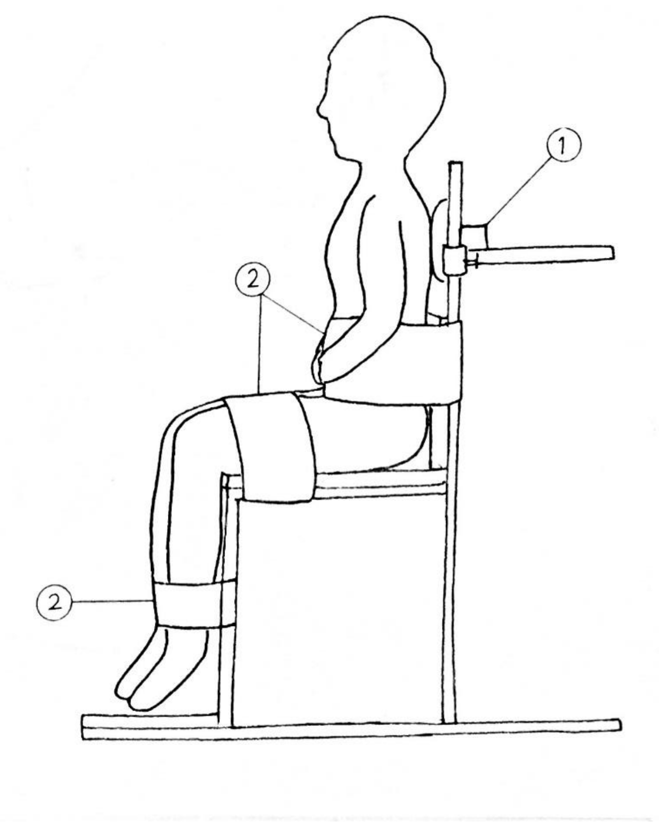

Figure 4. Assessing isometric back extensor strength and endurance using the designed setup. The participants sat on the chair, their hips and knees flexed 90 degrees, and their thighs parallel the seat. Arms were crossed on the abdomen, and the chair's height was set so that the participants' feet were off the ground. In order to restrain movements, the leg, thigh, and pelvis were tightened with inelastic belts and straps.

Figure 4 Alt Text. One schematic drawing demonstrates a person sitting in a neutral, upright posture on a chair with a backrest. Two vertical bars are firmly attached to the backrest, a board with a hole in the center to hold the load cell is also mounted on the vertical bars. Three straps are fastened around the pelvis, thighs, and ankles to restrict movements during performing isometric tests.

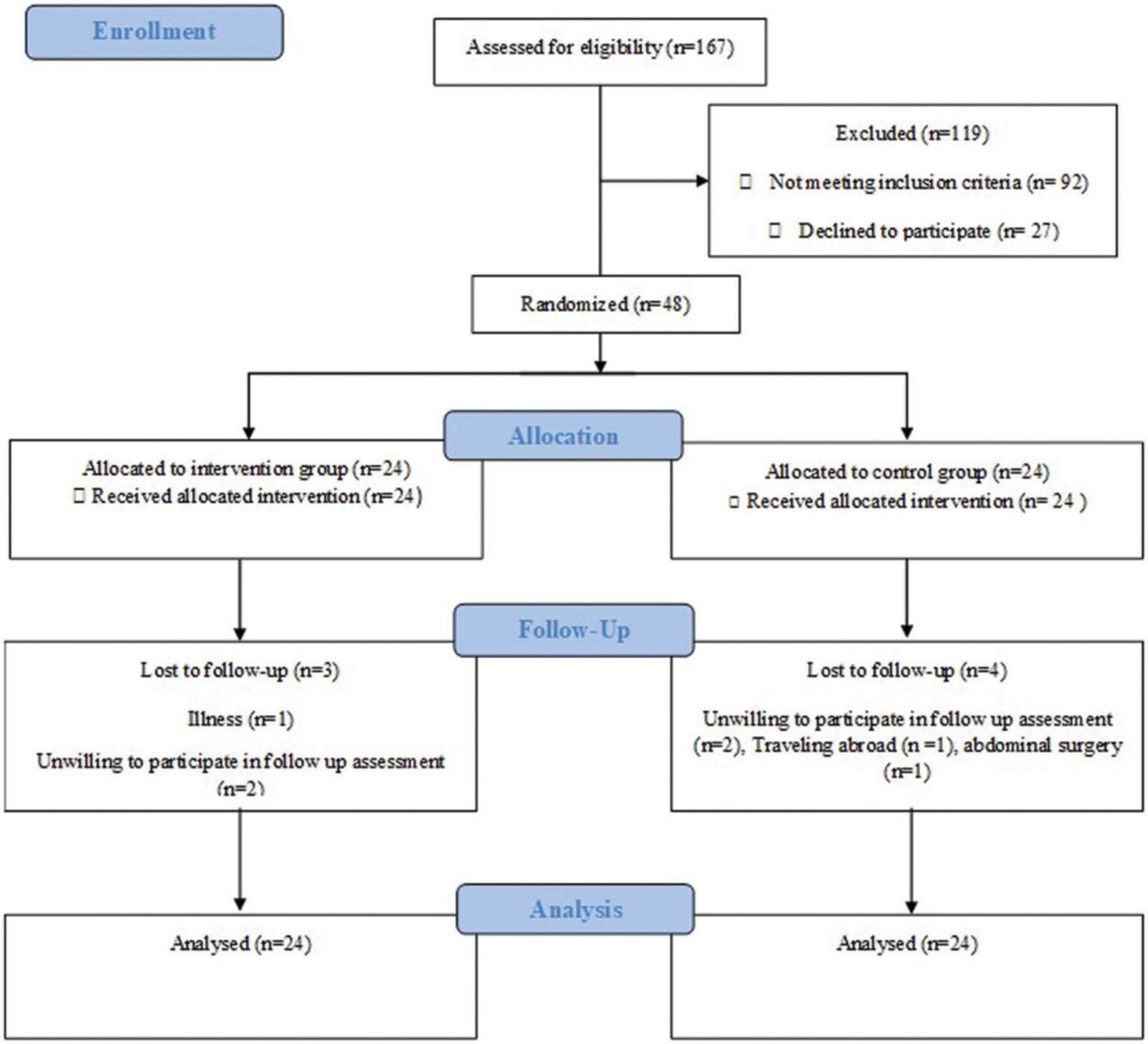

Figure 5. Flow diagram of participants' screening, allocation, and assessment.

Figure 5 Alt Text. This flow diagram shows that 167 individuals were assessed for eligibility, and 48 were included. Then, 24 participants were randomly allocated to an intervention and 24 persons into a control group.

TABLES

Table 1. Baseline demographic characteristics of participants in the experimental and control groups.

	Experimental group (n=24)	**Control group (n=24)**	**P-value**
Sex (male/female)	3/21	6/18	0.26
Age (years)	65.6 ± 7.1 (60 - 85)	65.6 ± 4.2 (60 – 74)	0.29
Height (cm)	155 ± 5	158 ± 8.9	0.23
Weight (Kg)	64.2 ± 8.9	70.2 ± 13.9	0.11
BMI (kg/m2)	26.5 ± 3.3	27.6 ± 3.4	0.24

Table 2. Mean ± SD, and changes in the dependent variables over 3 months (95% confidence interval) for the experimental and control groups.

			Experimental group at baseline	**Experimental group at end of 12th week**	**Before to after intervention (95%CI)**	**Control group at baseline**	**Control group at end of 12th week**	**Before to after intervention (95% CI)**	**P-value Baseline comparison of two groups**
Thoracic kyphosis angle (degree)			73.6 ± 9.8	58.7 ± 10.4	-14.8 (-19.4 to -10.1)	70.8 ± 9.3	72± 9.8	1.2 (-0.5 to 2.9)	0.31
Maximal extensor force / muscle strength (Kg)			24.6 ± 9.8	32.6 ± 10	7.9 (5.1 to 10.8)	30 ± 14	29.5 ± 13.4	-0.4 (-1.3 to 0.4)	0.13
Muscle endurance measured via load cell (Sec)			49.2 ± 41.1	73.1 ± 46.3	23.9 (9.1 to 38.6)	56.4 ± 60.2	61.1 ± 60.2	4.6 (-3.9 to 13.2)	0.44
Endurance time of Ito test (Sec)			132.8 ± 106.4	155.5 ± 94.8	22.6 (-7.7 to 53)	103.2± 87.4	102.1 ± 87	-1 (-6.8 to 4.7)	0.53
Reproduction trunk neutral position from a trunk flexed position (degree)	**Horizontal**	**AE**	1.2 ± 0.9	0.8 ± 0.6	-0.3 (-0.7 to -0.06)	0.9 ± 0.4	1.1 ± 0.6	0.2 (-0.04 to 0.5)	0.47
		VE	2.7 ± 2.1	1.8 ± 1.4	-0.8 (-1.5 to -0.1)	1.9 ± 0.9	2.5 ± 1.4	0.5 (-0.03 to 1.2)	0.4
	Vertical	**AE**	0.3 ± 0.3	0.2 ± 0.1	-0.08 (-0.22 to 0.05)	0.3 ± 0.4	0.3 ± 0.4	0.07 (-0.05 to 0.1)	0.34
		VE	0.7 ± 0.6	0.5 ± 0.3	-0.1 (-0.4 to 0.1)	0.7 ± 1	0.8 ± 1	0.5 (-0.05 to 1.1)	0.32
	Global	**AE**	1.3 ± 0.9	0.8 ± 0.6	-0.4 (-0.7 to 0.09)	1 ± 0.6	1.3 ± 0.8	0.3 (0.06 to 0.5)	0.43
		VE	2.9 ± 2.1	1.9 ± 1.4	-0.9 (-1.6 to -0.2)	2.3 ± 1.4	2.8 ± 1.6	0.1 (-0.03 to 0.4)	0.45
Reproduction trunk neutral position from a trunk extended position (degree)	**Horizontal**	**AE**	1.6 ± 1.1	1.1 ± 0.6	-0.5 (-0.9 to -0.02)	1.5 ± 0.9	2. ± 1	0.4 (0.05 to 0.9)	0.86
		VE	3.7 ± 2.4	2.7 ± 1.5	-1 (-2 to -0.02)	3.3 ± 1.6	4.6 ± 2.2	1.3 (0.4 to 2.2)	0.78
	Vertical	**AE**	0.3 ± 0.2	0.3 ± 0.3	0.01 (-0.1 to 0.1)	0.3 ± 0.2	0.4 ± 0.2	0.1 (-0.06 to 0.2)	0.74
		VE	0.8 ± 0.6	0.8 ± 0.6	0.05 (-0.2 to -0.4)	0.8 ± 0.6	1.1 ± 0.6	0.2 (-0.1 to 0.6)	0.75
	Global	**AE**	1.7 ± 1	1.3 ± 0.7	-0.4 (-0.8 to 0.07)	1.5 ± 0.7	2.2 ± 1.1	0.6 (0.2 to 1.1)	0.77
		VE	3.9 ± 2.4	2.9 ± 1.5	-0.9 (-2 to 0.05)	3.5 ± 1.7	4.6 ± 2.2	1.1 (0.1 to 2.1)	0.82

AE: absolute error; VE: variable error

Table 3. Summary of the Analysis of Variance for dependent variables.

			Time		Group	
			F	**P-value**	**F**	**P-value**
Thoracic kyphosis angle			27.3	<0.001	4	0.049
Maximal extensor force (muscle strength)			21.1	<0.001	0.1	0.75
Muscle endurance measured via load cell			7.3	0.001	0.1	0.745
Endurance time of Ito test			2.6	0.096	2.8	0.10
Reproduction trunk neutral position from a trunk flexed position	**Horizontal**	**AE**	0.9	0.398	1.5	0.22
		VE	1.5	0.221	1	0.314
	Vertical	**AE**	0.5	0.566	0.3	0.585
		VE	0.3	0.702	0.1	0.729
	Global	**AE**	1.5	0.230	1	0.301
		VE	1.9	0.160	0.8	0.361
Reproduction trunk neutral position from a trunk extended position	**Horizontal**	**AE**	0.04	0.941	3.9	0.053
		VE	0.2	0.720	4.5	0.038
	Vertical	**AE**	2.1	0.118	0.7	0.381
		VE	1.5	0.209	0.8	0.360
	Global	**AE**	0.4	0.637	3.2	0.077
		VE	0.1	0.825	3.1	0.081

AE: absolute error; VE: variable error