

RANDOMIZED TRIAL

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A Comparative Study of a Novel Postural Garment *Versus* Exercise for Women with Nonspecific Cervical Pain*A Randomized Cross-over Trial*Merce Avellanet, MD, PhD,^a Anna Boada-Pladellorens, MD,^a Esther Pages, MD, PhD,^a Aleix Dorca, PhD,^b Betlem Sabria, PhD,^b Michael Pfeifer, MD,^c and Elvira Gea, PharmD^{d,e}**Study Design.** Randomized cross-over study.**Objective.** The aim of this study was to compare exercise, the criterion standard, to the postural garment PosturePlusForce in the management of nonspecific cervical pain in women. We also analyzed both interventions with regards to baseline posture, use of pharmacological pain relievers, compliance, and comfort.**Summary of Background Data.** The prevalence of neck pain has increased during the last decade, preferentially affecting women. Those suffering from this condition may manifest a decrease in quality of life and inability to work. Consistent recommendations highlight the importance of exercise and posture for neck pain improvement.**Methods.** A total of 32 female health care professionals with cervical pain (≥ 3 on the visual analogue scale) entered the trial. Participants were allocated to either performing exercises or wearing the postural garment. The cross-over between interventions was separated by a 3-month washout period. Primary outcomes included pain intensity and posture. Secondary out-

comes comprised cervical pain-related disability, psychological factors, physical activity, global perceived effect of treatment, and garment comfort. Treatment compliance, medication use, and adverse events were also recorded.

Results. Both interventions showed a significant improvement in pain in subjects with an adherence $>60\%$. However, in participants with dorsal hyperkyphosis ($>45^\circ$), the garment demonstrated a greater reduction in pain than exercise ($P=0.019$). Additionally, those wearing the garment needed fewer pain relievers than those performing exercises ($P=0.007$). Compliance was $>50\%$ for both interventions and comfort was contingent on season.**Conclusion.** In our study, PosturePlusForce showed, at least, a similar effect on pain to exercise, although those with dorsal hyperkyphosis exhibited a greater reduction in pain and related variables with the garment. Pain relievers were less required by those wearing PosturePlusForce than by those performing the exercises.**Key words:** catastrophizing, chronic cervical pain, cross-over trial, disability, dorsal hyperkyphosis, exercise, neck pain, physical activity, postural garment, posture, rehabilitation.**Level of Evidence:** 1**Spine 2021;46:1517–1524**From the ^aRehabilitation Department, Hospital Nostra Sra. de Meritxell, Andorra, Research Group on Health Sciences and Health Services, University of Andorra, Andorra; ^bUniversity of Andorra, Andorra; ^cInstitute of Clinical Osteology, Bad Pyrmont, Germany; ^dHead of Pharmacy Department, Hospital Nostra Sra de Meritxell, Andorra; and ^eResearch Group on Health Sciences and Health Services, University of Andorra, Andorra.

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Musculoskeletal disorders are a leading cause of disability worldwide.¹ The number of years lived with disability have markedly increase from 2006 to 2016 with a 22% rise in neck pain.² The prevalence of cervical symptoms in the general population ranges between 10% and 15%, with a higher prevalence in females and, in particular, among health professionals.^{3,4} Women are more likely than men to suffer from persistent neck problems and less likely to experience resolution since they are less active and compliant with exercise than men at all ages.^{5,6}

The origin of neck pain is multifactorial and includes poor posture, anxiety, and depression.^{7,8} Among the different approaches for neck pain management, exercise is supported by the strongest evidence and is considered as the criterion standard.⁹ Consistent recommendations to



Figure 1. Effects of Posture Plus Force garment.

treat neck pain include exercise and the assessment of psychosocial factors,¹⁰ as well as improvements in body awareness.¹¹ Therefore, management should ideally include exercise and posture modification.

There are many devices designed to improve posture that work by pulling back shoulders and causing compensatory sagittal misalignments, such as a tilt of the head forward and a protrusion of the abdomen. Medi, a German orthopedic brand, launched a new garment (PosturePlusForce) that differs from other existing products because it enhances abdominal contraction and shoulder proprioception, acting as a functional reminder (Figure 1).

Therefore, this study aimed to compare the use of PosturePlusForce against exercise, the criterion standard, in the reduction of nonspecific cervical pain in women health care workers. We also analyzed the effect of both interventions in posture and in the use of pharmacological pain relievers. Finally, we also compared compliance and treatment perception for the PosturePlusForce garment and exercise.

MATERIALS AND METHODS

Study Design

This randomized cross-over clinical trial was executed at Hospital Nostra Senyora de Meritxell, Andorra, between April 2017 and July 2019. The study was approved by the Clinical Research Ethics Committee of the hospital and written informed consent was obtained from all participants. This study was registered on clinicaltrials.gov (ID number: NCT03560492).

Participants were allocated at random to receive first one of the two following interventions: wear PosturePlusForce garment or practice stretching and strengthening exercises involving cervical and dorsal areas. We designed the study to have two 3-month sequential interventions (exercise or PosturePlusForce) separated by a 3-month washout period.

For further details, see *Avellanet et al, 2020*.¹² The study is reported in agreement with the CONSORT statement.¹³

All the variables were included in an SPSS database by an external investigator. During the study, the database was audited at three different times by two investigators and the statistician.

Participants

Participants were women with nonspecific cervical pain, recruited through emails sent to nurses or allied health professionals from the Hospital and associated health facilities. We assessed candidates for eligibility through a complete medical consultation.

Nonspecific neck pain was defined as neck pain without an identified pathological basis.¹⁴ We included women with cervical pain ≥ 3 on the visual analogue scale (VAS),¹⁵ between 21 and 55 years' old, and able to wear the garment, perform the exercises, and attend follow-up assessments. Exclusion criteria were pregnancy, malignancy or other severe disease, radiculopathy, spondylotic myelopathy, psychiatric disorder, inability to perform exercises, or unwilling to do the follow-up.

MATERIALS

The PosturePlusForce is a T-shirt garment that includes tensional inelastic bands that exercise traction to produce a postural realignment. The breathable and highly elastic fabric consists of elastane, cotton, and polyamide. The enhancement of posture is centered on an anatomical and physiological approach, focusing on abdominal and periscapular muscles.

Interventions and Outcomes

We showed participants of the PosturePlusForce (P+) group how to wear the garment and told them to wear it for 2 to 4 hours per day, during day time, every day of the week, during 3 months. The exercise (Ex) group attended five sessions of 20 minutes (once a week during 5 weeks) with a physiotherapist to learn stretching and strengthening exercises of the cervical and dorsal areas. This group also received instructions to continue the exercises at home on a daily basis during 3 months. After a 3-month washout period to reverse any change that may have occurred with the first intervention, participants swapped intervention groups for another 3-month period.

Primary outcomes were pain intensity, measured with a VAS, and posture. To evaluate the minimal clinically important difference for pain, we adopted a 30% reduction or 2-point reduction in neck pain measured with a numerical VAS. Although a difference in pain >13 mm on a 100-mm VAS is generally considered significant in acute pain,¹⁵ in our study the threshold for a clinically relevant difference in chronic pain was set at 20 mm. To objectively measure posture, a device for computerized measurement of surface curvature (Spinal Mouse) in the upright position was used with proven reliability and validity.¹⁶ The investigator who performed the Spinal Mouse scan was blind to the participants' intervention groups.

Secondary outcomes included cervical pain-related disability, measured with the validated Spanish version of Neck Disability Index (NDI),¹⁷ and psychological factors, assessed with the Pain Catastrophizing Scale (PCS).¹⁸ We assessed physical activity with the International Physical Activity questionnaire (IPAQ)¹⁹ and the global perceived effect of treatment with a VAS scale and the garment comfort with a 5-point Likert-type scale questionnaire. We performed the assessment of primary and secondary outcomes at days 1, 30, 60, and 90 after intervention. We also measured the outcomes at the same intervals for the following intervention, after the washout period. The same investigators recorded the outcomes before and after the cross-over. We provided all participants with a logbook to record treatment compliance, medication, adverse events, and other comments. Compliance was measured as a percentage according to intervention adherence.

Statistical Analyses

We conducted statistical descriptive and cross-over analyses following intention-to-treat. Continuous variables were expressed as the mean and standard deviation (SD) and discrete variables as absolute frequencies and percentages. We determined the sample size with a 2-point expected difference or 30% reduction in the VAS for pain and a sample SD of 2.5. We analyzed between-treatment difference for each patient within each sequence and then across both sequences, providing an estimate of treatment effect and a 95% confidence interval. We calculated treatment effects using repeated measures for linear mixed models considering outcome change from baseline as the dependent variable. We used the Student *t* test and lineal regression for quantitative variables with a normal distribution, the non-parametric Wilcoxon test for quantitative variables with non-normal distribution, and the χ^2 test for qualitative variables. The statistical significance level was set at $P < 0.05$. Data analyses were performed by an independent researcher and reviewed by a second statistician to ensure proper execution and compliance with planned analysis.

RESULTS

During the recruiting period, 34 subjects were assessed for eligibility and 32 finally entered the trial: 17 were randomly assigned to the Ex group and 15 to the P+ group for the first intervention period. A total of 29 participants completed the study (Figure 2). Participants were followed for at least nine months (two 3-month intervention periods and a 3-month washout period). Baseline characteristics were similar in both groups except for physical activity, where the Ex group had a higher IPAQ score than the P+ group (Table 1). The mean age of the Ex group (38.05 ± 8.72 years) was lower than that of the P+ group (39.69 ± 10.60 years, $P = 0.65$). However, when stratifying by age (21–35 and >35 years), no statistically significant differences ($P = 0.51$) were detected. The body mass index was similar for the Ex group (24.31 ± 3.7) and the P+ group (23.22 ± 3.2 , $P = 0.40$). After the washout period no differences were found between

the groups, and the difference in physical activity disappeared (Table 1).

To analyze pain, absolute measures were used, that is, VAS and VAS_delta (the difference between baseline VAS and VAS at the end of the intervention), as well as relative measures, that is, the percentage change. A statistically significant reduction in absolute pain was observed for both groups when comparing VAS ($P = 0.07$ for Ex and $P = 0.00$ for P+) and PCS scores ($P = 0.038$ for Ex and $P = 0.015$ for P+) at baseline and at the end of the study. The mean percentage change from baseline to the end of the study was 33% for both groups with no statistically significant differences between groups ($P = 0.90$). However, during the first 3-month period of the study, the P+ group improved 58% and the Ex group 38%, although this difference was not statistically significant ($P = 0.26$).

The disability of the vast majority of patients was assessed with the NDI. The older participants showed the greatest disability with the highest NDI scores. At the end of study, pain catastrophizing improved significantly in both arms (Ex: $P = 0.038$; P+: $P = 0.015$), with no statistically significant differences between both interventions.

With regard to posture, we analyzed the subgroup of patients with dorsal hyperkyphosis, defined as a kyphotic angle $>45^\circ$. At baseline, there were 13 dorsal hyperkyphotic participants in the Ex group and eight in the P+ group. Both groups slightly improved dorsal kyphosis with no differences between groups (3° for Ex group, $P = 0.23$ and 1° for P+ group, $P = 0.88$). Lumbar lordosis showed no changes during the study. In this subgroup, pain and related variables (VAS, NDI, and PCS scores) also showed a reduction at the end of the study with no statistically significant differences between treatments (VAS, $p = 0.7$; NDI, $P = 0.81$; PCS, $P = 0.71$). However, as shown in Table 2, the difference in PCS after the intervention for the Ex group was not statistically significant ($P = 0.64$), whereas this difference was statistically significant for the P+ group ($P = 0.003$). Specifically, participants with dorsal hyperkyphosis showed significant improvements in VAS ($P = 0.019$), NDI ($P = 0.032$), and PCS ($P = 0.03$) when wearing the Posture PlusForce garment while the only score significantly improved during the exercise was NDI ($P = 0.025$) (Table 2).

The pharmacological treatment needs of the participants were analyzed. Negative or positive values were assigned, respectively, for a reduction or an increase in medication. Significant differences between groups were found when comparing both interventions: the P+ group needed less medication than Ex group ($P = 0.007$) (Figure 3).

Participants who appropriately followed the prescribed indications (wearing the garment or executing the daily exercises) for $>60\%$ of the planned time attained a clinically improvement in pain ($P = 0.059$) (Figure 4). The mean compliance was 50.3% in the Ex group and 61.7% in the P+ group. Interestingly, between 1 and 3 months after the end of the study, 58% of all participants were asked about their lifestyle choices. Of these, 38% continued to wear the garment voluntarily, 6% continued performing the exercises

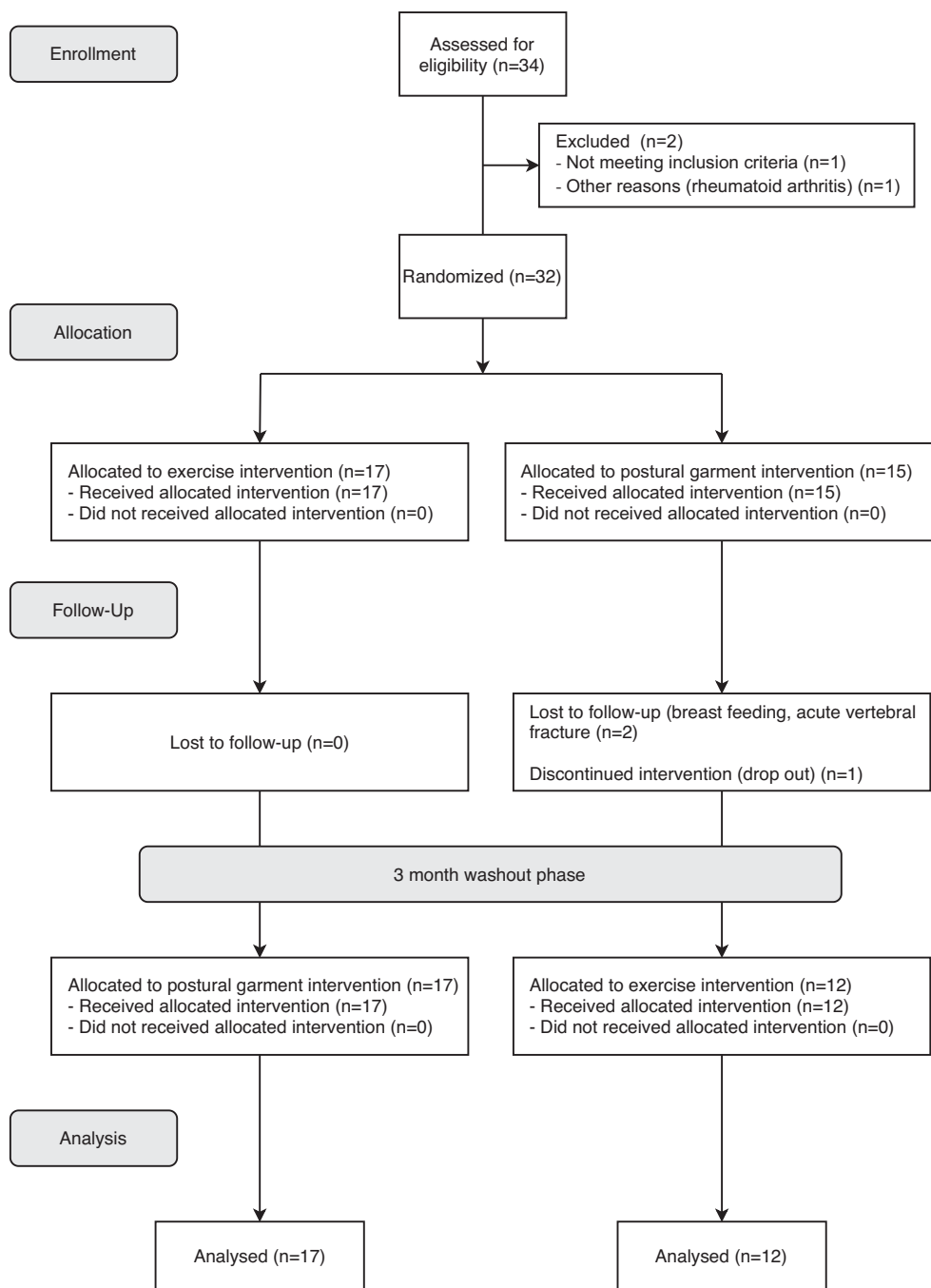


Figure 2. Study CONSORT flow diagram.

they were taught, and 56% did not carry on with either the garment or the exercises (Figure 5).

The global perceived effect of treatment was similar for both interventions: 5.2 of 10 for exercise and 5.6 of 10 for the garment. With regard to garment comfort, 54% of patients found the PosturePlusForce comfortable with no relation with compliance. However, we found that comfort was clearly related to seasonal differences. In summer, only 33% of the participants rated the garment as comfortable, compared to 71% during autumn and winter. The global perceived effect of treatment was positive in 68% of cases when the garment was rated as comfortable and in 41% of

cases when it was perceived as uncomfortable. When analyzing compliance and perceived effect of treatment, namely satisfaction, statistically significant differences were found ($P = 0.041$) between both interventions. Participants who perceived the garment as comfortable were more compliant, which resulted in a better perceived effect of treatment. No adverse events were reported by any participant.

DISCUSSION

This cross-over randomized study compared exercise, the criterion standard for cervical pain, and the PosturePlus-Force garment in female health care workers. Wearing the

TABLE 1. Characteristics Before Each Intervention Period at Baseline and After Washout

Variable	Baseline		P*	After Washout		P*	
	Exercise (Mean ± SD)	P+ (Mean ± SD)		Exercise (Mean ± SD)	P+ (Mean ± SD)		
VAS, mm	5.35 ± 2.47	5.86 ± 1.79	0.51	4.82 ± 2.25	4.17 ± 2.3	0.46	
Neck Disability Index	11.05 ± 4.09	10.38 ± 4.42	0.67	9.42 ± 4.6	8.65 ± 3.79	0.62	
Pain Catastrophizing Scale	12.82 ± 10.34	11.92 ± 11.04	0.82	6.5 ± 7.14	7.18 ± 5.95	0.78	
IPAQ (MET)	8415.44 ± 8191.4	3069.69 ± 2795.56	0.02	1065.4 ± 1632.6	4743.2 ± 7090.6	0.23	
Spinal mouse (°)	Dorsal Spine	48.23 ± 8.4	52.23 ± 13.41	0.35	47.42 ± 10.5	43.88 ± 9.11	0.35
	Lumbar Spine	-31.58 ± 12.3	-30.07 ± 16.87	0.78	-24.58 ± 14.71	-27.63 ± 12.06	0.55
	Inclination	0.41 ± 2.52	1.61 ± 4.33	0.38	0.58 ± 1.9	0.19 ± 3.4	0.72

BMI indicates body mass index; *IPAQ*, International Physical Activity Questionnaire; *MET*, metabolic equivalent of task; *P+*, Posture Plus Force; *SD*, standard deviation; *VAS*, Visual Analogic Scale.
*Welch *t* test.

TABLE 2. Patients With Dorsal Hyperkyphosis Defined as >45°

Variable		Exercise (N = 21) (Mean ± SD)	P*	P+ (N = 20) (Mean ± SD)	P*
VAS	Baseline	4.63 (±2.5)	0.81	4.39 (±2)	0.019
	Final	3.16 (±2.8)		2.87 (±1.98)	
NDI	Baseline	10.19 (±3.9)	0.025	9.57 (±4.15)	0.032
	Final	7.24 (±4.2)		6.95 (±3.27)	
PCS	Baseline	9.81 (±9.7)	0.64	10 (±6.97)	0.003
	Final	4.86 (±6.9)		4.15 (±4.68)	

NDI indicates Neck Disability Index; *PCS*, Pain Catastrophizing Scale; *VAS*, Visual Analogic Scale.
*Welch *t* test between baseline assessment and final follow-up within treatments.

garment resulted in similar improvements to those achieved with exercise. Patients with dorsal hyperkyphosis showed a significant reduction in pain, disability, and pain

catastrophizing when wearing the PosturePlusForce. Importantly, participants needed less medication when wearing the garment and were more compliant.

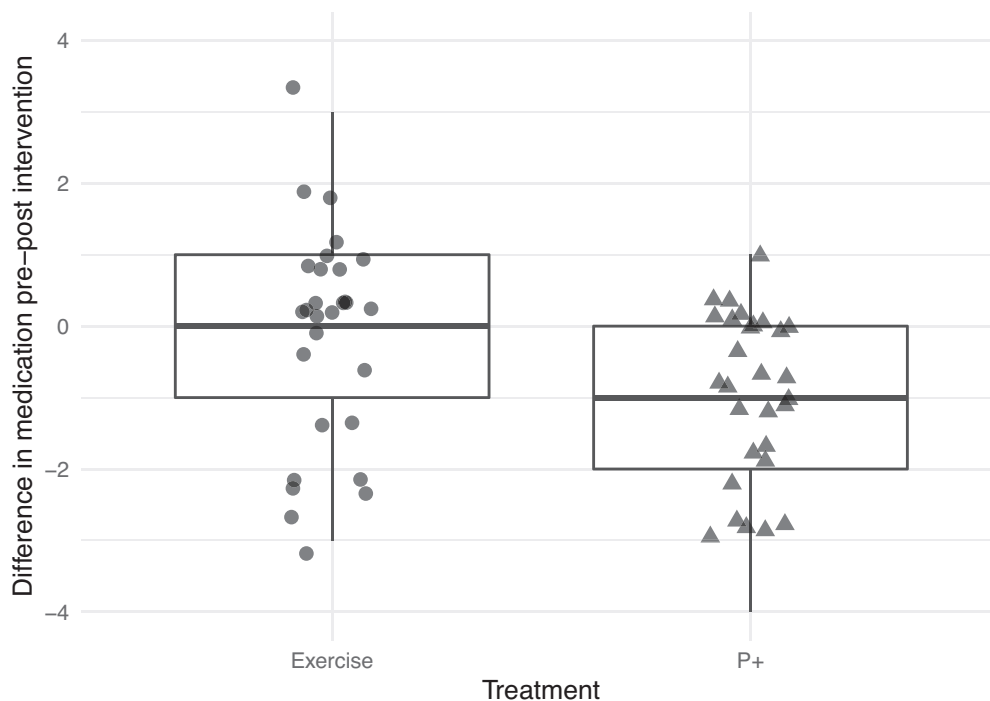


Figure 3. Pharmacological treatment changes for intervention group.

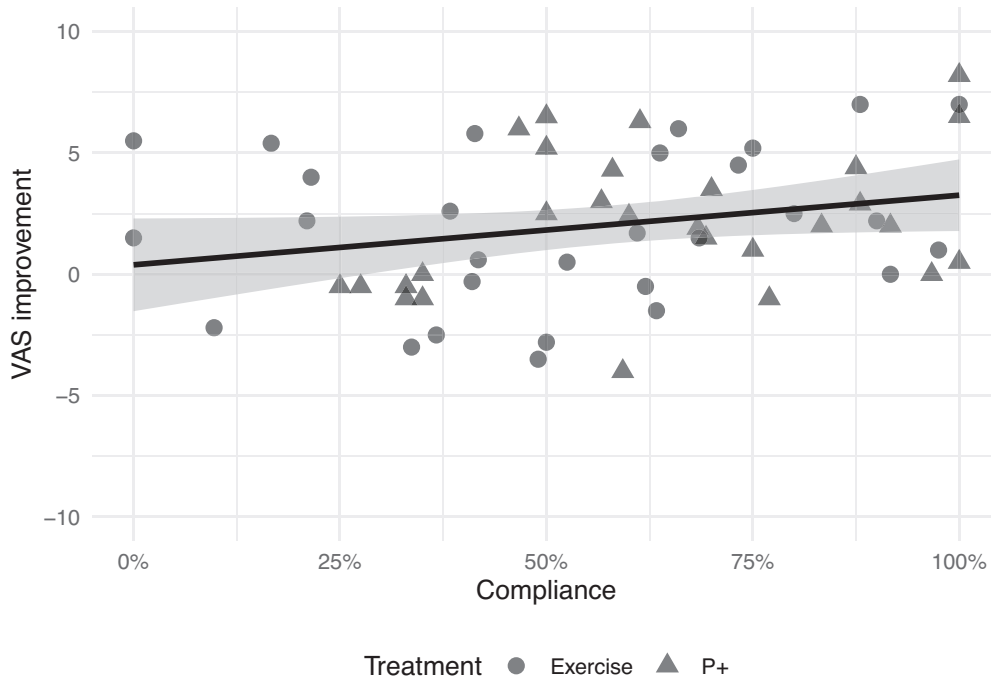


Figure 4. VAS_delta according to compliance. VAS_delta indicates difference between baseline and final VAS.

Pain Intensity

The VAS is a unidimensional measure of pain intensity validated to assess the construct of subjective pain in patients with chronic pain, which has demonstrated sensitivity to changes for up to 4 weeks.²⁰ In this study, the postural garment significantly improved pain measured with this scale. Percentage reduction was used to account for the variation in minimum clinically important difference caused by baseline pain.²¹ When using repeated measures, there was a relevant improvement in pain towards P+ compared to Ex that did not reach a statistically significant difference. This could be explained by differences in baseline pain, since, when analyzing solely the first intervention, there was a significant difference in pain reduction between the Ex (38%) and P+ (58%) groups. If the threshold for a clinically relevant difference had been set lower, the PosturePlusForce would have been proved to be better than exercise.

Secondary Outcomes Related to Pain

Although pain intensity is the domain assessed most often in clinical and research settings, treatment-related improvements

in pain need to consider other variables whose ratings contribute on pain intensity scales, such as catastrophizing or perceived effect of treatment.^{13,22} In our study, both the postural garment and exercise showed significant positive effects in functional and psychological outcome measures. When considering women with dorsal hyperkyphosis, NDI and PCS only improved significantly with the postural garment.

Randomized clinical trials analyzing the effects on cervical pain of posture enhancers are scarce. In a double-blinded, randomized placebo-controlled study, the use of an elastic taping (Kinesio Taping) significantly improved cervical pain, analyzed with VAS and pressure pain threshold. The taping also improved cervical flexion-extension, but had no effect in cervical rotation, cervical lateral flexion, and neck pain disability.²³ In our study, PosturePlusForce not only reduced cervical pain but also neck pain disability. In addition, only a short explanation on how to wear the T-shirt was required in our study, whereas a certified physiotherapist was necessary for the taping.

Posture in Women

More than two decades ago, Itoi and Sinaki showed that exercises helped decrease thoracic kyphosis in healthy women.²⁴ With the increase in technology usage in our daily lives, posture has become a major issue. Very recently, differences in spinal curvature have been found in women with cervical pain, in relation with NDI.⁷ In our study, dorsal kyphosis improved in the Ex group as in the P+ group. In the subgroup of participants with dorsal hyperkyphosis, the garment clearly demonstrated more beneficial effects. Besides, proper posture and scapular positioning is important to avoid injury during overhead movements.²⁵ A previous report on a posture-cueing compression garment

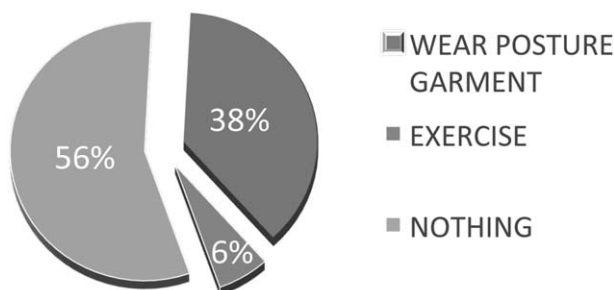


Figure 5. Voluntary lifestyle choices after the study.

(IntelliSkin™) showed an improvement in scapular positioning during static standing compared to a control garment.²⁶ However, other studies have proven that the addition of abdominal control feedback, such as the one provided by PosturePlusForce, to scapular stabilization exercises is superior to scapular stabilization exercises alone for improving posture and neck pain.²⁷

Better Compliance, Less Pharmacological Treatment

Physical activity and exercise is beneficial for chronic pain. However, women are less active than men throughout their lives and are less compliant with exercise.²⁸ In our study, women showed greater adherence or compliance with the garment than with exercise. Wearing the Posture Plus Force garment was significantly associated with less medication needed.

Despite the benefits of both interventions in their chronic pain, more than half of the interviewed participants returned to inactivity after the study. In contrast, nearly 40% voluntarily wore the garment. They reported more benefits in terms of pain reduction and made less time-consuming efforts with PosturePlusForce.

Limitations

In contrast to parallel group trials, in cross-over trials each individual receives more than one intervention in a random order. Thus, participants act as their own controls,¹³ which is considered a highly efficient design in rehabilitation research.²⁹ However, the potential for a carry-over effect is one of the particular challenges present in randomized cross-over trials. Treatments that are expected to be at least partially reversible can pose a problem of internal validity. In a cross-over study, this is handled by a washout period. In our study, the 3-month washout period was estimated to be sufficient to avoid a carry-over effect for exercise, but it could have not been enough for the PosturePlusForce. Nevertheless, after the cross-over, participants who started wearing the PosturePlusForce still showed a 15% improvement in pain compared to baseline, whereas those starting with exercise had a 5% improvement from baseline pain. This could be interpreted as PosturePlusForce showing a larger carryover effect than exercise.

Far from being a static condition, posture changes over time. We suspect that, for some participants of the study, dorsal hyperkyphosis was not a structural deformity and its measurement was variable.

Another limitation was the sample size. This was partially compensated by our study design and methodological approach. Further trials including more participants are required to validate our results and the benefits of this garment for cervical pain and posture.

CONCLUSION

The PosturePlusForce garment demonstrated at least a similar effect than exercise for chronic nonspecific cervical pain improvement in female health care workers. In participants

with dorsal hyperkyphosis, the garment was more effective for neck pain than exercise. Furthermore, women needed less pharmacological pain relievers and intervention adherence was better with the postural garment. Further studies are needed to confirm the benefits of this garment for cervical pain and posture.

➤ Key Points

- ❑ Neck pain management should be treated with a combination of exercise and posture modification.
- ❑ This randomized cross-over trial found that, similarly to exercise, the postural garment Posture Plus Force improved nonspecific cervical pain in female health care workers.
- ❑ Women wearing PosturePlusForce required less pharmacological pain relievers than those performing exercise.
- ❑ Adherence was higher with Posture Plus Force than with exercise.

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