Effectiveness of a "Spring Pillow" Versus Education in Chronic Nonspecific Neck Pain: A Randomized Controlled Trial

Carla Vanti, Federico Banchelli, Claudia Marino, Andrea Puccetti, Andrew A. Guccione, Paolo Pillastrini

Background. Different types of pillows have been proposed for neck pain, but no previous randomized controlled trial has investigated the effectiveness of a "spring pillow" for adults with chronic nonspecific neck pain.

Objective. We evaluated the effectiveness of using a pillow made from viscoelastic polyurethane and 60 independent springs compared with an educational intervention in individuals with chronic nonspecific neck pain.

Design. This was a randomized controlled trial with crossover study design.

Setting. The setting was the Occupational Medicine Unit, University Hospital, Bologna (Italy).

Participants. We recruited 70 adults with chronic nonspecific neck pain, of whom 64 completed the trial.

Intervention. Participants were randomly assigned to 2 groups. One group used the spring pillow for 4 weeks, and the other group followed educational advice for 4 weeks while continuing to use their own pillows. After 4 weeks of treatment and 4 weeks of washout, groups were crossed over. Pain perceived in the neck, thoracic, and shoulder areas and headache were the primary outcome measures. In addition, disability, sleep quality, subjective improvement, and pillow comfort were assessed. Measures were captured at pretreatment, after 4 weeks, after the 4-week washout period, and 4 weeks after crossover. The mean differences (MD) in outcomes between groups were assessed.

Results. Treatment with the spring pillow appeared to reduce neck pain (MD = −8.7; 95% confidence interval [CI] = −14.7 to −2.6), thoracic pain (MD = −8.4; 95% CI = −15.2 to −1.5), and headache (MD = −16.0; 95% CI = −23.2 to −8.7). Reductions in shoulder pain were not statistically significant between groups (MD = −6.9; 95% CI = −14.1–0.3). Neither the crossover sequence nor the period (first vs second intervention administration) significantly affected the results.

Limitations. Education may not have been the best comparator for the spring pillow; drug consumption, actual pillow use, and the implementation of the educational suggestions as prescribed were not controlled.

Conclusions. Use of the spring pillow in this study was more effective than an educational intervention for improving cervical, thoracic, and head pain. Whether a spring pillow is more effective than other ergonomic pillows remains to be tested.

C. Vanti, PT, MSc, Department of Biomedical and Neurological Sciences, Occupational Medicine Unit, University of Bologna, Bologna, Italy.

F. Banchelli, PhD, Department of Diagnostics, Clinical and Public Health Medicine, Statistics Unit, University of Modena and Reggio Emilia, Modena, Italy.

C. Marino, PT, Department of Biomedical and Neurological Sciences, Occupational Medicine Unit, University of Bologna.

A. Puccetti, PT, Department of Biomedical and Neurological Sciences, Occupational Medicine Unit, University of Bologna.

A.A. Guccione, PT, DPT, PhD, Department of Rehabilitation Science, College of Health and Human Services, George Mason University, Fairfax, Virginia.

P. Pillastrini, PT, MSc, Department of Biomedical and Neurological Sciences, Occupational Medicine Unit, University of Bologna, via P. Palagi 9–40138, Bologna, Italy. Address all correspondence to Prof Pillastrini at: paolo.pillastrini@unibo.it

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Neck pain is a significant cause of disability, with impact similar to low back pain, depression, and joint pain,[1] and is more prevalent among women and populations in middle age. The 12-month prevalence of neck pain ranges between 30% and 50%, and the 12-month prevalence of activity-limiting pain is 1.7% to 11.5%.[2] Individuals who enter the chronic stage account for the majority of social and economic costs of this condition.[3]

Neck pain can affect several activities of daily living, including sleep. Quantity and quality of sleep are essential for the maintenance of psychological and biological functions as sleep may impact a person's mental and physical health.[4] Fewer hours of sleep can be associated with hormonal dysfunctions, mood swings, and a high risk of obesity and type 2 diabetes.[5]

Disturbed sleep is one of the consequences of chronic pain, often interfering with the perception and modulation of pain to the point of causing hyperalgesia and posing a potential risk factor for the exacerbation of chronic pain.[6] Sleep deprivation is significantly related to the intensity of pain,[7] and it can cause further pain, fear of movement, anxiety, and depression.[8] In contrast, good sleep quality has been associated with improvements in both acute and chronic pain.[9]

Different types of pillows have been proposed to maintain neck posture during sleep and to relax cervical muscles in the case of neck pain. The "ideal" pillow should be soft and moderately high (about 10 cm), support cervical lordosis in supine, and prevent neck lateral flexion in the side position.[10] Moreover, it should be allergy-tested, lightweight, and washable.[10] Other factors influencing neck pillow acceptability are the degree of thermal dispersion,[11] the material, the shape, and the length of time it has been used.

Different pillow features, structures, and sizes can potentially modify neck, head, and shoulder pain. Recommending the best pillow for individuals is still a difficult task because there has been insufficient evidence to identify the best model among those pillows currently available on the market. Several types of pillows have been suggested: medicinal pillows with herbs,[12] pillows made from polyester[13] or polyurethane,[10] water-based pillows,[14] and rubber pillows.[15] Different shapes of pillow have also been suggested: roll-shaped orthopedic pillows,[13,16] contour pillows,[17] pillows with a firm support for cervical lordosis,[10] or a combination of standard, cylindrical, and shoulder pillows.[18]

A new type of cervical pillow (called a "spring pillow") was recently introduced on the market. It is externally made from viscoelastic polyurethane and internally contains 60 independent springs. This combination is thought to promote better posture of the cervical spine because of the continuous adaptation of the pillow to the shape and movements of the head during sleep. This type of pillow has been certified as "ergonomic" (Marcolin F, Bordignon M, Tulissi C. Instrumental verification of the alignment of the cervical spine during the use of three versions of the postural pillow and relative certification. ErgoCert, Udine, November 14th, 2016), but it has never been tested on individuals with neck pain.

Considering that pillow comfort and sleep quality are often related, it can be assumed that an "ideal" pillow may improve subjective well-being, especially upon awakening. Some low-quality studies have investigated the effectiveness of 1 or more different types of pillows on pain, disability, and sleep quality in chronic neck pain[13,14,19,20,21] and suggested different pillows types and sizes. A systematic review of these studies concluded that there is insufficient evidence regarding cervical pillow effectiveness in reducing neck pain[22] given the small effect sizes (from −0.05 to 0.99) and the wide confidence interval (CI) that were reported for the controlled trials comparing cervical pillows vs usual pillows. Nevertheless, a subsequent study suggested significant benefits by the interaction between the effects of exercise and the use of a cervical support during sleep.[23]

Among the different therapeutic approaches for neck pain, information about prognosis and advice to remain active are also suggested[24] and considered cost-effective interventions.[25] Patient education, supported by informational brochures, also provides advice concerning movements and postures, including night-time positioning, to be adopted during daily life activities to reduce the development and persistence of neck pain.[26] Systematic reviews of structured oral and written educational interventions align in concluding that there is only low or very low-quality evidence with no support for educational interventions compared with other conservative treatment.[27,28] Also, the effect sizes in these studies were small with large CIs. Nevertheless, it has also been noted that education seems to provide small benefits when combined with physical therapy treatments.[28,29]

Although current evidence has indicated similar effectiveness for both ergonomic pillows and structured educational advice in chronic neck pain, no study to our knowledge has compared the efficacy of the use of neck pillows with an educational intervention. Furthermore, few studies have assessed the impact of neck pillows on the quality and quantity of rest.[15,19,20] This randomized controlled trial (RCT) with crossover aimed to investigate the effectiveness of spring pillow use vs education in chronic nonspecific neck pain. More specifically, effectiveness was measured on pain as primary outcome measure, and disability, sleep quality, global perception of the treatment effectiveness, and satisfaction with neck pillow were considered secondary outcome measures.

Methods

Ethics Approval

Informed consent was obtained from all participants and procedures were conducted according to the Declaration of Helsinki. The study protocol was registered with the Clinical Trial Registry of the US National Institutes of Health (code NCT03165669) and was approved by the Independent Ethics Committee in Clinical Research of the University Hospital, Bologna, Italy (code 34/2017/U/Disp).

Study Design, Randomization, and Masking

The present study is a RCT with crossover conducted at the University Hospital S. Orsola-Malpighi, Bologna, Italy. This was a single-center, fixed-sample trial consisting of 70 people with a 1:1 allocation ratio. Two groups of participants were randomized in 2 parallel arms. Randomization followed a fixed-size design with a concealed allocation ratio of 1:1 and was performed in 2 steps. First, each of a progressive list of numbers was randomly assigned to a sequence of treatments by means of a software procedure. Then, participants were asked to choose 1 among a set of opaque sealed envelopes, each containing 1 of those progressive numbers. Study arms were then assigned to participants following the randomized sequence of numbers established by the first step of the randomization process.

At the start of the study (time 0), demographic data were recorded. No specific information was captured about participants' usual pillow. The first group received the spring pillow, and the second group received education. After 4 weeks, the first follow-up was conducted (time 1), and participants who used the spring pillow returned it. After 4 weeks of washout (time 2), the second follow-up was carried out. A crossover was then performed at time 2, which consisted of exchanging treatments between the 2 groups: the group that received the spring pillow received education, and vice versa. After 4 weeks, the final follow-up was conducted (time 3).

The principal investigator received the results of outcome measures without any information concerning group assignment. The outcome assessors were masked regarding the group assignment because they received only the list of participants without notations of group assignment. The report of this trial follows the CONSORT checklist.[30]

Sample Size

Sample size was calculated based on a study power of 80%, 95% confidence level, using an average expected change of 7 (SD = 10) on a numerical rating scale (NRS) (0–100), and with a 1:1 allocation ratio. The sample estimate was 64 units, increased to 70 units assuming a dropout percentage of 10%. This sample size also respected the availability of resources and the study budget.

Population

Participants were included if they fulfilled the following criteria: both sexes; 18 to 80 years old; chronic nonspecific neck pain (pain lasting 3 months or more, not related to specific pathologies), with or without irradiation to the upper limb or to the head, noted as $\geq$ 2 on a scale of 0 to 10; good comprehension of written and spoken Italian language; and providing informed consent.

Exclusion criteria were: acute or subacute neck pain (lasting $<$ 3 months); specific causes of neck pain (eg, trauma, herniated disc, vertebral deformity, fractures, and dislocations); central or peripheral neurological signs; systemic pathologies; rheumatic disorders; neuromuscular pathologies; tumors; cognitive deficits; surgical interventions in the last 6 months prior to the study; physical therapy treatments in the last 6 months prior to the study; and using no pillow or 2 pillows during nighttime sleep.

The rules to leave the study (stopping rules) included pregnancy; onset of acute or subacute neck pain; onset of trauma, herniated disc, or fracture; onset of central or peripheral neurological signs; onset of systemic, rheumatic, or neuromuscular disorders; need to undergo surgery; individual absent from scheduled appointments; adverse effects; any modification of the type or dosage of analgesic or anti-inflammatory drugs taken at baseline or new drug intakes; and the delivery of other treatments for neck pain (eg, physical therapy, manipulation, and acupuncture).

Neither inclusion nor exclusion criteria were changed during the trial. All eligible participants underwent a medical examination by an occupational health physician, who excluded specific causes of neck pain and cognitive impairments. All participants were instructed to pursue their usual activities (eg, work, recreation, and physical activity) for the entire duration of the study.

Pillow Characteristics

The external construction of the spring pillow is viscoelastic polyurethane;; internally, it contains 60 independent, individually coated springs made by harmonic phosphated steel. The spring pillow exploits the well-known properties of the viscoelastic material, which allows a good adaptation to an individual's shape. The spring pillow used for this study was 41 cm wide and 70 cm long, and its thickness (12 cm) was considered adequate for the majority of the population with reference to a single anthropometric parameter, the average width of 1 shoulder. It had medium resistance and was able to respond to a wide range of body types. The spring pillow was allergy-tested, and the holes made in the viscoelastic material favored an exchange of air, at each movement of the head, to eliminate excessive heat and humidity. The outer covering fabric of the spring pillow was made of 100% cotton.

The University of Udine, Udine, Italy, carried out the instrumental verification of the alignment of the cervical spine while using the spring pillow, both in supine and in side position. The Ergonomics Certification attested that the spring pillow was compliant with the requirements established by the technical specification ERGO-CERT ST-11 (certification of the ergonomic features of the sleeping system pillows) (Marcolin FPlease see our previous reply, Bordignon M, Tulissi C. Instrumental verification of the alignment of the cervical spine during the use of three versions of the postural pillow and relative certification. ErgoCert, Udine, November 14th, 2016).

This device is intended for use during sleep for both healthy people and individuals with musculoskeletal disorders and dysfunctions. It does not require any training or experience, except following the instructions provided in the user manual.

Interventions

The spring pillow intervention consisted of the delivery and use of the spring pillow during nighttime sleep. Participants were encouraged to use the spring pillow consecutively for 4 weeks, unless symptom onset or lack of sleep required cessation of its use. This arm of the intervention included an individual half-hour meeting with a physical therapist who explained how to use and maintain the pillow, supporting this information with the delivery of a user manual (eAppendix 1, available online at https://academic.oup.com/ptj). Each participant had the opportunity to clarify any concerns and to receive answers to questions.

The education arm was an ergonomic educational intervention conducted by a physical therapist and consisted of advice on proper positions, movements, and activities recommended or not recommended for people with chronic neck pain, both in the workplace and in leisure time, including nighttime postures. Moreover, the physical therapist explained pain mechanisms and the relevance of implementing active behavior against pain. Each educational intervention lasting half an hour was carried out individually and was supported by the delivery of an informative brochure (eAppendix 2). As was the case with the other arm of the study, the physical therapist clarified any concerns and answered any questions.

During the 4 weeks of education and the washout period, participants continued to utilize their own pillows during nighttime sleep.

Outcome Measures

The primary outcome measure of this study was pain. This measure is one of the most relevant for physical therapist practice in chronic pain, as stated by the International Association for the Study of Pain in its "Curriculum Outline on Pain for Physical Therapy."[31] Mean rates of perceived pain during the last 24 hours were measured by using an NRS (0–100), widely used in individuals with mechanical neck pain.[32] Because neck pain frequently refers to areas different from the cervical one, we used 4 separate NRSs for neck, shoulders, thoracic pain, and headache.[13]

Secondary outcome measures were cervical disability (measured by the Neck Disability Index–Italian version [NDI-I]), sleep quality (measured by the Pittsburg Sleep Quality Index–Italian version [PSQI-I]), perceived improvement (measured by the Global Perceived Effect [GPE] instrument), and pillow comfort (measured by the Neck Pillow Satisfaction [NPS] tool). The NDI-I is the most used questionnaire for measuring neck disability, and its reliability and validity have been demonstrated in different languages.[33] The PSQI-I is a self-administered retrospective questionnaire, which measures the quality of sleep in the last month.[34] The global PSQI-I score ranges from 0 to 21, where lower scores correspond to better sleep quality.[34] The PSQI-I has been demonstrated to be a useful, valid, and reliable tool for ascertaining the quality of sleep comparable to the original English version.[35] The GPE is composed of 1 question on a 7-point Likert-type scale evaluating the subjective self-reported improvement or deterioration after the intervention. GPE is widely used in the physical therapy literature.[36] Also, satisfaction with the pillow was measured with 1 question on a 7-point Likert-type scale.

The NRS, NDI-I, and PSQI-I questionnaires were administrated to all participants at the start of the study and at each follow-up (times 1, 2, and 3), whereas GPE and NPS were administrated only at time 1 and time 3 to collect information about the subjective satisfaction. Participants were also required to complete a daily pain diary during the entire period of the study[15,21] to monitor neck pain, sleeping habits, and events that would discharge participants from the study. Each 4-week daily questionnaire was returned to the physical therapist at times 1, 2, and 3.

Statistical Analysis

Descriptive characteristics of the 2 cohorts at time 0 were calculated. Continuous variables were expressed as mean and standard deviation, and categorical variables were expressed as absolute and percentage frequency.

Because we adopted a 2-treatment, 2-sequence, and 2–follow-up–period design for our crossover study, the major terms of interest were between-group differences with respect to treatment (spring pillow vs education) as well as to sequence (spring spring pillow-to-education vs education-to-spring pillow) or intervention period (second intervention vs first intervention). These differences were estimated by means of repeated-measures linear mixed models; postintervention outcome values were the dependent variables, and independent fixed effects variables were treatment, sequence, and intervention period. A Gaussian-distributed random-effect term was

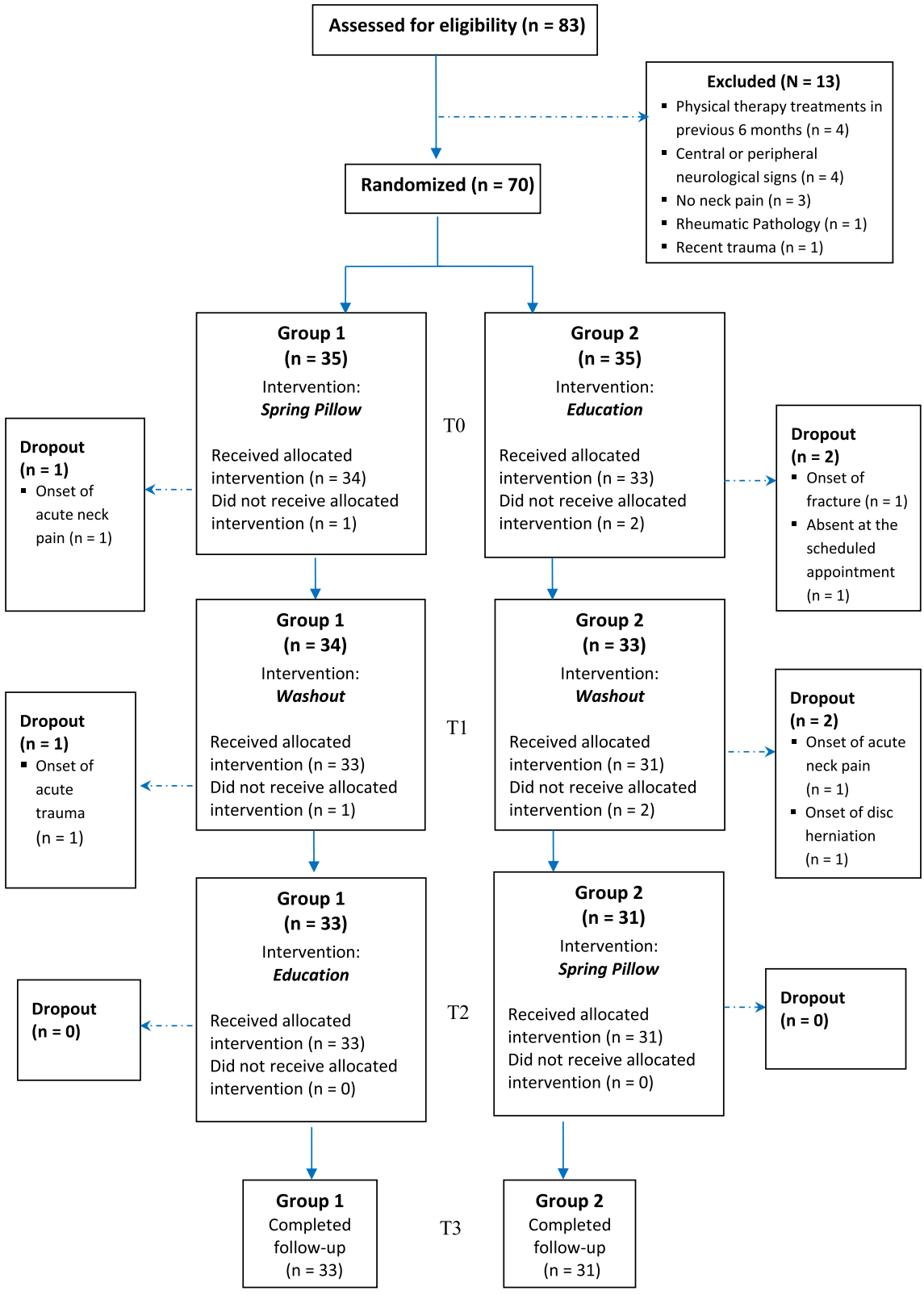

Figure 1.
Flow chart of the participants.

Table 1.
Sample Characteristics at Baseline[a]

Characteristic	SP → EI (n = 35)			EI → SP (n = 35)		
	Mean (SD)	No. of Participants	% of Participants	Mean (SD)	No. of Participants	% of Participants
Age, y	48.3 (9.9)			50.9 (7.8)		
Sex, men		6	17.1		5	14.3
Married, yes		21	60.0		25	71.4
Worker status, yes		30	85.7		32	91.4
Master's degree, yes		35	100.0		35	100.0
Smoking status, yes		15	42.9		7	20.0
Sports activity, yes		19	54.3		21	60.0
Hours in sitting position	5.4 (2.9)			6.1 (3.1)		
Hours in front of computer	2.7 (2.6)			3.6 (3.0)		
Body mass index, kg/m^2	24.3 (4.0)			23.4 (4.2)		
Reports of neck pain, yes		35	100.0		35	100.0
Reports of shoulder pain, yes		27	77.1		27	77.1
Reports of thoracic pain, yes		17	48.6		16	45.7
Reports of headache, yes		27	77.1		23	65.7
Frequency of neck pain						
0 to < 1 d		9	25.7		13	37.1
1–2 d		11	31.4		9	25.7
2 to ≥ 3 d		15	42.9		13	37.1
Duration of neck pain, d	169.7 (142.3)			184.8 (142.2)		
Antidepressants, yes		2	5.7		2	5.7
Pain medications, yes		10	28.6		13	37.1
Muscle relaxants, yes		0	0.0		1	2.9
NSAIDs/steroids, yes		7	20.0		4	11.4
Other musculoskeletal pain, yes		24	68.6		21	60.0
Heart diseases, yes		5	14.3		4	11.4
Respiratory diseases, yes		0	0.0		1	2.9
Endocrine diseases, yes		5	14.3		7	20.0
Gastrointestinal diseases, yes		9	25.7		7	20.0
Kidney diseases, yes		1	2.9		1	2.9
Anxiety/depression, yes		5	14.3		1	2.9
Outcomes at baseline						
Neck NRS	40.8 (27.3)			47.0 (22.9)		
Shoulder NRS	40.3 (32.7)			41.8 (27.6)		
Thoracic NRS	27.7 (30.9)			27.3 (25.6)		
Head NRS	39.1 (34.8)			30.7 (29.9)		
NDI-I	12.9 (7.4)			13.8 (5.6)		
PSQI-I	10.3 (3.2)			9.7 (2.9)		

[a]Values are reported as number (percentage) of participants unless otherwise noted. EI = educational intervention; NDI-I = Neck Disability Index–Italian Version; NRS = numerical rating scale; NSAIDs = nonsteroidal antiinflammatory drugs; PSQI-I = Pittsburg Sleep Quality Index–Italian Version; SP = spring pillow (intervention).

Table 2.
Outcome Measurements Across Study Time Points[a]

Outcome Measurement	Time 0				Time 1				Time 2				Time 3			
	SP → EI (n = 35)		EI → SP (n = 35)		SP → EI (n = 34)		EI → SP (n = 33)		SP → EI (n = 33)		EI → SP (n = 31)		SP → EI (n = 33)		EI → SP (n = 31)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Neck NRS	40.8	27.3	47.0	22.9	26.1	22.3	37.8	21.4	31.5	29.2	40.8	23.7	32.3	27.2	28.3	22.4
Shoulder NRS	40.3	32.7	41.8	27.6	24.1	23.8	34.6	28.2	30.4	30.0	35.0	27.3	30.1	26.4	27.6	25.1
Thoracic NRS	27.7	30.9	27.3	25.6	19.5	21.0	25.5	24.1	22.7	24.1	26.7	23.7	28.4	26.5	18.7	20.1
Head NRS	39.1	34.8	30.7	29.9	23.8	23.9	33.7	27.5	25.7	30.6	32.2	26.4	32.9	31.8	18.5	24.4
NDI-I	12.9	7.4	13.8	5.6	8.7	5.2	12.7	4.4	8.9	6.3	11.9	6.0	11.2	6.7	9.5	6.0
PSQI-I	10.3	3.2	9.7	2.9	9.1	3.0	9.7	2.5	9.2	3.1	8.6	2.4	9.8	2.7	7.9	2.4

[a]EI = educational intervention; NDI-I = Neck Disability Index–Italian Version; NRS = numerical rating scale; PSQI-I = Pittsburg Sleep Quality Index–Italian Version; SP = spring pillow (intervention).

used to take intra-participant correlations into account. Moreover, to further control for residual imbalances in the 2 groups of interest, baseline score (T0 for the first follow-up, T2 for the second follow-up) was also used as an independent variable. Results were reported as estimated mean differences (MD) in outcome values with 95% CIs.

As exploratory reporting, we also evaluated differences in clinically meaningful improvements between treatment groups by the minimal clinically important difference (MCID) for pain and disability, adopting a 28% or 17-point reduction in neck pain measured with the NRS[37] and a 5-point reduction on a 50-point NDI-I.[38]

The proportions of participants who reached MCID at time 1 and time 3 were calculated. Repeated-measures logistic mixed models were used with MCID status (yes or no) as the dependent variable, and independent fixed effects variables were treatment, sequence, intervention period, and baseline outcome score; a participant-specific random-effect term was also included in the model. Results were reported as odds ratios (ORs) with 95% CIs.

The statistical analysis was carried out by the per-protocol method, including only those participants who completed the first and second treatment periods, because participants who dropped out did not participate in outcome assessment after leaving the study. Furthermore, to control for the potential bias due to dropout, we performed an intention-to-treat analysis using a "worst-case" scenario. Under this scenario, missing outcome data were imputed as being a "good" outcome in the education group and as a "bad" outcome in the spring pillow group. A good outcome was defined as the median absolute improvement in the score among the improved participants, whereas a bad outcome was defined as the median absolute worsening in the score among the nonimproved participants. For MCID exploratory analysis, a good outcome was to reach the MCID, and a bad outcome was to not reach the MCID.

All analyses were performed using R 3.3.2 statistical software (The R Foundation for Statistical Computing, Vienna, Austria) at a significance level of .05.

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Results

From June 2017 and July 2017, 116 outpatients diagnosed with chronic nonspecific neck pain referred to an

Table 3.
Comparison of Treatments, Sequences, and Periods: Per-Protocol Analysis[a]

Variable	Comparison	Outcome	MD	95% CI	*P*
Treatment	SP vs EI	Neck NRS	−8.7	−14.7 to −2.6	.0057
		Shoulder NRS	−6.9	−14.1–0.3	.0619
		Thoracic NRS	−8.4	−15.2 to −1.5	.0173
		Head NRS	−16.0	−23.2 to −8.7	.0000
		NDI-I	−3.3	−4.8 to −1.8	.0001
		PSQI-I	−1.2	−1.9 to −0.5	.0008
Sequence	SP → EI vs EI → SP	Neck NRS	0.2	−7.5–8.0	.9517
		Shoulder NRS	2.0	−5.2–9.3	.5736
		Thoracic NRS	−2.8	−10.3–4.6	.4474
		Head NRS	−1.7	−10.0 to 6.7	.6919
		NDI-I	0.2	−1.6–1.9	.8567
		PSQI-I	−0.4	−1.2–0.4	.3450
Period	Second intervention vs first intervention	Neck NRS	1.9	−4.2–8.1	.5351
		Shoulder NRS	4.1	−3.2–11.4	.2648
		Thoracic NRS	2.3	−4.5–9.2	.5039
		Head NRS	−0.2	−7.4–7.0	.9549
		NDI-I	1.1	−0.5–2.7	.1665
		PSQI-I	0.1	−0.6–0.8	.8479

[a]EI = educational intervention; MD = between-groups mean difference; NDI-I = Neck Disability Index–Italian Version; NRS = numerical rating scale; PSQI-I = Pittsburg Sleep Quality Index–Italian Version; SP = spring pillow (intervention).

Occupational Medicine Unit were eligible for this study and asked to participate. Of these, 31 people declined participation and 2 people were absent at the baseline appointment, leaving a sample of 83 people verified for inclusion criteria. The first 70 individuals of the 83 who met inclusion criteria were divided with concealed randomization into 2 groups by choosing a sealed opaque envelope containing the group number.

Sixty-four participants completed the crossover RCT to investigate the effects of the spring pillow vs education. Outcome measurements were completed on 67 participants at time 1 (34 in the spring pillow-to-education group and 33 in the education-to-spring pillow group) and on 64 participants at time 2 and time 3 (33 in the spring pillow-to-education group and 31 in the education-to-spring pillow group). Figure 1 provides a flow diagram of participants' recruitment and retention through the study.

The characteristics of the sample are shown in Table 1. No relevant differences in baseline characteristics were found between the spring pillow-to-education group and the education-to-spring pillow group or between dropout participants and participants who completed the crossover (data not shown). No important adverse events or side effects occurred in either intervention group.

Table 2 shows the results of the outcome measures at the 4 different time points for neck, shoulder, and thoracic pain, headache, and disability (NDI-I) and for sleep quality (PSQI-I), according to a per-protocol analysis.

The treatment (spring pillow vs education) appeared to reduce neck pain (MD = −8.7; 95% CI = −14.7 to −2.6; $P = .006$), thoracic pain (MD = −8.4; 95% CI = −15.2 to −1.5; $P = .017$), and headache (MD = −16.0; 95% CI = −23.2 to −8.7; $P = .000$). With respect to shoulder pain, the treatment effect was not statistically significant (MD = −6.9; 95% CI = −14.1–0.3; $P = .062$). Furthermore, the treatment significantly reduced disability (MD = −3.3; 95% CI = −4.8 to −1.8; $P = .000$) and improved sleep quality (MD = −1.2; 95% CI = −1.9 to −0.5; $P = .001$). Neither the sequence of the crossover (spring pillow-to-education vs education-to-spring pillow) nor the period (first administration vs crossed-over second administration of the intervention) significantly affected the results (Tab. 3). These results were confirmed by the worst-case intention-to-treat analysis, except for the thoracic pain outcome (Tab. 4).

Table 4.
Comparison of Treatments, Sequences, and Periods: Intention-to-Treat Worst-Case Analysis[a]

Variable	Comparison	Outcome	MD	95% CI	*P*
Treatment	SP vs EI	Neck NRS	−6.64	−12.54 to −0.74	.0279
		Shoulder NRS	−5.37	−12.31–1.57	.1270
		Thoracic NRS	−6.06	−12.87–0.75	.0803
		Head NRS	−13.63	−20.63 to −6.62	.0002
		NDI-I	−2.63	−4.17 to −1.09	.0011
		PSQ-I	−0.96	−1.67 to −0.26	.0079
Sequence	SP → EI vs EI → SP	Neck NRS	0.58	−6.75–7.92	.8743
		Shoulder NRS	1.71	−5.23–8.65	.6248
		Thoracic NRS	−2.32	−9.34–4.71	.5129
		Head NRS	−0.64	−8.78–7.48	.8741
		NDI-I	0.48	−1.26–2.20	.5909
		PSQ-I	−0.22	−0.98–0.54	.5666
Period	Second intervention vs first intervention	Neck NRS	2.80	−3.21–8.81	.3555
		Shoulder NRS	4.85	−2.15–11.85	.1716
		Thoracic NRS	3.45	−3.37–10.28	.3158
		Head NRS	1.54	−5.44–8.52	.6608
		NDI-I	1.48	−0.10–3.05	.0665
		PSQI-I	0.19	−0.53–0.91	.5970

[a]EI = educational intervention; MD = between-groups mean difference; NDI-I = Neck Disability Index–Italian Version; NRS = numerical rating scale; PSQI-I = Pittsburg Sleep Quality Index–Italian Version; SP = spring pillow (intervention).

After dichotomizing GPE into "improved" (a score of 1–3 on the GPE) and "worsened" (a score of 5–7 on the GPE), we observed that 69.3% of participants improved after using the spring pillow, 39.4% improved after education, 6.1% worsened after using the spring pillow, and 3.0% worsened after education. Regarding the comfort of the spring pillow compared with the usual pillow, after a similar dichotomization, 83.1% of the participants judged the spring pillow as comfortable, whereas 44% of participants in the education group attributed this score to their own pillow. The pillow was rated uncomfortable by 7.7% of the participants following the spring pillow intervention and by 21.2% of the participants following education and the use of their own pillow (Tab. 5).

Our further exploratory analysis on the clinical relevance of these results showed a higher proportion of participants whose scores reached the MCIDs for neck pain or disability in the spring pillow group compared with the education group (eAppendix 3). In the per-protocol analysis, the probability of reporting clinically meaningful improvements was higher in the spring pillow group with respect to neck pain (OR = 3.4; 95% CI = 1.6–7.1; $P = .001$), thoracic pain (OR = 2.4; 95% CI = 1.1–5.5; $P = .034$), headache (OR = 3.7; 95% CI = 1.3–10.7; $P = .017$), and disability (OR = 7.7; 95% CI = 1.1–52.4; $P = .037$). The probabilities of being clinically improved were similar in both groups for shoulder pain (OR = 1.6; 95% CI = 0.7–3.5; $P = .193$) (eAppendix 4). The worst-case intention-to-treat analysis confirmed the clinically relevant effect of the spring pillow only on neck pain outcome (eAppendix 5).

Discussion

The results of this crossover RCT showed that the spring pillow was more effective than education combined with the usual standard pillows for improving cervical pain, thoracic pain, and headache at short-term follow-up in chronic neck pain. In addition, disability reduction, sleep quality, subjective improvement, and the evaluation of the pillow as comfortable were also superior in the spring pillow group. No statistically significant effect was found for shoulder pain.

Pain reduction results were similar to those obtained in previous low-quality studies (Physiotherapy Evidence Database - PEDroscore of < 6 points) comparing a water-based cervical pillow with a usual one or a roll pillow,[14] a cervical pillow with a travel pillow,[20] or using an Align-Right cylindrical cervical pillow.[13] Improvements

Table 5.
GPE and NPS Results[a]

Outcome	Result	SP		EI	
		No. of Participants	% of Participants	No. of Participants	% of Participants
GPE	1. Recovered	0	0.0	0	0.0
	2. Much improved	12	18.5	1	1.5
	3. A little improved	33	50.8	25	37.9
	4. Not changed	16	24.6	38	57.6
	5. A little worse	2	3.1	1	1.5
	6. Much worse	1	1.5	1	1.5
	7. Worst ever	1	1.5	0	0.0
NPS	1. Perfectly comfortable	15	23.1	1	1.5
	2. Very comfortable	25	38.5	10	15.2
	3. Quite comfortable	14	21.5	18	27.3
	4. Neither comfortable nor uncomfortable	6	9.2	23	34.8
	5. Quite uncomfortable	2	3.1	10	15.2
	6. Very uncomfortable	2	3.1	3	4.5
	7. Perfectly uncomfortable	1	1.5	1	1.5

[a]EI = educational intervention; GPE = Global Perceived Effect; NPS = Neck Pillow Satisfaction; SP = spring pillow (intervention).

in disability and sleep duration were also observed in a previous study of a water-based pillow.[21]

A height of 10 cm was also considered the most comfortable and reduced muscle activity in a previous study on the relationship between pillow height and comfort.[39] Moreover, we can hypothesize that the spring pillow may favor relaxation of the superficial neck muscles that has positive consequences on neck pain.[40] Another potential explanation for the better results produced by spring pillow use is that our sample had neck pain for long time, so they may have a more negative attitude toward educational interventions because of past experiences of ineffective treatments, fear of being a "placebo responder," or negative experiences from participating in clinical trials.[41] Conversely, delivering a new device may have fostered a positive attitude and expectation about this novel type of neck pillow,[19] similar to a placebo effect.[42] Moreover, poor effectiveness of booklets has been reported by individuals with chronic neck pain,[43] and a 30-minute educational session supported by a brochure may have been an insufficient dosage for an actual educational program.[27]

A strength of this study is the crossover design, which can minimize some sources of bias influencing the results of an RCT. Differences between the 2 samples at baseline, the skills of physical therapists involved in the treatment, the various settings, or specific participant characteristics—including the expectations for treatment, belief in the therapist's competence, and other psychosocial factors—all could influence outcomes.[44] Nevertheless, we cannot exclude a carryover effect, especially the impact that a therapy might have on a particular outcome after cessation period, and a learning effect because of the first therapy received, which could have an impact in the development of the second therapy. To address these limitations, we chose a long washout period (4 weeks) based on clinical studies with a similar design.[45]

The primary limitation of our study is a lack of blinding of the participants and therapists, which may have exaggerated the effects of the experimental intervention. Moreover, education may not have been the best comparator for the spring pillow. Dropout is also a potential limitation because outcome data were not recorded; however, the number of dropouts was very low (8.5% of the sample), fewer than 2 previous studies[14,21] and similar to another study.[13] The reasons for dropping out of our study were not adverse effects of using the spring pillow, except in 1 case. We did not find relevant differences in baseline characteristics of dropout participants compared with participants who completed the study. Another limitation is related to the poor accuracy of chronic pain measurement and self-report reliability, especially for retrospective questionnaires.[14]

We were not able to verify drugs used by participants, actual pillow use, and the implementation of the educational suggestions as prescribed. Moreover, usual pillows could be modified in their shape and property through everyday use, whereas the spring pillow was a new pillow. We did not assess the characteristics of head pain in our sample by neurological examination; therefore, we cannot classify the headache reported by the participants at baseline. Moreover, individuals recruited into the study were presumably dissatisfied with their usual standard pillows. Finally, an important limitation of our study was also the fact that we did not measure long-term follow-up.

Concerning the clinically significant reduction of pain, we observed that the 95% CIs included the MCID for only 1 pain site (head) and included none for another site (shoulder), suggesting that effect sizes are small for cervical and thoracic pain and neutral for shoulder pain. Nevertheless, because of the improvements of disability and sleep quality, this type of pillow may be useful for individuals with chronic neck pain. The results of this study may be generalizable to clinical practice, because of the characteristics of the participants, similar to those of individuals who normally receive physical therapy treatments, and the spring pillow, which can be easily obtained.

The spring pillow used in this study is safe, simple to use, and without evidence of adverse events. However, our study does not rule out the possibility that similar results could be obtained with other brand-new, high-quality pillows of similar height and comfort. As a consequence, whether the spring pillow in this study is more effective than other ergonomic/high-quality pillows remains to be tested.

Further studies should investigate the effects of the spring pillow at long-term follow-up and as addition to other therapeutic procedures. Future studies should also attempt to quantify the actual pillow use. Other suggestions for future research include comparing different types of "new" pillows, investigating the preferred size for side and supine sleepers, and the relationship between improved comfort/sleep and satisfaction.

Author Contributions

Concept/idea/research design: C. Vanti, F. Banchelli, A.A. Guccione, P. Pillastrini
Writing: C. Vanti, F. Banchelli, A.A. Guccione, P. Pillastrini
Data collection: C. Vanti, F. Banchelli, C. Marino, A. Puccetti
Data analysis: F. Banchelli, A.A. Guccione
Project management: C. Vanti, P. Pillastrini
Clerical: C. Marino, A. Puccetti
Consultation (including review of manuscript before submitting): C. Vanti, A.A. Guccione

Ethics Approval

The study protocol was approved by the Independent Ethics Committee in Clinical Research of the University Hospital, Bologna, Italy (34/2017/U/Disp). Informed consent was obtained from all participants and procedures were conducted according to the Declaration of Helsinki.

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Clinical Trial Registration

The study protocol was registered in the Clinical Trial Registry of the National Institutes of Health (NCT03165669).

Disclosures

The authors completed the ICJME Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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