PRM+ (2019) Volume 2 Issue 2 35-40
ISSN 2489-8457

"Spinal alignment" cushion in the management of low back pain – a randomized controlled study

Ambreen Chohan PhD[1], Katherine Ramli MSc[1], Adam Cook PGDip[1], Karen May MSc[1], James Selfe DSc[2], Jim Richards PhD[1]

Abstract

Objectives

To assess the clinical effectiveness of using a spinal alignment cushion compared to standardized care in the management of simple mechanical LBP, whilst laying in the semi-fetal position.

Methods

71 individuals (aged between 18 and 50) with simple mechanical LBP for at least 3 months were recruited to the 4-week intervention after screening using the Red Flags and STarT Back tools. Participants were randomly assigned to either the control (standardized care) or intervention group (standardized care plus spinal alignment cushion). Pre and post assessments were taken using the Roland Morris Disability Questionnaire (RMDQ) (0-24), to assess physical disability associated with low back pain; the Core Outcomes Measure Index (COMI) (0-10), and Patient Reported Outcome Measures that included measures of sleep quality and comfort as well as back and muscle pain and stiffness. Questionnaires were completed online using SNAP survey. Each post assessment was analyzed using ANCOVA with corresponding pre-assessment as a covariate.

Results

Clinically and statistically significant differences were seen in the RMDQ ($p=0.034$) and COMI scores ($p=0.008$) with the intervention group showing the greater improvement in scores over the four-week intervention. Significant differences were also seen in favor of the intervention group in the frequency ($p=0.004$) and intensity of back pain ($p<0.001$), joint/muscle stiffness ($p=0.046$) and intensity of back stiffness ($p=0.022$).

Conclusions

Overall, results suggest that use of targeted treatments such as a spinal alignment cushion, for symptoms at night can provide clinically important and statistically significant improvements for individuals with LBP with high levels of treatment satisfaction and adherence.

Keywords:

Low back pain; Roland Morris Disability Questionnaire; Core Outcome Measures Index; Patient Reported Outcome Measures; Spine; Sleep

INTRODUCTION

Low back pain (LBP) is a common and costly, worldwide problem (1-5), experienced by most people at some point in their life (5-6). In 2010 LBP was estimated to have the highest impact on global health in terms of years lived with disability (7), showing a real long-term effect on individuals. Low Back Pain (LBP) is often related to poor postural control (8-9) and movement habits, causing an imbalance of the spine's supporting structures leading to tissue overload and the symptoms of pain (10). Individuals with LBP often report their pain interferes with work, daily activities, mental health, sleep and overall quality of life (11-13). For this reason, NICE guidance for the management of low back pain is not limited to just pharmacological management but also advises self-management, exercise, orthotics, manual therapy, acupuncture and psychological therapies (3)

An association between chronic LBP and sleep disorders has previously been reported (14-16) with sleep disturbance and pain at night being recognized as clinically important symptoms of LBP (17-19). Within a large prospective study of 482 LBP patients attending a back-pain triage clinic, 44% of the patients complained of some pain at night, of which 42% experienced pain every night (20). In addition, a highly significant relationship has been documented between sleep and pain levels, with 55% of LBP patients reporting restless/light sleep after the onset of

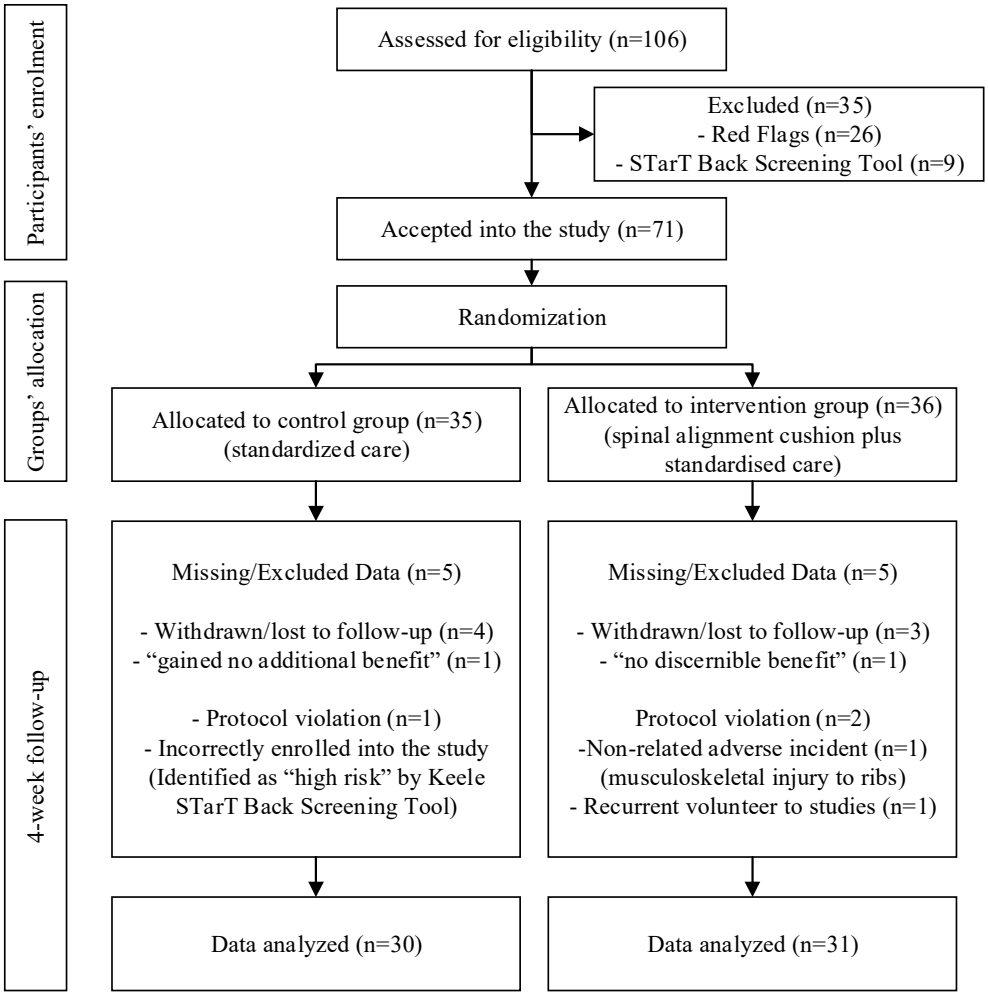
Figure 1. The spinal alignment cushion

[1] Allied Health Research Unit, University of Central Lancashire, Preston, Lancashire, PR1 2HE; [2] Department of Health Professions, Manchester Metropolitan University, Manchester, M15 6GX

Conflicts of interest: None to declare

Corresponding author: Dr Ambreen Chohan, Allied Health Research Unit, School of Sport and Health Sciences, University of Central Lancashire, Preston, PR1 2HE, UK. Email: AChohan@uclan.ac.uk Tel: +44 1772 892793

Figure 2. CONSORT flow chart illustrating participant enrolment, group allocation and data analyses



pain (21). Sleep disruptions have therefore been shown to have detrimental impacts on quality of life, such as increasing the severity of pain and negatively impacting function and mood (22). Harding et al. (20) suggest the use of targeted treatments specifically for night pain could be used as a method of reducing the overall distress and disability associated with individuals with LBP.

Within the research literature the choice of sleep system is commonly referred to as an influential factor of LBP with the idea that some sleeping surfaces will provide better support and comfort than others (10). In a survey of orthopedic surgeons 95% agreed with this and believed that a mattress could play a part in the management of LBP, with 75% recommending a firm to hard mattress to help provide relief (24). In clinical practice health professionals routinely advise LBP patients to sleep in a side-lying semi-fetal position with a cushion or a rolled duvet between their legs (25). This concept follows the theoretical discussion of Gracovetsky (27) who proposed that a fetal sleeping position could help minimize spinal rotation and potentially reduce mechanical damage to the intervertebral disc. However, clinical guidance for management of rest related low back pain is sparse (25, 26).

A spinal alignment cushion aims to improve sleeping posture and therefore prevent or reduce low back pain by utilizing the above theory and minimizing spinal rotation whilst in a side lying position. In a small-scale biomechanical crossover study of 15 individuals with LBP (27), the spinal alignment cushion appeared to move participants into a more neutral position through biomechanical changes by increasing alignment at the hip and thoraco-lumbar region. Subjectively the treatment also brought about improvements in the participants perception of back stiffness, back pain intensity and sleep comfort over a 7-day period, however a larger trial is necessary to further explore clinical outcomes and support these claims. This study aims to explore the clinical effectiveness of a spinal alignment cushion in the management of simple mechanical LBP over a 4-week period when compared to standardized care advice (28).

METHODS

This was a two-arm intervention trial (control vs. intervention). A sample size calculation based on a previous repeated measures study considering the use of a spinal alignment cushion (29) determined a sample of at least 30 participants in each arm was required to attain significance. A total of 71 participants (30 males, 41 females), between the ages of 18 and 50, were accepted into the study. Participants were recruited from within a university staff and students through campus-based advertisements. Volunteers from outside the University who had heard of the study through word of mouth (due to the study's snowballing effects) were also included. If willing to take part in the study, participants were required

to contact the research team via email. Participants were to have suffered with LBP for at least three months and have trouble sleeping.

Participants were screened for eligibility using a Red Flags screening form (adapted from Greenhalgh & Selfe 2010 (30)) and the Keele STarT Back Screening Tool (31). Volunteers who exhibited Red Flags or who were classified as "high risk" according to the Keele STarT back screening tool (31), were excluded from the study. To reduce the risk of other age-related factors all participants were between 18 and 50 years of age (30). Exact age of participants was not recorded to keep response time to a minimum and to try to reduce drop-out rates. The study was approved by the University of Central Lancashire Ethics committee and was performed in accordance with the Declaration of Helsinki.

All participants were asked to complete a pre-intervention assessment providing baseline information on pain and function levels. All data was collected online using SNAP Webhost Version 10 (Snap Survey Ltd, UK). By completing the assessment participants were informed that they were consenting to be in the study. The assessment consisted of 3 questionnaires designed for and previously used in back pain research (23, 26, 32-33).

24-item Roland Morris Disability Questionnaire (RMDQ)

The primary outcome measure was the 24-item Roland Morris Disability Questionnaire (Scoring range 0-24) (32), which has been recommended for use in a population with less functional disability due to LBP (34-37). The RMDQ can be completed in 5-10 minutes and consists of 24 functional activity limitations due to LBP. The minimal clinical important difference (MCID) is a change of 30%from baseline.

Core Outcome Measures Index (COMI):

The secondary outcome measure was the 6-item Core Outcome Measures Index (COMI) (34), which is a self-report, standardized measurement of outcomes assessment. The participant is asked to respond to 6 questions about how they have been feeling over the last week. The items cover 5 dimensions: symptoms, function, general well-being, work disability and satisfaction with care.

Patient Reported Outcome Measure questionnaire

The final outcome measure was the Patient Reported Outcome Measure questionnaire derived from previous back pain related sleep studies (23, 27). The questionnaire assessed sleep comfort, quality of sleep, back pain when waking and joint or muscle stiffness when waking on an 11-point Likert scale (scores ranging from 0-10).

On completion of the preintervention assessment all participants were randomly allocated to either the standardized care "control group" (The Back Book (28)) or the "intervention group" (spinal alignment cushion plus The Back Book) for a period of four weeks. The Back Book (28) was developed to promote a stay-active approach for LBP patients by providing simple self-help messages on the benefits of general exercise, such as walking, which is widely accepted practice in the UK National Health Service (39). Those allocated to the intervention group additionally received a spinal alignment cushion which they were asked to wear whilst sleeping according to the manufacturer's instruction. Participants in the intervention group were also sent a leaflet which included general information about back pain and instructions for using the spinal alignment cushion. All study materials were sent to participants via post.

Group allocation was block randomized by an independent researcher. The randomization plan was created for a control group versus a single treatment group using www.randomization.com. Four weeks after receiving the intervention materials participants were sent a follow-up questionnaire to determine any changes in outcome measures. The post-intervention assessment comprised the same questionnaires as the pre-intervention assessment plus a question regarding participant satisfaction with their overall medical care. Those assigned to the intervention group were additionally asked 4 questions regarding their use, perceived benefit, comfort of the cushion and whether they experienced any negative effects from it. This was included to help evaluate the potential impact of the cushion on individuals with LBP.

Statistical Analyses

In order to carry out a complete case analysis, all data was exported to SPSS Version 20 (SPSS Inc, Chicago, IL) for statistical analysis of all outcome measures (RMDQ score (32), COMI score (32) and all aspects of the Patient Reported Outcome Measures questionnaire). Intervention effectiveness on each post assessment was analyzed using ANCOVA with corresponding pre-assessment as a covariate. The distributions of the residuals were examined using the Kolmogorov-Smirnov test and were found to be consistent with normality. Statistical significance was set at $P \leq 0.05$. The Kruskal Wallace test was used for the non-parametric analysis of category data. Definite clinical improvement was shown if the RMDQ score was reduced by 30% from baseline (40) and complete recovery was defined by an RMDQ score ≤2 with zero pain (41).

Table 1. Pre/post estimates for controls and cases

Variable	Control Group		Intervention Group	
	Pre	Post	Pre	Post
Back pain at waking up, days/30 days	11-15	6-10	11-15	0-5[c]
Sleep quality [d]	5.5 (2.2)	4.6 (2.4)	4.8 (2.2)	3.5 (2.4)
Sleep comfort [d]	5.6 (2.1)	4.5 (2.4)	5.2 (2.3)	3.6 (2.2)
Back pain during sleep [d]	3.0 (2.0)	2.8 (1.9)	2.9 (2.1)	1.5 (1.3)
Joint/muscle stiffness [d]	3.1 (1.8)	2.6 (1.8)	3.6 (1.9)	2.2 (1.7)
Back stiffness [d]	4.6 (3.1)	3.7 (3.0)	5.1 (2.9)	2.8 (2.5)[b]
RMDQ [c]	5.9 (4.9)	4.4 (4.2)[a]	4.3 (3.2)	2.2 (2.2)[a]
COMI [d]	3.9 (1.6)	3.6 (1.6)[a]	3.5 (1.1)	2.5 (1.6)[a]

[a] = Significant between group effects ($p<0.05$); [b] = MCID attained within group; [c] = Significant difference in change ($p<0.05$); [d] 0 to 10 points; [e] 0 to 24 points

RESULTS

A total of 71 participants were accepted into the study, (35 within the control group and 4 in the intervention group), 10 of which (5 in each group) withdrew from the therapy prior to the end of the intervention period. In the intervention group 3 participants were lost to follow-up (1 reported no benefit) and 2 participants were lost to protocol violations (non-related adverse incident, recurrent volunteer for study). In the control group 4 participants were lost to follow-up (1 reported no benefit) and 1 participant was a protocol violation (incorrectly enrolled). Despite the level of non-adherence for purposes of statistical analysis they were included in accordance with "intention to treat" principles of analysis. The mean time

from receiving the intervention to completion of the post-intervention questionnaire was 32.9 days for the control group and 31.2 days for the intervention group.

Baseline assessments

There was no significant difference between the two groups in terms of their RMDQ scores ($t(49.99) = 1.54$, $p = 0.13$) or their COMI scores ($t(50.16) = 0.96$, $p = 0.34$) at baseline

RMDQ and COMI score

A significant reduction in the primary outcome measure (RMDQ score) of the intervention group compared with the control group was seen ($F(1, 58) = 4.901$, $p = 0.03$, $\eta p^2 = 0.078$, indicating a medium effect size. Participants in the intervention group experienced a mean 48% reduction in score compared with a 26% reduction in the standardized care control group. 72% of participants in the intervention group showed a definite clinical improvement, whilst 37% of the control group showed definite clinical improvement (40). Complete recovery however was only seen in 14% of the intervention group and 11% of the control group (41). A significant reduction in the mean COMI Score of the intervention group compared with the control group was also seen ($F(1, 58) = 8.382$, $p=0.005$, $\eta p^2 = 0.126$), however this was not seen to be clinically important (42) (Table 1). Participants who used the cushion for a 4-week period experienced a mean 34% reduction in score compared with a mean 9% reduction in the standardized care control group.

Patient Reported Outcome Measures

There was a significant change in number of nights woken with back pain for the intervention group ($p=0.017$) and the intensity of back pain when waking was significantly different between groups. There was an overall 48% reduction in back pain intensity in the intervention group compared with 7% in the control group ($p<0.001$). In addition, a clinically significant (43) difference in back stiffness when waking was seen between groups, with a 34% reduction in the intervention group ($P = 0.022$) and a significant difference was seen in the joint/muscle stiffness experienced between groups ($P = 0.046$) (Table 1).

Significant alterations in sleeping position were reported between the two groups following the 4- week intervention period. The intervention group significantly increased the time spent in a side lying sleeping position by 24% ($P = 0.002$) and reduced the time spent on their back by 37% ($P = 0.001$). No change was seen within the control group (Table 1).

On average the participants perceived the cushion to be beneficial and comfortable with a trend towards "Extremely Beneficial" and "Excellent Comfort". The intervention group reported to have used the cushion frequently over the 4-week period, with a trend towards "Every Night" and the intervention group were significantly more satisfied with the overall medical care provided ($p<0.005$). Adverse effects reported by the participants included; an increase in temperature at the knee associated with the cushion (n=5), shoulder and hip pain similar to that of bed sores (n=1) and a mild allergic reaction (n=1).

DISCUSSION

The results of this randomized control trial identify the spinal alignment cushion to have a positive impact on pain and function levels within individuals with LBP over a 4-week period. In agreement with previous findings those who used the spinal alignment cushion reported significant improvements in the RMDQ, COMI, frequency and intensity of back pain and stiffness of the back, joint and muscles when waking (28).

The RMDQ was the primary outcome measure for this study and identified a statistically significant difference between the groups. This suggests that the intervention produced greater improvement over the control condition, although both positively influence day-to-day function levels of individuals with LBP. To further understand whether these changes in score are relevant to the patient it is important to consider the minimal clinical important difference (MCID) (42). Though a change of 5 points on the RMDQ has previously been calculated as the MCID, more recently the patient's initial score has been taken into consideration and a change of 30% from baseline has been deemed more suitable, indicating definite clinical improvement (40). Within this study both the intervention group and control group surpassed this threshold (control group 37%, intervention group 72%) identifying that both groups experienced a clinically important improvement. In addition, it has been recently defined that complete recovery may be characterized by complete relief from pain alongside an RMDQ score of ≤ 2 (41). The difference experienced by the intervention group suggests that the spinal alignment cushion provides a substantially greater clinical improvement in general pain and function levels of individuals with LBP compared to standardized advice alone. This corresponds to the significantly greater satisfaction levels for overall care experienced by the intervention group.

This study demonstrates that the cushion used during the intervention, which was designed for use at night resulted in a significant reduction in the number of nights woken with back pain and back stiffness whilst also reducing the number of nights poor sleep quality was experienced (Table 1). The significant improvement over the control group, in both frequency and intensity of symptoms at night would suggest that the cushion has a greater impact on night symptoms. A plausible explanation for this could relate to a change in sleeping posture, as the intervention group reported spending an additional 24% of their time in a side lying position during the 4-weeks. These findings support the work of both Gracovetsky (27) who proposed that a side-lying semi fetal position could potentially unload surrounding structures, and a previous biomechanical assessment of the spinal alignment cushion (29) which identified participants adopt a more neutral sleeping position when comparing the spinal alignment cushion to a control. Significant reductions in symptoms at night coupled with a clinically important change in RMDQ score emphasize the relevance of specifically designed treatments for night pain, and their ability to help improve overall stress and disability experienced by individuals with LBP. Despite this, in the current study, the validity of asking participants to self-report their sleeping positions should be questioned.

Within this study considerations should be made for the severity of pain reported by participants, due to the mean RMDQ scores for both groups (5.9 and 4.3) being markedly lower than that previously described in the literature (mean 9.1 - 12.5) (40, 44). Therefore, it should be acknowledged that the intervention used within this study may have a different impact on a population group who report more severe pain. Future research should identify the clinical effects of spinal alignment cushions on different forms of low back pain and also be compared against other commonly prescribed interventions.

It should also be questioned whether standardized care was a suitable comparison for the spinal alignment cushion. The Back Book was chosen for a variety of reasons. Firstly, participants who took part in the study only had mild/moderate LBP and so researchers wanted to make a comparison between two interventions which targeted this group and provided them with self-management techniques for their pain. Both interventions may therefore be used before consulting a clinician for help. Use of the Back Book also meant that the control condition was easier to standardize and was therefore a more reliable comparison. This leads on to a related limitation that the spinal alignment cushion was not compared with a normal pillow. Therefore, it is not known whether the spinal alignment cushion adds any further benefit compared with just using an ordinary cushion. Future studies should look to investigate this.

Conclusions

Overall, this was a pragmatic study aimed to determine the clinical effectiveness of a spinal alignment cushion in the management of LBP over a 4-week period. Future research may consider how long the pain reduction due to the use of the spinal alignment cushion lasts, by conducting a longitudinal study. Consideration could also be given to the effects of the spinal alignment cushion on the incidence and duration of sick leave due to LBP. It is concluded that when compared with general information and guidance on LBP, a spinal alignment cushion can positively influence a LBP sufferer’s perception of pain and function and significantly alter sleeping position. Results of this study may have implications in that future studies investigating targeting intervention approaches for symptoms at night can provide clinically important improvements for individuals with LBP with high levels of treatment satisfaction and adherence. Further research is required to assess the rate of compliance and impact of treatments that target sleeping position, on other groups of individuals with LBP and compared against other similar interventions.

REFERENCES

1. Chaiamnuay P, Darmawan J, Muirden KD, Assawatanabodee P. Epidemiology of rheumatic disease in rural Thailand: a WHO-ILAR COPCORD study: community oriented programme for the control of rheumatic disease. The Journal of Rheumatology. 1998;7:1382-87.
2. Hoy D, Toole MJ, Morgan D, Morgan C. Low back pain in rural Tibet. The Lancet. 2003;361:225-26.
3. Bernstein IA, Malik Q, Carville S, Ward S. Low back pain and sciatica: summary of NICE guidance. The British Medical Journal. 2017;356:i6748.
4. Maher C, Underwood M, Buchbinder R. Non-specific low back pain. The Lancet. 2017; 389:736-47.
5. Hoy D, Brooks P, Blyth F, Buchbinder R. The epidemiology of low back pain. Best Practice & Research Clinical Rheumatology. 2010;24:769-81.
6. Andersson GBJ. Epidemiological features of chronic low back pain. The Lancet. 1999;354: 581-85.
7. GBD. Global, regional and national incidence, prevalence and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990-2017: a systematic analysis for the Global Burden of Disease Study. 2017. The Lancet. 392:1789-1858.
8. Caffaro RR, França FJ, Burke TN, Magalhães, Ramos LA, Marques AP. Postural control in individuals with and without non-specific chronic low back pain: a preliminary case-control study. European Spine Journal. 2014;4:807-13.
9. Carmo CM, Takara KS, Santos FG, Souza FMB, Siqueira CM, Tanaka C. Poorer postural control of patients with low back pain compared to a control group. Annals of the Rheumatic Diseases: The Eular Journal. 2013;71.
10. Comerford MJ, Mottram SL. (2001) Movement and stability dysfunction – contemporary developments. Man Therapy 6:15-26.
11. Martin BI, Deyo RA, Mirza SK, Turner JA, Comstock BA, Hollingworth W, et al. Expenditures and health status among adults with back and neck problems. JAMA. 2008;299:656-64.
12. Lidgren L. The bone and joint decade 2000-2010. Bulletin of the World Health Organization. 2003;81:629.
13. McGrail MP, Lohman WH, Gorman R. Disability prevention principles in the primary care office. Am Fam Phys. 2001;63:679–684.
14. Marty M, Rozenberg S, Duplan B, et al. Quality of sleep in patients with chronic low back pain: a case-control study. Eur Spine J. 2008:17;839-844.
15. Axén I. Pain-related Sleep Disturbance - A Prospective Study with Repeated Measures. Clinical Journal of Pain. 2015; 32(3);254-258.
16. Alsaadi SM, McAuley JH, Hush JM, Maher CG. Prevalence of sleep disturbance in patients with low back pain. European Spine Journal. 2011:20;737-743.
17. O'Donoghue GM, Fox N, Heneghan C and Hurley D. Objective and subjective assessment of sleep in chronic low back pain patients compared with healthy age and gender matched controls: a pilot study. BMC Musculoskelet Disord. 2009:10:122.
18. Wang SM, Dezinno P, Maranets I, Berman MR and Caldwell-Andrews AA. Low back pain during pregnancy: prevalence risk factors, and outcomes. Obstetrics and Gynecology. 2004;104:65-70.
19. Hurley DA, Eadie J, O’Donoghue G, Kelly C, Lonsdale C, Guerin S, Tully MA, van Mechelen W, McDonough SM, Boreham CA, Heneghan C, Daly L. Physiotherapy for sleep disturbance in chronic low back pain: a feasibility randomised controlled trial. BMC Musculoskelet Disord. 2010: 11: 70.
20. Harding IJ, Davies E, Buchanan E, et al. The symptom of night pain in a back pain triage clinic. Spine. 2005: 30:1985-1988.
21. Marin R, Cyhan T and Miklos W. Sleep disturbance in patients with chronic low back pain. Am J Phys Med Rehabil. 2006:5:430-435.
22. Haack M and Mullington JM. Sustained sleep restriction reduces emotional and physical well-being. Pain. 2005. 119(1-3):56-64.
23. Jacobson BH, Boolani A, Dunklee G, et al. (2010) Effect of prescribed sleep surfaces on back pain and sleep quality in patients diagnosed with low back and shoulder pain. Appl Ergon. 2010: 42(1):91-97.
24. Jacobsen BH, Wallace T, Gemmell H. Subjective rating of perceived back pain and stiffness and sleep quality following introduction of medium-firm bedding systems. Journal of Chirpractic Medicine. 2006: 5(4);128-134.
25. NHS UK. Back pain - Treatment - NHS Choices. 2015. online. Available at: www.nhs.uk/Conditions/Back-pain/Pages/Treatment.aspx Accessed September, 2019..
26. Pelvic Obstetric and Gynaecological Physiotherapy. Pelvic Girdle Pain and other common conditions in pregnancy. 2018. Available at: https://pogp.csp.org.uk/system/files/publication_files/POGP-PGP%28Pat%29%28UL%29.pdf Accessed September 2019.
27. Gracovetsky SA. The Resting Spine. A conceptual approach to the avoidance of spinal reinjury during rest. Physical Therapy. 1987:67(4):549-553.
28. Burton K. (2001) The Back Book. 2nd ed, Norwich: The Stationery Office.

29. Chohan A, Payne K, Selfe J, Richards J. Biomechanical testing of a spinal alignment cushion (RophiTM Cushion) in adults with lower back pain. The Bone and Joint Journal (Orthopaedic Proceedings) 2013: 95B (4);12.
30. Greenhalgh S and Selfe J. Red Flags II: A guide to solving serious pathology of the spine. London, Churchill Livingstone. 2010.
31. Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: Identifying patient subgroups for initial treatment. Arthritis Rheum. 2008:59(5):632–641.
32. Roland M and Morris R. A study of the natural history of low back pain. Part 1: Development of a reliable and sensitive measure of disability in low-back pain. Spine. 1983; 8: 141–4.
33. Deyo R, Battie M, Buerskens A, et al. (1998) Outcome measures for low back pain research: a proposal for standardized use. Spine. 1998: 23;2003–13.
34. Bombardier C. Outcome assessments in the evaluation of treatment of spinal disorders: Summary and general recommendations. Spine. 2000:15;3100-3.
35. Grotle M, Brox JI, Vøllestad NK. Concurrent comparison of responsiveness in pain and functional status measurements used for patients with low back pain. Spine. 2004; 29: E492-501
36. Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability questionnaire. Spine. 2000:15; 3115-24.
37. Carey TS, Mielenz TJ. 2007. Measuring outcomes in back care. Spine.; 32: S9-14
38. Leclaire R, Blier F, Fortin L, Proulx R. A cross-sectional study comparing the Oswestry and Roland-Morris functional disability scales in two populations of patients with low back pain of different levels of severity. Spine. 1997:22; 68-71.
39. NICE. Low back pain: Early management of persistent non-specific low back pain. NICE Clinical Guideline 88. 2009. www.ncbi.nlm.nih.gov/books/NBK11702/
40. Jordan K, Dunn K, Lewis M, et al. A minimal clinically important difference was derived for the Roland-Morris Disability Questionnaire for low back pain. J Clin Epidemiol. 2006: 59:45-52
41. Kamper SJ, Maher CG, Herbet RD, et al. How little pain and disability do patients with low back pain have to experience to feel that they have recovered? Eur Spine Journal. 2010: 19(9);1495- 501.
42. Mannion AF, Porchet F, Kleunstuch FS, et al. The quality of spine surgery from the patient's perspective. Part 1: the Core Outcome Measures Index in clinical practice. Eur Spine Journal. 2009:18 (3);367-373.
43. Childs, J. D., Piva, S. R., et al. Responsiveness of the numeric pain rating scale in patients with low back pain. Spine. 2005:30(11);1331-1334.
44. Riddle DL, Stratford PW and Binkley JM. Sensitivity to change of the Roland Morris Back Pain Questionnaire: Part 2. Phys Ther. 1998: 78(11);1197-1208.

ACKNOWLEDGMENTS

Staff time was funded by Orthodocs Ltd. But the company were not involved in the project planning, data collection, or analysis of this study. Orthodocs also provided the test materials for the study