Article

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Alexander, Jill, Selfe, James, May, Karen Alison, Richards, James and Chohan, Ambreen

Alexander, Jill ORCID: 0000-0002-6492-1621, Selfe, James, May, Karen Alison ORCID: 0000-0001-9621-8466, Richards, James ORCID: 0000-0002-4004-3115 and Chohan, Ambreen ORCID: 0000-0003-0544-7832 (2019) Determining effectiveness of a passive gravity assisted traction (PGAT) device in the management of simple, mechanical low back pain. PRM+ Journal of Quantitative Research in Rehabilitation Medicine, 2 (1). pp. 11-15. ISSN 2489-8457

PRM+ (2019) Volume 2 Issue 1 11-15
ISSN 2489-8457

Determining effectiveness of passive gravity assisted traction (PGAT) device in management of low back pain

Jill Alexander MSc[1], James Selfe DSc[2], Jim Richards PhD[1], Karen May MSc[1], Ambreen Chohan PhD[1]

Abstract

Objectives

Anecdotal evidence supports stretching exercises to minimize symptoms of low back pain and improve function. This study aimed to assess whether a passive gravity assisted traction (PGAT) device can reduce LBP through stretching techniques.

Methods

Sixty-seven participants with mechanical LBP were randomly assigned to a control or intervention group for 4 weeks, the intervention group receiving standardized advice and PGAT device. The control group received standardized advice. Questionnaire assessment included Roland Morris Disability Questionnaire (RMDQ), Patient Reported Outcome Measure (PROMs), Oswestry Disability Index (ODI) and Core Outcome Measures Index (COMI).

Results

Statistically significant score reduction in RMDQ (p=0.01) occurred within the intervention group and PROMs (p=0.01) when comparing intervention to control. No significant differences (p=0.06) within the control group were detected. Within the intervention group significant reductions in 'average' pain over the previous 24 hours, 7 days and 'worst' pain scores over previous 7 days ($p<0.05$). Significant decreases in 'average' and 'worst' pain (p=0.01) when comparing intervention to control group when rating an activity that participants found difficult to do, due to low back pain.

Conclusions

Improvements in low back pain demonstrated within the intervention group and comparing intervention to control group. Further research should consider assessing subgroups of posture types to compare response between groups. The use of PGAT devises such as LumbaCurve™ may be useful in the management of back pain.

Keywords:

Lumbar spine, low back pain, extension, exercise, pgat

INTRODUCTION

Simple, mechanical low back pain (LBP) is a costly musculoskeletal disorder [1], and a major worldwide health problem [2]. Sufferers of LBP report that symptoms often interfere with work and daily activities [3,4]. Mechanical LBP may be classed as pain of musculoskeletal origin in the absence of underlying progressive non-mechanical causes or neurologic deficits, usually treated conservatively in order to maintain activity and function [2;4]. LBP is commonly associated to poor postural control and movement habits caused by imbalances in the supporting structures of the spine [5], such as bone, ligaments, discs, joints [6]. Accounting for 97% of cases [6] mechanical back pain may often be a challenge for clinical management [7]. A balanced multidisciplinary care approach may increase the likelihood of success from back pain interventions with a range of therapeutic methods, including exercises and stretching [8-11]. NICE guidelines recommend a number of non-pharmacological interventions to manage LBP including, but not limited to; exercise programs, manual therapy and the facilitation of return to normal ADL's through advice/information [NG59, 2016]. More recently, alternative interventions for the treatment of simple, mechanical LBP have been observed; Purepong et al [3], investigated the effects of an acupoint-stimulating lumbar backrest on pain reporting significant improvement in LBP symptoms. Previous reports suggest manual Acupressure to be effective in the reduction of LBP, by decreasing disability and pain scores, and improving functional ability [12]. Recent research also reports other alternative options to manage conservatively LBP, such as lumbosacral orthoses to improve postural control [13] and exercises incorporating extension of the lumbar spine [14].

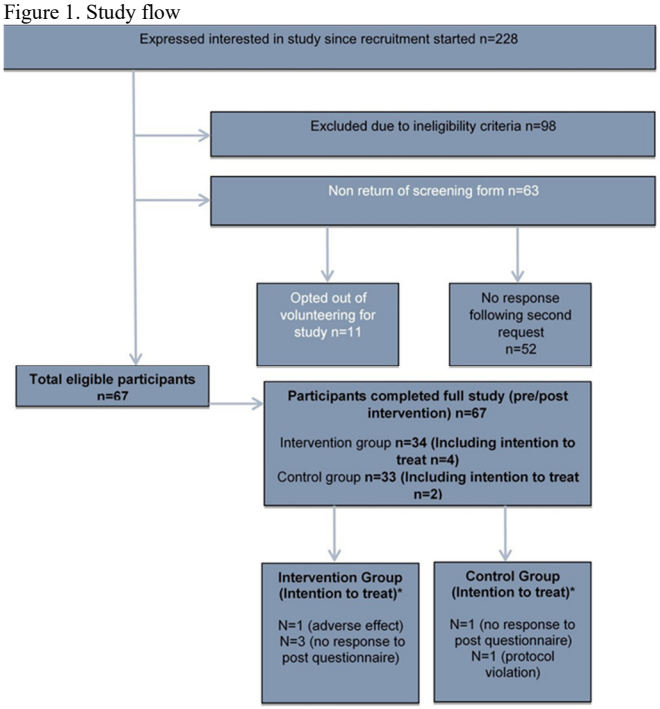
The physiological changes associated with extension and gravity-assisted traction of the lumbar spine have been shown to separate the vertebral joints, lengthening

[1] Division of Physiotherapy and Sports Therapy, School of Health Sciences, University of Central Lancashire, UK; [2] Department of Health Professions, Manchester Metropolitan University, UK

Conflicts of interest: None to declare

Corresponding author: Jill Alexander, University of Central Lancashire, Division of Physiotherapy and Sports Therapy, School of Health Sciences, Brook Building, BB126, Fylde Rd, Preston PR1 2HE, UK. jalexander3@uclan.ac.uk

Figure 1. Study flow



connective tissues in muscles and ligaments, which in turn reduce pressure on spinal nerves, aiding mobility and decreasing LBP [15]. Sherman et al [16] reported the use of stretching exercises for the spine in the management of LBP to minimize symptoms and improve function in patients with chronic LBP. There is however, limited quality evidence available to support the claims that traction may have a significant clinical impact on LBP intensity or functional outcomes [17]. The theory behind the use of a passive gravity assisted traction (PGAT) device is to relieve LBP through a stretching technique exercise. A common protocol adopted in the care of simple, mechanical LBP is the dissemination of standardized advice, such as 'The Back Book' [18]. This modality is intended as a guide to provide appropriate evidence-based advice for patients with back pain, using current research advice proposed to help with early pain management for simple, mechanical LBP [18], widely used in the National Health Service (NHS, UK) and supports NICE guideline recommendations [NG59] alongside exercise prescription [19].

The assessment of outcomes for LBP vary across the literature, and with diverse methods, and innumerable outcome scores represented across LBP studies [20]. Previous studies commonly report patient-reported outcomes measures (PROMS) [21] using measures such as Roland and Morris Disability Questionnaire (RMDQ) [22], Numerical Pain Rating Scale (NPRS), Oswestry Disability Index (ODI) [23] and Core Outcome Measures Index (COMI) [24]. These assessments involve a number of relevant measures, which include function, pain, activities of daily living, disability level associated with chronic low back pain [25], important to identify participant presentation and change following intervention applications that claim to reduce LBP.

The current study reflects recent research priorities to investigate new advances, opportunities and highlight limitations in the ability to improve primary patient care of LBP patients [9]. Anecdotal evidence reports users of PGAT techniques with LBP have experienced reductions in their symptoms and improvements in their back pain. To our knowledge, however no supportive clinical research evidence is available on the use of PGAT devices to support these anecdotal views. Therefore, this study aimed to explore the clinical effectiveness of a PGAT device in the management of LBP when compared to a control group of standardized advice. Study objectives were to determine post intervention effects on activities of daily living and PROMS, activity and function for the intervention group compared to the control group.

METHODS

This study consisted of a repeated measures design with pre-baseline and post-intervention data collection following a 4-week intervention period. The study was approved by the University ethics committee (BuSH:156) and was performed in accordance with the Declaration of Helsinki [26]. Informed consent was obtained through an 'opt in' procedure from each individual, preceding participation, and prior to completion of the pre intervention online questionnaire. Eligibility criteria included no red flags, less than 4 points equated on the 9-item STarT Back screening Tool [7] and participants with simple mechanical low back pain. In the assessment and management of people presenting with low back pain, the awareness of red flags is imperative following clinical guidelines for patient safety [27]. Volunteers with multiple spinal red flags [27] classed as 'high risk' or equated to four or more points on the 9-item STarT Back screening Tool [7] were excluded from the study. Exclusion to take part encompassed volunteers diagnosed with rheumatic, arthritic, degenerative or stenotic conditions, suffering from sciatica, diabetes, currently pregnant or with a history of any spinal surgery.

Sixty-seven participants with a mean age of 35.5±10.4 years (range 18-50) were eligible for the study. Following completion of the pre-intervention online questionnaire participants were randomly assigned to either the control (n=33) or intervention group (n=34) within the study (randomisation.com) (Figure 1). The intervention group received a PGAT device (Figure 2) in addition to standardized advice, and the control group given standardized advice alone (Figure 2). Participants in each group used the materials provided over a four-week period and instructed to use the materials provided on a daily basis. The intervention group receiving the PGAT device were instructed to watch the instructional DVD for how and when to use the device.

Questionnaires were implemented online at baseline, with follow up measures taken at 4 weeks post interventions. The primary clinical outcome measure was the RMDQ; 0-24 scale; severe disability indicated by high scores [22]. To assess average and worst back pain levels over the previous 24 hours and previous 7 days; secondary outcome measures included PROMs [21]; Numerical Pain Rating Scale (NPRS), The Oswestry Disability Index (ODI) [23] and Core Outcome Measures Index (COMI) [24]. The differences derived from the RMDQ questionnaire post-intervention observed for minimal clinically important change, incorporates measurement

Table 1. Within group and pre/post measures reported by patients for low back pain rating scores, percentage differences, and statistical differences

Variable	Baseline	4 weeks later	% Reduction	*p*-value
Intervention Group (n=34)				
Average pain for the previous 24 hours	2.9	2.1	28%	0.039
Worst pain for the previous 24 hours	4.0	3.2	20%	0.074
Average pain for the previous 7 days	3.2	2.1	34%	0.001
Worst pain for the previous 7 days	4.7	3.7	21%	0.017
Average pain (participant reported activity)	4.5	2.9	36%	0.001
Worst pain (participant reported activity)	5.8	3.9	35%	0.001
Control Group (n=33)				
Average pain for the previous 24 hours	2.9	2.6	10%	0.331
Worst pain for the previous 24 hours	3.9	3.8	3%	0.654
Average pain for the previous 7 days	3.1	2.9	6%	0.630
Worst pain for the previous 7 days	4.4	4.3	2%	0.781
Average pain (participant reported activity)	3.9	3.3	15%	0.044
Worst pain (participant reported activity)	4.8	4.4	8%	0.252

error of the RMDQ and allows different grades of pain severity noted by participants to show improvement [28]. If RMDQ score reduces by 30% from baseline measures, clinical improvement is present [28].

Statistical analysis

Questionnaire data collected within SNAP Webhost and transferred to SNAP 10 Professional (Version 10.16) followed by exportation to Excel 2010 (Microsoft, Corporation). Data analysis was by intention to treat. SPSS (Version 22.0, SPSS Inc. Chicago, IL) applied an ANOVA with general linear model was applied to assess the within group changes (pre and post), as well as independent samples t-test to assess between group changes (Intervention group vs Control group) with a post-hoc Bonferroni correction applied. Significance level was set at p=0.05. PROMs included, RMDQ, NPRS, ODI, VAS, and COMI.

RESULTS

RMDQ

Results reported significant reductions in RMDQ scores (p=0.01) within the intervention group (n=34), however, no significant differences occurred within the control group (p=0.06) or when comparing the intervention group with the control group (p=0.51). Forty-eight per cent of participants in the intervention group demonstrated a 'definite improvement' [28] compared to 36% of participants in the control group. A 'definite improvement' is defined by a reduction in symptoms by>30%.

PROMs

Significant reductions in PROMs for the intervention group over 24 hour and 7-day periods for both average and worst LBP ratings demonstrated in table 3 and 4.

ODI

Results demonstrated no significant differences (p=0.636) in ODI results when comparing the intervention group against the control group, following the 4-week period. No significant difference (p=0.116) in ODI results within the intervention group and no significant differences (p=0.473) in ODI results within the control group were found.

COMI

COMI results demonstrated no significant differences (p=0.113) when comparing the intervention group against the control group, or when comparing pre vs post results within the intervention group (p=0.726) following the 4-week period. No significant differences (p=0.113) in COMI results within the control group were found.

DISCUSSION

The aim of the study was to determine the clinical effectiveness of a PGAT device in the management of simple, mechanical LBP and identify whether the intervention group improved patient outcome when compared to control group. Findings in the current study show that in a group of individuals with simple, mechanical LBP the intervention group demonstrated more significant changes toward an improvement in pain / function after 4 weeks when assessing RMDQ and PROMs compared to the control group.

RMDQ, a common method of assessing pain and disability in individuals with LBP [22], demonstrated a greater improvement (13.6%) in score reduction when comparing the intervention group to the control group. Within the intervention group, 48% of participants achieved the minimum clinical change reduction of 30% threshold representative of a 'definite improvement' in LBP [28;29]. Previously standardized advice has demonstrated clinically important reductions in the management of LBP [30]. Data reports a reduction in RMDQ scores when assessing fear-avoidance beliefs in relation to the implementation of physical activity interventions for LBP management [30]. The combination therefore of the PGAT device, which incorporates a type of low-level physical exercise, alongside standardized advice [18] appears to work in unison to support and enable clinical change reductions in LBP.

Table 2. Significance of differences between intervention and control groups (*p*-values)

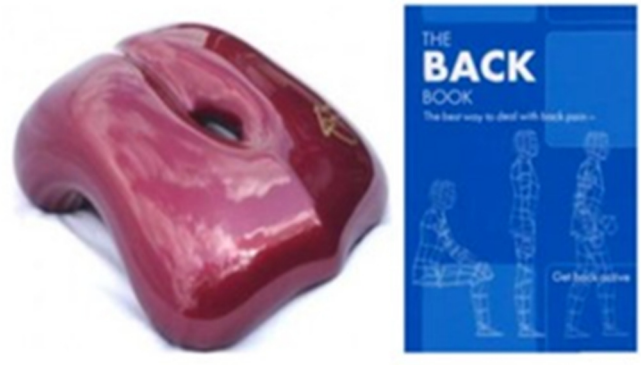
Average pain			Worst pain		
24 hours	7 days	Participant reported activity	24 hours	7 days	Participant reported activity
0.212	0.019	0.074	0.201	0.099	0.033

Explanations behind why 52% of participants did not demonstrate a clinically important reduction in pain perception from exposure to the intervention may have been due to low baseline levels of pain recorded. If low levels of pain were initially recorded in these particular participants the sensitivity of adjustment in perceived RMDQ, ODI or COMI scores may not have occurred, therefore not achieving a 'clinically important change'. Furthermore, the period of 4 weeks for the applied intervention may not have been long enough to induce a reduction in RMDQ scores therefore not meeting the 'definite improvement' threshold. Burton et al [30] reported at a 1-year follow up that patients receiving standardized care demonstrated significant improvement in

beliefs that physical activity benefits the management of their LBP. Therefore, a follow up of participants using the intervention at 6-8 weeks and at 1-year post, in the current study, may have been appropriate and essential for consideration in future studies.

This exploratory study supports the notion that there may be subgroups of people who are more suited to the PGAT device based on their posture type, with some postural characteristics therefore responding better to the device than others. For example, participants presenting with an increased lordosis in their lumbar spine and LBP, may not respond favorably to then placing themselves in a lordotic position on the intervention device. Recently a study by Macedo et al [10] developed a process to identify within a group of chronic LBP patients that respond to motor control exercises or graded activity better based on certain characteristics. Devising or applying a similar screening method of postural assessment in future studies may help determine typical characteristics of responders to such PGAT devices.

Figure 2. Passive gravity assisted traction (PGAT) device



In present healthcare, PROMs are an important outcome measure to assess patients and inform practice [21]. In the current study, secondary outcome measures included PROMs to assess average and worst LBP levels over the previous 7 days and 24 hours following the 4-week intervention period in each group. When comparing the intervention to the control group a significant reduction in average pain scores over the previous 7 days occurred. Within the intervention group, data analysis reported significant improvements in 'average' pain rating over the previous 24 hours and 7 days and significant improvements in 'worst' pain scores over the previous 7 days. With reductions in pain scores ranging between 20-36% post intervention the effectiveness of the device appears productive, within short time periods (24 hours-7 days), in terms of reducing simple, mechanical LBP. The clinical implications of these findings might suggest the integration of a PGAT device alongside standardized advice constitutes consideration in future management of simple, mechanical LBP.

PROMs questions asked participants to name an activity of which they found difficult to do due to their back pain prior to the start of the 4-week protocols, for both intervention and control groups. Participants in both groups rated worst and average pain scores for the same activity post-intervention period. Significant decreases reported in 'average' and 'worst' pain scores within the intervention group. The combined PGAT device plus Back Book approach therefore demonstrates the ability to reduce LBP symptoms in a range of activities specific to the participant.

Maher et al [2] suggests the application of non-effective or non-cost-effective interventions increases the high economic and social burden of low back pain. The wider implications of this study imply that the PGAT device may be applicable as a supplementary adjunct to conventional methods of LBP management by providing some therapeutic benefits. Further research needs to consider longer follow-up periods of such devices in order to observe whether it reduces LBP more effectively in a shorter time-period than that of standardized advice alone. Investigation may be appropriate to observe whether ongoing use of the device is necessary to continue the management of LBP symptom reduction long term. Future considerations into the cost-effectiveness of this device compared to standardized patient care for simple, mechanical LBP may be of benefit. It would be advisable to investigate whether subgroups of people with different presentations of simple, mechanical LBP may respond better or differently to the PGAT device than others. This may support its use in specific presentations of simple, mechanical LBP in a program of targeted intervention.

Although results are generalizable to a population presenting with simple, mechanical low back pain, screening of participant's postural characteristics prior to their inclusion into either group did not commence. Potentially, there may be subgroups of postural characteristics that respond better to the PGAT device than others. To understand the mechanisms behind the theoretical design of this particular PGAT device in relation to postural characteristics, biomechanical assessment would be desirable to investigate the positive effects demonstrated in this initial study. If a typical characteristic in posture is identified it may be appropriate to explore biomechanically the effects of the PGAT device in this responsive population. Further screening and research of postures prior to use would therefore be required to assess the rationality of this concept.

CONCLUSION

This study proposes the use of PGAT devices in support of 'standardized advice' in the management of simple, mechanical LBP. The broader use of such devices as a therapeutic measure to fit a range of LBP conditions however requires further research. Compared to standardized advice alone the PGAT device in conjunction with The Back Book demonstrates a marked improvement in a reduction of low back pain. Although the current study reports significant reductions and positive clinical changes in simple, mechanical LBP populations post intervention, diverse types of postures may respond better to PGAT devices than others. Further investigation of this is necessary to understand the impact of this device on LBP.

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