Physiotherapy 101 (2015) 75–81

Novel continuous passive motion device for self-treatment of chronic lower back pain: a randomised controlled study☆

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Abstract

Objective To evaluate the efficacy of a novel, angular, continuous passive motion device for self-treatment at home in patients with mild-to-moderate, non-specific, chronic low back pain (LBP).
Design Prospective, randomised, waiting-list-controlled (WLC) trial.
Setting Recruitment and assessment were conducted at the Koren Centre for Physical Therapy. Self-treatment was performed at home.
Participants Thirty-six patients with a score ≤6 on the numeric rating scale (NRS) for pain were enrolled. Twenty-eight patients completed treatment.
Interventions Participants were randomised to receive the Kyrobak (Radiancy, Hod-hasharon, Israel) at enrolment [immediate treatment (IT) group] or 3 weeks later (WLC group). Self-treatment was prescribed for 10 minutes, one to three times per day, for 3 weeks. The treatment period was followed by a 3-week follow-up period.
Main outcome measures Primary outcome was self-reported pain level (NRS).
Results Three weeks of self-treatment with the Kyrobak reduced pain levels significantly in the IT group compared with the WLC group {mean [standard deviation (SD)] ΔNRS score from baseline to post-treatment: IT group, 1.4 (1.5), 95% confidence interval (CI) 0.5 to 2.3; WLC group, −0.1 (2.2), 95% CI −1.1 to 1.2; effect mean difference 1.5}. This benefit was maintained over the follow-up period [from baseline to end of follow-up, mean (SD) ΔNRS score 1.1 (1.8), 95% CI 0.4 to 1.8]. Multi-linear regression analysis found that higher baseline pain resulted in greater pain reduction ($P = 0.003$). Eighty-three percent of participants with a baseline NRS score >4.35 (threshold determined by logistic regression, $P = 0.01$) achieved the minimal important change criterion of ΔNRS score ≥2. Daily NRS score reduced gradually over the treatment period [regression slope −0.052 (0.01), 95% CI −0.07 to −0.03].
Conclusions Preliminary evidence suggests that the Kyrobak may be beneficial for short-term relief of non-specific, chronic LBP, particularly in participants with a moderate level of pain. A longer treatment period may lead to a further reduction in pain.

Keywords: Motion therapy; Continuous passive; Low back pain; Self-treatment; Home care device

Introduction

Non-specific low back pain (LBP), not attributable to a specific pathology, is a widespread problem that affects all age groups, with the most prominent impact on quality of life in adults [1]. Chronic LBP lasting for more than 3 months [2] is increasing as the population ages [3].

☆ Clinical Trial Registration Number: NCT01620281.

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http://dx.doi.org/10.1016/j.physio.2014.06.003
0031-9406/

Treatment options for non-specific LBP include treatment by a physiotherapist, medications, acupuncture and exercise. However, the level of effectiveness of these treatments varies between individuals [4–8]. Therefore, there is a need for additional interventions with proven efficacy.

An alternative approach to treatment of LBP is the use of devices based on continuous passive motion (CPM). These motorised devices provide passive movement in a specific plane, thereby enabling the joint to pass through a predetermined range of motion [9]. The most common indication for CPM in the clinical setting is the avoidance of arthrofibrosis following trauma or joint surgery, particularly after total knee arthroplasty [10], although recent studies questioned the effectiveness of CPM in postacute rehabilitation [11–14]. Over the past decade, CPM management of LBP has been investigated in experimental models [15–18] and a case study in humans has been published [19]. A small number of CPM devices have been developed for self-treatment of LBP. These devices have been engineered to mobilise the lower spine in various planes, including anterior/posterior pelvic tilt in the supine position at home [20] or lumbar spinal (rotational) movement during sitting at work [21,22]. A CPM device that creates alternate side flexion of the back has not been described to date. To the authors' knowledge, a pragmatic study of self-treatment at home using a CPM device for management of LBP in humans has not been published, to date, in the medical literature.

This study describes a novel CPM self-treatment device for use at home that moves the lower vertebra by angular oscillation in the supine position, thereby creating alternate side flexion of the back. This clinical study was designed to determine the efficacy of the device for short-term pain reduction in participants with mild-to-moderate, non-specific, chronic LBP.

Methods

Design overview

This study was a prospective, randomised controlled trial (RCT). Participants with mild-to-moderate, non-specific, chronic LBP were randomised to receive the device either at enrolment [immediate treatment (IT) group] or 3 weeks later [waiting-list-control (WLC) group]. The 3-week treatment period was followed by a 3-week follow-up period.

Participant-reported outcomes including pain levels [numeric rating scale (NRS) for pain and Oswestry disability index (ODI) for functional health status] were documented at each clinic visit. In addition, throughout the study, participants were required to document daily NRS pain scores and complete weekly ODI questionnaires in a diary.

The primary outcome was the pre- to post-treatment change in NRS score after 3 weeks of daily treatment. Secondary outcomes were the pre- to post-treatment change in ODI score after 3 weeks of daily treatment, and changes in NRS and ODI scores from baseline to the end of the 3-week follow-up period.

Setting and participants

Participants were recruited from the Jerusalem district through advertising in local media, and were initially screened over the telephone. Potentially eligible participants were invited for an interview at the Koren Centre for Physical Therapy (Mevasseret-Zion, Israel; 10-minute drive from Jerusalem). Screening procedures over the telephone and at the clinic were conducted by certified physiotherapists. The inclusion criteria were: age $\geq$18 years; and mild-to-moderate (NRS score $\leq$6), chronic (present for more than 3 months) LBP of non-specific aetiology. The exclusion criteria were: LBP of specific and known aetiology; recent history of violent trauma; and history of back surgery. A detailed list of the inclusion/exclusion criteria can be found in the online supplementary material.

An orthopaedic spinal surgeon was consulted if questions were raised regarding the aetiology of the LBP during enrolment, and during the study in cases of pain aggravation, evaluation of a potential adverse event, or if a patient felt the need to consult with the surgeon during the treatment/post-treatment period.

Randomisation

Randomisation was performed by a third party who was not involved in either the screening process or any evaluations during the study. A detailed description of the randomisation procedure can be found in the online supplementary material.

Interventions

The Kyrobak (Radiancy, Hod-hasharon, Israel) is an electrically operated CPM device that creates slow angular oscillations of 6° (total amplitude 12°). It consists of a lightweight plastic body and a treatment surface that is padded with expanded rubber (ethylene vinyl acetate), and contains a control unit to select the oscillation frequency (low, medium or high = 24, 28 or 30 cycles/minute, respectively) and turn the device on or off (Fig. 1). The participant places their pelvis on the centre of the platform in the supine position, and either flexes the knees to 30° to 45° while placing their feet on the floor, or flexes the knees to 90° while placing their legs and feet on a chair. The Kyrobak turns off automatically after 10 minutes of continuous treatment.

At the clinic, on receipt of the Kyrobak, a physiotherapist instructed the participants about proper use of the device, correct body position, and the possibility that temporary discomfort or pain could be experienced during initial treatment because new movements that the body is not used to may elicit temporary pain aggravation. This was also disclosed