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Protocol Paper

Effects of functional taping compared with sham taping and minimal intervention on pain intensity and static postural control for patients with non-specific chronic low back pain: a randomised clinical trial protocol

F.J. Jassi [a], T. Del Antônio [a], R. Moraes [b], S.Z. George [c], T.C. Chaves [d,*]

[a] *Center for Health Sciences, State University of Northern Paraná, Jacarezinho, Paraná, Brazil*
[b] *School of Physical Education and Sport of Ribeirão Preto, Rehabilitation and Functional Performance Post Graduation Program, University of Sao Paulo, Ribeirão Preto, SP, Brazil*
[c] *Brooks-PHHP Research Collaboration, University of Florida, Gainesville, FL, USA*
[d] *Department of Neuroscience and Behavioral Science, Rehabilitation and Functional Performance Post Graduation Program, Ribeirão Preto Medical School, University of Sao Paulo, Ribeirão Preto, SP, Brazil*

Abstract

Objectives To investigate the immediate and 1-month effects of functional taping to lumbar spine for pain intensity and postural control in patients with chronic non-specific low back pain.
Design Randomised clinical trial.
Participants One hundred and twenty participants aged 18 to 50 years.
Interventions Participants will be allocated at random to receive one of three interventions: functional star-shape taping for 7 days, sham functional taping for 7 days or minimal intervention, one session.
Main outcome measures The primary outcomes will be pain intensity and postural control. Four measurements of static posturography will be conducted: pre-intervention, immediately after application of the tape, 7 days post-intervention (after removal of the tape) and 1-month follow-up. The secondary outcomes will be low-back-pain-related disability, global perceived effect of treatment and fear avoidance beliefs. Primary and secondary outcomes will be assessed on three occasions: pre-intervention, 7 days post-intervention and at 1-month follow-up. All statistical analyses will be conducted following intention-to-treat principles, and the treatment effects will be calculated using linear mixed models.
Discussion The results of this study will determine the effects of functional taping on pain intensity and postural control compared with sham taping and minimal intervention.
Clinical Trial Registration Number NCT02546466.

Keywords: Chronic low back pain; Functional taping; Balance; Posture; Rehabilitation; Psychosocial factors; Minimal intervention

Introduction

Low back pain is an important public health problem [1], affecting approximately 60% to 80% of the population at some point in their lifetime [2], and resulting in wide-ranging social and economic consequences [3]. Approximately 75% to 85% of low back pain is non-specific with no evidence of anatomical or pathological changes [4]. Currently, chronic low back pain (CLBP) is considered to be a multifactorial disorder that can include cognitive, psychological, social, physical and lifestyle factors [5].

Some studies have investigated postural control in patients with CLBP [2,6] demonstrating modifications in centre of

* Corresponding author. Address Department of Neuroscience and Behavioral Sciences, Ribeirão Preto Medical School, University of São Paulo, USP, University Campus, CEP: 14049-900 Ribeirão Preto, SP, Brazil.
Tel.: +55 16 3315 44 18/3315 46 94; fax: +55 16 3315 44 18/3315 46 94.
E-mail address: chavestc@fmrp.usp.br (T.C. Chaves).

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pressure (COP) excursion. Such changes in postural control suggest that low back pain is associated with peripheral and central processing disorders of proprioceptive information [6] and pain [7]. In a recent systematic review, greater COP excursions and a higher mean velocity of oscillation were reported in patients with CLBP, as well as a relationship between pain intensity and postural control [7].

There are several proposed treatments for CLBP, and functional taping (FT) has become a popular treatment method [8–10]. Systematic reviews have demonstrated conflicting evidence for the use of FT in clinical practice to reduce pain and disability [11,12]. The mechanisms by which FT achieves the expected results have not been fully clarified. The mechanical effect of applying tape to the skin (taping tension) may increase receptor inputs, relieving pain directly through the gate-control theory [13], as well as stimulating supraspinal centres and thus improving balance [14].

It has been reported that the direction of FT application and the tension applied define its purpose [15]. The star-shape method of application seems to be related to reductions in disease-related disability and pain intensity [16] compared with other types of application [9] in non-specific CLBP. It is possible that the greater area of mechanical skin stimulation with the star-shape method results in greater improvement in postural control. Additionally, 25% tape tension has been reported to facilitate muscle activation by an excitatory neuromuscular mechanism [17]. In this way, inert treatment effects are expected in the absence of tape tension.

To the best of the authors' knowledge, no reports have been published about the treatment effects of FT on postural control in CLBP. FT could act directly to improve pain and postural control parameters, and could indirectly reduce fear avoidance beliefs. Accordingly, these effects can improve confidence to perform daily life activities and to minimise low-back-pain-related disability.

Psychosocial aspects are intrinsic to the maintenance of chronic pain and disease-related disability, so one would expect changes in these variables to predict positive outcomes [18]. Wertli *et al.* [19] suggested the systematic assessment of fear avoidance beliefs, catastrophic thoughts, self-efficacy and satisfaction to understand these effects on treatment outcomes in patients with CLBP. Another recent systematic review showed that depression may have an adverse effect on the prognosis of low back pain [20]. In this way, psychosocial aspects have been adopted as baseline covariates in clinical trials [21].

It is important to verify the effects of FT compared with a minimal intervention (MI) based on a brief psychosocial approach [11,22]. Comparisons between treatment modalities enable better clinical decision making about therapeutic modalities available to manage CLBP.

Therefore, the objective of this study is to compare the effects of FT with sham FT and MI on primary outcomes for pain intensity and postural control in patients with CLBP. Secondary outcomes will be low-back-pain-related disability, global perceived effect of treatment and fear avoidance beliefs. The hypotheses of this trial are as follows:

- Functional star-shape taping (FST) will result in significant improvements in primary and secondary outcomes in non-specific CLBP compared with sham FT and MI immediately after the intervention and 7 days post-intervention, and in the long term (1-month follow-up).
- Baseline psychosocial factors will be associated with changes in clinical outcomes (within and between treatment groups).

Methods

Study design

This study is a sham-controlled, randomised, three-arm parallel-group clinical trial.

Study participants and eligibility criteria

Participants ($n = 120$) with non-specific CLBP referred to the physiotherapy clinic of the Center for Health Sciences, State University of Northern Paraná will be considered for enrolment. Participants who meet the following criteria will be considered eligible for the study: (1) aged between 18 and 50 years; (2) medical diagnosis of non-specific CLBP in the last 3 months, and/or pain for at least half of the time over the past 6 months [23], located between T12 and the gluteal folds; (3) pain intensity $\geq$3 on the Numerical Pain Rating Scale (NPRS); (4) mechanical pain behaviour defined operationally as being caused by postures, activities and movements during a standard physical examination that includes assessment of pain provocative postures for bending and functional movement tasks; and (5) score >14% on the Oswestry Disability Index [24].

Exclusion criteria will be: (1) red flags indicative of systemic involvement; (2) neurological symptoms, and psychiatric, rheumatologic and cardiac diseases; (3) disc herniation; (4) lumbar stenosis; (5) spondylolisthesis; (6) history of spinal surgeries; (7) pregnancy; (8) previous physical therapy for low back in past year; (9) previously diagnosed balance disorders (vestibular disorders); (10) other disorders that interfere with balance (e.g. ankle sprain during the past 6 months or during the treatment); and (11) medications that alter sensory perception. Patients will be instructed not to use pain relief medications during the intervention period of this trial. At 1-month follow-up, participants will record the use of medications in a pain diary [25].

Randomisation and allocation

This trial will follow the recommendations of the Consolidated Standards of Reporting Trials statement [26]. Once the patient has accepted an invitation to participate in the trial,