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CLINICAL TRIAL PROTOCOL

Effectiveness of physical therapy interventions for low back pain targeting the low back only or low back plus hips: a randomized controlled trial protocol

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Abstract
Background: Recent evidence suggests that physical therapy interventions targeting the hips may improve outcomes, including pain and disability, for patients with low back pain (LBP). Currently, there is conflicting data in regard to whether an individual with LBP needs to have a concurrent hip impairment in order to respond to this approach. The purpose of this clinical trial will be to determine the short and long-term effectiveness of physical therapy interventions directed at the lumbar spine only, versus lumbar spine and hip(s), in individuals with a primary complaint of LBP with a concurrent hip impairment.
Methods: A multi-center, randomized controlled trial of 76 adult individuals with a primary complaint of LBP, who also have at least one concurrent hip impairment. Participants will be randomized into the 'LBP only' or 'LBP + Hip' group. Treatment to the low back in both groups will be a pragmatic approach consisting of interventions targeting the low back without targeting the hip(s). Participants randomized to the LBP + Hip group will also receive a semi-prescriptive set of manual therapy and exercise techniques that target the hips. The primary outcome measures will be the modified Oswestry Disability Index and the Numeric Pain Rating Scale at discharge.
Discussion: These two treatment strategies are commonly utilized in physical therapy practice, but there is uncertainty which is superior. This trial will also help to provide a better understanding of the role of concurrent hip impairments in LBP.
Trial registration: This trial has been prospectively registered at clinicaltrials.gov (ID# NCT03550014, https://clinicaltrials.gov/ct2/show/NCT03550014) on June 7, 2018.

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Introduction

Background and rationale

Low back pain (LBP) is a leading cause of disability worldwide.[1,2] According to the Global Burden of Disease 2010 study, LBP ranked as the top condition for years living with disability accounting for 10.7% of total years lived with disability.[2] LBP is the fifth leading reason that patients seek care from physicians in the United States.[3] With an increase in patients seeking care, the healthcare expenditures related to LBP have outpaced other medical conditions.[4]

Over the past several years, studies have suggested providing interventions targeting adjacent regions may provide beneficial effects for the individual's primary region of complaint.[5,6] Using this regional approach to LBP, several studies have investigated the role of physical therapy interventions directed at one or both hips for individuals with LBP.[7–9] These preliminary studies have suggested that physical therapy interventions targeting one or both hips may improve outcomes for LBP.[7–9] In 2011, Burns et al.[8] provided a standardized approach of manual therapy and exercise targeting one or both hips in eight consecutive patients with chronic LBP (>6 months). In this small case series, over 60% of patients experienced a reduction in disability and reported a global improvement in their symptoms.[8] This approach to treating individuals with LBP was further investigated in a recent randomized clinical trial.[10] Bade et al.[9] randomized 84 participants to receive either pragmatic physical therapy program targeting the lumbar spine only (LBP only) or to receive pragmatic physical therapy to the lumbar spine plus a prescriptive set of manual therapy and exercise interventions directed at the hip(s) (LBP + Hip).[9] At two weeks, significant differences ($p < 0.05$) favoring the LBP + Hip group in terms of perceived recovery and patient satisfaction were identified. At discharge from physical therapy, significant differences ($p < 0.05$) were observed in favor of the LBP + Hip group for perceived disability, pain rating, patient satisfaction and perceived recovery. The effect size for the improvement in perceived disability was 0.36 and for pain rating 0.58, indicating small to medium effects. A possible reason for the small to medium effect sizes was that most of the participants (87%) did not have a concurrent hip problem.[10] An intervention targeting the hip might be expected to be more effective in a patient presenting with LBP and a concurrent hip problem. The prevalence of hip problems in patients presenting with LBP is estimated to be 80%, suggesting that interventions targeting the hip(s) might have a greater effect in a typical population of patients with LBP than what has been previously reported.[11]

Objectives

The aim of the current study is to determine the impact of physical therapy interventions directed at the lumbar spine only (LBP only) versus lumbar spine + hip(s) (LBP + Hip) on patient perceived disability and pain rating at discharge and at 12 month follow-up, specifically for individuals with a primary complaint of LBP and with concurrent hip impairment(s). Additionally, we will conduct a pre-planned secondary analysis to determine which possible factors (e.g., body mass index, perceived disability) may explain why some participants achieve a successful outcome following physical therapy interventions and others do not.

Trial design

This multi-center clinical trial was designed in accordance with the CONSORT guidelines for randomized trials[12] and will compare two parallel interventions (LBP only versus LBP + Hip) for patients presenting to physical therapy for treatment of LBP. The primary outcomes will be the modified Oswestry Disability Index (ODI) and numeric pain rating scale (NPRS) at discharge from physical therapy care and at 12 months after enrollment in the study. Fig. 1 illustrates the trial design.

Methods

Trial setting & recruitment

We estimate that we need to recruit from six physical therapy centers across a range of geographic regions.[10] The pragmatic design of the trial and large geographic area represented will ensure the generalizability and applicability of the study findings. The physical therapy sites that will participate in recruitment of participants in the trial are Bellin Heath Systems, BSR Physical Therapy, Franciscan Health Physical Therapy, Kinetic Physical Therapy, OSF Healthcare System and Temple University.

The research team will assess all recruitment sites for feasibility of being able to deliver the trial interventions. Each clinical site will have a site coordinator and at least one additional licensed physical therapist who will be trained in the study procedures. The pre-recorded training session will include instruction in the administrative aspects of the study (e.g., informed consent, subject recruitment) and specific training in the performance of the examination and treatment procedures, including the manual therapy techniques and the exercise program. The purpose of this training will be to ensure the participant screening examination is performed consistently across sites and that treating therapists fully understand the interventions for each group. The physical therapists involved frequently use the examination and treatment procedures in this study as part of their usual clinical practice, so the training is designed to facilitate consistency in delivery across practitioners. Each participating physical therapist will also be provided with a detailed Manual of Standard Operations and Procedures (MSOP) that describes all the study procedures in detail. Each participating physical therapist will complete an assessment of their understanding of these procedures and complete an experience survey. This survey will include questions regarding years of clinical experience and training and experience with manual therapy, including experience with the specific manual therapy techniques used in this study. We will also record each therapist's entry-level degree (MPT, DPT, etc.), post-professional academic degrees (MS, DSc, PhD, etc.), and post-professional specialty certification (OCS, FAAOMPT, etc.).

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