

Mechanical Low Back Pain: Secular Trend and Intervention Topics of Randomized Controlled Trials

Greta Castellini, PT, MSc;* Silvia Gianola, PT, MSc, OMT;†‡ Giuseppe Banfi, MD;§¶
Stefanos Bonovas, MD, MSc, PhD;** Lorenzo Moja, MD, MSc, PhD†**

ABSTRACT

Purpose: To evaluate the number of published randomized controlled trials (RCTs) focusing on mechanical low back pain (MLBP) rehabilitation, the secular (i.e., long-term) trend, and the distribution of interventions studied. **Methods:** All included RCTs were extracted from all Cochrane systematic reviews focusing on rehabilitation therapies for MLBP, and two independent reviewers screened and analyzed the information on interventions. **Results:** After removal of duplicates, the data set consisted of 196 RCTs published between 1961 and 2010. The number of RCTs published increased consistently over time: 2 trials (1% of the total) were published in 1961–1970, 10 (5%) in 1971–1980, 41 (21%) in 1981–1990, 68 (35%) in 1991–2000, and 75 (38%) in 2001–2010. The intervention of interest in the majority of RCTs was exercise therapy (115/399; 29%), followed by spinal manipulation therapies (60/399; 15%). **Conclusion:** The number of RCTs focusing on MLBP has risen over time; of all interventions studied, exercise therapy has attracted the most research interest.

Key Words: intervention studies; low back pain; randomized controlled trials as topic; rehabilitation.

RÉSUMÉ

Objet : Évaluer le nombre d'essais contrôlés randomisés (ECR) publiés qui portent avant tout sur la réadaptation d'une lombalgie mécanique, la tendance séculaire (c. -à-d. à long terme) et la répartition des interventions étudiées. **Méthodes :** Tous les ECR inclus ont été extraits de toutes les critiques systématiques Cochrane portant avant tout sur les traitements de réadaptation de la lombalgie mécanique. Deux examinateurs indépendants ont filtré et analysé l'information portant sur les interventions. **Résultats :** Après l'élimination des doubles, l'ensemble de données consistait en 196 ECR publiés entre 1961 et 2010. Le nombre d'ECR publiés augmentait régulièrement avec le temps: 2 essais (1 % du total) ont été publiés de 1961 à 1970, 10 (5 %), de 1971 à 1980, 41 (21 %), de 1981 à 1990, 68 (35 %), de 1991 à 2000 et 75 (38 %), de 2001 à 2010. Dans la majorité des ECR, l'intervention d'intérêt était le traitement par l'exercice ($n = 115$; 29 %), suivi des manipulations de la colonne ($n = 60$; 15 %). **Conclusion :** Le nombre d'ECR portant avant tout sur la lombalgie mécanique a augmenté avec le temps. Sur toutes les interventions étudiées, l'exercice a attiré le plus d'intérêt en recherche.

The number of randomized controlled trials (RCTs) published each year is increasing across all medical specialties. Rehabilitation does not appear to be an exception, although here the increase is more recent, particularly within the past two decades.¹ Mechanical low back pain (MLBP) is one of the most common causes of disability and lost work days in many countries,^{2,3} and it is ranked as the greatest contributor to global disability (as measured in years lived with disability).³ MLBP imposes significant economic and social burdens.⁴ Although several interventions are used to treat MLBP, including drug therapies and rest, rehabilitation plays a central role. Therefore, many researchers have devoted time and effort

to examining the efficacy and safety of various rehabilitation interventions aimed at decreasing the impact of MLBP.⁵ The purpose of our study was to explore the extent of such experimental research by determining the number of published RCTs that focused on rehabilitation interventions for MLBP. We also explored the secular (i.e., long-term) trend of these studies and the distribution of interventions studied.

METHODS AND RESULTS

Our study was carried out in accordance with the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement.⁶ To retrieve all relevant

From the: *Health Professional Science of Rehabilitation; **Department of Biomedical Sciences for Health, University of Milan; †Unit of Clinical Epidemiology; §Scientific Directorate, IRCCS Galeazzi Orthopedic Institute; ¶Vita – Salute San Raffaele University, Milan; ‡Center of Biostatistics for Clinical Epidemiology, Department of Health Sciences, University of Milano-Bicocca, Monza, Italy.

Correspondence to: Greta Castellini, Health Professional Science of Rehabilitation, University of Milan, via Festa del Perdono 7, 20122 Milan, Italy; gre.caste@gmail.com.

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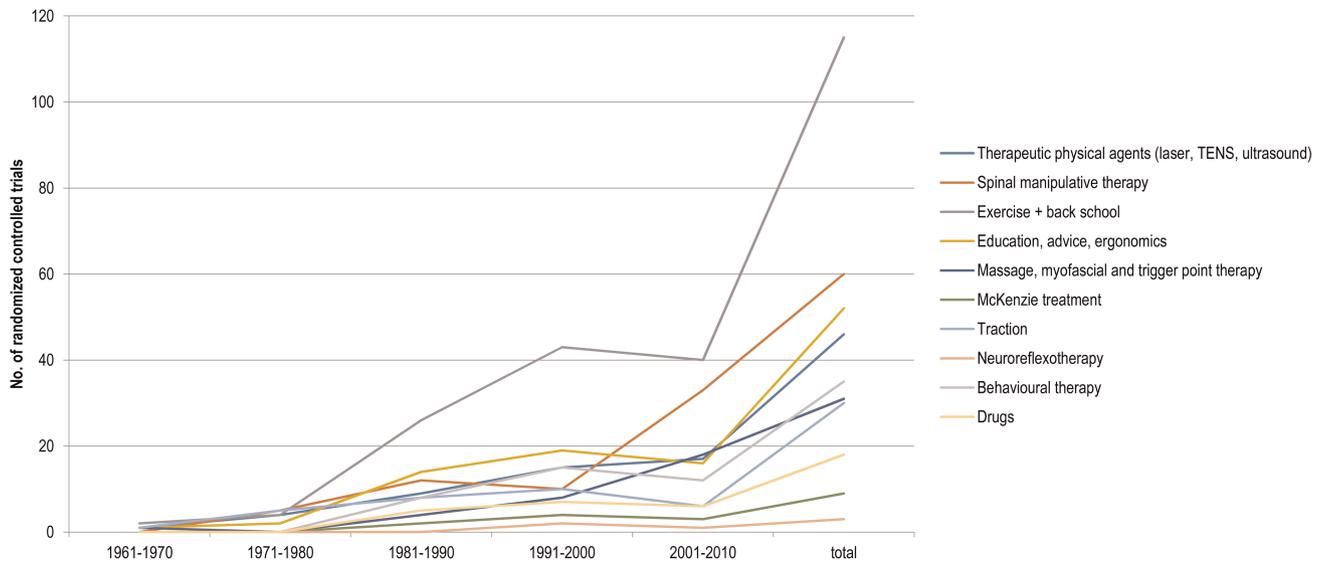


Figure 1 Rehabilitation interventions for mechanical low back pain studied in published randomized controlled trials, 1961–2010.

RCTs, we searched the Cochrane Database of Systematic Reviews for systematic reviews (SRs) published up to March 2013, using the search terms *back pain* and *rehabilitation* in the title, in the abstract, or as an index term.

Cochrane SRs were eligible if they assessed the efficacy or harm of rehabilitation interventions for the treatment of adult patients with MLBP. SRs focusing on preventive interventions or the accuracy of diagnostic tests, as well as those that included women who were pregnant, itself a specific condition defined as “pregnancy-related low back pain,” were excluded.

To explore the trend of studies published over time, we categorized RCTs by publication date. To further investigate the trend of topics over time, we classified interventions into 10 categories: behavioural therapy; exercise; education, advice, and ergonomics; massage, myofascial, and trigger-point therapy; therapeutic physical agents (laser, transcutaneous electrical nerve stimulation, ultrasound); neuroreflexotherapy (i.e., temporary implantation of epidermal devices into trigger points in the back and referred tender points in the ear);⁷ spinal manipulation; McKenzie treatment; traction; and drug therapy. We extracted data on both experimental and comparison–control interventions, even if the latter would not traditionally be considered a rehabilitation intervention (e.g., drug therapy). Two independent reviewers performed all data extraction and classification, and disagreements were resolved by discussion.

From 11 eligible SRs, we retrieved 220 RCTs published between 1961 and 2010. After removal of duplicates, we retained 196 RCTs for analysis. The number of publications increased over time, from 2 trials (1% of the total) in 1961–1970 to 10 (5%) in 1971–1980, 41 (21%) in 1981–1990, 68 (35%) in 1991–2000, and 75 (38%) in 2001–2010.

This increase has been consistent over the past five decades (univariate linear regression; $p = 0.004$).

The 196 included trials addressed a total of 399 interventions. The intervention most frequently evaluated was exercise ($n = 115$), followed by spinal manipulation therapies ($n = 60$). The distribution of interventions studied also changed over time, although this trend did not reach statistical significance (Fisher’s exact test; $p = 0.19$). The 1990s featured an increase in research on exercise therapy, and the 2000s saw a greater focus on spinal manipulation (see Figure 1).

DISCUSSION AND CONCLUSION

The incidence of MLBP is highest in the third decade of life and is more common in men than in women; its prevalence peaks during middle age, the most productive period of a person’s working life, and thus has a major economic impact on society.⁸ The proportion of people affected by MLBP episodes each year ranges from 1.5% to 36%; between 24% and 80% of those affected will experience a recurrence at 1 year.⁸ Disability and pain usually persist for months, though it is difficult to appraise the real duration and remission of MLBP because of its heterogeneity.

In terms of disease burden, MLBP is among the top five musculoskeletal disorders (along with osteoarthritis, rheumatoid arthritis, gout, and neck pain); its costs are primarily related to work loss.⁹ It is essential that the best way of treating and managing MLBP be found so as to reduce the economic and social burden of expensive and unnecessary consultations, ambulatory visits, surgeries, rehabilitation interventions, and drug therapies. Although the amount of research relevant to rehabilitation practice has increased exponentially over the past two decades (from 1,925 trials in 1990 to 5,301 in 2000

and 15,293 in 2011),¹ our findings show that only a very small proportion of these trials focused on MLBP. Although our study may be limited by the fact that our literature search was restricted to one database, the Cochrane Database of Systematic Reviews represents a gold standard for identifying all relevant RCTs^{10,11} in a field through sensitive search strategies.

A discrepancy exists between the prevalence of this disorder and research efforts directed toward reducing its burden. However, interest in trials seeking effective therapies for highly prevalent conditions, including MLBP, has increased over the past 50 years.

In the past two decades, the focus of interest has shifted from treatments such as electrophysical therapies, drugs, and others to exercise therapy and spinal manipulation. It is not easy to determine the reasons for this shift. It may be attributable to the advancement of research (perhaps exercise therapies have been comprehensively explored and their clinical hypotheses resolved?), or it may represent an early abandonment of hypotheses before their full evaluation and generation of conclusions. Some combination of these two explanations is likely; however, exercise and spinal manipulation are the most commonly investigated therapies for MLBP and may also be those most commonly applied by rehabilitation health professionals. Researchers should continue to conduct RCTs focusing on unresolved issues, looking at all aspects of clinical research including priority setting (prioritize specific rehabilitation topics as MLBP); adequate study design; and the best way to implement and apply evidence to practice, policy, and public health improvements. Given the significant public health concern posed by MLBP, RCTs should be supported by government agencies through financial and infrastructure funding, similar to drug research. In rehabilitation, a different priority setting for experimental studies is desirable, supporting mostly this field. This change in priority could better align the effort and energy invested in highly prevalent conditions, maintaining the focus of research until the evidence becomes definitive.

KEY MESSAGES

What is already known on this topic

In many countries, mechanical low back pain (MLBP) is one of the most common causes of disability and lost

work days. MLBP is ranked as the greatest contributor to global disability, as measured in years lived with disability.

What this study adds

The number of RCTs on MLBP therapies has increased exponentially since 1961 but still represents a small proportion of research on rehabilitation practice. Exercise therapy is the most frequently studied rehabilitation intervention for MLBP, followed by spinal manipulation.

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