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Title

Assessing the effects of manual therapy on pain in patients living with Persistent Non-Specific Low Back Pain (PNSLBP): Which evaluation criteria and measurement tools used in randomised controlled clinical trials? A systematic review.

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Author Agreement

All authors contributed to the conception and design of the study, analysis and interpretation of the data, drafting of the manuscript and critical revision, and gave their agreement to the final version of the manuscript submitted for publication. In addition, AHO, MM and AB acquired the data.

Abstract

Objective

To identify the evaluation criteria and measurement tools that are used in Randomised Controlled Trials to assess the effects of manual therapy on pain in adults living with PNSLBP.

Methods

RCT were included if: participants were adults (18-65 years old) with PNSLBP, experimental group received manual therapies (osteopathy, physiotherapy and chiropractic) and they had been published in English or French since 2010. The search was conducted between May 2021 and April 2023, using the Cochrane Library, Ebscohost, EMBASE, MEDLINE Pubmed, PEDro, ScienceDirect and Scopus databases. Three independent reviewers have checked eligibility. The PEDro scale have been used for quality appraisal.

Results

In the 29 studies included, 131 measurement tools were identified in three main areas: 76% of the measurement tools were related to *life impact* (which 24% related to *pain intensity* and 23% to *functional difficulties*) and 24% were related to *pathophysiological manifestations* (which 8% related to *Range of motion*).

Conclusion

Most measurement tools focus on *pain intensity* and *physical functioning* using scales and questionnaires. Two perspectives must be considered: responding to current recommendations by standardizing the measurement tools relating to *life impact* and *physiopathological manifestations*, and using biomechanical markers making it possible to evaluate patients in daily life situations.

Key Words

Low Back Pain, Chronic Pain, Manual Therapies, Evaluation Criteria, Measurement Tools

Main body of the paper

Introduction

One of the most prevalent types of pain, and currently cited as one of the two main causes of disability worldwide, is low back pain (LBP) [1]. Most episodes of LBP are short-lived and resolve within 4 weeks, but if they persist for more than 12 weeks, they are considered to be chronic persistent [2]. 85%

of persistent LBP is defined as non-specific (PNSLBP), with no specific patho-anatomical cause [3]. PNSLBP is defined as primary persistent pain, which is characterised by pain associated with significant emotional distress or functional impairment that interferes with a patient's daily activities and participation in social roles [4]. PNSLBP is therefore considered as a disease in its own right [5].

The most recent recommendations on the management of PNSLBP suggest a multidisciplinary approach, involving general behavioural, pharmacological, psychological, rehabilitative and educational interventions, as well as the use of manual therapy [6]. The latter is supported by a moderate level of evidence, which may be explained by an insufficient number of high-quality trials [6].

Manual therapies are regarded as 'hands-on' practices involving body manipulation and mobilisation [7]. Those mobilisation techniques are described as "low-grade velocity, small or large amplitude passive movement techniques within the patient's range of motion and control", whereas the manipulation techniques are defined as "a force applied perpendicularly to the articular surfaces." [8].

However, their mechanisms of action are numerous [7] and are still the subject of much debate [9]. Two mechanisms related to two different processes are specifically discussed: a biomechanical process related to a decrease in internal constraints [10] and a neurophysiological process involved in a shift in pain regulation [11].

Recent editorials have opened the debate on the lack of evidence related to the "real mechanism" of manual therapy and proposed exploring new models such as the biopsychosocial and/or the enactive model [12,13]. While previous work has focused on the use of outcome measures in clinical studies by comparing them to guidelines for the management of chronic low back pain [14–16], to our knowledge there is no systematic review that is specifically interested in clinical studies relating to manual therapies. Most systematic reviews aim to investigate the effects of manual therapies, primarily focusing on efficacy [14,15]. Nevertheless, there is a significant heterogeneity in the parameters measured and the chosen measurement tools [14,15]. One of the key challenges would be to establish the required outcome domains for a core set of outcomes in clinical studies evaluating PNSLBP managed by manual therapy. Thus, the aim of our study is to list the set of assessment criteria and associated measurement tools in the management of LBP by manual therapies. Additionally, this present paper discusses how assessments can be improved.

Methods

Protocol and registration

This systematic review was conducted under the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [16] and registered with the Prospective Register of Systematic

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Reviews (PROSPERO - Registration ID: CRD42021268722). The research question was: What evaluation criteria and measurement tools are used in RCT to evaluate the effects of manual therapy on pain in adults living with PNSLBP?

Eligibility criteria

Trials were included according to the following inclusion criteria: (1) participants had to live with non-specific persistent low back pain and be aged between 18 and 65 (to exclude the potential effects of age [17]), (2) the effect of the intervention had to result from the following manual therapies: osteopathy, physiotherapy or chiropractic, (3) a control intervention needed to be used to compare the intervention (without intervention or sham intervention or control intervention) and participants had to be randomised into several groups, (4) at least one pain-related outcome measure had to be reported by the trials, (5) to have received ethics committee approval, they had to be published in full text in a peer-reviewed journal, (6) and they had to have been published in either English or French. Any trial meeting one of the following criteria was excluded: (1) participants living with acute or subacute low back pain and/or of specific or neuropathic origins and to be under 18 or over 65 years of age, (2) the intervention in the experimental group involved a therapy other than those listed in the inclusion criteria, (3) trials without a control group and not randomised or quasi-randomised, (4) results not relating to one of the components of pain (sensory-discriminative, emotional, cognitive and behavioural). This review systematically assessed trials published from 2010 onwards because it corresponds to the most recent systematic review to our knowledge that addressed the identification, description and evaluation of measurement tools for patients with chronic low back pain and to the articles that were published just before and after the recommendations for the use of a core outcome set for evaluating randomised controlled trials on the management of patients with chronic low back pain [18].

Information sources

The search was conducted between May 2021 and April 2023, using the Cochrane Library, Ebscohost, EMBASE, MEDLINE Pubmed, PEDro, ScienceDirect and Scopus databases. The year 2010 was used as the cut-off point because the last systematic review identifying, describing, and evaluating standard outcome measures in patients with persistent low back pain assessing treatment success, was published in that year [19].

Search strategy

The following keywords served as the basis for the search strategy, in accordance with the research question: target population, interventions, control conditions, outcomes and study designs of this review: low back pain AND chronic OR persistent AND Manual Therapy AND placebo control OR sham

1 control AND controlled clinical trials. Boundary: 2010-present (for more details on database search, see
2 supplementary material 1).
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4 *Selection process*

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7 The eligibility check was carried out by three independent reviewers. Any disagreement was settled by
8 all the independent reviewers. The selection was made first using the title and abstract of the trials
9 (1/uploading on Rayyan, 2/ duplicates removed and 3/ title and abstract screening), followed by
10 screening the entire text of the remaining articles. A table summarizing the excluded studies and the
11 reasons for their exclusion was added in supplementary material 2.
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15 *Data collection process and data items*

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18 The data extraction process also required two independent reviewers, any resulting discrepancy being
19 resolved through discussion or by a third independent reviewer. All the data from the selected trials were
20 imported into a specially designed Excel spreadsheet (Microsoft), containing tables designed to be filled
21 out with their bibliographical information (title, authors, date of publication and journal), the
22 characteristics of the participants according to the control or experimental group (number of participants,
23 age and female/male ratio), the description of the manual therapy and control group intervention, the
24 evaluation criteria, the measurement tools and the risk of bias. The evaluation criteria and measurement
25 tools were classified according to the recommendations defined by Chiarotto et al. [18] for clinical
26 studies on the assessment of non-specific low back pain into four levels: "Core Areas", "Domains",
27 "Evaluation Criteria", "Measurement Tools". Those recommendations are categorised into four core
28 areas: death (the specific reason for the disease or intervention), *life impact* (including International
29 Classification of Functioning, Disability and Health (ICF) domains [20] and domains relating to the
30 concept of health-related quality of life), use of resources and economic impact (describing the economic
31 impact of health problems on both society and the individual) and *pathophysiological manifestations*
32 (reversible and irreversible manifestations and biomarkers) [18]. The domains defined by Chiarotto et
33 al. [18] were listed in each of the core areas according to the evaluation criteria found in each study.
34 Finally, the measurement tools used were listed for each evaluation criterion.
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48 *Risk of bias*

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51 The PEDro scale [21] was used to assess methodological quality. The PEDro scale includes 11
52 methodological elements specific to RCT: 1) specification of eligibility criteria; 2) random assignment;
53 3) secret distribution; 4) basic comparability; leading the intervention without the 5) knowledge of the
54 subjects; 6) therapists and 7) evaluators; 8) the completion of the study with measurements for at least
55 85% of the subjects; 9) analysis of data from all subjects enrolled at the start of the study; 10) statistical
56 comparisons between groups; and 11) means and measures of variation. Each item is scored as 'yes' or
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1 'no' and is worth 1 and 0 points respectively [21]. The total score of the PEDro scale corresponds to the
2 number of 'yes' responses for items 2 to 11, i.e. a total score expressed out of 10 points. A deviation was
3 made from the published PROSPERO protocol. We chose to use the PEDRO risk of bias scale rather
4 than the RoB2 scale, because this scale is particularly useful for rehabilitation research [22]. In fact, the
5 PEDro scale is less penalising for RCT evaluating the effectiveness of physical interventions, which
6 cannot be carried out in triple blind [22]. The PEDro scale therefore integrates three of its constituent
7 elements by assessing separately whether the subject, therapist and assessor are unaware of the
8 intervention received (items 5 to 7) [21].
9

13 *Synthesis methods*

14 A narrative format was used to summarise the findings of this systematic review. The research strategy
15 was presented through a flow chart (Figure 1). The characteristics of the studies related to the population,
16 the experimental and control groups, and the evaluation of the risk of bias were presented through tables
17 (Tables 1 and 2). The characteristics of the studies in terms of country and year of publication were
18 presented through figures (Figure 2 and 3). The results of the systematic review of evaluation criteria
19 and measurement tools were summarised in Figures 4 and 5 and Tables 3 and 4.
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27 **Results**

28 *Study selection*

29 The search strategy (Figure 1) identified 323 records in the Cochrane Library, 837 in Ebscohost, 140 in
30 EMBASE, 845 in MEDLINE Pubmed, 427 in PEDro, 535 in ScienceDirect and 418 in Scopus, resulting
31 in 2498 records without duplicates. According to the eligibility check, 29 trials were included (2390
32 records were excluded after screening titles and abstracts, and 67 after a full-text screening).
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40 *Study characteristics*

41 Year of publication

42 The earliest study included in this review was published in 2010 because it was our cut-off year. Since
43 2016, there has been an upward trend in the number of publications. The number of trials undergone per
44 year is shown in Figure 2 and in supplementary material 3.
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52 Country of origin

53 The publications included come from 12 different countries (Turkey, the United States of America,
54 Spain, Brazil, Egypt, India, Italy, Saudi Arabia, China, Switzerland and Iran). All continents but Oceania
55 are represented in this distribution. The most represented countries are Turkey (n = 5), the United States
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of America (n = 4) and Spain (n = 4). The full geographical distribution of the included trials is shown in Figure 3 and in supplementary material 3.

Population

The characteristics of the population are described in Table 1. 1954 participants in total were recruited into the included trials, with a mean of 67.4 (+/- 60.2) participants per trial. On average, participants in the control group were 38.97 years old and 50.08% female. For the intervention groups, the mean age was 38.07 years and comprised 52.18% females.

Risk of bias in studies

The assessment of the included trials with the PEDro scale is shown in Table 2. Two were of excellent methodological quality [23,24]. The majority of trials (17 trials) presented a good methodological quality [25–41]. Nine were of moderate methodological quality [42–49]. The following quality evaluation criteria for these trials were lacking: “allocation concealed”, “subjects, therapists and assessors blinded”, “adequate follow-up” and “intention-to-treat analysis”. Two trials presented a low methodological quality [50,51].

Data synthesis

Evaluation criteria and measurement tools for all trials

A total of 131 measurement tools were listed and indexed in two Core Areas: *life impact* and *pathophysiological manifestations* (Figure 4.a. and Table 3). 99 measurement tools (76%) were organised in the *life impact* core area and classified into eleven domains: *pain intensity*, *physical functioning*, *health-related quality of life*, *cognitive functioning*, *satisfaction with treatment services*, *pain quality*, *psychological functioning*, *pain behaviour*, *medication*, *temporal aspect of pain* and *pain interference*. The two fields where measurement tools were most prevalent was *pain intensity* (31 measurement tools – 24%) measured mainly by self-administered scales (Visual Analogue Scale -VAS or Numerical Pain Rating Scale - NPRS) and *physical functioning* (30 measurement tools – 23%) measured solely by self-administered questionnaires (Oswestry Disability Questionnaire - ODI, Roland-Morris Disability Questionnaire - RMDQ, Quebec Back Pain questionnaire - QBP, Waddell Disability Index - WDI, Multidimensional Assessment Of Interoceptive Awareness - MAIA). 32 measurement tools (24%) were organised in the *pathophysiological manifestations* core area and classified into seven domains: *range of motion*, *pain biomarkers*, *spinal control*, *muscle endurance*, *muscle activity*, *body structure* and *proprioception* (Table 3). The field where measurement tools are most prevalent was the *range of motion* (11 measurement tools – 8%) assessed through trunk movements (Finger-to-Floor test, Schober test with modified versions) and measured mainly by a metre and *pain biomarkers* (7

1 measurement tools – 5%) assessing blood sample and measured by Electro Interstitial Scanner. All data
2 were available in supplementary material 3.
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4 Evaluation criteria and measuring tools used in trials with excellent and good methodological quality 5

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7 A total of 96 measurement tools were listed and indexed in two Core Areas: *life impact* and
8 *pathophysiological manifestations* (Figure 4.b. and Table 4). 72 measurement tools (75%) were
9 organised in the *life impact* core area and classified into same eleven domains previously mentioned.
10 The two fields where measurement tools were most prevalent was *pain intensity* (22 measurement tools
11 – 23%) measured mainly by self-administered scales (VAS or NPRS) and *physical functioning* (21
12 measurement tools – 22%) measured solely by self-administered questionnaires (ODI, RMDQ, QBP,
13 WDI, MAIA). 24 measurement tools (25%) were organised in the *pathophysiological manifestations*
14 core area and classified into five domains: *range of motion*, *pain biomarkers*, *spinal control*, *muscle*
15 *endurance* and *muscle activity* (Table 4). The field where measurement tools are most prevalent was the
16 *range of motion* (7 measurement tools – 7%) assessed through trunk movements and measured mainly
17 by a metre and *pain biomarkers* (7 measurement tools – 7%). All data were available in supplementary
18 material 3.
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28 Evaluation criteria and measuring tools used in osteopathic trials only 29

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31 There were trials dealing exclusively with osteopathic manipulation and/or mobilisation [38,45] (Figure
32 4. c. and in supplementary material 3). All of these trials used measurement tools to quantify *life impact*,
33 in particular the following evaluation criteria: *pain intensity* (VAS, all trials), *physical functioning* (ODI:
34 [38,45]) and *quality of life* (SF-12 : [38]). One trial looked at *pathophysiological manifestations*,
35 focusing on *muscular activity* (EMG examination during trunk flexion-extension) and *range of motion*
36 (Finger-to-Floor test) [45].
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42 **Discussion** 43

44 This systematic review aimed to explore the evaluation criteria and measurement tools used in RCT to
45 assess the effect of manual therapy on pain in PNSLBP adults, allowing one to discuss the strengths and
46 limitations of these tools and to propose new approaches to evaluate manual therapies.
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50 *Summary of findings* 51

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53 Self-administered scales or questionnaires are the measurement tools most commonly used to measure
54 the effect of manual therapy on pain. Out of the 131 measurement tools listed, 99 consist in self-
55 administered scales or questionnaires, covering 18 evaluation criteria and including 30 different
56 measurement tools. *Impact on life* was the core area that was most frequently represented, and the most
57 frequently represented domains were *Pain intensity* and *Physical functioning*. When it comes to the
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1 second most represented core area, *pathophysiological manifestations*, 18 evaluation criteria and 25
2 measurement tools were listed, and the most frequently represented domains were *Range of motion* and
3 *Pain biomarkers*. With regard to the evaluation criteria and measurement tools used in trials with
4 excellent and good methodological quality, the results are similar.
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7 *Comparison with evidence-based recommendations*

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10 Authors of systematic reviews on the management of PNSLBP patients have reported that outcomes are
11 often inconsistently measured and reported in RCTs [52]. One proposal to address this bias would be to
12 use a standardised set of endpoints [52]. A core outcome set (COS) was proposed in 1998 by Deyo et
13 al. [53] then updated in 2015 by Chiarotto et al. [18] and proposes specific recommendations for 4
14 outcome domains: *physical functioning*, *pain intensity*, *health-related quality of life (HRQOL)* and
15 *number of deaths*. In this study, no trials reported on all four outcome domains, and none reported the
16 number of deaths. Nine trials reported on the other three areas [26,31,33,36,38,42,44,46,48]. In addition
17 to the evaluation criteria, the researchers must agree on the best tools for measuring these outcomes,
18 making it possible to standardise and compare the results between studies [52]. Thus, a consensus has
19 been reached (COMS) that the Numerical Rating Scale (NRS) should be used to assess pain intensity,
20 the Oswestry Disability Index (ODI) version 2.1a or the 24-item Roland-Morris Disability Questionnaire
21 (RMDQ) should be used to assess physical functioning, the Short-Form Health Survey 12 (SF-12) or
22 the 10-item Patient-Reported Outcome Measurement Information System (PROMIS) for Global Health
23 (PROMIS-GH-10) questionnaire should be used to assess HRQOL, and a simple report of the number
24 of deaths that occurred during the trial should be used to report the number of deaths [54].
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36 In this study, the two most reported scales to quantify the pain intensity are the Visual Analogue Scale
37 (VAS) and the Numerical Pain Rating Scale (NPRS). These scales are reliable and valid [55] and show
38 a strong correlation between them [56]. The VAS is more sensitive to change and the NRS is more
39 reliable when used in specific populations such as older adults, people with cognitive disorders and
40 people from low socio-educational levels [55,56]. The ability to administer the NRS verbally or in
41 writing is another benefit [55]. Therefore, the administration conditions will determine which of these
42 two scales is used: standardisation of anchoring descriptors (i.e. the descriptors defining the intensity of
43 perceived pain), administration methods, time limits, interpretation of thresholds and clinical
44 significance [56]. In addition to these scales, two other evaluation criteria (measurement tools) were
45 identified: pain sensitivity (algometer) and amplitude of temporal summation (with VAS). These
46 evaluation criteria aim to refine the parameters used to define pain sensitivity [59]. To our knowledge,
47 there are no recommendations regarding the evaluation of pain sensitivity in the management of
48 PNSLBP. Future work is still needed to include these variables, despite the growing number of trials
49 and their findings, in particular those supporting a correlation between the psychological questionnaire
50 scores and the level of pain sensitivity [57].
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When it comes to the *physical functioning* domain, the Roland Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI) were the two most commonly used questionnaires to quantify physical functioning. These questionnaires are considered to be reliable and valid [19,58,59]. The ODI focuses on how back pain affects an individual's ability to cope with their daily life and the RMDQ addresses the difficulties in performing daily physical activities that are directly related to low back pain [58]. While the RMDQ has less measurement error and better construct validity, the ODI has better test-retest reliability [58]. Conflicting evidence has been found concerning the sensitivity of the two instruments, and their internal consistency is unknown due to the methodological quality or lack of trials on this measurement's relevance/accuracy [58]. In fact, the ODI questionnaire consistently shows higher correlations with other instruments measuring identical or unrelated constructs such as perceived pain intensity, general health status, mental health and social functioning [58]. These findings suggest that the construct measured by the ODI may be broader than when measured by the RMDQ, the latter allowing one to measure a narrower construct and thus providing a more targeted evaluation of physical functioning in patients with low back pain [58]. There is therefore no compelling reason to favor one of these two tools over the other when assessing physical functioning in PNSLBP patients, but more reliable research is required to support this conclusion [58]. In addition to these questionnaires, three other evaluation criteria were identified: the Waddell Disability Index (WDI), the Quebec Back Pain Questionnaire (QBP) and the Orebro Musculoskeletal Pain Screening Questionnaire (OMPSQ). The WDI and QBP are easy to administer and to assess [60]. The WDI offers an advantage for clinical studies with its moderate test-retest reliability, good inter-rater reliability, concept validity, and data pooling capacity [60]. This index allows significant changes to be detected in patients after an interval of one month following treatment, but its reactivity has not been thoroughly investigated and it should be used in conjunction with other disability scoring systems to provide a comprehensive evaluation of pain [60]. The QBP is easy to administer and to assess, with high test-retest reliability, good content and construct validity, and has strong correlations with other disability tools (ODI, RMDQ) [60]. The OMPSQ is used to identify LBP patients at risk for chronicity and prolonged disability [60]. Although the OMPQS presents high reliability and used to be strongly correlated with recovery time [61], a recent review of the literature indicates that screening instruments for low back pain administered in primary care fail to assign higher risk scores to people who develop persistent pain and recommends new trials with larger cohorts and an extension of the control period [62].

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In regards to the *health-related quality of life* domain, the 36-item Short Form Health Survey questionnaire (SF-36) was the most used one to assess the patients' Quality Of Life. The SF-36 measures their physical health (PCS) and mental health (MCS) [63]. Other self-administered questionnaires have been mentioned in this study: the Short Form (12) Health Survey, which is a shortened version of the SF-36 and measures the same eight health concepts [64], the EQ-5D-5L and the EQ-5D-3L, which cover mobility, personal care, usual activities, pain/discomfort and depression/anxiety associated with a

1 vertical visual analogue scale [65]. The difference between these last two measurement tools is the
2 number of response options, 5 versus 3 [65]. At present, the current literature does not identify superior
3 measurement properties for any of these tests for the evaluation of persistent low back pain, which is
4 partly explained by the fact that these tools are not sufficiently specific when it comes to low back pain
5 [59]. Thus, time is the primary factor that determines which of these scales should be used (SF-36 Health
6 Survey includes more items).
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10 *Biopsychosocial model*

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13 The trials also identified other evaluation categories where authors considered the contributions of
14 biological, psychological, and social factors. Some trials investigated the biological factors, in particular
15 brain metabolites, heart rate variability and hemodynamics. To our knowledge, there are no
16 recommendations concerning these measurement tools. No study examined the social elements.
17 Psychological factors were assessed using different domains such as cognitive functioning, pain quality,
18 anxiety and depression and fear of movement. Cognitive functioning was assessed with two
19 measurement tools: the Fear avoidance belief questionnaire (FABQ) and the Pain Catastrophizing Scale
20 (PCS). The FABQ measures the fear of pain caused by a patient's physical activity and is reliable and
21 valid [66]. Specifically, it assesses his attitude towards physical activities and towards professional
22 activities [66]. The PCS assesses three dimensions: rumination, amplification and helplessness [67].
23 Catastrophizing, a cognitive process in which nervous people focus on the worst possible outcomes,
24 refers to this interpretation of pain as being exceedingly threatening [68]. Pain quality was assessed with
25 Short-form McGill Pain (SF-MPQ) [69] and Brief Pain Inventory (BPI) [70] questionnaires, which are
26 used to measure pain intensity as well as the qualitative aspects accompanying the pain. Psychological
27 functioning was assessed by three questionnaires: Hospital Anxiety and Depression Scale (HADS) [71],
28 Beck Depression Inventory (BDI) [74] and Patient Health Questionnaire-9 (PHQ-9) [72], which
29 measures one's level of anxiety and depression. The fear of movement level was measured by the Tampa
30 Scale Kinesiophobia (TSK) [73]. In clinical research, these scales and questionnaires provide an
31 accurate picture of the symptoms that accompany pain. In addition, measurement tools such as FABQ
32 [74], PCS [75], SF-MPQ [76], HADS [77], BPI [78], TSK [79] have been validated in a low back pain
33 population.
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50 *Biomechanical measurement tools*

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52 Another approach when assessing the consequences of PNSLBP is to conduct a biomechanical analysis
53 of the patient. Thus, the trials focused on five areas: range of movement, spinal control, proprioception,
54 muscular endurance and muscular activity. The range of movement, muscular endurance and muscular
55 activity were assessed by asking the participants to perform trunk flexion-extension and/or lateral
56 flexion. The patient's joint amplitude was measured mainly using a tape measure, their trunk control by
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1 using kinetic markers (body sway and analysis of different joints), his muscular endurance by the total
2 repetition score performed for a given movement and his proprioception by a dynamometer. The
3 evaluation criteria and measurement tools used are in line with the recent results of a systematic review
4 and meta-analysis which sought to identify a list of biomarkers relevant for differentiating patients with
5 PNSLBP from an asymptomatic population [80]. The results showed that range of motion, body sway
6 in the anterior-posterior axis, intersegmental and/or muscle coordination and variability were the most
7 relevant biomarkers for discriminating patients with low back pain [80]. Hence, no trial has considered
8 movements involving a displacement of the base of support, i.e. with displacement of the feet, which
9 does not allow us to assess painful subjects in a context close to the conditions encountered in one's
10 daily life. More and more studies are looking at the effect of low back pain on walking, and a recent
11 systematic review showed that PNSLBP patients had a slower comfort walking speed, a smaller range
12 of rotation in the pelvis and lumbar spine, and more in-phase coordination than asymptomatic subjects
13 [81]. In addition, motor difficulties in PNSLBP patients appear to be correlated with certain
14 psychological domains such as fear of movement, level of catastrophising and anxiety [68]. Thus,
15 measurement tools focusing on the patient's biomechanics seem relevant to assess, intervene on and
16 manage PNSLBP patients.
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27 *Strengths and limitations*

30 To our knowledge, this systematic review is the first to identify and discuss the measurement tools used
31 in manual therapy for the treatment of persistent non-specific low back pain. The entire study selection
32 and data extraction process was carried out by three independent reviewers. However, there were several
33 biases. The first was the narrowing of the eligibility criteria, and although this was intentional, only trials
34 on general populations were included, leaving out trials on a particular profession, such as nursing or
35 the army, which seemed to us to open up a different social context. Secondly, we decided to include
36 only trials involving three manual therapies. Thirdly, we decided to select only trials published since
37 2010, which allows us to draw conclusions that are only valid for this period. Fourthly, Compared to the
38 protocol described for PROSPERO, we modified the choice of the risk of bias scale for PEDro, which
39 we felt was relevant given its widespread use in the literature for systematic reviews of manual therapies.
40 Fifthly, we had initially included 3 studies led by Licciardone [82–84] but had to exclude them because
41 the age of the participants was over 65. Interestingly, the overall results of the review were similar and
42 perhaps age has less of an effect than expected. The issue of ageism in RCTs is not new (see for example
43 [85]) and future research should consider whether it is useful and important to exclude older adults from
44 reviews and trials with clear data, and if so, in what specific situations this should or should not happen.
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56 *Implications for research and education*

1 While questionnaires are commonly used to assess the effect of manual therapy in the context of pain
2 management, one of the main findings of our study is that the assessment of patients' functional capacity
3 in everyday situations through movement analysis is not widely available in this literature. Indeed,
4 several authors have proposed different types of assessments, mainly based on joint amplitude or
5 muscular endurance. Although of major interest, these variables do not provide an exhaustive and
6 complete view of the assessment of PNSLBP and notably patient's daily life like walking for instance.
7 As an example, previous work found that walkers take into account their anthropometric characteristics
8 such as shoulder width [86], as well as their movement abilities [87] to perform an action in a specific
9 environment, such as crossing through a door-like opening. If non-specific low back pain affects
10 patients' movement as well as their perception of their action capabilities [88], one could emphasise that
11 the perception-action loop may be affected as a consequence. Designing new experimental models to
12 assess low back pain in everyday tasks would allow us to expand on the findings from scales and
13 questionnaires pertaining to the perceptual-motor approach of these patients, especially daily living
14 activities.
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24 An important area of research, particularly in osteopathic care, is the understanding and assessment of
25 chronic pain in manual therapy settings. This means that it is essential to educate future osteopaths in
26 how to determine treatment outcomes using affordable measurements [89] that can be applied in clinical
27 settings, and to encourage future practitioners to participate in practice-based research networks to
28 support in research efforts [90].
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33 **Conclusion**

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36 The present study provides new information on the evaluation criteria and measurement tools used in
37 RCT to evaluate the effects of manual therapy on pain in adults living with PNSLBP. The primary
38 findings indicate that, firstly, assessing its impact on one's life is the most commonly used evaluation
39 criterion and, secondly, self-administered scales and questionnaires are the most commonly used
40 measurement tools. Most of the questionnaires chosen were consistent with the existing literature and
41 met the customary recommendations. A few trials also used assessment criteria relating to physiological
42 manifestations, particularly the patient's amplitude of movement. However, although the tasks assessed
43 were of major interest, they failed to draw an exhaustive and complete picture of how the PNSLBP was
44 evaluated, particularly when it came to daily living activities, the challenges of which were made
45 apparent by the questionnaires on physical functioning (walking, climbing stairs, sitting down, standing
46 up). Finally, very few trials evaluated the effect of manual therapy by correlating the results obtained
47 from scales and questionnaires with physiological manifestations. Trials still need to be set up to
48 continue to evaluate the effect of manual therapy in order to further our understanding of these
49 mechanisms and their action on the patient.
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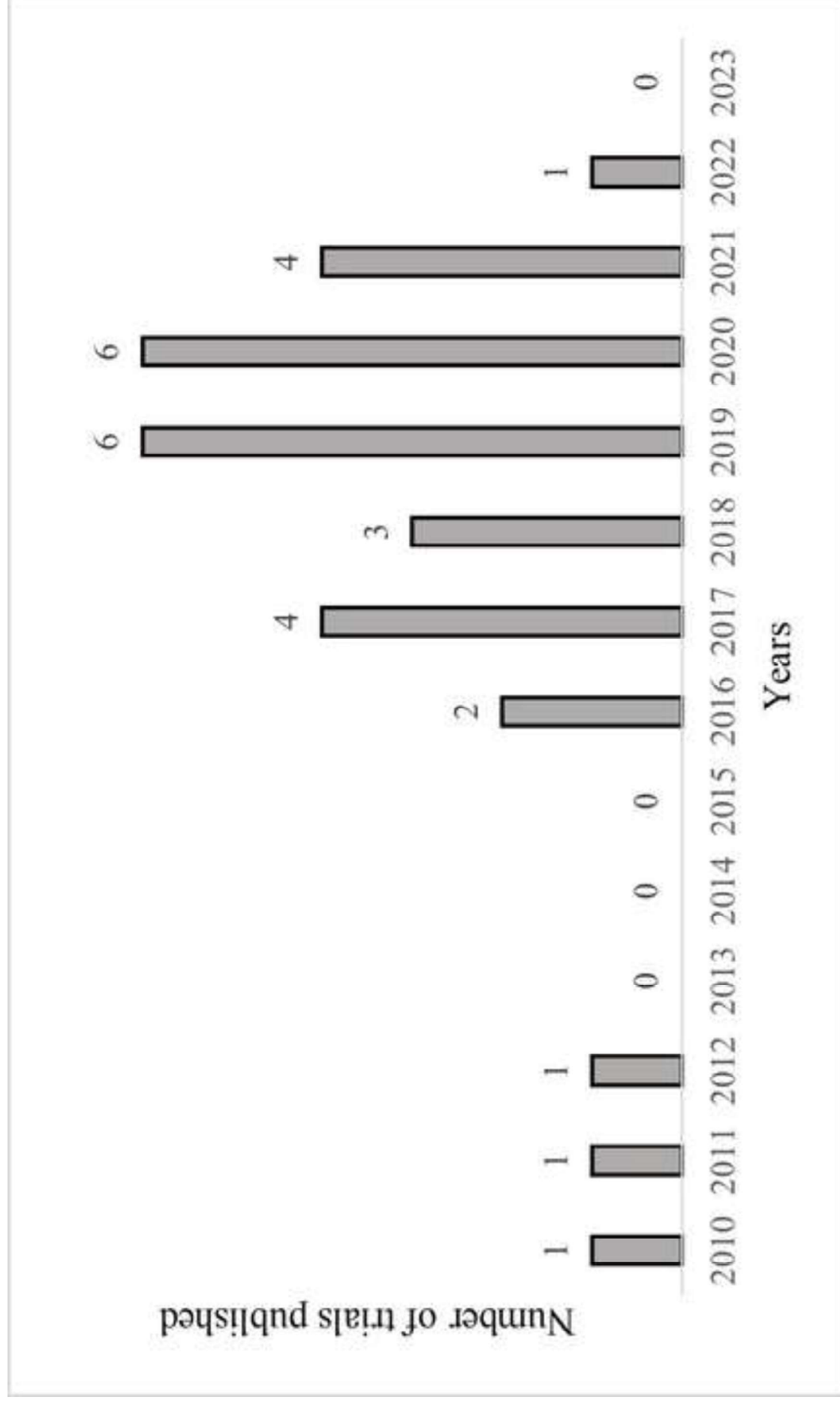
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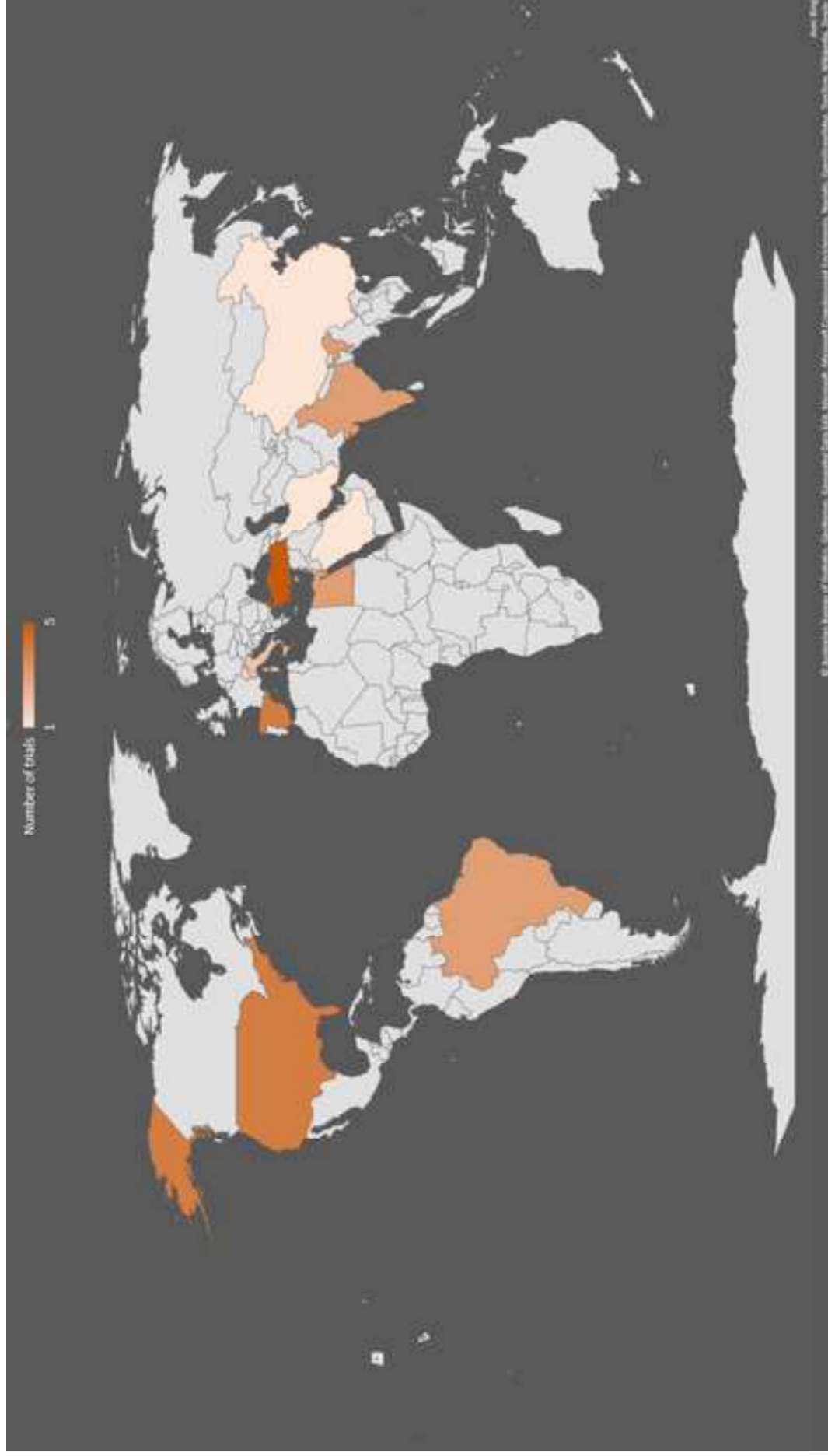
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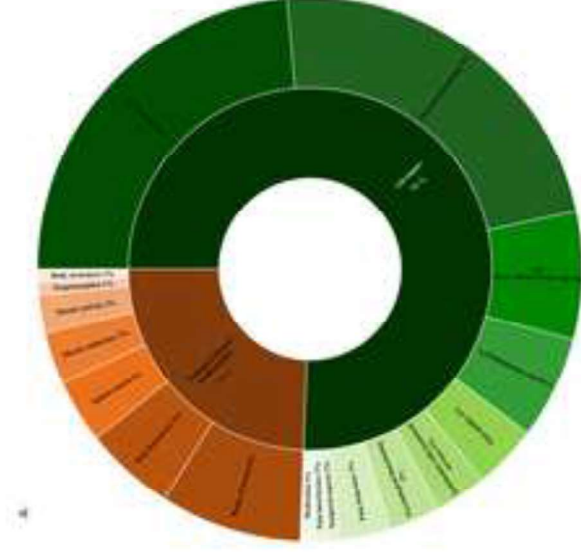
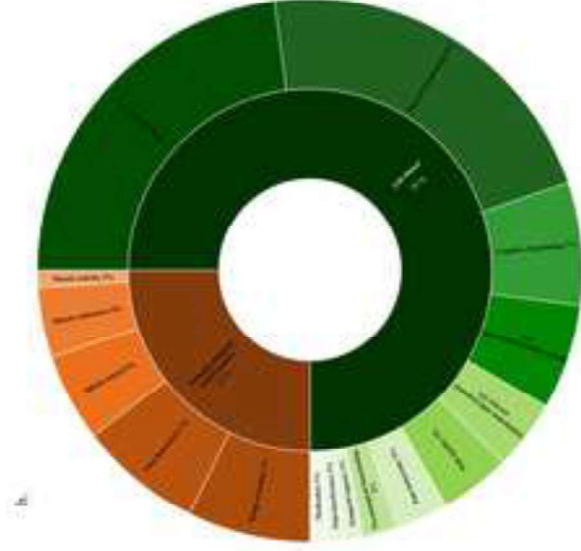
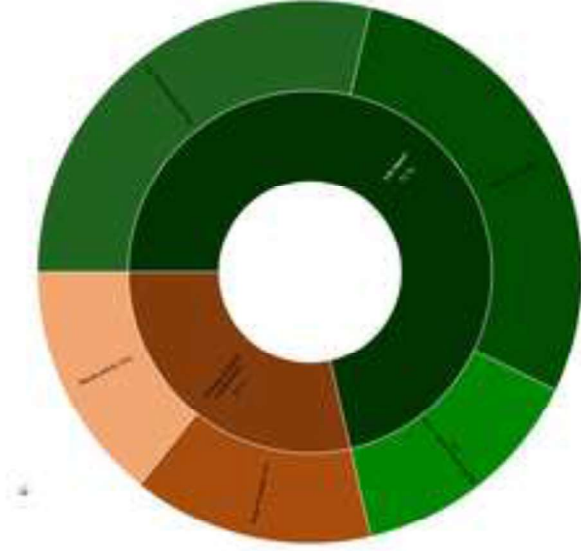


Figure 1. Preferred Reporting Items for Systematic Review and Meta-Analysis flow diagram showing the identification, screening, and selection process of records for this systematic review. Reasons for exclusion at the full-text eligibility screening phase are provided.

Figure 2. Number of trials published between 2010 and 2023.

Figure 3. Country of origin of trials included.

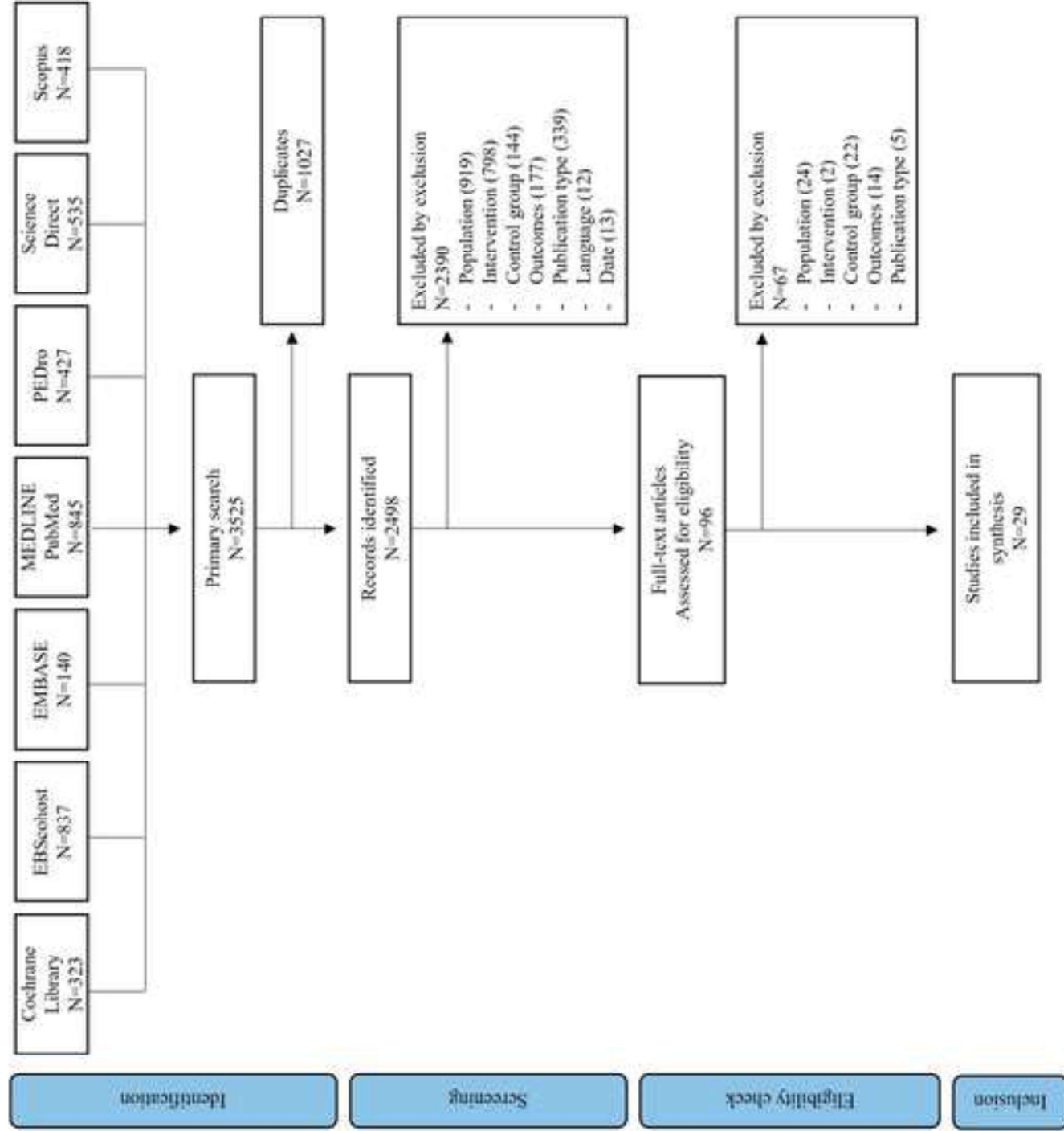
Figure 4. Core Areas, Domains, Parameters and measurement tools for all included trials (a), for trials with excellent and good methodological quality (b) and for osteopathic trials only (c).

sTables 1. Characteristics of the population.

Table 2. The assessment of Risk Of Bias (ROB) of included trials with the PEDro scale.

Table 3. Occurrence frequency of measurement tools listed in *life impact* core area, in *pathophysiological manifestations* and in *resource use/economical impact* for all included trials.

Table 4. Occurrence frequency of measurement tools listed in *life impact* core area, in *pathophysiological manifestations* and in *resource use/economical impact* for trials with excellent and good methodological quality.



Trials	Number of participants (n)	CG	EG	Age (mean ± sd)		Female (%)	
				CG	EG	CG	EG
(Endamli et al., 2019)	55	PT	PT+ FR	37.93 ± 10.87	37.14 ± 11.56	-	-
(Branchini et al., 2016)	24	PT	PT + FR	44 (8.2)	48 (12)	69.2	63.6
(Arguisuelas et al., 2017)	54	Sham MFR	MFR	46.4 (11.4)	46.6 (10.3)	62.9	40.7
(Arguisuelas et al., 2019)	36	Sham MFR	MFR	48.6 (10.1)	47.2 (9.8)	66.7	66.7
(Boff et al., 2020)	72	HVLA	MFR	38.7 (6.8)	38.1 (7.0)	17	19
(Auger et al., 2021)	40	Sham MFR Sham BEMER	1) MFR 2) BEMER 3) MFR + BEMER	25.3±1.6	1) 25.9±2.5 2) 24.6±1.6 3) 24.8±1.8	60	1) 40 2) 50 3) 60
(Castro-Sánchez et al., 2016)	64	Light massage	CrT	53± 9	50± 11	59.4	71.8
(Martí-Salvador et al., 2018)	66	Sham DI + OMT	DI + OMT	41.7 ± 10.3	43.4 ± 10.8	60.6	51.5
(Hussien et al., 2017)	42	PT	PT + lumbar SNAG	28.9 ± 7.7	27.1 ± 8.3	31.6	13
(Hussein et al., 2021)	64	Sham SNAG	SNAG	22.00 ± 1.4	22.00 ± 1.46	-	-
(Ahmed et al., 2021)	137	PT	1) MET + DSE 2) DSE	41.22 ± 8.4	1) 38.76 ± 9.87 2) 39.21 ± 8.62	28.9	1) 43.9 2) 35.9
(Divya et al., 2021)	-	CT + LSE	TMSE + CT + LSE	40.33 ± 8.6	38.53 ± 7.8	-	-
(Yagci et al., 2020)	112	PT	PT + Soft Tissue Mobilisation	53.47±11.45	49.98±9.77	28.1	56
(Joshi et al., 2021)	45	Exercises	1) SMIT + IFT + Exercises 2) IFT + Exercises	38.20 ± 7.27	1) 34.93 ± 9.43 2) 42.47 ± 10.15	-	-
(Saracoglu et al., 2022)	69	Home exercise	1) JMT + HE 2) PNE + JMT + HE	40.25 ± 9.70	1) 41.38 ± 12.70 2) 39.67 ± 13.71	55	1) 53 2) 60
(Zangrando et al., 2017)	51	Traditional massage therapy	New Rehabilitative Massage Program	50.54±9.13	50.77±6.80	58.33	55.56
(Grande-Alonso et al., 2019)	50	PT	PT + OMPT	38.29 (13.10)	39.88 (13.20)	56	56
(Bicalho E et al., 2010)	40	Without intervention	HVLA	26.5 ± 8.27	29.5 ± 9.64	60	75
(Senna & Machaly, 2011)	60	Sham manipulation	HVLA: 1) Maintened 2) No maintained	42 ± 10	1) 41.6 ± 11 2) 40.2 ± 12	24.3	1) 24 2) 27
(Nambi et al., 2018)	330	LT + exercises	HVLA and: 1) LT + exercises 2) LT	21-60	1) 21-60 2) 21-60	CG 67 (60.9)	1) 62.7 2) 58.2
(Didehdar et al., 2020)	25	Without intervention	HVLA	37.2 ± 7.01	36 ± 8.61	46.7	40
(Fagundes Loss et al., 2020)	24	Sham manipulation	HVLA	43.9 ± 9.6	41.7 ± 12.8	50	50
(Sarker et al., 2019)	90	SE+EA	HVLA + EA	24.20±6.78	1) 25.10 ± 7.75 2) 24.93 ± 8.46	-	-
(Wang et al., 2019)	60	SET	LPT + SET	32.01 ± 4.59	30.45 ± 5.55	43.3	36.7
(Tamer et al., 2017)	39	OMT	vOMT	36 (29–47)	42 (34.2–51.5)	47.4	60
(Balthazard et al., 2012)	37	UT + AE	MT + AE	42.0 ± 12.0	44.0 ± 12.0	30	36
(Thomas et al., 2020)	162	LT	Spinal : 1) Manipulation 2) Mobilization	24.4 (5.9)	1) 26.8 (7.2) 2) 24.3 (5.3)	58	1) 59 2) 58
(Zafereo et al., 2018)	40	PT	RMT + PT	38.2 (13.1)	46.7 (14.1)	50	75

(Celenay et al., 2019)	66	PT	1) PT + CTM 2) PT + SM	55 (24–65)	1) 53 (40–65) 2) SM 48 (39–63)	71.4	1) 90.5 2) 81
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CG: Control Group; EG: Experimental Group; FR: Fascial Release; MFR: Myofascial Release; CrT: Craniosacral Therapy; DI: Diaphragm Intervention; OMT: Osteopathic Manual Therapy; SNAG : Sustained Natural Apophyseal Glide; PT: PhysioTherapy; MET: Muscle EnergyTechnique ; DSE: Dynamic Stabilization Exercise ; TMSE: Thoracic Mobilisation and Strengthening Exercises; CT : Conventional therapy; LSE: Lumbar Stabilization Exercises ; STM : Soft Tissue Mobilisation; SMIT : Sub-Occipital Muscle Inhibition Technique; IFT: Interferential Current Therapy; JMT: Joint Mobilisation Techniques; PNE: Pain Neuroscience Education; OMPT: Orthopedic Manual Physical Therapy; HVLA: High-Velocity Low-Amplitude; LT: Laser therapy; LPT: Lumbar Pulling Technique; OMT: Osteopathic Manual Therapy; vOMT: Visceral Osteopathic Manual Therapy; MT: Manual Therapy; UT: Ultrasound Therapy; AE: Active Exercises; SMT: Spinal Manual Therapy; CTM: connective tissue manipulation; SM: sham massage.

Trials	1	2	3	4	5	6	7	8	9	10	11	Total
(Didehdar et al., 2020)	0	1	0	0	0	0	0	0	0	1	1	3
(Tamer et al., 2017)	0	1	0	1	0	0	0	0	0	1	0	3
(Arguisuelas et al., 2019)	0	1	0	1	0	0	0	0	0	1	1	4
(Auger et al., 2021)	1	1	0	0	0	0	1	0	0	1	1	4
(Hussein et al., 2021)	1	1	0	1	0	0	0	0	0	1	1	4
(Grande-Alonso et al., 2019)	1	1	0	0	0	0	0	1	0	1	1	4
(Bicalho et al., 2010)	1	0	0	1	0	0	1	0	0	1	1	4
(Endamli et al., 2019)	0	1	0	1	0	0	0	1	0	1	1	5
(Ahmed et al., 2021)	1	1	1	1	0	0	0	0	0	1	1	5
(Balthazard et al., 2012)	1	1	0	1	1	0	0	0	0	1	1	5
(Arguisuelas et al., 2017)	1	1	1	1	0	0	0	1	0	1	1	6
(Divya et al., 2021)	1	1	1	1	0	0	0	1	0	1	1	6
(Zangrando et al., 2017)	1	1	0	1	0	0	0	1	1	1	1	6
(Senna & Machaly, 2011)	1	1	0	1	0	0	0	1	1	1	1	6
(Castro-Sánchez et al., 2016)	1	1	1	1	0	0	1	1	0	1	1	7
(Joshi et al., 2021)	1	1	0	1	0	0	1	1	1	1	1	7
(Saracoglu et al., 2022)	1	1	1	1	0	0	1	1	0	1	1	7
(Nambi et al., 2018)	1	1	0	1	0	0	1	1	1	1	1	7
(Fagundes Loss et al., 2020)	1	1	1	1	0	0	1	0	1	1	1	7
(Celenay et al., 2019)	1	1	1	1	0	0	1	1	0	1	1	7
(Branchini et al., 2016)	1	1	1	1	1	0	1	1	0	1	1	8
(Marti-Salvador et al., 2018)	0	1	1	1	0	0	1	1	1	1	1	8
(Sarker et al., 2019)	1	1	0	1	1	0	1	1	1	1	1	8
(Wang et al., 2019)	1	1	1	1	0	0	1	1	1	1	1	8
(Thomas et al., 2020)	1	1	1	1	1	0	1	1	0	1	1	8
(Zafereo et al., 2018)	1	1	1	1	1	0	1	1	0	1	1	8
(Boff et al., 2020)	1	1	1	1	1	0	1	1	1	1	1	9
(Hussien et al., 2017)	1	1	1	1	1	0	1	1	1	1	1	9
(Yagci et al., 2020)	1	1	1	1	1	0	1	1	1	1	1	9

1	2	3	4	5	6	7	8	9	10	11
Eligibility criteria	Random allocation	Concealed allocation	Baseline comparability	Blind subjects	Blind therapists	Blind assessors	Adequate follow-up	Intention-to-treat analysis	Between-group comparisons	Point estimates and variability

Core Areas	Domains	Parameters	Measurements Tools	Occurrence frequency	
Life impact	Cognitive functioning	Fear Avoidance Beliefs	Fear Avoidance Belief Questionnaire	4	
		Pain catastrophization	Pain Catastrophizing Scale	4	
	Health-related quality of life	Quality Of Life	12-Item Short Form Survey		2
			36-Item Short Form Survey		5
			Euroqol - 5 Dimensions - 3 Levels		1
			Euroqol - 5 Dimensions - 5 Levels		1
			Healthy Days Measures		1
	Medication	Intake and Frequency of Medication	Data Repository	1	
	Pain behaviour	Fear of movement	Tampa Scale Kinesiophobia	4	
	Pain intensity	Level of pain	Numerical Pain Rating Scale	9	
			Visual Analog Scale	18	
		Pain sensivity	Algometer	3	
	Pain intensity	Temporal Summation Magnitude	Visual Analog Scale	1	
		Pain interference	Self-efficacy	Chronic Pain Self-Efficacy Scale	1
	Pain quality	Sensorial and affective	Brief Pain Inventory	1	
			Short-Form McGill Pain Questionnaire	3	
		Two-Point Discrimination Test	Esthesiometer	1	
	Physical functioning	Functional disability	Örebro Musculoskeletal Pain Screening Questionnaire	1	
			Owestry Disability Index	17	
			Quebec Back Pain Questionnaire	1	
			Roland Morris Disability Questionnaire	9	
			Waddel Disability Index	1	
	Psychological functioning	Interoception	Multidimensional Assessment Of Interoceptive Awareness	1	
		Anxiety and Depression	Hospital Anxiety Depression Scale	2	
			Depression	Beck Depression Inventory	1
	Satisfaction with treatment services	Global Rating of Change	Patient Health Questionnaire-9	1	
			Global Rating Of Change Questionnaire	2	
Satisfaction with back care		Global Rating Of Change Scale	1		
Satisfaction with treatment services	Satisfaction with back care	Patient'S Global Assessment Of Outcomes	1		
	Temporal aspects	Frequency	Data Repository	1	
Pathophysiological manifestations	Body structures	Lumbar lordosis	Flexible Ruler	1	
	Muscle activity	Maximum low back muscle strength	Taiwan Test	1	
		Muscle activation flexion-extension	Electromyogram	2	
	Muscle endurance	Abdominal muscles	Mcquade Test	1	
			Shirado Test	1	
		Trunk extensor muscles	Ito Test	1	
	Pain biomarkers		Sorensen Test	1	
			Diastolic blood pressure	Electro Interstitial Scanner	1
			Heart Rate Variability	Photoplethysmogram	1
			Hemodynamic measures	Electro Interstitial Scanner	1
Pain biomarkers		Hemoglobin oxygen	Electro Interstitial Scanner	1	

		saturation		
		Interstitial fluid biochemical estimation	Electro Interstitial Scanner	1
		Measure of brain metabolites	N-Acetylaspartate, Choline, Creatinine Levels	1
		Systolic blood pressure	Electro Interstitial Scanner	1
	Proprioception	Lumbar Repositioning Error	Dynanometer	1
	Range of motion	Bending angle	Inclinometer	1
		Lumbar Flexion	Finger-To-Floor Test	2
			Modified-modified Schober	2
			Mowestry Disability Indexfied Schober	1
			Mowestry Disability Indexfied-Mowestry Disability Indexfied Schober	1
		Lumbar Flexion-Extension	Sit And Reach Test	1
		Lumbar Flexion-Extension Lateral Bending	Behavioral Pain Scale	1
			Motion-Analysis System	1
	Lumbar lateral bending	Lateral Bending Test	1	
	Spinal control	Hip and knee flexion	Pressure Biofeedback	1
		Postural sway	Force Platform	2
			Motion-Analysis System	1
		Precision	Y-Balance Test	1

CoreAreas	Domains	Parameters	Measurements Tools	Occurrence frequency	
Life impact	Cognitive functioning	Fear Avoidance Beliefs	Fear Avoidance Belief Questionnaire	4	
		Pain catastrophization	Pain Catastrophizing Scale	3	
	Health-related quality of life	Quality Of Life		12-Item Short Form Survey	2
				36-Item Short Form Survey	1
				Euroqol - 5 Dimensions - 3 Levels	1
				Euroqol - 5 Dimensions - 5 Levels	1
				Healthy Days Measures	1
	Medication	Intake and Frequency of Medication	Data Repository	1	
	Pain behaviour	Fear of movement	Tampa Scale Kinesiophobia	3	
	Pain intensity	Level of pain		Numerical Pain Rating Scale	7
				Visual Analog Scale	11
		Pain sensitivity	Algometer	3	
		Temporal Summation Magnitude	Visual Analog Scale	1	
	Pain interference	Self-efficacy	Chronic Pain Self-Efficacy Scale	1	
	Pain quality	Sensorial and affective	Short-Form McGill Pain Questionnaire	3	
		Two-Point Discrimination Test	Esthesiometer	1	
	Physical functioning	Functional disability		Örebro Musculoskeletal Pain Screening Questionnaire	1
				Owestry Disability Index	9
				Quebec Back Pain Questionnaire	1
				Roland Morris Disability Questionnaire	8
				Waddel Disability Index	1
	Interoception	Multidimensional Assessment Of Interoceptive Awareness	1		
Psychological functioning	Anxiety and Depression	Hospital Anxiety Depression Scale	1		
	Depression	Patient Health Questionnaire-9	1		
Satisfaction with treatment services	Global Rating of Change	Global Rating Of Change Questionnaire	3		
	Satisfaction with back care	Patient'S Global Assessment Of Outcomes	1		
Temporal aspects	Frequency	Data Repository	1		
Pathophysiological manifestations	Muscle activity	Muscle activation flexion-extension	Electromyogram	1	
	Muscle endurance	Abdominal muscles	Mcquade Test	1	
			Shirado Test	1	
	Trunk extensor muscles	Ito Test	1		

			Sorensen Test	1
	Pain biomarkers	Diastolic blood pressure	Electro Interstitial Scanner	1
		Heart Rate Variability	Photoplethysmogram	1
		Hemodynamic measures	Electro Interstitial Scanner	1
		Hemoglobin oxygen saturation	Electro Interstitial Scanner	1
		Interstitial fluid biochemical estimation	Electro Interstitial Scanner	1
		Measure of brain metabolites	N-Acetylaspartate, Choline, Creatinine Levels	1
		Systolic blood pressure	Electro Interstitial Scanner	1
	Range of motion	Bending angle	Inclinometer	1
		Lumbar Flexion	Finger-To-Floor Test	1
			Modified-Modified Schober	2
		Lumbar Flexion-Extension Lateral Bending	Behavioral Pain Scale	1
			Motion-Analysis System	1
	Lumbar lateral bending	Lateral Bending Test	1	
Spinal control	Hip and knee flexion	Pressure Biofeedback	1	
	Postural sway	Force Platform	2	
		Motion-Analysis System	1	
	Precision	Y-Balance Test	1	