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[Intervention Protocol]

Lumbar braces and other assistive devices for treatment of chronic low back pain

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ABSTRACT

Objectives

This is a protocol for a Cochrane Review (intervention). The objectives are as follows:

To assess the benefits and harms of assistive technologies (i.e. non-rigid and rigid lumbar braces, belts, supports, and devices to assist mobility and gait) for improving pain and function (and consequently reducing disability) in adults with chronic low back pain.

BACKGROUND

Low back pain (LBP) is a major global health problem, the most common cause of activity limitation among people younger than 45 years, and the second most frequent reason for visits to a physician (Maher 2017). The Global Burden of Disease study 2019 estimated LBP as the most common cause of the need for rehabilitation (568 million people) (Cieza 2021). There is also a dramatic socio-economic burden with a substantial impact of LBP-related costs on national gross domestic products (Olafsson 2018; Wenig 2009), deriving both from productivity loss (Carregaro 2020; Jackson 2016) and healthcare services utilisation (Kim 2019). Specifically, chronic LBP (CLBP) condition results in long-term pain and suffering and causes a relevant increase in healthcare expenditure (Hong 2013).

Description of the condition

LBP is defined as pain localised below the costal margin and above the inferior gluteal folds, with or without pain referred to as the leg(s) (Chou 2010). Most people who experience CLBP are diagnosed as having 'non-specific LBP' (now referred to as primary CLBP in the *International Classification of Diseases 11th Revision* (*ICD-11*) classification system), which is defined as symptoms not attributed to a recognisable, known, specific pathology (e.g. fracture, ankylosing spondylitis, spondylarthritis, infection, neoplasm, or metastasis) (Balagué 2012). Different structures have been identified as contributors to LBP symptoms, including muscles, joints, and discs; in addition to these biological substrates, psychosocial factors, functional impairment, psychiatric comorbidities, and low general health status seem to play a crucial role in LPB pain perception (Chou 2010). This clinical picture becomes even more frequent and disabling with ageing, especially from age 60 years onward (de Souza 2019). CLBP is defined as pain, muscle tension, or stiffness lasting longer than 12 weeks; recurrent LBP is defined as two episodes in a year, lasting more than 24 hours, with more than 30 days pain-free in between. Many factors including biophysical, psychological, social, and genetic factors and comorbidities can contribute to worsening the impact of CLBP on functioning, participation, and quality of life (Hartvigsen 2018).

Description of the intervention

A wide variety of assistive technologies may be used to manage CLBP. These can be divided into two main categories, as follows.

- Non-rigid and rigid lumbar braces, belts, and supports, which wrap the lumbar/thoracolumbar trunk and can be made of different materials:
  - rigid braces are built of plastic material and greatly reduce (if not block) movements of the spine. They can be prefabricated or custom-made. The latter can be based on casting or CAD/CAM moulding;
  - soft braces are built of different materials, but they all allow movements with some restrictions. They can be elastic or anelastic, with or without rigid inserts. The different material is meant to provide different hypothetical actions.
- Devices to assist mobility and gait.

According to the United Nations General Marketplace proposal request (United Nations Global Marketplace 2021), we also included other devices like wheelchairs, mobility scooters, tricycles, crutches, walking sticks/canes, and walking frames/walkers, which are used by people with disability and are meant to change mobility in different ways. All of these devices change the position and the biomechanical load on the spine.

How the intervention might work

All of the devices considered mainly provide a mechanical contribution to the movement of the person with CLBP, with different modalities and degrees of assistance. Lumbar braces, belts, and supports are expected to reduce strains and physical demands on the lower back. They are commonly used for CLBP either as a treatment or to reduce exacerbations of CLBP conditions (van Duijvenbode 2008).

- Rigid braces are meant to have an antalgic personalised action achieved by:
  - reducing/blocking movement, based on the hypothesis that pain is due to movement;
  - unloading (supporting) the spine because most of the gravity forces are driven to the rigid external support;
  - repositioning the spine, based on the hypothesis that keeping antalgic postures in time will help tissue healing;
  - a neuromotor action with motor reprogramming due to exteroceptive and proprioceptive stimuli on the trunk also cannot be excluded.
- Soft braces' supposed actions depend on the material used and can include the following:
  - neuromotor reprogramming and or adaptation due to the proprioceptive and exteroceptive stimuli;
  - spine unloading due to an increase in abdominal pressure (one of the main biomechanical mechanisms to reduce spine load);
  - an action due to partial repositioning also cannot be excluded, particularly when rigid inserts are added. Compared to plastic braces, repositioning will be less specific and localised, but more general on the entire lumbar area.

Mobility and assistive gait devices aim to reduce the mechanical load on the low back due to limb movements (mobility) (Holtermann 2015; Jakobsen 2019). Each device has a different action due to the position required by the spine and the mechanical way in which movement is achieved. Consequently, they can increase or decrease the load and biomechanical demand on the spine. Their use can facilitate or reduce the appearance and quantity of back pain.

Why it is important to do this review

The scientific literature on LBP is extremely wide and heterogeneous. Many rehabilitative studies include assistive devices in LBP management, but a comprehensive and methodologically rigorous literature review is still missing in the field. Summarising robust evidence on the topic is fundamental to delivering practitioners the most significant possible number of therapeutical options. Lumbar assistive devices are frequently prescribed in some countries (Hu 2022), by some medical specialists (Phaner 2009), and in specific clinical situations (Bogaert 2019), but whether or not there is evidence for these treatments is unclear (van Duijvenbode 2008). This review will help patients, policymakers, and practitioners to achieve evidence-informed decisions about health issues and related costs. Moreover, devices to assist mobility concern frail and disadvantaged populations, and

appropriate evidence-based decisions also involve relevant equity issues.

This review is based on a report commissioned by the World Health Organization (WHO), WHO Guidelines for management of chronic primary low back pain in adults (not yet published).

OBJECTIVES

To assess the benefits and harms of assistive technologies (i.e. non-rigid and rigid lumbar braces, belts, supports, and devices to assist mobility and gait) for improving pain and function (and consequently reducing disability) in adults with chronic low back pain.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs). Lower-level evidence (e.g. non-randomised studies of interventions (NRSI)) may be considered in the absence of RCT-level evidence for some types of assistive devices, such as for mobility. We will therefore also include NRSI, defined as any quantitative study estimating the effectiveness of an intervention (harm or benefit) that does not use randomisation to allocate units (individuals or clusters of individuals) to intervention groups, such as prospective or retrospective controlled cohort studies and controlled before-after studies (CBA). We will exclude uncontrolled observational and cross-over studies because the rehabilitation interventions are not symptomatic treatments with short-term effects, and the condition of interest is unstable.

Types of participants

We will include studies involving adults (aged 18 years and older) with CLBP (*ICD-11* terminology and International Association for the Study of Pain (IASP) classification criteria: > 12 weeks duration; experienced in the region between the 12th rib and gluteal fold), with or without radiation to lower limbs (non-specific or characterised as a radicular or radiculopathy presentation), experienced either continuously or intermittently. We will consider studies with a mixed population (children and adults) if the data for adults (18 years and older) are presented separately, or at least 75% of the sample is 18 years or older. Studies targeting participants with specific musculoskeletal conditions may be included if they report results separately for participants with chronic non-specific LBP.

We will exclude studies where all participants had surgery on the spine. We will include studies with a mixed population if separate data for the subgroup of participants without surgery are provided. We will also include studies involving mixed populations if the proportion of participants with prior surgery is less than 15%.

We will exclude studies where all participants are pregnant patients. We will include studies with mixed populations if separate data for the subgroup of participants without pregnancy are provided, or the proportion of participants with pregnancy is less than 15%.

We will exclude studies involving participants in whom a specific cause for their LBP has been clearly determined (e.g. vertebral fracture, malignancy, inflammatory disease), that is chronic secondary LBP, and participants treated with braces primarily for a spinal deformity and the specific cause for LBP listed above. We will also exclude juvenile diseases such as adolescent idiopathic scoliosis, neuromuscular disorders, and Scheuermann's disease.

We will include studies with mixed populations if separate data for the subgroup of participants without such conditions are provided, or the proportion of participants with such conditions is less than 15%.

Types of interventions

We will include all types of assistive technologies and equipment provided for use in primary care or community settings that target improving health or well-being outcomes for adults with CLBP, used alone or in combination with other rehabilitation treatments provided the effect of the assistive technology can be isolated. Specific technologies include:

- non-rigid and rigid lumbar braces, belts, and supports;
- devices to assist with ambulation and mobility, such as wheelchairs, mobility scooters, tricycles, crutches, walking sticks/canes, and walking frames/walkers.

The comparators of interest are placebo/sham, no intervention, or usual care.

We will not include studies comparing one type of device versus another, or adding a device to another treatment that is not 'usual care'. Given that usual care and no intervention will be hard to define and standardise across trials, and that 'no intervention' is often not really the absence of intervention, in order to increase transparency and applicability of the results we will provide a detailed description of components of the usual care or no intervention, or both, as reported in the studies. We will therefore include usual care if the effect of the experimental intervention can be isolated, and no intervention will consist of the absence of intervention. The three comparators will be considered separately.

Types of outcome measures

We will consider the following time points for the extraction of outcomes: short term (< 3 months), intermediate term (3 to 12 months), and long term (> 12 months).

The primary time point for the purpose of the review will be the end of treatment.

The tools suggested by the construct are examples and not an exhaustive list, and all outcomes for a construct will be considered and extracted.

Primary outcomes

We will include the following primary outcomes.

- Pain, measured using validated scales (e.g. visual analogue scale (VAS), numerical rating scale (NRS), McGill pain score, Brief Pain Inventory (BPI), and others). We will treat pain as a continuous outcome if the study reports means and standard deviation (SD) of the postintervention values or the change from baseline.
- Disability, measured by a back pain-specific scale (e.g. the Roland-Morris Disability Questionnaire (RMDQ) or the Oswestry Disability Index (ODI)) or a non-specific one, e.g. WHO Disability

Assessment Schedule (WHODAS 2.0). We will treat disability as a continuous outcome if the study reports means and SD of the postintervention values or the change from baseline.

- Health-related quality of life (e.g. 36-Item Short Form Health Survey (SF-36), EQ-5D, WHOQOL, or similarly validated index).
- Participant-reported treatment success, measured by the number of participants with pain or disability improvement or according to the study's definition of success.
- Falls (for older people subgroup only, i.e. 60 years and older).
- Adverse events.
- Withdrawals due to any adverse events.

We will measure pain and disability as continuous and dichotomous (e.g. number of participants improved).

Secondary outcomes

We will include the following secondary outcomes.

- Depression, measured by a validated scale (e.g. Beck Depression Inventory, Hamilton Depression Rating Scale).
- Anxiety, measured by a validated scale (e.g. Hamilton Anxiety Rating Scale).
- Social participation (including paid and unpaid work; return to work).
- Reduction in use of painkiller medications.

Search methods for identification of studies

We will attempt to identify all relevant published and ongoing studies.

Electronic searches

We will search the following databases from inception to present:

- Cochrane Central Register of Controlled Trials (CENTRAL), published in the Cochrane Library;
- MEDLINE (PubMed) (1946 to present);
- Embase (via Embase.com) (1974 to present);
- CINAHL (Cumulative Index to Nursing and Allied Health Literature) (EBSCOhost) (1982 to present).

We will also search the World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) and ClinicalTrials.gov for ongoing studies. The search strategies have been devised by a review author with experience in bibliographic searches (SGL) under the supervision of a clinical expert in the topic addressed by the review (SN). The search strategies have been specifically adapted for each database (see Appendix 1).

Searching other resources

We will search the reference lists of all included studies and any relevant systematic reviews published within the search dates. We will also perform a forward citation search of all included studies. We will contact trialists of known ongoing studies for any relevant unpublished data.

Data collection and analysis

Selection of studies

Two review authors (SGL and CC) will independently screen the citations and abstracts identified in the search. A third review author (CA) will resolve any disagreements. We will use Covidence for screening (Covidence). We will obtain the complete reports for potentially eligible studies, which two review authors (SGL and CC) will independently screen for eligibility. Any disagreements will be resolved by consulting a third review author (CA). We will record the selection process in sufficient detail to complete a PRISMA flow diagram and 'Characteristics of excluded studies' table (PRISMA Statement 2020).

Data extraction and management

We will record extracted data on pre-designed and tested forms using Covidence. Two review authors (CC and SGL) will extract study information, and a third review author (CA) will check the data extraction against the original study publications. The review authors will not be blinded to authors, institutions, or publication journals due to feasibility and familiarity with the literature. We will resolve any disagreements about data extraction by referring to the study documents and discussing them amongst the review team. We will contact published trial authors to clarify or provide additional information as required.

We will extract the following study characteristics.

- Methods: study design, total study duration, details of any 'run-in' period, number of study centres and location, study setting, withdrawals, and study date.
- Participants: N, mean age, age range, sex, disease duration, severity of the condition, diagnostic criteria, important baseline data, inclusion criteria, and exclusion criteria.
- Interventions: intervention, comparison, concomitant medications, and excluded medications. For non-pharmacological interventions, a detailed and transparent description of the interventions should be provided following the guidance of established tools, e.g. using the Template for Intervention Description and Replication (TIDieR) (Hoffmann 2014).
- Outcomes: major and minor outcomes specified and collected, and time points reported.
- Characteristics of the trial design as outlined below in Assessment of risk of bias in included studies.
- Notes: funding for the trial and notable declarations of interest of trial authors.
- Information needed to conduct GRADE assessment (e.g. baseline risk in the control group for key outcomes).

Two review authors (SGL and CC) will independently extract outcome data from the included studies. We will extract the number of events and participants per treatment group for dichotomous outcomes, means and SDs and the number of participants per treatment group for continuous outcomes. We will note in the 'Characteristics of included studies' table if outcome data were not reported in a usable way and when data were transformed or estimated from a graph. We will resolve any disagreements by consensus or by involving a third review author (CA).

We will extract the following data:

- if both final values and change from baseline values are reported for the same outcome, we will extract the final values;
- if both unadjusted and adjusted values for the same outcome are reported, we will extract the adjusted values;
- if data are analysed based on an intention-to-treat (ITT) sample and another sample (e.g. per-protocol, as-treated), we will extract the data from per-protocol analysis.
- if multiple time points are used, we will extract the longest time point.

Assessment of risk of bias in included studies

Two review authors will independently assess the risk of bias in each included study. Any disagreements will be resolved through discussion or by consulting a third review author if necessary. For RCTs, we will use the Cochrane RoB 1 tool as recommended in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2017). We will assess potential bias related to the following risk of bias domains: random sequence generation, allocation of treatment concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective outcome reporting, and other sources of potential bias (similar groups and co-interventions, compliance, timing). We will score each risk of bias domain as low, high, or unclear risk of bias. We will present the figures generated by the tool to provide summary assessments of the risk of bias.

We will assess the risk of bias in primary outcomes assessed in NRSI using the ROBINS-I tool (Risk Of Bias In Non-randomised Studies - of Interventions) (Sterne 2016). We will specify a target trial, and assess the risk of bias of NRSI based on the following seven domains (Sterne 2016):

- bias due to confounding;
- bias in the selection of participants for the study;
- bias in the classification of interventions;
- bias due to deviations from the intended intervention;
- bias due to missing data;
- bias in the measurement of outcomes;
- bias in the selection of the reported result.

Measures of treatment effect

For dichotomous outcomes, we will calculate risk ratios (RR) with their respective 95% confidence intervals (CIs). For continuous outcomes, we will calculate mean differences (MD). If the same outcome is reported using different scales, we will calculate standardised mean differences (SMD) if data pooling is deemed appropriate and meaningful by content experts. To enhance the interpretability of continuous outcomes, we will back-transform pooled SMD values for functional status to a standard metric by multiplying the SMD and 95% CI by an SD pooled from all studies that used the most common instrument at that follow-up. We will calculate this pooled SD as described in Section 15.5.3.2 of the *Cochrane Handbook* (Schunemann 2022a).

For pain, research has established an agreement between NRS and VAS for pain intensity, enabling meta-analysis of trials using different measures of pain intensity (Shafshak 2021). We will consider a minimum clinically meaningful change on the 0-to-100 pain scale to be 15 for VAS and 1.5 for NRS (0 to 10) (Ostelo 2008). For disability, given the variability in available scales, we will report the SMD for the primary analysis. Evidence indicates that standard measures of function, such as the RMDQ and the ODI, are correlated and similarly responsive to the pool in the meta-analysis (Chiarotto 2016). For continuous outcomes, we will define the magnitude of effects as small (less than 10% difference on the scale or SMD of 0.2 to less than 0.5); medium (10% to 20% or 0.5 to 0.8); and large (greater than 20% or greater than 0.8), as used in another Cochrane review from the Back and Neck group (Rubinstein 2011). We will consider differences below the threshold for small to indicate no difference.

Unit of analysis issues

Cluster-randomised trials

For cluster-RCTs, we will extract the intracluster correlation coefficient (ICC) when this is available; we will also record the number of clusters per group, the total size of clusters per group, and the unit of randomisation (e.g. household or institution). We will document the statistical methods used to analyse the trial results, along with details describing whether these methods were adjusted for clustering or other covariables.

Using the generic inverse variance random-effects method, we will pool cluster-RCT data that have been adjusted for clustering with data from trials that randomly assigned individuals (individually randomised RCTs). When the results of a cluster-RCT have not been adjusted for clustering, we will adjust the data using the clustering effect (ICC) imputed from another study (Higgins 2022).

Studies with multiple treatment groups

Where multiple trial arms are reported in a single trial, we will include only the relevant arms. If two comparisons are combined in the same meta-analysis, we will halve the control group to avoid double-counting. If a single trial compares two or more treatment arms, we will label the arms separately in pairwise analyses. We will group suitable multiple treatment arms (e.g. arms that evaluated different treatment modes), and exclude irrelevant trial arms.

Dealing with missing data

If data on specific outcomes or population groups are missing, we will attempt to contact the study authors or data owners to request these data.

For dichotomous outcomes (e.g. number of withdrawals due to adverse events), we will calculate the withdrawal rate using the number of participants randomised in the group as the denominator.

For continuous outcomes (e.g. mean change in pain score), we will calculate the MD or SMD based on the number of participants analysed at that time point. If the number of participants analysed is not presented for each time point, we will use the number of randomised participants in each group at baseline.

Where possible, we will calculate missing SDs from other statistics, such as standard errors, CIs or P values. When none of the above methods allows calculation of the SDs from the trial report (and the information is not available from the trialists), we will borrow the SD from one or more other studies according to the methods recommended in Chapter 6 of the *Cochrane Handbook* (Higgins 2022a).

Assessment of heterogeneity

We will pool data if studies are clinically homogeneous for the study population, interventions, and outcomes. We will assess the presence of clinical heterogeneity within each pairwise comparison by comparing the trial and study population characteristics across all eligible trials. For pairwise analyses, we will inspect forest plots visually to detect heterogeneity. We will use the I^2 statistic to assess statistical heterogeneity, interpreting it as follows:

- 0% to 40%: heterogeneity might not be important;
- 30% to 60%: may represent moderate heterogeneity;
- 50% to 90%: may represent substantial heterogeneity;
- 75% to 100%: considerable heterogeneity.

These overlapping intervals reflect that the interpretation of the I^2 statistic depends on the value size and direction of the treatment effect and variance of the I^2 estimate. Results with considerable heterogeneity ($I^2 > 75\%$) will not be pooled.

Assessment of reporting biases

Where more than 10 studies are included in meta-analysis, we will create a funnel plot to explore possible publication bias, interpreting it with other considerations for publication bias within the GRADE assessment (Page 2021; Schunemann 2022).

Data synthesis

When pooling is considered to be appropriate, we will use the DerSimonian and Laird method and inverse-variance method for RCTs and NRSI, respectively, and analyse them separately (DerSimonian 1986).

We will pool adjusted estimates for relevant confounders from NRSI, when available. We will employ a random-effects meta-analysis given that a certain degree of clinical heterogeneity is expected amongst the included studies.

Data not usable for analyses (e.g. reported only as P values) will be tabulated and reported narratively.

Subgroup analysis and investigation of heterogeneity

We will perform a subgroup analysis for studies including people with and without radicular leg pain and studies including a mixed population with and without radicular leg pain at the end of treatment for the outcomes of pain and disability, as we expect a different treatment response from the two subgroups of people.

We will use the formal test for subgroup interactions in RevMan (RevMan 2024). We will use caution in interpreting subgroup analyses, as advised in Chapter 10 of the *Cochrane Handbook* (Deeks 2022). We will compare the magnitude of the effects between the subgroups by assessing the overlap of the CIs of the summary estimate, with non-overlap of the CIs indicating statistical significance.

Sensitivity analysis

We will perform sensitivity analysis at the end of treatment for pain and disability outcomes, excluding studies with inadequate allocation concealment. For subjective outcomes, we will exclude studies with inadequate blinding of the outcome assessor.

Summary of findings and assessment of the certainty of the evidence

We will follow the guidelines in Chapters 14 and 15 of the *Cochrane Handbook* for interpreting results (Schunemann 2022; Schunemann 2022a), and will be aware of distinguishing a lack of evidence of effect from a lack of effect. We will base our conclusions only on the findings from this review's quantitative or narrative synthesis of included studies. We will avoid making recommendations for practice, and our implications for research will suggest future research priorities and outline the remaining uncertainties in the area.

We will create a summary of findings (SoF) table using the following outcomes measured at the end of treatment.

- Pain
- Disability
- Health-related quality of life
- Participant-reported treatment success
- Falls
- Adverse events
- Withdrawals due to adverse events

The comparison in the first SoF table will be assistive devices compared with usual care. We also plan other SoF tables for the following comparisons: assistive devices compared with placebo/sham and assistive devices compared with no intervention.

The profiles will provide the effect estimate and the associated certainty of the evidence for each outcome of interest. Data from RCTs will start as high-certainty evidence. As we will use ROBINS-I for the risk of bias assessment of NRSI, these will also start as high-certainty evidence. We will consider the following criteria for upgrading the certainty of the evidence for observational studies: large effect, dose-response gradient, and plausible confounding effect.

We will use the five GRADE considerations (study limitations (overall risk of bias), consistency of effect, imprecision, indirectness, and publication bias) to assess the certainty of a body of evidence as it relates to the studies which contribute data to the analyses for the prespecified outcomes, and report the certainty of evidence as high, moderate, low, or very low.

- **Risk of bias.** We will consider the study's contribution (i.e. 'weight') to the pooled estimate. If > 50% of the weight in the overall estimate comes from studies at high risk of selection or attrition bias, or if all the studies are judged as at unclear risk of bias of selection and attrition bias, we will downgrade by one level. If > 75% of the weight in the overall estimate comes from studies at high risk of selection or attrition bias, we will downgrade by two levels.
- **Imprecision.** For dichotomous outcomes, we will evaluate whether the sample size or the number of events does not meet the optimal information size and whether the CIs of the pooled estimate include large benefits and large harms; we will consider downgrading by two levels if the total number of events is less than 100. For continuous outcomes, we will apply the 'rules of thumb' of 400 participants as a cut-off for downgrading by one level; we will downgrade by two levels if the total number of participants is less than 100.

- **Indirectness.** We will consider downgrading by one level if the results are not be fully generalisable to all countries/settings/participants; we will not downgrade by two levels for this domain.
- **Inconsistency.** We will consider the statistical test for heterogeneity (I^2), the overlap of CIs, and the similarity of point estimates. We will consider downgrading by one level if I^2 is substantial (between 50% and 75%) and if the point estimates of individual studies are in different directions. We will consider downgrading by two levels if I^2 is considerable (above 75%) and if the point estimates of individual studies are in different directions.
- **Publication bias.** We will consider downgrading by one level if the funnel plot shows asymmetry, suggesting the possibility of publication bias.

Two review authors (CA and SGL) will independently assess the certainty of the evidence, with any disagreements resolved by discussion or by involving a third review author (SM). We will use GRADEpro GDT software to prepare the SoF tables (GRADEpro GDT). We will justify and document all decisions to down- or upgrade the certainty of the evidence using footnotes and make comments to aid the reader's understanding of the review where necessary.

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APPENDICES

Appendix 1. Search strategies

Database	Search strategy
MEDLINE (via PubMed)	1. dorsalgia[tiab] 2. "Back Pain"[Mesh] 3. backache*[tiab] OR "back ache*"[tiab] OR "back pain"[tiab] 4. "lumbar pain"[tiab] OR "lumbosacral pain"[tiab] 5. coccyx[tiab] 6. coccydynia[tiab] 7. sciatic*[tiab] OR ischialgia[tiab] 8. "Sciatic Neuropathy"[Mesh] 9. spondylosis[tiab] OR spondylolysis[tiab] OR spondylolisthesis[tiab] 10."Spondylosis"[Mesh] 11.lumbago[tiab] 12."back disorder*"[tiab] 13."Low Back Pain"[Mesh] 14."disc displace*"[tiab] OR "discal displacement"[tiab] OR "displaced disc*"[tiab] OR "disk displace*"[tiab] OR "displaced disk*"[tiab] 15."disc herniat*"[tiab] OR "discal herniat*"[tiab] OR "herniated disc*"[tiab] OR "disk herniat*"[tiab] OR "herniated disk*"[tiab] 16."disc prolaps*"[tiab] OR "discal prolaps*"[tiab] OR "prolapsed disc*"[tiab] OR "disk prolaps*"[tiab] OR "prolapsed disk*"[tiab] 17."disc slipp*"[tiab] OR "slipped disc*"[tiab] OR "slipped disk*"[tiab] 18."Intervertebral Disc Displacement"[Mesh] 19."disc degenerat*"[tiab] OR "discal degenerat*"[tiab] OR "disk degenerat*"[tiab] OR "degenerated disc*"[tiab] OR "degenerated disk*"[tiab] 20."disc degradat*"[tiab] OR "disk degradat*"[tiab] 21."Intervertebral Disc Degeneration"[Mesh] 22.#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 23.brace*[tiab] 24.belt*[tiab] 25."lumbar support*"[tiab] 26.corset*[tiab] 27."Braces"[Mesh] OR "Orthotic Devices"[Mesh] 28."lumbar orthos*"[tiab] 29."lumbosacral orthos*"[tiab] 30.cane*[tiab] 31.stick*[tiab] 32.pole*[tiab] 33."Canes"[Mesh] 34.walker*[tiab] 35."walking frame*"[tiab] 36."Walkers"[Mesh] 37.crutch*[tiab] 38."Crutches"[Mesh] 39.wheelchair*[tiab] 40.tricycle*[tiab]

(Continued)

41."Wheelchairs"[Mesh] OR "Self-Help Devices"[Mesh]
42."mobility scooter*"[tiab]
43.#23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42
44.animals [mh] NOT humans [mh]
45.#22 AND #43 NOT #44

Embase (via Embase.com)

1. dorsalgia:ti,ab,kw
2. (backache* OR (back NEAR/1 ache*) OR 'back pain'):ti,ab,kw
3. 'backache'/exp
4. (lumb* NEAR/4 pain):ti,ab,kw
5. coccyx:ti,ab,kw
6. coccydynia:ti,ab,kw
7. (sciatic* OR ischialgia):ti,ab,kw
8. 'ischialgia'/exp
9. 'sciatic neuropathy'/exp
10. lumbago:ti,ab,kw
11. (spondylosis OR spondylolysis OR spondylolisthesis):ti,ab,kw
12. 'spondylosis'/exp
13. (back NEAR/1 disorder*):ti,ab,kw
14. 'low back pain'/exp
15. ((disc OR disk OR discal OR diskal) NEAR/1 (displacement OR hernia* OR prolaps* OR slipped)):ti,ab,kw
16. 'intervertebral disk hernia'/exp
17. ((disc OR disk OR discal OR diskal) NEAR/1 (degenerat* OR degradat*)):ti,ab,kw
18. 'intervertebral disk degeneration'/exp
19. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18
20. brace*:ti,ab,kw
21. belt*:ti,ab,kw
22. (lumb* NEAR/2 support*):ti,ab,kw
23. corset*:ti,ab,kw
24. (lumb* NEAR/1 orthos*):ti,ab,kw
25. 'spine orthosis'/exp
26. 'corset'/exp
27. 'lumbosacral corset'/exp
28. 'lumbo sacral orthosis'/exp
29. 'lumbar support'/exp
30. 'thoracolumbosacral orthosis'/exp
31. 'spinal brace'/exp
32. cane*:ti,ab,kw
33. stick*:ti,ab,kw
34. pole*:ti,ab,kw
35. crutch*:ti,ab,kw
36. walker*:ti,ab,kw
37. (walking NEAR/1 frame*):ti,ab,kw
38. 'walking aid'/exp
39. 'cane'/exp
40. 'crutch'/exp
41. 'walker'/exp
42. 'rollator'/exp

(Continued)

43.'walking orthosis'/exp
44.wheelchair*:ti,ab,kw
45.tricycle*:ti,ab,kw
46.'wheelchair'/exp OR 'self help device'/exp
47.'tricycle'/exp
48.'mobility scooter*':ti,ab,kw
49.#20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48
50.((rat:ti,tt OR rats:ti,tt OR mouse:ti,tt OR mice:ti,tt OR swine:ti,tt OR porcine:ti,tt OR murine:ti,tt OR sheep:ti,tt OR lambs:ti,tt OR pigs:ti,tt OR piglets:ti,tt OR rabbit:ti,tt OR rabbits:ti,tt OR cat:ti,tt OR cats:ti,tt OR dog:ti,tt OR dogs:ti,tt OR cattle:ti,tt OR bovine:ti,tt OR monkey:ti,tt OR monkeys:ti,tt OR trout:ti,tt OR marmoset*:ti,tt) AND 'animal experiment'/de)
51.('animal experiment'/de NOT ('human experiment'/de OR 'human'/de))
52.#50 OR #51
53.#19 AND #49 NOT #52

CENTRAL (via Cochrane Library)

1. dorsalgia:ti,ab,kw
2. MeSH descriptor: [Back Pain] explode all trees
3. backache*:ti,ab,kw OR (back NEAR/1 ache*):ti,ab,kw OR "back pain":ti,ab,kw
4. (lumb* NEAR/4 pain):ti,ab,kw
5. coccyx:ti,ab,kw
6. coccydynia:ti,ab,kw
7. (sciatic* OR ischialgia):ti,ab,kw
8. MeSH descriptor: [Sciatic Neuropathy] explode all trees
9. (spondylosis OR spondylolysis OR spondylolisthesis):ti,ab,kw
10. MeSH descriptor: [Spondylosis] explode all trees
11. lumbago:ti,ab,kw
12. (back NEAR/1 disorder*):ti,ab,kw
13. MeSH descriptor: [Low Back Pain] explode all trees
14. ((disc OR disk OR discal OR diskal) NEAR/1 (displacement OR hernia* OR prolaps* OR slipped)):ti,ab,kw
15. MeSH descriptor: [Intervertebral Disc Displacement] explode all trees
16. ((disc OR disk OR discal OR diskal) NEAR/1 (degenerat* OR degradat*)):ti,ab,kw
17. MeSH descriptor: [Intervertebral Disc Degeneration] explode all trees
18. #1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17
19. brace*:ti,ab,kw
20. belt*:ti,ab,kw
21. (lumb* NEAR/2 support*):ti,ab,kw
22. corset*:ti,ab,kw
23. MeSH descriptor: [Orthotic Devices] explode all trees
24. MeSH descriptor: [Braces] explode all trees
25. (lumb* NEAR/2 orthos*):ti,ab,kw
26. cane*:ti,ab,kw
27. stick*:ti,ab,kw
28. pole*:ti,ab,kw
29. MeSH descriptor: [Canes] explode all trees
30. walker*:ti,ab,kw
31. (walking NEAR/1 frame*):ti,ab,kw
32. MeSH descriptor: [Walkers] explode all trees

(Continued)

	33.crutch*:ti,ab,kw 34.MeSH descriptor: [Crutches] explode all trees 35.wheelchair*:ti,ab,kw 36.tricycle*:ti,ab,kw 37.MeSH descriptor: [Wheelchairs] explode all trees 38.MeSH descriptor: [Self-Help Devices] explode all trees 39.(mobility NEXT/1 scooter*):ti,ab,kw 40.#19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 41.#18 AND #40 – in Trials
CINAHL (via EBSCOhost)	1. (MH "Back Pain+") OR (MM "Low Back Pain") OR (MM "Sciatica") OR (MH "Spondylosis+") OR (MM "Intervertebral Disk Displacement") 2. TI(dorsalgia OR backache OR (back W1 ache*) OR "back pain" OR (lumb* N4 pain) OR coccyx OR coccydynia OR sciatic* OR ischialgia OR spondylosis OR spondylolysis OR spondylolisthesis OR lumbago OR (back W1 disorder*) OR ((disc OR disk OR discal OR diskal) N1 (displacement OR hernia* OR prolaps* OR slipped)) OR ((disc OR disk OR discal OR diskal) N1 (degenerat* OR degradat*))) OR AB(dorsalgia OR backache OR (back W1 ache*) OR "back pain" OR (lumb* N4 pain) OR coccyx OR coccydynia OR sciatic* OR ischialgia OR spondylosis OR spondylolysis OR spondylolisthesis OR lumbago OR (back W1 disorder*) OR ((disc OR disk OR discal OR diskal) N1 (displacement OR hernia* OR prolaps* OR slipped)) OR ((disc OR disk OR discal OR diskal) N1 (degenerat* OR degradat*))) OR SU(dorsalgia OR backache OR (back W1 ache*) OR "back pain" OR (lumb* N4 pain) OR coccyx OR coccydynia OR sciatic* OR ischialgia OR spondylosis OR spondylolysis OR spondylolisthesis OR lumbago OR (back W1 disorder*) OR ((disc OR disk OR discal OR diskal) N1 (displacement OR hernia* OR prolaps* OR slipped)) OR ((disc OR disk OR discal OR diskal) N1 (degenerat* OR degradat*))) 3. #1 OR #2 4. (MH "Orthoses+") OR (MH "Assistive Technology Devices+") OR (MH "Ambulation Aids+") OR (MM "Canes") OR (MM "Crutches") OR (MM "Walkers") OR (MH "Wheelchairs+") 5. TI(brace* OR belt* OR (lumb* N2 (support* OR orthos*)) OR corset* OR cane* OR stick* OR pole* OR walker* OR (walking N1 frame*) OR crutch* OR wheelchair* OR tricycle* OR (mobility N1 scooter*)) OR AB(brace* OR belt* OR (lumb* N2 (support* OR orthos*)) OR corset* OR cane* OR stick* OR pole* OR walker* OR (walking N1 frame*) OR crutch* OR wheelchair* OR tricycle* OR (mobility N1 scooter*)) OR SU(brace* OR belt* OR (lumb* N2 (support* OR orthos*)) OR corset* OR cane* OR stick* OR pole* OR walker* OR (walking N1 frame*) OR crutch* OR wheelchair* OR tricycle* OR (mobility N1 scooter*)) 6. #4 OR #5 7. MH animals+ 8. MH (animal studies) 9. TI (animal model*) 10.#7 OR #8 OR #9 11.MH (human) 12.#10 NOT #11 13.#3 AND #6 NOT #12
US National Institutes of Health Ongoing Trials Register ClinicalTrials.gov (www.clinicaltrials.gov)	1. Other terms: ("back pain" OR backache OR "lumbar pain" OR "sciatica" OR lumbago) AND (brace OR braces OR belt OR belts OR "lumbar support" OR "lumbar supports" OR corset OR corsets) 2. Other terms: ("back pain" OR backache OR "lumbar pain" OR "sciatica" OR lumbago) AND ("lumbar orthosis" OR "lumbar orthoses" OR "lumbosacral orthosis" OR "lumbosacral orthoses")

(Continued)

	3. Other terms: ("back pain" OR backache OR "lumbar pain" OR "sciatica" OR lumbago) AND (cane OR canes OR stick OR sticks OR pole OR poles OR walker OR walkers OR crutch OR crutches OR wheelchair OR wheelchairs OR tricycle OR tricycles OR scooter OR scooters) 4. #1 OR #2 OR #3
WHO International Clinical Trials Registry Platform (ICTRP) (trialsearch.who.int)	1. back pain AND brace* OR back pain AND belt* OR back pain AND lumbar support* OR back pain AND corset* OR back pain AND lumbar orthos* OR lumbar pain AND brace* OR lumbar pain AND belt* OR lumbar pain AND lumbar support* OR lumbar pain AND corset* OR lumbar pain AND lumbar orthos* OR sciatica AND brace* OR sciatica AND belt* OR sciatica AND lumbar support* OR sciatica AND corset* OR sciatica AND lumbar orthos* 2. back pain AND cane* OR back pain AND stick* OR back pain AND pole* OR back pain AND walker* OR back pain AND crutch* OR back pain AND wheelchair* OR back pain AND tricycle* OR back pain AND scooter* OR lumbar pain AND cane* OR lumbar pain AND stick* OR lumbar pain AND pole* OR lumbar pain AND walker* OR lumbar pain AND crutch* OR lumbar pain AND wheelchair* OR lumbar pain AND tricycle* OR lumbar pain AND scooter* OR sciatica AND cane* OR sciatica AND stick* OR sciatica AND pole* OR sciatica AND walker* OR sciatica AND crutch* OR sciatica AND wheelchair* OR sciatica AND tricycle* OR sciatica AND scooter* 3. #1 OR #2

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