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[Intervention Protocol]

Exercise for low back pain in adolescents and children

Fabio Zaina[1], Federico Balagué[2], Francesca Di Felice[1], Sabrina Donzelli[3], Michele Romano[1], Stefano Negrini[4,5]

[1]ISICO (Italian Scientific Spine Institute), Milan, Italy. [2]Rheumatology, HFR Fribourg, Fribourg, Switzerland. [3]National Scoliosis Center, Fairfax, Virginia, USA. [4]Department of Biomedical, Surgical and Dental Sciences, University of Milan "La Statale", Milano, Italy. [5]IRCCS Galeazzi-S. Ambrogio Hospital, Milan, Italy

Contact: Fabio Zaina, fabio.zaina@isico.it.

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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 exercise compared to placebo/sham/attention control or no treatment for low back pain in adolescents and children.

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BACKGROUND

Description of the condition

Low back pain (LBP) is a complex clinical condition characterised by pain between the costal margin and the gluteal fold, the pain possibly radiating to one or both legs but not below the knee. The condition includes function loss and adaptation of everyday activities, affecting work and social activities. In general, it is not possible to identify any specific anatomical damage, therefore it is described by experts as non-specific LBP (Allegri 2016). Many different elements of the spine and back can be the source of the pain (muscles, joints, ligaments, discs, etc.). Still, we have no specific tools to make a precise aetiological diagnosis (Negrini 2013). Classification of LBP is usually based on its duration, that is acute, subacute, or chronic (Qaseem 2017). This temporal classification defines different pathophysiological phenomena, with acute LBP predominantly representing a biological problem, chronic LBP being a biopsychosocial syndrome, and subacute LBP as a transition from one to the other. Recurrent LBP is defined as two episodes in a year, lasting more than 24 hours, with more than 30 days pain-free in between (Hayden 2021). These conditions impact quality of life (QoL), therapeutic approaches, and social costs differently. Furthermore, LBP is the leading cause of burden in terms of years lived with disability (Global Burden of Disease Study 2021 Collaborators).

Recently, children and adolescents have also been reported to suffer from non-specific LBP (Balagué 2012). Point prevalence during adolescence ranges between 10% and 14%; monthly prevalence is between 18% and 24%; and lifetime prevalence is close to 40% (Calvo-Muñoz 2013; Kamper 2016). Prevalence increases with age, starting at about 11 to 12 years of age and reaching a level comparable to that of adults at the end of adolescence (Kamper 2016). Evidence also demonstrates that LBP during adolescence predisposes individuals to chronic or recurrent pain during adulthood (Harreby 1995; Hestbaek 2006). Moreover, LBP, especially when chronic, can significantly reduce QoL in young patients (Balagué 2012a; Fontecha 2011). The correct interpretation of symptoms and the correct definition of the LBP condition is expected to be more complex in children and adolescents than in adults, as it represents, in most cases, the first experience of pain. Goals and expectations of treatment, as well as treatment response, could also differ from adults.

Description of the intervention

According to Caspersen, "Exercise is a physical activity that is planned, structured, repetitive, and purposive in the sense that improvement or maintenance of one or more components of physical fitness is an objective" (Caspersen 1985). Exercise represents a common approach in rehabilitating many conditions, including LBP. Exercise therapy aims to increase muscle and joint strength, and improve muscle function and range of motion. This should reduce pain and disability, and speed recovery and return to usual activities (Hayden 2021). There are many different kinds of exercise, all of which have different aims, such as muscle strengthening, stretching, flexibility, stabilisation, and aerobic exercise. A recent clinical guideline recommended an approach based on home exercise and physical activity to treat LBP in adolescents (Frosch 2022).

How the intervention might work

It is still unclear how exercise can improve LBP, given the many different kinds of exercise, and so far, no differences have been demonstrated in terms of results for chronic LBP. Some recent reviews reported low-quality evidence in favour of Pilates, stabilisation/motor control, resistance training, and aerobic exercise training to improve LBP (Owen 2020). Exercises have different goals and potentially act via different mechanisms, especially as they range from strengthening, core stability, endurance, stretching, and relaxation exercises. We expect similar results in children and adolescents as in adults.

Why it is important to do this review

Exercise is a common approach for treating LBP. For this reason, a group of Cochrane reviews and protocols have recently updated the evidence on exercise for LBP in adults and the elderly (Geneen 2017; Jesus-Moraleida 2016; Macedo 2016). The awareness of the potential effectiveness of exercise in younger people suffering from LBP is important to improve QoL in the short term and to prevent chronic pain in adulthood in the long term. No Cochrane review has covered this topic in children and adolescents. The present review will fill that gap.

OBJECTIVES

To assess the benefits and harms of exercise compared to placebo/sham/attention control or no treatment for low back pain in adolescents and children.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomised controlled trials (RCTs) and quasi-RCTs. We will include data from studies reported as full text. We will describe the characteristics of studies published as abstract only, unpublished data, and ongoing studies, but will not include their results in the data syntheses. There will be no language or date restrictions.

Types of participants

We will include children from 6 to 18 years of age suffering from non-specific LBP. We will include participants with LBP irrespective of the duration, and will perform a subgroup analysis that considers acute, subacute, chronic, and recurrent LBP. We will also include children and adolescents with prior LBP who were treated with exercise to prevent the recurrence of LBP.

In the case of mixed populations involving adults, we will include studies only if data on children are reported separately.

We will exclude participants with pain secondary to specific causes of pain, such as spondylolysis and spondylolisthesis, Scheuermann's disease, scoliosis, trauma, and other severe pathologies.

Types of interventions

We will include every kind of exercise therapy, performed with or without machines. We will attempt to group studies according to

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the treatment protocol (e.g. kind of exercise, duration of treatment, number of sessions).

We will include studies that compared aerobic exercise treatment to:

- placebo, sham, or attention control;
- no treatment provided in the trial.

'Placebo/sham/attention control' is the primary comparison and is considered the least biased estimate of a treatment's effect. The comparison group will be described as a placebo/sham/attention control or will be judged as intended by the trial authors to be a placebo/sham/attention control (e.g. the trial authors describe the comparison group intervention using placebo, sham, or attention control language, for example detuned electrotherapy). We will not include regular electrotherapy in the placebo/sham/attention control comparison group, since it remains doubtful that all electrotherapy is ineffective.

The comparison group 'no treatment provided in the trial' will be described as no specific treatment including:

- wait list (no other description provided by the trial authors);
- control group (described specifically as no intervention, or no other description provided by the trial authors);
- usual/normal care (it is stated that participants could receive normal care, but this was not controlled by the trial);
- exercise and comparison groups are offered, or receive, the same co-interventions, allowing isolation of the effect of the exercise treatment.

Analyses comparing the specific exercise type to other comparison treatments or comparing different kinds of exercises could be conducted in other subsequent reviews if it is established that the specific form of exercise is efficacious.

Types of outcome measures

Major outcomes

- Pain intensity (e.g. visual analogical scale (VAS), numerical rating scale (NRS), graphical rating scale (GRS), or questionnaires like the McGill Pain Questionnaire).
- Back-specific functional measures (e.g. Oswestry Disability Index (ODI), Roland Morris (RM)).
- Health-related quality of life (e.g. 36-item Short Form Health Survey (SF-36), as measured by the general health subscale; EQ-5D, general health, measured on a VAS or a similarly validated index) and other specific tools to assess QoL.
- Participant-reported treatment success
- Adverse events
- Withdrawals due to adverse events

Minor outcomes

- Return to school/absenteeism
- Return to sports practice

Timing of outcome assessments

We will evaluate outcome measures up to three months from the end of the intervention, up to six months, up to one year, and more than one year. Withdrawal and adverse event data will be collected at the end of the trial.

Search methods for identification of studies

Electronic searches

We will search the following electronic databases from inception to present with no language restrictions:

- Cochrane Central Register of Controlled Trials (CENTRAL) via Ovid (latest issue);
- MEDLINE (Ovid) (1946 to current);
- Embase (Ovid) (1947 to current).

We will search the following trials registries for ongoing trials:

- ClinicalTrials.gov (clinicaltrials.gov/);
- World Health Organization International Clinical Trials Registry Platform (WHO ICTRP) (trialsearch.who.int/).

We will adopt the search strategy developed by the Cochrane Back Review Group using free text words and MeSH headings (Furlan 2015). The draft strategy for MEDLINE can be found in Appendix 1.

Searching other resources

We will search the reference list of relevant reviews and studies.

Data collection and analysis

Selection of studies

Two review authors (FD, SD) will independently screen the titles and abstracts of studies identified by the search for potential relevance, coding them as 'retrieve' (eligible or potentially eligible/unclear) or 'do not retrieve'. We will retrieve the full-text study reports/publications, and two review authors (FD, SD) will independently screen the full texts and identify studies for inclusion, and identify and record reasons for exclusion of ineligible studies. Any disagreements will be resolved through discussion or in consultation with a third review author (FZ) if necessary. We will identify and exclude duplicates and collate multiple reports of the same study under a single reference ID so that each study, rather than each report, is the unit of interest in the review. A third review author (FZ) will be invited to make the final decision only when needed.

We will record the selection process in sufficient detail to complete a PRISMA flow diagram (PRISMA Statement 2020) and 'Characteristics of excluded studies' table.

Data extraction and management

Two review authors (FD, SD) will extract study characteristics and outcome data from the included studies using a data collection form that has been piloted on at least one study in the review. We will extract the following study characteristics.

- Methods: study design, total duration of study, details of any 'run-in' period, number of study centres and location, study setting, withdrawals, and date of study.
- Participants: number, mean age, sex, disease duration, severity of condition, diagnostic criteria, important chronic LBP baseline data, inclusion criteria, and exclusion criteria.

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- Interventions: intervention, comparison, concomitant interventions, and excluded interventions. We will provide a detailed description of the interventions using the Consensus on Exercise Reporting Template (CERT) checklist for exercise interventions, as required by Cochrane Musculoskeletal (Slade 2016).
- Outcomes: major and minor outcomes specified and collected, and time points reported.
- Characteristics of trial design as outlined below in the Assessment of risk of bias in included studies section.
- Notes: trial funding and notable declarations of interest of trial authors.
- Information needed for the GRADE assessment (e.g. baseline risk in the control group for key outcomes).

We will extract the number of events and number of participants per treatment group for dichotomous outcomes, and means and standard deviations and 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 (FZ). One review author (FD) will transfer data to the RevMan file (RevMan 2024). We will double-check that data are entered correctly by comparing the data presented in the systematic review with the study reports.

For continuous and dichotomous outcomes, if studies report between-group differences that are adjusted for baseline scores with final values or change from baseline values for the same continuous outcome, we will extract adjusted final values over change scores, where necessary.

We will extract data analysed by intention-to-treat (ITT) wherever possible. If we identify cross-over RCTs, we will extract data from the first time point only.

We plan to synthesise the characteristics of all studies that contribute to each comparison and present these in the 'Characteristics of included studies' table in the full review.

Assessment of risk of bias in included studies

Two review authors (FD, SD) will independently assess the risk of bias in each study. We will resolve any disagreements by discussion or by involving a third review author (FZ).

We will assess risk of bias using the Cochrane RoB 1 tool, which includes the following domains (Higgins 2017).

- Random sequence generation
- Allocation concealment
- Blinding of participants and personnel
- Blinding of outcome assessment
- Incomplete outcome data
- Selective outcome reporting
- Other bias

We will grade each potential source of bias as low, high, or unclear risk, and provide a quote from the study report together with a justification for our judgement in the 'Characteristics of included studies' table. We will summarise the risk of bias judgements across different studies for each of the domains listed. We will grade overall study risk of bias as low risk of bias if all domains are low risk, high risk of bias if at least one domain is high risk, or unclear risk if at least one domain is unclear risk and none are high risk. We will consider blinding separately for self-reported outcomes like pain, functional disability, and quality of life and assessor-reported outcomes. We will also consider the impact of missing data for each outcome.

Where information on risk of bias relates to unpublished data or correspondence with a trialist, we will note this in the 'Characteristics of included studies' table. When considering treatment effects, we will take into account the risk of bias in the studies that contribute to that outcome.

We will present the figures generated by RoB 1 to provide summary assessments of the risk of bias; where possible, we will add this information to forest plots of meta-analyses. The results of the risk of bias assessment will inform the GRADE assessment.

Assessment of bias in conducting the systematic review

We will conduct the review according to this published protocol and report any deviations from it in the 'Differences between protocol and review' section of the systematic review.

Measures of treatment effect

We will analyse dichotomous data as risk ratios (RRs) or Peto odds ratios (ORs) when the outcome is a rare event (approximately less than 10%), and use 95% confidence intervals (CIs). We will analyse continuous outcomes by calculating the mean difference (MD) or the standardised mean difference (SMD) with a 95% CI, depending on whether the same scale is used to measure the outcome. We will enter data presented as a scale with a consistent direction of effect across studies.

When different scales are used to measure the same conceptual outcome (e.g. disability), we will calculate SMDs with corresponding 95% CIs. SMDs will be back-translated to a typical scale (e.g. 0 to 10 for pain) by multiplying the SMD by a typical among-person standard deviation (e.g. the standard deviation of the control group at baseline from the most representative trial) (Higgins 2023). For pain, we will convert scales to a common 0-to-100 scale. For function, given the variability in available scales, for the primary analysis, we will report the SMD. For continuous outcomes, we will define the magnitude of effects as small (< 10% difference on the scale, or SMD of 0.2 to < 0.5), medium (10% to 20% difference, or SMD of 0.5 to 0.8), and large (> 20% difference, or SMD > 0.8) (Higgins 2023).

For dichotomous outcomes, we will calculate the absolute per cent change from the difference in risks between the intervention and control group using GRADEpro GDT software and expressed as a percentage (GRADEpro GDT).

Unit of analysis issues

If studies include multiple exercise treatment arms (e.g. treatment arms using different exercise protocols), we will combine the arms if the results are similar. If two comparisons (e.g. exercise A versus placebo and exercise B versus placebo) are combined in the same meta-analysis, we will halve the control group to avoid double-counting. For cross-over trials, we will only use data collected prior to cross-over of the intervention.

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Dealing with missing data

We will contact the authors of the included studies to obtain missing numerical outcome data where possible. When this is not possible, and the missing data are thought to introduce serious bias, we will explore the impact of including such studies in the overall assessment of results by a sensitivity analysis.

For dichotomous outcomes (e.g. number of withdrawals due to adverse events), the withdrawal rate will be calculated 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 standard deviations from other statistics, such as standard errors, CIs, or P values, following the recommendations in Chapter 6 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2023). If standard deviations cannot be calculated, they will be imputed (e.g. from other studies in the meta-analysis).

Assessment of heterogeneity

We will assess clinical and methodological diversity in terms of participants, interventions, outcomes, and study characteristics (e.g. study design, outcome measurement tools, etc.) for the included studies to determine whether meta-analysis is appropriate. We will make this determination by observing these data in the 'Characteristics of included studies' table. We will assess statistical heterogeneity by visual inspection of the forest plot to assess the direction and magnitude of effects and the degree of overlap between CIs.

We will use the I^2 statistic to quantify inconsistency among the trials in each analysis. We will also consider the P value from the Chi^2 test. When there are few studies, we will use caution in applying the thresholds below to interpret statistical heterogeneity.

We will use this approximate guide to interpret the I^2 value (Deeks 2023):

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

We will keep in mind that the observed value of I^2 depends on: (i) magnitude and direction of effects and (ii) strength of evidence for heterogeneity (e.g. P value from the Chi^2 test, or a CI for the I^2 statistic; uncertainty in the I^2 value is substantial when the number of studies is small).

In interpreting the Chi^2 test, we will consider a P value ≤ 0.10 as indicative of statistical heterogeneity.

If we identify substantial heterogeneity, we will report it and investigate possible causes by following the recommendations in Section 10.10 of the *Cochrane Handbook* (Deeks 2023).

Assessment of reporting biases

We will create and examine a funnel plot to explore possible small-study biases if there are at least 10 studies in a meta-analysis. In interpreting funnel plots, we will examine the different possible reasons for funnel plot asymmetry as outlined in Chapter 13 of the *Cochrane Handbook for Systematic Reviews of Interventions* and relate this to the results of the review (Page 2023). If we are able to pool more than 10 trials, we will undertake formal statistical tests to investigate funnel plot asymmetry (Egger 1997), following the recommendations in Section 13.3 of the *Cochrane Handbook* (Page 2023).

To assess outcome reporting bias, we will check trial protocols against published reports. For studies published after 1 July 2005, we will screen ClinicalTrials.gov and WHO ICTRP trial registers for the a priori trial protocol. We will evaluate whether selective reporting of outcomes is present.

Data synthesis

Our primary comparison will be exercise therapy versus placebo/sham/attention control.

Our secondary comparison will be exercise therapy versus no treatment.

We will undertake meta-analysis only if the treatments, participants, and underlying clinical questions are similar enough for pooling to make sense. We will use a random-effects model and perform a sensitivity analysis with a fixed-effect model. Our primary analysis will include all trials regardless of their risk of bias.

Subgroup analysis and investigation of heterogeneity

We plan to carry out the following subgroup analyses for pain and function:

- age;
- duration of symptoms.

The age groups will be prepubertal (6 to 10), adolescents (11 to 16), and young adults (16 to 18). The cut-off rationale is based on different periods of growth and bone maturity. This is also related to different periods of life when psychosocial factors intervene differently. There are also different capacities for performing exercises at different ages.

Regarding the duration of symptoms, we expect a different impact on outcome depending on the duration of symptoms. We have therefore defined four subgroups: acute pain lasting less than 6 weeks, subacute pain between 6 and 12 weeks, chronic pain lasting more than 12 weeks, and recurrent (two episodes in a year, lasting more than 24 hours, with more than 30 days pain-free in between).

If sufficient detail is available, we will perform a subgroup analysis based on the different kinds of exercise tested (e.g. core strengthening, Pilates, general strengthening exercises, aerobic exercise, mixed exercises).

We will use the formal test for subgroup interactions in RevMan (RevMan 2024), exercising caution when interpreting the results, as advised in Chapter 10 of the *Cochrane Handbook for Systematic Reviews of Interventions* (Deeks 2023). We will compare the

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magnitude of the effects between the subgroups by assessing the overlap of the CIs of the summary estimate.

Sensitivity analysis

We plan to carry out the following sensitivity analyses to investigate the robustness of the treatment effect on pain and function, evaluating the impact of including studies with:

- high or unclear risk of selection bias;
- high or unclear risk of detection bias;
- high or unclear risk of attrition bias;
- imputed data.

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 Systematic Reviews of Interventions* for interpreting results, and will be aware of distinguishing a lack of evidence of effect from a lack of effect (Schünemann 2023; Schünemann 2023a). We will base our conclusions only on findings from the quantitative or narrative synthesis of the studies included in this review. We will avoid making recommendations for practice, and our implications for research will suggest priorities for future research and outline what the remaining uncertainties are in the area.

We will create a summary of findings table using the following outcomes at short term (up to six months).

- Pain intensity
- Back-specific functional measures
- Health-related quality of life
- Participant-reported treatment success
- Adverse events
- Withdrawals due to adverse events

The comparison in the first summary of findings table will be exercise therapy versus placebo/sham/attention control. The comparison in the second summary of findings table will be exercise therapy versus no treatment.

Two review authors (FD, SD) will independently assess the certainty of the evidence, with any disagreements resolved by discussion or by involving a third review author (FZ). 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. We will justify, document, and incorporate these judgements into the reporting of results for each outcome.

We will use GRADEpro GDT software to prepare the summary of findings tables (GRADEpro GDT). We will use version 3 of the GRADEpro view to display our summary of findings tables, which has the 'What happens' column. We will justify all decisions to downgrade the certainty of evidence for each outcome using footnotes and will make comments to aid the reader's understanding of the review where necessary.

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APPENDICES

Appendix 1. MEDLINE search

1 dorsalgia.tw

2 exp Back Pain/

3 (backache or back pain).tw

4 (lumb* adj pain).tw

5 coccyx.tw

6 coccydynia.tw

7 sciatica.tw

8 exp sciatic neuropathy/

9 spondylosis.tw

10 lumbago.tw

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11 exp low back pain/

12 or/1-11

13 (Pediatric* or paediatric* or peadiatric*).tw

14 (Child* or children or childhood).tw

15 (adolescen* or juvenile* or youth* or teen* or teen-ager* or teenager* or preteen* or pre-teen*).tw

16 exp Pediatrics/

17 exp Child/

18 exp Adolescent/

19 or/13-18

20 exp Alexander Disease/

21 exp Williams Syndrome/

22 20 or 21

23 19 not 22

24 12 or 23

25 exp Exercise/

26 exercis*.tw

27 exp Exercise Therapy/

28 exp Exercise Movement Techniques/

29 exp Physical Therapy Modalities/

30 McKenzie.tw

31 Alexander.tw

32 William.tw

33 Feldenkrais.tw

34 exp Yoga/

35 exp Recreation/

36 exp Physical Fitness/

37 (yoga or pilates).tw

38 (Tai Chi or Tai Ji or Taiji or Taijiquan).tw

39 or/25-38

40 exp randomized controlled trial/

41 controlled clinical trial.pt.

42 randomized.ab.

43 placebo.ab.

44 drug therapy.fs.

45 randomly.ab.

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46 trial.ab.

47 groups.ab.

48 or/40-47

49 exp animals/not humans.sh.

50 48 not 49

51 24 AND 39 AND 50

CONTRIBUTIONS OF AUTHORS

Conception, design, and drafting of the protocol: F Zaina, F Balagué, F Di Felice

Critical revision of the protocol for important intellectual content: M Romano, S Donzelli, S Negrini

Final approval of the protocol: all authors

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FZ, FB, FD, and SD have no known conflicts of interest.

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