Exercise-based interventions in multidisciplinary rehabilitation for reducing fear avoidance in non-specific chronic low back pain: a systematic review and meta-analysis

Konstantina Kyrou, Pavlos Bobos, Liba Sheeran

Citation

Review question
Are exercise-based interventions a beneficial addition in multidisciplinary rehabilitation for reducing fear avoidance in patients with non-specific chronic low back pain?

Searches
We will perform systematic electronic searches to identify relevant studies in MEDLINE, EMBASE, CINAHL, Web of Science, Scopus and Cochrane Library from inception to June 2019.

Types of study to be included
Only Randomized Controlled Trials (RCTs) will be included in this review.

Condition or domain being studied
Low back pain (LBP) is now the most disabling condition globally with 18% increase in years lived with disability, from 2006 to 2016. LBP is defined as pain and discomfort below the costal margin and above the inferior gluteal folds, with or without referred leg pain. The majority of LBP patients present with non-specific low back pain (the pathoanatomical cause of pain is unknown). Chronic low back pain (CLBP) has been defined as LBP that is persistent for more than 3 months or does not subside after the normal healing period. CLBP is usually experienced as recurrent episodes of LBP in primary care.

The individual’s false beliefs about their condition, defined as fear-avoidance beliefs (FABs), cause a raise in pain-related fear leading to avoidance behaviours, such as fear of movement/ (re)injury or kinesiophobia, which is described as avoiding activities, that are irrationally expected to elevate the levels of pain or constitute a potential threat of re-injury. Due to the strong association of FABs and disability, persistent elevated FABs in CLBP can reduce the treatment effect on disability outcomes, result in underperformance on functional tasks and constitute a strong prognostic factor for long-term work disability and delayed return to work.

Participants/population
Inclusion criteria: adults (>18yrs) with non-specific chronic low back pain (NSCLBP) (recurrent or persistent LBP > 12 weeks)

Exclusion criteria:
- Acute/ sub-acute LBP (<12 weeks)
- <18 years old
- spinal surgery
- specific pathoanatomical cause of LBP (e.g. any type of arthritis, spondylolysis/spondylolisthesis etc.)
- red flag pathologies (e.g. cancer, spinal fracture etc.)

Intervention(s), exposure(s)
Exercise-Based Interventions that are LBP-specific, intensive, progressive and under supervision.

**Comparator(s)/control**
Usual care defined as:

- patient advice/education,
- guidance to exercise,
- unsupervised/home-based exercise (as the main treatment),
- low key exercise
- not progressive exercise,
- exercise not specific to condition (general exercise),
- or passive treatments (manual therapy, electrophysical agents, medication).

**Context**

**Main outcome(s)**
Fear avoidance. Based on the preliminary literature review the most common outcome measures identified were the Fear-Avoidance Beliefs Questionnaire (FABQ) and the Tampa Scale of Kinesiophobia (TSK), which have both been tested for validity and reliability, revealing positive results.

* Measures of effect
Timing: short-term (3-4 months or less), midterm (6-8 months) and long term (12 months or more)

Effect Measures: To quantify and interpret our data, an improvement of a standard deviation (effect size) of 0.5 points will be used to indicate a clinically important change.

**Additional outcome(s)**
Pain intensity and disability, due to their intricate link to fear avoidance. Pain intensity will be evaluated with the Visual Analogue Scale (VAS) or the Numeric Rating Scale (NRS) and disability with the Roland-Morris Disability Questionnaire (RMDQ) or the Oswestry Disability Index (ODI), as these are widely used in the literature for CLBP.

* Measures of effect
Timing: short-term (3-4 months or less), midterm (6-8 months) and long term (12 months or more)

Effect Measures: To quantify and interpret our data, an improvement of a standard deviation (effect size) of 0.5 points will be used to indicate a clinically important change.

**Data extraction (selection and coding)**
The selection of individual studies will involve two independent reviewers (KK and PB) who will perform the systematic electronic searches in each database. The two reviewers will then identify and remove the duplicate studies and then independently screen titles and abstracts. The full text format of any study marked as included/uncertain, by either reviewer will be obtained, and inclusion/exclusion criteria will be applied to determine final study eligibility.

One independent researcher (KK) will extract the data from the eligible included studies and one other researcher (PB) will cross-check the extracted data. Data extraction will include the study/authors, year, sample characteristics, intervention/comparison groups, adverse events, compliance rates, outcomes assessed and follow up. Follow-up periods, if applicable, will also be categorized as following: short-term (3-4 months or less), midterm (6-8 months) and long term (12 months or more). When insufficient data are presented, (KK) will contact the authors by email and request further data.
Risk of bias (quality) assessment
Two independent review authors will assess the included RCTs for risk of bias using the Cochrane Risk of Bias tool and any discrepancies will be resolved through discussion, or with the arbitration of a third rater, to ensure dependability. We will summarize the assessment of risk of bias per outcome, as Low risk of bias (if low risk of bias was judged for all the seven domains); as Unclear risk of bias (if unclear risk of bias was judged for one or more of the seven domains); and, as High risk of bias (if high risk of bias was judged for one or more of the seven domains). Funnel plots will be utilized to estimate visually the potential publication bias.

The GRADE approach for systematic reviews will be used, to assess the quality of individual trials per outcome.

Strategy for data synthesis
We will utilise the Review Manager 5.3 (RevMan 5.3) software to perform our review and a random-effects model to pool outcomes (fear avoidance, disability and pain). For outcomes of the same construct that are quantified using a different metric, we will use the standardized mean difference (SMD) and reported 95% confidence intervals. If all eligible trials quantify an outcome using the same metric, we will report the weighted mean difference (WMD) along with the 95% confidence intervals.

Analysis of subgroups or subsets
In the presence of statistical heterogeneity in the meta-analyses, we plan to perform the following subgroup analyses (a priori): trials at low risk of bias (low risk of bias in randomization, allocation concealment and blinding domains) – would show a smaller effect size. An I² estimate of at least 50% along with a statistically significant ?² statistic (P = 0.10), will be used to interpret for evidence of a substantial heterogeneity. A meta-regression will be performed if more than 10 studies can be pooled to assess potential sources of heterogeneity.

Contact details for further information
Konstantina Kyrou
konstantina.kyrou@gmail.com

Organisational affiliation of the review
Cardiff University
https://www.cardiff.ac.uk/

Review team members and their organisational affiliations
Miss Konstantina Kyrou. Cardiff University
Mr Pavlos Bobos. Western University
Dr Liba Sheeran. Cardiff University

Type and method of review
Meta-analysis, Systematic review

Anticipated or actual start date
05 June 2019

Anticipated completion date
05 December 2019

Funding sources/sponsors
None.

Conflicts of interest

Language
English

Country
Wales

Stage of review
Review Ongoing

Subject index terms status
Subject indexing assigned by CRD

Subject index terms
Avoidance behaviour; Humans; Low Back Pain; Therapy, Exercise

Date of registration in PROSPERO
08 July 2019

Date of publication of this version
08 July 2019

Details of any existing review of the same topic by the same authors

Stage of review at time of this submission

<table>
<thead>
<tr>
<th>Stage</th>
<th>Started</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary searches</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Piloting of the study selection process</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Formal screening of search results against eligibility criteria</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Data extraction</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Risk of bias (quality) assessment</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Data analysis</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions
08 July 2019

This information has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. The registrant confirms that the information supplied for this submission is accurate and complete. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.