

Individual recovery expectations and prognosis of outcomes in non-specific low back pain: prognostic factor exemplar review (Protocol)

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[Prognosis Protocol]

Individual recovery expectations and prognosis of outcomes in non-specific low back pain: prognostic factor exemplar review

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

The primary objective in this review is to synthesize available evidence on the association between individual recovery expectations (including general outcome expectations, treatment expectations, and self-efficacy expectations) and disability outcomes in adults with acute, subacute or chronic non-specific low back pain (LBP). We will explore sources of heterogeneity to identify the impact of differences in participants, measurement of expectations, outcome, follow-up length and study design.

We will use internationally-accepted standards for systematic reviews while taking advantage of the opportunity to test methods of two important steps of prognostic reviews, the literature search, and 'Risk of bias' assessment, to inform future syntheses.

BACKGROUND

Low back pain (LBP) is one of the most common health conditions, and has high and increasing socioeconomic impact (Freburger 2009; Hoy 2010; Lim 2012). In the general population, the one month prevalence of LBP has been estimated to be 23% (Hoy 2012) and LBP was identified in the most recent Global Burden of Disease study as the leading cause of disability globally (Buchbinder 2013). There is evidence that the prevalence and associated costs of LBP are rising (Freburger 2009).

Description of the condition

Researchers define LBP as pain on the posterior aspect of the body from the lower margin of the twelfth ribs to the lower gluteal folds, with or without pain referred to the leg(s) that is severe enough to limit usual activities for more than one day (Dionne 2008). Most patients who experience LBP have 'non-specific LBP', a diagnosis of exclusion that includes heterogeneous presentation and symptoms not attributed to a recognizable, known specific pathology (for example, fracture, rheumatoid arthritis, infection, neoplasm, or metastasis).

The majority of the social and economic costs associated with LBP are attributed to a small number of patients who have prolonged disability and require increased use of health services and time off work (Freburger 2009; Hayden 2010). For patients presenting to healthcare providers with LBP, most individuals experiencing a new episode of LBP recover within a few weeks although a quarter to a third continue to report LBP after 12 months (Hayden 2010). Recurrences are common and individuals who develop chronic, longstanding LBP tend to show a more persistent course (Hayden 2010); studies of chronic LBP indicate that 42% to 75% from general populations (Hestbaek 2003), and 60% to 80% from healthcare consulting populations (Hayden 2010) will continue to have LBP after one year.

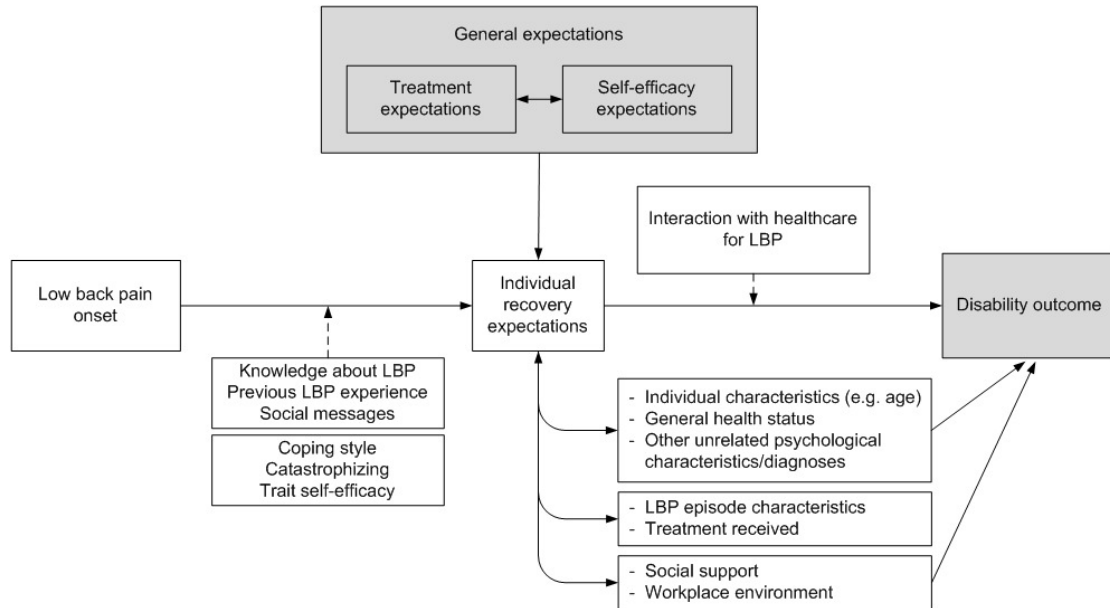
Consideration of prognosis and important prognostic factors is important in LBP, as it has not been possible to identify a specific cause for most cases of LBP, and interventions with strong evidence of effectiveness have not been identified. Research studies have found many factors to be associated with poor outcome in LBP, often with conflicting results (Hayden 2007). A recent 'review of reviews' found that several factors were consistently reported to be associated with poor outcome, including factors related to the back pain episode (baseline disability, sciatica), individual characteristics (older age, poor general health) and psychological characteristics (increased stress, negative cognitive characteristics), as well as the work and social environments (poor relations with colleagues, heavy physical demands, receipt of compensation) (Hayden 2009). However, there is still substantial inconsistency in findings reported across LBP studies. High quality evidence about prognostic factors associated with outcomes can improve management of LBP by: helping healthcare providers and patients understand likely prognosis; informing treatment decisions; informing the development/refinement of outcome prediction models to identify subgroups of LBP patients; and potentially influencing the development of new treatment strategies consid-

ering modifiable prognostic factors (Riley 2013).

Description of the prognostic factor

This exemplar review will explore individual recovery expectations, an understandable, potentially modifiable prognostic factor that has shown promise in existing LBP prognostic factor reviews (Fadyl 2008; Iles 2008; Iles 2009). Recovery expectations are what the individual 'expects will occur' in the future with respect to their health condition. We refer to the Social Cognitive Theory (Bandura 1977; Bandura 2004) to develop a theoretical framework to guide our assessment of evidence about individual recovery expectations. In this model, individual recovery expectations involve cognitive processing and may be informed by past personal experience, knowledge and beliefs, and suggestions from or observations of other people. We will consider three types of related individual recovery expectations relevant to the LBP field: general outcome expectations, treatment expectations, and self-efficacy expectations. General outcome expectations are broadly defined recovery expectations, related to a future LBP outcome; an example of a single item question would be, "I expect to return to work within six months", or "My low back pain will last a short time". Treatment expectations are expectations of future LBP outcome specifically related to ongoing treatment; for example, "My treatment will help improve my LBP", or "My treatment can prevent my back pain from getting worse". Self-efficacy expectations are a person's perceptions concerning their ability to execute behaviors to achieve a future outcome; for example, "I believe that I will be able to do my usual work activities to return to my job", or "I am confident that I will be able to learn to cope with the pain and get back to my normal activities". Figure 1 presents a conceptual framework of the relationship between individual recovery expectations and LBP outcomes.

Figure 1. Conceptual framework of the relationship between individual recovery expectations and low back pain (LBP) disability outcomes.



How the prognostic factor may be related to health outcomes

Individual recovery expectations may be related to LBP outcomes through several potential pathways; these include modifying individual coping behaviors, withdrawal related to fear of pain or low mood, or by influencing treatment compliance or healthcare seeking. In the Social Cognitive Theory, Bandura proposed that self-efficacy expectations can modify individual behaviors by determining the amount of effort that a patient will exert to cope with their health condition (Bandura 1977; Bandura 2004). Following the fear-avoidance model (Vlaeyen 2000), processes related to the fear of pain may lead to avoiding movements and activities based on fear, hypervigilance to illness information, muscular reactivity, and disuse/deconditioning, all potentially leading to worse health outcomes (Price 1999). Furthermore, individual recovery expectations may be associated with changes to treatment received due to modified compliance, overuse, or non-compliance with medications and advice, or changes in health consulting behaviors, which may influence health outcomes.

Alternatively, individual recovery expectations, which are influenced by what people know about themselves and their circumstances, may reflect, at least in part, a realistic evaluation of the patient's likely prognosis. This would mean that attempts to modify individual recovery expectations may constitute false reassurance and, at best, have no impact on outcomes.

Why it is important to do this review

Numerous primary studies using various study design phases and research methods have investigated the relationship between individual recovery expectations and LBP outcomes. Several studies' results suggest an association between recovery expectations and LBP outcomes. Kapoor and colleagues (Kapoor 2006) reported that there was a medium to large effect size between negative patient expectations and return to work outcomes in an acute LBP population. Other researchers have observed similar relationships between individual recovery expectations and return to work outcomes in chronic LBP populations (for example, Hagen 2005; Reme 2009; Sandstrom 1986; Schultz 2005). However, some studies have reported weak or no relationships between recovery expectations and return to work outcomes (for example, Dozois 1995; Gross 2005; Schultz 2002). Gross and colleagues (Gross 2005) found no significant association between work-related recovery expectations and working status at one year follow-up in a sample with subacute occupational LBP.

Three existing focused systematic reviews have synthesized evidence about recovery expectations (Fadyl 2008; Hallegraeff 2012; Iles 2009). Fadyl 2008 reviewed the literature and included 10 studies that investigated how expectations relate to return to work outcomes after injuries (including, but not limited to, LBP). These authors reported that evidence is limited and they recommended further investigation. Hallegraeff and colleagues (Hallegraeff 2012) conducted a review to assess whether negative

expectations in patients with acute LBP resulted in increased odds of being off work. Ten studies were included and synthesized; the authors of this review concluded that the odds of not returning to work were two times greater for patients with negative recovery expectations. Iles and colleagues (Iles 2009) aimed to determine the predictive strength of negative recovery expectations for the outcome 'activity limitations' in people with acute or subacute non-specific LBP. The review included 10 studies and reported that recovery expectations measured within the first 3 weeks of LBP onset are strong predictors of activity limitations. The literature searches of these reviews are now out of date. We have also identified potential limitations with their methods, including reliance on search terms focused on recovery expectations. Use of a more comprehensive search strategy will identify additional studies missed by these previous focused searches and will be more likely to identify studies reporting no effect. We have conducted a comprehensive scoping review using various strategies, including searches of broad LBP prognosis reviews (Chou 2010; Hayden 2007; Heitz 2009), and citation searches of existing expectation measurement tools (Levin 1996; Nicholas 2007; Smeets 2008) and have identified more than 35 prospective cohort studies that would likely be included in this review. The three existing focused systematic reviews on the topic (Fadyl 2008; Hallegraef 2012; Iles 2009) each include less than 30% of these potentially-eligible studies.

Furthermore, existing reviews about recovery expectations have not explored the impact of different types or measures of expectations, different populations (setting and/or duration of symptoms), or different outcomes (pain, functional limitations, return to work). These factors may explain some inconsistencies of results reported in the literature.

Importance of evidence about prognostic factors

Identifying prognostic factors that are associated with worse or better outcomes can help us to understand the course of health conditions, and associated factors, and inform future research into potential mechanisms of effect. Understanding the relationship of a prognostic factor with future outcomes can help to define the health condition at its onset, either directly or incorporated into outcome prediction models for risk prediction (Riley 2013); this information can be used to inform patients and clinicians of the likely outcome, and can help guide informed care decision making (Steyerberg 2013).

Systematically synthesized evidence specifically about the association of individual recovery expectations and LBP outcomes will help inform management of LBP and will guide future LBP research; this research is in line with recent calls for further exploration of the mechanisms of chronic pain as the next stage in clinical trial research (Morley 2013). Understanding the strength and consistency of the relationship between recovery expectations and LBP outcome could lead to improved understanding of overall prognosis of LBP, which will aid patient communication. If re-

covery expectations are found to be strongly associated with LBP outcomes, this could lead to refinement of LBP outcome prediction models/tools (for example, the STarTBack tool (Hill 2008)) to include this factor, further improving LBP subgrouping and treatment matching. Future studies may be appropriate to test the interaction effect between individual recovery expectations and outcomes with specific types of treatments. Finally, there is a belief among many back pain stakeholders that expectations are potentially modifiable (Guzman 2007), and that positive expectations should be encouraged (for example Workers' Compensation Boards and practice guidelines). If recovery expectations are found to be associated with LBP health outcomes, future studies should investigate the effectiveness of interventions to improve patient expectations.

OBJECTIVES

The primary objective in this review is to synthesize available evidence on the association between individual recovery expectations (including general outcome expectations, treatment expectations, and self-efficacy expectations) and disability outcomes in adults with acute, subacute or chronic non-specific low back pain (LBP). We will explore sources of heterogeneity to identify the impact of differences in participants, measurement of expectations, outcome, follow-up length and study design.

We will use internationally-accepted standards for systematic reviews while taking advantage of the opportunity to test methods of two important steps of prognostic reviews, the literature search, and 'Risk of bias' assessment, to inform future syntheses.

METHODS

This review will be conducted within the framework of the Cochrane Back Review Group (Furlan 2009) and reported according to PRISMA guidelines (Moher 2009), while supplemented as necessary for a prognostic factor systematic review. Similar to systematic reviews of intervention studies, there are six key steps to prognosis reviews: 1. defining the review question, 2. identifying studies, 3. selecting studies, 4. critically appraising studies, 5. collecting data, and 6. synthesizing and interpreting results. Each of these steps will be considered and best methods used to limit potential biases.

We will conduct a focused systematic review (as opposed to a broad review that investigates evidence on many prognostic factors) to facilitate the most complete assessment and interpretation of the evidence available (Hayden 2009).

Criteria for considering studies for this review

Our review question will include prognostic study evidence with the definitions of participants (LBP), prognostic factor (individual recovery expectations), outcomes, and study design described below.

Types of study designs

We will include published reports of prospective and retrospective longitudinal studies investigating the prognosis of LBP with baseline measurement and at least three months' follow-up. We will separately consider phases of prognostic factor investigation: Phase 1 (exploratory), and Phase 2 (confirmatory) studies, which provide different levels of evidence (Hayden 2008). Exploratory studies identify associations of many potential prognostic factors and outcomes. While these studies are necessary to identify new prognostic factors, they provide the least conclusive information regarding the independence of a variable as a valid prognostic factor. Studies in this exploratory phase of investigation often have widely varying results, as spurious associations are common due to the high number of factors explored, and studies may overstate their conclusions (Hayden 2008). Confirmatory studies test the independence of the association between a prognostic factor and the outcome of interest. These studies aim to measure the independent effect of a prognostic factor while controlling for confounders. We will classify included studies according to the authors' objectives and approach to design and analysis, and will consider the phase of investigation of studies in our assessment of the strength of the evidence available.

Types of participants - defining LBP

We will include studies involving any population of adult participants with non-specific LBP, including general populations, occupational, and non-surgical clinical populations. Studies will be included if they investigate mixed pain populations (including conditions other than LBP, such as thoracic or neck pain) only if the majority (>75%) of the population is experiencing non-specific LBP, or subgroup information is presented for this population. We will exclude studies that involve a majority of individuals with LBP caused by specific pathologies (including nerve root impingement, fracture, ankylosing spondylitis, spondyloarthritis, infection, neoplasm, or metastasis), or specific conditions (for example, pregnancy). The operationalization of LBP will be based on symptoms, signs, or consequences of LBP such as sick leave, medical consultation, or treatment.

We will include studies with participants at any point in the course of LBP. If feasible, we will separately consider general, worker, and healthcare source populations and explore subgroup analyses with acute (< 6 weeks), subacute (6 to 12 weeks) and chronic (> 12 weeks) LBP populations. We will use sensitivity analysis to

explore the robustness of results excluding studies with mixed pain or specific LBP populations.

Types of prognostic factors - defining individual recovery expectations

We will include studies that assess individual participant recovery expectations at baseline or an early point in patient management (i.e. at initial consultation). We define individual recovery expectations as 'what participants expect will occur with respect to their LBP condition'. Included measures of recovery expectations should capture two things: 1. individual participant cognition (for example beliefs, perceptions, anticipations, expectations), and 2. related to a future outcome (for example pain, functional limitations, return to work). We will separately consider evidence on general recovery expectations, treatment outcome expectations, and self-efficacy expectations, if possible. We will exclude current state or trait type of self-efficacy measures, and expectations from outside perspectives (for example, healthcare provider expectations), as well as measures of expected 'process of care' if they do not refer to a future primary outcome of interest. Studies investigating treatment expectations will be included if the variable is assessed as a prognostic factor. In this review we will not include studies reporting only treatment effect modification data.

We will include individual recovery expectations assessed using any measurement approach: one-dimensional measurement of expectations, for example, "Do you expect that you will be recovered in 6 months?", and more complex measurements, for example, using multi-dimensional validated measurement tools such as the Credibility/Expectancy Questionnaire (Smeets 2008), the Back Pain Self-Efficacy Scale (Levin 1996), the Revised Illness Perception Questionnaire (Moss-Morris 2002), or the Pain Self-Efficacy Questionnaire (Nicholas 2007). We will use subgroup and sensitivity analyses to explore the impact of different and more robust measurement approaches.

Types of primary outcome measures

We will include the following primary outcomes according to the International Classification of Functioning, Disability and Health (ICF) framework (WHO 2002):

- Body function - Pain intensity, measured by a visual analogue scale (VAS) or other pain scale (for example, numerical rating scale (NRS), or McGill pain score)
- Activity limitation - Functional status, measured by a LBP-specific scale (for example, the Roland-Morris Disability Questionnaire (RMDQ), or the Oswestry Disability Index (ODI))
- Participation restriction - Work participation, measured as return to work, absenteeism, or time on benefits (Steenstra 2012).

We will record study reported associations of individual recovery expectations with outcomes analyzed using continuous measures (for example, pain VAS on a 100 point-scale, or RMDQ on a 24-point scale), and also (if available) with the measure dichotomized to reflect improvement at the described time points. We will accept any study-defined definition of improvement, however will separately consider evidence using our ideal definition of 'improvement' as clinically important individual patient response where improvement in score is $\geq 30\%$ of its baseline value, with a minimum value of 20-point (/100) in pain and 10-point (/100) in functioning (Kovacs 2007; Ostelo 2008). Study authors will be contacted for missing data.

We will group outcome data into three time periods for analysis purposes: short-term (closest to 3 months), medium-term (closest to 6 months), and long-term follow-up (12 months or more).

Types of secondary outcome measures

We will compile results narratively for the following secondary outcomes, when available:

- Global improvement or perceived recovery
- Health-related quality of life (for example SF-36 (as measured by the general health sub-scale), EuroQol, general health (for example, as measured on a VAS scale) or similarly validated index)
 - Satisfaction with treatment
 - Mood (for example, depression, measured with the Center for Epidemiologic Studies Depression Scale (CES-D))
 - Healthcare utilization, including costs.

Search methods for identification of studies

The search strategy will include electronic searches and additional strategies to retrieve as many relevant publications as possible. Overlapping electronic searches will be used to allow testing of search strategies, as described below.

Electronic searches

Focused and broad electronic searches will be conducted with the help of an experienced library scientist using indexed terms and free text words, with no date or language restrictions, in the following databases: MEDLINE, EMBASE, PsycINFO, and CINAHL. Our focused strategy, the typical approach to searching adopted in published prognostic factor reviews, will include terms related to LBP (Cochrane Back Review Group recommended strategy) (Furlan 2009), expectations, and prognostic study methods ('broad' prognosis strategy of Wilczynski 2004); see Appendix 1 for the full focused MEDLINE strategy.

We previously observed in a 'review of reviews' on LBP prognosis, the possible introduction of 'positive study' bias in review search strategies that include prognostic factor terms (Hayden 2009).

Therefore we will also include a broad search that takes advantage of previously conducted searches (Hayden 2007). This search strategy includes terms related to LBP and prognostic study methods, without focused terms related to expectations (Appendix 2).

Searching other resources

Recognizing potential limitations of electronic search strategies, we will supplement our search to identify potentially relevant studies from other sources:

1. Reference searches of relevant reviews will be conducted, including previously published systematic reviews of expectations and LBP or musculoskeletal pain (Fadyl 2008; Hallegraeff 2012; Iles 2009; Parsons 2007), and identified broad systematic reviews of LBP prognostic factors (for example, Haskins 2012; Hendrick 2011; Ramond 2011).

2. Citation searches of relevant recovery expectation measurement tools (Deville 2000; Levin 1996; Lim 2007; Metcalfe 2005; Nicholas 2007; Sarda 2007; Smeets 2008; Tate 1999).

3. Review of personal files of investigators, which includes authors of previous focused reviews of expectations (Iles 2009; Parsons 2007), and broad reviews of LBP prognostic factors (Hayden 2007; Iles 2008).

The comprehensive search will be executed and downloaded into EndNote X4 for electronic bibliographic management. Source(s) for all identified citations will be recorded and duplicates removed. Retrieved citations will be cross-referenced with results of earlier searches relevant to this review (for example, a broad electronic search spanning 1966 to November 2003 (Hayden 2007) to avoid unnecessary duplication of screening work.

Testing prognostic factor search strategies

A secondary goal of this prognosis exemplar project is to conduct methodological investigations of prognostic factor systematic reviews, and to provide guidance for future prognosis reviews. We will explore prognostic factor systematic review search strategies by testing the sensitivity, specificity, and precision of different search strategy approaches, including broad and focused electronic searches using different combinations of prognosis terms, reference searches, and citation searches, by comparing to a 'gold standard' comprehensive search. Complete methods and results of methodological investigations will be reported separately.

Data collection and analysis

Selection of studies

We will use an online electronic systematic review software package (Distiller SR, Ottawa, ON) to organize and track the selection process. Initial screening of titles identified through electronic

searches will be conducted with a single review author removing clearly irrelevant articles (i.e. those not relevant to non-specific low back or other musculoskeletal pain). Subsequently, titles and abstracts of citations will be independently screened for relevance by two authors using a pre-tested electronic form (see Figure 2). We will advance studies if they comprehensively investigate prognostic factors or predictive models associated with any one of our primary outcome measures in a non-specific LBP population or

subgroup. Disagreements will be resolved by consensus. All articles deemed to be relevant, or whose relevance cannot be determined from the abstract, will be retrieved in full. At the full article screening stage, we will include prognostic studies that investigate individual recovery expectations and their association with at least one of our primary outcomes of interest. Relevance will be confirmed independently by two authors, with consensus and discussion with a third author if necessary.

Figure 2. Preliminary study selection data form; screen shot in DistillerSR software (Note: included abstract is for a 'dummy' citation).

DistillerSR

Project: Expectations LBP User: jill.hayden (My Settings)

Messages: Nothing new

Live Support: Currently Unavailable User Guide

Review | Datarama | Reports | References | Forms | Manage Levels | Users | Project | Logout

Refid: 12, Skateboards: Are they really perilous? A retrospective study from a district hospital.
Rethnam U, Yesupalan RS, Sinha A.

BACKGROUND: Skateboarding has been a popular sport among teenagers even with its attendant associated risks. The literature is packed with articles regarding the perils of skateboards. Is the skateboard as dangerous as has been portrayed?

METHODS: This was a retrospective study conducted over a 5 year period. All skateboard related injuries seen in the Orthopaedic unit were identified and data collated on patient demographics, mechanism & location of injury, annual incidence, type of injury, treatment needed including hospitalisation.

RESULTS: We encountered 50 patients with skateboard related injuries. Most patients were males and under the age of 15. The annual incidence has remained low at about 10. The upper limb was predominantly involved with most injuries being fractures. Most injuries occurred during summer. The commonest treatment modality was plaster immobilisation. The distal radius was the commonest bone to be fractured. There were no head & neck injuries, open fractures or injuries requiring surgical intervention.

CONCLUSION: Despite its negative image among the medical fraternity, the skateboard does not appear to be a dangerous sport with a low incidence and injuries encountered being not severe. Skateboarding should be restricted to supervised skateboard parks and skateboarders should wear protective gear. These measures would reduce the number of skateboarders injured in motor vehicle collisions, reduce the personal injuries among skateboarders, and reduce the number of pedestrians injured in collisions with skateboarders.

[Submit Form](#) and go to or [Skip to Next](#)

- Is the paper a full-text peer-reviewed publication, and not an abstract/thesis/summary or commentary?
 - Yes
 - No
 - Unsure
 - [Clear Response](#)
- Does the study population represent adults with non-specific low back pain, or a subgroup analysis for this population is presented?
 - Yes
 - No
 - Unsure
 - [Clear Response](#)
- Does the study assess the relationship between expectations and low back pain outcome?
 - Yes
 - No
 - Unsure
 - [Clear Response](#)
- Is at least one of the following outcomes assessed: pain, functional limitations, participation restriction (e.g. time off work, return to work)?
 - Yes
 - No
 - Unsure
 - [Clear Response](#)
- Is there at least 3 months between the measurement of the prognostic factor of interest (expectations) and low back pain outcome? (longitudinal study - prospective or retrospective; cross-sectional studies are excluded)
 - Yes
 - No
 - Unsure
 - [Clear Response](#)
- Additional notes:

Data extraction and management

We will extract data and reach consensus using electronic MS Access extraction forms, modified from an existing LBP systematic review data extraction database. We will extract participant characteristics (population source and setting, inclusion criteria, and duration of LBP episode at baseline), prognostic factor(s) (the individual recovery expectations constructs as described above, including measurement approach, timing of measurement, prevalence of positive/negative expectations), outcomes (measures assessed and the incidence of poor outcome), study design, follow-up length, and all unadjusted (simple) and adjusted (multivariable) associations reported between the prognostic factor and outcomes, with details on any adjustment factors that are used. We will extract incidence of disability outcomes for each study population overall, if available, or for the group defined as having good/high recovery expectations at available follow-up points, to allow comparison across populations and outcome measures; if survival curves are provided we will extract information from digital reproductions of each curve plotted using a minimum of 25 data points.

If multiple measures of individual recovery expectations are assessed in a single study, we will extract information about all measures and associations with outcomes. For primary analyses, we will choose the 'best' measurement based on evidence of validity and reliability. Examples of reliable and valid measurement of recovery expectations include the Revised Illness Perception Questionnaire to address recovery expectations (Timeline acute/chronic subscale) and treatment expectations (Treatment control subscale) (Moss-Morris 2002); and the Credibility/Expectancy Questionnaire (Smeets 2008).

The data extraction database has been created by a database development expert to ensure appropriateness and ease of use for the current and future prognosis reviews. The electronic data extraction forms have been tested and modified a priori, using studies included in existing systematic reviews focused on recovery expectations and LBP outcomes. One independent review author will extract information and a second author will check all data extracted. A consensus method will be used and a third author consulted if there are disagreements.

Assessment of risk of bias of included studies

Included studies will be critically appraised by two independent review authors using a standardized approach. In the case of discrepancies, authors will attempt to reach consensus; if necessary a third author will resolve any disagreements. The review authors will not be blinded to study authors, institution, or journal of publication due to feasibility.

We will assess each study's risk of bias using an approach based on the QUIPS tool (Hayden 2013), appropriate for prognostic factor review questions. This approach has been recommended by the Cochrane Prognosis Methods Group, used in several reviews

(Jimenez 2009; Johnson 2008; Moolaert 2009), and has acceptable inter-rater reliability. We will assess each study's risk of bias considering six domains: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding, and statistical analysis and reporting (Appendix 3 presents a copy of the QUIPS tool modified for this review; see Hayden 2013 for full presentation and description of the generic tool). We describe each of the six domains, paraphrased from Hayden 2013, in Appendix 4.

For each of the six domains, responses to the prompting items will be assessed together (while considering missing or poorly reported information) to inform the 'Risk of bias' judgment. We will record information and methodological comments supporting the item assessment, cited directly from the study publication. We will then judge using the QUIPS tool, as recommended, by rating each domain as having high, moderate, or low risk of bias. We will also judge overall study validity by defining studies with a low risk of bias as those in which all of the six bias domains are rated as having low risk of bias; sensitivity analysis will use ratings of low or moderate risk of bias for all domains (Hayden 2013). We will use subgroup analyses to explore the impact of biases on the observed size and direction of effect across the six risk of bias domains, and overall for studies with high and low risk of bias.

A secondary objective of this prognosis exemplar project is to conduct methodological investigations of prognostic factor systematic reviews, and to provide guidance for future prognosis reviews. Further testing of the QUIPS 'Risk of bias' tool for prognostic factor studies will include reliability testing between individual raters and between consensus agreements of teams of raters. We will assess the validity of the tool by examining the association between study and domain 'Risk of bias' ratings and prognostic factor effect size. Complete methods and results of methodological investigations will be reported separately.

Measures of association

We will extract all unadjusted and adjusted measures of association from included studies and convert effect sizes, as necessary, to avoid possible selection bias by allowing us to use data from as many studies as possible. Odds ratios (ORs) will be used as the common measure of the relationship between individual recovery expectations and disability. Relative risks and hazard ratios will be used to estimate ORs (Symons 2002) and we will convert standardized regression coefficients for continuous outcomes to log ORs for synthesis (Peterson 2005; Borenstein 2009). When available, we will separately extract and analyze hazard ratios for studies providing this measure of association.

For consistency, we will re-calculate associations to be in the same direction, as necessary, with associations above 1 indicating worse prognosis. We will calculate standard errors (SE) from confidence intervals and appropriately transform the individual study associations and SE to their natural logarithms to normalize their distri-

butions. When data are available, adequately adjusted (multivariable) associations between expectations and LBP outcomes will be synthesized separately from unadjusted (univariable) associations. We will contact study authors for missing or unusable data, as necessary.

Unit of analysis issues

Data for studies included in this review will have been collected and analyzed for association with LBP outcomes at the individual participant level. Some studies may present data stratified for specific characteristics, creating independent subgroups (for example, for males and females). If relevant for our analyses to combine effect measures for subgroups within a study, we will calculate a composite score for the study following the methods of [Borenstein 2009](#) by performing a fixed effects meta-analysis of within-study subgroups.

Some relevant characteristics may be reported only at the study level (for example, the study includes only participants with a new, acute episode of LBP, or is restricted to a primary healthcare population). Future individual participant data (IPD) meta-analyses (to be considered outside of the scope of this project) will allow standardization of analyses across studies and directly derive the information desired, independent of how it was reported.

Dealing with missing data

We will include studies that investigate the relationship between individual recovery expectations and LBP outcomes even if there are missing data or limited evidence is provided about the size of the effect (for example if the factor is mentioned only as being 'non-significant' in the analyses). We will contact study authors for clarification and to attempt to retrieve any missing information.

Assessment of heterogeneity

We will consider the clinical heterogeneity of included studies based on the population, measure of individual recovery expectations, outcome measurement, and methodological heterogeneity due to study design/potential biases. We will synthesize associations within these clinically-relevant subgroups. To assess statistical heterogeneity across studies included in all syntheses, we will inspect forest plots and quantify heterogeneity using the I^2 statistic and Tau^2 (the estimate of between-study variance).

Reporting bias

Publication bias will be examined for each meta-analysis containing 10 or more studies by visually examining asymmetry on funnel plots and testing for asymmetry at the 10% level, using Egger's test for hazard ratios, and Peters' test for ORs ([Sterne 2011](#)).

Data synthesis

We expect that most studies will measure and present data about individual recovery expectations and their association with LBP disability outcomes with the independent and dependent variables analyzed as dichotomous variables (good or poor recovery expectations; return to work or no return to work at follow-up points). For studies that present data about individual recovery expectations using continuous or categorical measures, analyses will be conducted on the same scale. We will group studies with similar cut-points together, to obtain meta-analysis results for each cut-point as far as possible. To allow combination of as much data as possible, dichotomous associations will be computed from data in the study reports or provided by the study authors on request for studies that present continuous and categorical measures of association. We will explore the impact of data transformations using sensitivity analyses.

Meta-analyses will be conducted if valid data are available assessing associations between individual recovery expectations and an outcome of interest for three or more studies from sufficiently homogeneous subgroups of studies. We will define sufficiently homogeneous subgroups according to population (acute (< 6 weeks), and subacute/chronic (> 6 weeks)), measures of individual recovery expectations (general recovery expectations, treatment outcome expectations, and self-efficacy expectations), and outcome measurement (pain, functional limitations, return to work). We will conduct separate meta-analyses of ORs (at similar follow-up points) and hazard ratios, and unadjusted and adequately adjusted results. We will conduct a meta-regression analysis if there are more than 10 studies providing sufficient data.

Meta-analyses will be conducted using Review Manager (RevMan version 5.3, the Cochrane Collaboration) with a random-effects generic inverse variance meta-analysis model, which accounts for any between-study heterogeneity in the prognostic effect. Such heterogeneity is common in prognostic factor studies. The meta-analysis will be summarized by the pooled estimate (the average prognostic factor effect), its 95% CI, the estimate of Tau^2 (between-study variance), and a 95% prediction interval for the prognostic effect in a single population ([Riley 2011](#)).

Clinical importance of observed associations will be defined, for binary factors, based on effect size as small ($\text{OR} < 1.5$), moderate ($1.5 \leq \text{OR} \leq 2$), or large ($\text{OR} > 2$) (modified from [Hartvigsen 2004](#) and [Hemingway 1999](#)). We will consider differences to be statistically significant at the 5% level.

If it is not appropriate to combine results using meta-analysis (for example if there is a small number of studies with available data and/or if the heterogeneity would make summary results difficult to interpret), the results will be presented qualitatively, considering the strength and consistency of results using the following schema:

1. **Strong evidence of effect:** Consistent findings (defined as > 75% of studies showing the same direction of effect) in multiple low risk of bias studies
2. **Moderate evidence of effect:** Consistent findings in

multiple high risk of bias and/or one study with low risk of bias

3. **Limited evidence of effect:** One study available

4. **Conflicting evidence:** Inconsistent findings across studies

5. **No evidence:** No association between patient expectations and the outcome of interest.

We will use an approach modified from the GRADE framework (Guyatt 2011) to assess the overall quality of evidence regarding the relationship between individual recovery expectations and LBP outcomes (Huguet 2013). We will judge and report the overall quality of evidence for our primary outcomes using a modified GRADE approach that was previously used in another prognostic factor review (Huguet 2013). We will rate the overall strength of evidence as 'high', 'moderate', 'low' or 'very low' considering phase of investigation, internal validity, size and precision of effect, heterogeneity, generalizability, and potential reporting bias. See Appendix 5 for a guide on assessing the overall quality of evidence, reproduced from Huguet 2013.

Subgroup and sensitivity analyses

We will use sensitivity analyses to explore the impact of our judgment of study risk of bias, alternatively including studies rated as low or moderate risk of bias for all domains to indicate overall low risk of bias. Sensitivity analyses will also explore the impact on the effect size and direction for studies including only LBP

populations versus studies including a small proportion of mixed pain populations, surgical candidates or individuals with lumbar disc herniation.

Subgroup analyses will explore the differences in effect size for different participants, prognostic factor measures, outcomes, follow-up length, and study designs. If feasible, we will separately consider general, worker, and healthcare source populations. We will use subgroup analyses to explore the impact of types and measurement approaches for assessing expectations and will group outcome data into 3 time periods for analysis purposes: short-term (closest to 3 months), medium-term (closest to 6 months), and long-term follow-up (12 months or more). We will separately consider evidence from different phases of prognostic factor investigation: Phase 1 (exploratory), and Phase 2 (confirmatory) studies, and explore the association of recovery expectations and LBP outcomes for studies judged to have low and high risk of bias (by each domain, and overall).

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- * Indicates the major publication for the study

APPENDICES

Appendix I. Initial MEDLINE and EMBASE search strategy and resulting citations for focused search using population ('back pain'), exposure ('expectations'), and study design ('prognosis') terms

Searches developed by Rachel Couban, Trials Search Coordinator, Cochrane Back Review Group

Database: MEDLINE (Ovid)

- 1 dorsalgia.ti,ab.
- 2 exp Back Pain/
- 3 backache.ti,ab.
- 4 exp Low Back Pain/
- 5 (lumbar adj pain).ti,ab.
- 6 coccyx.ti,ab.
- 7 coccydynia.ti,ab.

8 sciatica.ti,ab.
 9 sciatic neuropathy/
 10 spondylosis.ti,ab.
 11 lumbago.ti,ab.
 12 back disorder\$.ti,ab.
 13 or/1-12
 14 Cohort Studies/
 15 incidence.tw.
 16 Mortality/
 17 Follow-Up Studies/
 18 prognos\$.tw.
 19 predict\$.tw.
 20 course.tw.
 21 Survival Analysis/
 22 or/14-21
 23 expectancy.mp.
 24 expectation*.mp.
 25 exp Attitude to Health/
 26 Health Knowledge, Attitudes, Practice/
 27 self efficacy/
 28 self efficacy.mp.
 29 illness beliefs.mp.
 30 ((disab* or self* or injur*) adj3 percept*).mp.
 31 expectation\$.mp.
 32 (outcome adj3 expect*).mp.
 33 (questionnaire* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelihood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
 34 (recovery* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelehood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
 35 (measure* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelihood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
 36 or/23-35
 37 13 and 22 and 36

Database: EMBASE (Ovid)

1 dorsalgia.mp.
 2 back pain.mp.
 3 exp LOW BACK PAIN/
 4 exp BACKACHE/
 5 (lumbar adj pain).mp.
 6 coccyx.mp.
 7 coccydynia.mp.
 8 sciatica.mp.
 9 exp ISCHIALGIA/
 10 spondylosis.mp.
 11 lumbago.mp.
 12 back disorder\$.ti,ab.
 13 or/1-12
 14 cohort analysis/
 15 incidence/
 16 mortality/
 17 follow up/

- 18 survival/
- 19 prognosis/
- 20 prediction/
- 21 disease course/
- 22 or/14-21
- 23 expectancy/
- 24 expectancy.mp.
- 25 expectation*.mp.
- 26 attitude to health/
- 27 attitude to disability/
- 28 attitude to illness/
- 29 self concept/
- 30 self efficacy.mp.
- 31 health belief/
- 32 illness belief*.mp.
- 33 ((disab* or self* or injur*) adj3 percept*).mp.
- 34 (outcome adj3 expect*).mp.
- 35 (questionnaire* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelihood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
- 36 (recovery* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelihood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
- 37 (measure* adj3 (belief* or hope* or perceive* or expect* or desire* or percept* or likelihood or likely or anticipat* or want* or certainty or self-efficacy)).mp.
- 38 or/23-37
- 39 13 and 22 and 38

Appendix 2. Initial MEDLINE and EMBASE search strategy and resulting citations for broad search using population ('back pain'), and study design ('prognosis') terms (limiting potential reporting bias)

Screen of citations will take advantage of existing work (searches to 2003 ([Hayden 2007](#))) resulting in required screen load in this project of approximately 3500 citations. Searches developed by Rachel Couban, Trials Search Coordinator, Cochrane Back Review Group.

Database: MEDLINE (Ovid)

- 1 dorsalgia.ti,ab.
- 2 exp Back Pain/
- 3 backache.ti,ab.
- 4 exp Low Back Pain/
- 5 (lumbar adj pain).ti,ab.
- 6 coccyx.ti,ab.
- 7 coccydynia.ti,ab.
- 8 sciatica.ti,ab.
- 9 sciatic neuropathy/
- 10 spondylosis.ti,ab.
- 11 lumbago.ti,ab.
- 12 back disorder\$.ti,ab.
- 13 or/1-12
- 14 Cohort Studies/
- 15 incidence.tw.
- 16 Mortality/

17 Follow-Up Studies/
18 prognos\$.tw.
19 predict\$.tw.
20 course.tw.
21 Survival Analysis/
22 or/14-21
23 13 and 22

Database: EMBASE (Ovid)

1 dorsalgia.mp.
2 back pain.mp.
3 exp LOW BACK PAIN/
4 exp BACKACHE/
5 (lumbar adj pain).mp.
6 coccyx.mp.
7 coccydynia.mp.
8 sciatica.mp.
9 exp ISCHIALGIA/
10 spondylosis.mp.
11 lumbago.mp.
12 back disorder\$.ti,ab.
13 or/1-12
14 cohort analysis/
15 incidence/
16 mortality/
17 follow up/
18 survival/
19 prognosis/
20 prediction/
21 disease course/
22 or/14-21
23 13 and 22

Appendix 3. Modified QUIPS tool

We will use the quality assessment strategy recommended by [Hayden 2013](#) for assessing the quality of included studies. The quality assessment considers each of 6 potential biases: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding, statistical analysis & reporting. Below we present a version of the QUIPS tool modified for this prognostic factor review. An electronic (MS Access) version of the full generic QUIPS tool is available at www.annals.org.

Summary: QUIPS identifies issues to consider for judging the overall risk of bias for a study. These issues will guide your thinking and judgment about the risk of bias within each of 6 domains. Some 'issues' may not be relevant to the specific study or the review research question. These issues are taken together to inform the overall judgment of potential bias for each of the 6 domains. Provide comments or text excerpts in the boxes below, as necessary, to facilitate the consensus process that will follow. Rate the adequacy of reporting for each applicable item as yes, partial, no or unsure, then (at the bottom of the page) rate potential risk of bias for each of the 6 domains as High, Moderate, or Low considering all relevant issues.

BIAS: STUDY PARTICIPATION

Goal: To judge the risk of selection bias (likelihood that relationship between *PF and outcome is different for participants and eligible non-participants*).

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Source of target population</i>	<p>The source population or population of interest is adequately described, including who the target population is (e.g. is the desired target population all workers? individuals filing compensation claims?), when (time period of study), where (location), and how (description of recruitment strategy).</p> <p>Comprehensive description would include characteristics of: individual (e.g., age, sex, depression), back pain (history of LBP, current functioning), work (type and characteristics of work environment), treatment (type and extent of care received) and social context (compensation status)</p>	
<i>Method used to identify population</i>	<p>The sampling frame and recruitment (e.g. newspaper advertisement, presentation to a health clinic, or captured from a claims database) are adequately described, including methods to identify the sample sufficient to limit potential bias (number and types used, e.g., referral patterns in health care)</p>	
<i>Recruitment period</i>	<p>Period of recruitment is adequately described.</p>	
<i>Place of recruitment</i>	<p>Place of recruitment (setting and geographic location) are adequately described</p>	
<i>Inclusion and exclusion criteria</i>	<p>Inclusion and exclusion criteria are adequately described and should define a discreet group with LBP (e.g. the study may include physician diagnosis or explicit diagnostic codes)</p>	

(Continued)

<i>Adequate study participation</i>	There is adequate participation in the study by eligible individuals		
<i>Baseline characteristics</i>	The baseline study sample (i.e., individuals entering the study) is adequately described. Comprehensive description would include characteristics of: individual (for example, age, sex, depression), back pain condition (history of LBP, current functioning), work (type and characteristics of work environment), treatment (type and extent of care received) and social context (compensation status)		

Summary study participation:

The study sample represents the population of interest on key characteristics, sufficient to limit potential bias of the observed relationship between PF and outcome.

- Low risk of bias**
- Moderate risk of bias**
- High risk of bias**

BIAS: STUDY ATTRITION

Goal: To judge the risk of attrition bias (likelihood that relationship between PF and outcome are different for completing and non-completing participants).

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Proportion of baseline sample available for analysis</i>	Response rate (i.e., proportion of study sample completing the study and providing outcome data) is adequate	
<i>Attempts to collect information on participants who dropped out</i>	Attempts to collect information on participants who dropped out of the study are described	
<i>Reasons and potential impact of subjects lost to follow-up</i>	Reasons for loss to follow-up are provided.	

(Continued)

<i>Outcome and prognostic factor information on those lost to follow-up</i>	Participants lost to follow-up are adequately described for characteristics of: individual (for example, age, sex, depression), back pain condition (history of LBP, current functioning), work (type and characteristics of work environment), treatment (type and extent of care received) and social context (compensation status)		
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Summary study attrition:

Loss to follow-up (from baseline sample to study population analyzed) is not associated with key characteristics (i.e., the study data adequately represent the sample) sufficient to limit potential bias to the observed relationship between individual recovery expectations and LBP outcome.

- Low risk of bias**
- Moderate risk of bias**
- High risk of bias**

BIAS: PROGNOSTIC FACTOR (PF) MEASUREMENT

Goal: To judge the risk of measurement bias related to how individual recovery expectations were measured (differential measurement of the prognostic factor related to the level of outcome).

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Definition of the PF</i>	A clear definition or description of individual recovery expectations is provided, capturing individual participant cognition (e.g. beliefs, perceptions, anticipations, expectations) and related to a future outcome. The description allows differentiation of general recovery expectations, treatment outcome expectations, and self-efficacy expectations	
<i>Valid and reliable measurement of PF</i>	Method of 'individual recovery expectations' measurement is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on mea-	

(Continued)

	<p>surement properties, also characteristics, such as limited reliance on recall). Examples of reliable and valid measurement of recovery expectations include the Revised Illness Perception Questionnaire to address recovery expectations (Timeline acute/chronic subscale) and treatment expectations (Treatment control subscale); and the Credibility/Expectancy Questionnaire</p>		
	<p>Continuous variables are reported or appropriate cut-points (i.e., not data-dependent) are used</p>		
<i>Method and setting of PF measurement</i>	<p>The method and setting of measurement of individual recovery expectations is the same for all study participants</p>		
<i>Proportion of data on PF available for analysis</i>	<p>Adequate proportion of the study sample has complete data for the 'individual recovery expectations' variable</p>		
<i>Method used for missing data</i>	<p>Appropriate methods of imputation are used for missing individual recovery expectations data</p>		

Summary prognostic factor measurement:

Individual recovery expectations are adequately measured in study participants to sufficiently limit potential bias.

- Low risk of bias**
- Moderate risk of bias**
- High risk of bias**

BIAS: OUTCOME MEASUREMENT

Goal: To judge the risk of bias related to the measurement of LBP outcome (differential measurement of outcome related to the baseline level of prognostic factor).

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Definition of the outcome</i>	A clear definition of the LBP outcome is provided, including duration of follow-up and ICF disability construct; return to work should be clearly defined if it means off work, work re-integration, work maintenance, or advancement	
<i>Valid and reliable measurement of outcome</i>	<p>The method of outcome measurement used is adequately valid and reliable to limit misclassification bias (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and confirmation of outcome with valid and reliable test).</p> <p>Valid and reliable LBP outcome measures include: pain intensity, measured by a visual analogue scale (VAS) or other pain scale (for example, numeric rating scale, or McGill pain score), functional status, measured by a LBP-specific scale (for example, the Roland-Morris Disability Questionnaire, or the Oswestry Disability Index). Administrative return to work outcomes are considered valid</p>	
<i>Method and setting of outcome measurement</i>	Clear and appropriate cut-points for continuous outcome measures (i.e., not data-dependent) are used	
<i>Method and setting of outcome measurement</i>	The method and setting of outcome measurement is the same for all study participants	

Summary outcome measurement:

LBP disability outcome is adequately measured in study participants to sufficiently limit potential bias.

- Low risk of bias**
- Moderate risk of bias**
- High risk of bias**

BIAS: STUDY CONFOUNDING

Goal: To judge the risk of bias due to confounding (i.e. the effect of PF is distorted by another factor that is related to PF and outcome).

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Important confounders measured</i>	All important potential confounders are measured, including a reasonably comprehensive set of factors representing each of the domains: individual (general demographic), LBP complaint related factors, psychological, treatment received, work environment, and social support factors	
<i>Definition of the confounding factor</i>	Clear definitions of the important confounders measured are provided (e.g., including dose, level, and duration of exposures)	
<i>Valid and reliable measurement of confounders</i>	Measurement of all important confounders is adequately valid and reliable (e.g., may include relevant outside sources of information on measurement properties, also characteristics, such as blind measurement and limited reliance on recall)	
<i>Method and setting of confounding measurement</i>	The method and setting of confounding measurement are the same for all study participants	
<i>Method used for missing data</i>	Appropriate methods are used if imputation is used for missing confounder data	
<i>Appropriate accounting for confounding</i>	Important potential confounders are accounted for in the study design (e.g., matching for key variables, stratification, or initial assembly of comparable groups; see variables below)	

(Continued)

	<p>Important potential confounders are accounted for in the analysis (i.e., appropriate adjustment). Minimum control for potential confounding in included studies will consider: age, sex, and socioeconomic status. We will judge 'ideal' control for confounding based on our proposed theoretical framework of the relationship between individual recovery expectations and LBP outcomes. This will include studies that adequately assess potential confounders representing each of the domains: individual (general demographic), LBP complaint related factors, other unrelated psychological, treatment received, workplace environment, and social support factors</p>		
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Summary study confounding:

Important potential confounders are appropriately accounted for, limiting potential bias with respect to the relationship between individual recovery expectations and LBP outcome.

- Low risk of bias**
- Moderate risk of bias**
- High risk of bias**

BIAS: STATISTICAL ANALYSIS & REPORTING

Goal: To judge the risk of bias related to the statistical analysis and presentation of results.

Issues to consider for judging overall rating of risk of bias	Study methods & comments	Rating of reporting
<i>Presentation of analytical strategy</i>	There is sufficient presentation of data to assess the adequacy of the analysis	
<i>Model development strategy</i>	The strategy for model building (i.e., inclusion of variables in the statistical model) is appropriate and is based on a con-	

(Continued)

	ceptual framework or model		
	The selected statistical model is adequate for the design of the study		
<i>Reporting of results</i>	There is no selective reporting of results.		

Summary statistical analysis and reporting:

The statistical analysis is appropriate for the design of the study, limiting potential for presentation of invalid or spurious results, and selective reporting is unlikely.

- **Low risk of bias**
- **Moderate risk of bias**
- **High risk of bias**

Modified from: [Hayden 2013](#). An electronic (MS Access) version of the full generic QUIPS tool is available at www.annals.org.

Appendix 4. Description of the six domains of the QUIPS

This description is paraphrased from [Hayden 2013](#).

Study participation

The study participation domain addresses whether the study sample is representative of the population of interest. A study will be considered as having high risk of bias if the participation rate is low, a very selective rather than consecutive sample of eligible LBP individuals was recruited, or the study sample has a very different demographic and LBP characteristic distribution from our population of interest. Conversely, studies with high participation of eligible and consecutively recruited LBP individuals who have characteristics similar to those in the source population would have low risk of bias.

Study attrition

The study attrition domain addresses whether participants completing the study (i.e. with follow-up data) represent the baseline sample. A study will be considered to have high risk of bias if it is likely that persons who completed the study differ from those lost to follow-up in a way that distorts the association between individual recovery expectations and LBP outcome. Conversely, studies with complete follow-up, or evidence that participants lost to follow-up are likely to be missing at random, will have low risk of bias.

Prognostic factor measurement

The prognostic factor measurement domain addresses adequacy of measurement of our factor of interest, individual recovery expectations toward non-differential measurement related to LBP disability. Studies that use an unreliable method to measure individual recovery expectations or use different approaches for participants with different outcomes that may result in systematic misclassification will be rated as high risk of bias. Conversely, a study will be considered to have low risk of bias if individual recovery expectations are measured similarly (same method and setting) for all participants and use a valid, reliable measure, such as the Illness Perceptions Questionnaire.

Outcome measurement

The outcome measurement domain addresses the adequacy of LBP disability outcome measurement toward non-differential measurement related to recovery expectations. A study will have high risk of bias if there is likely to be differential measurement of outcome; for

example, patients with negative expectations for recovery are assessed using a different approach than those with positive expectations. A study will be considered to have low risk of bias if the outcome is measured using the same method/setting for all participants and uses a valid, reliable measure (e.g., pain intensity by a visual analogue scale (VAS) or associated disability using the Roland-Morris Disability Questionnaire (RMDQ)).

Confounding

The study confounding domain addresses potential confounding, or distortion of the relationship between recovery expectations and LBP outcomes by another factor. A study will have high risk of bias if a third factor related to both individual recovery expectations and outcome is likely to explain the effect of expectations. Conversely, studies with adequate measurement of important potential confounding variables and inclusion of these variables in a pre-specified multivariable analysis will have low risk of bias. Minimum control for potential confounding in included studies will consider: age, sex, and socioeconomic status. We will judge 'ideal' control for confounding based on our proposed theoretical framework of the relationship between individual recovery expectations and LBP outcomes (Figure 1). This will include studies that adequately assess potential confounders, not on the proposed causal pathway, representing each of the domains: individual (general demographic), LBP complaint-related factors, general health status, other psychological characteristics/diagnoses unrelated to expectations, treatment received, work environment, and social support factors. We will assess the impact of minimal and ideal control for confounding on observed associations, if sufficient data are available.

Statistical analysis and reporting

The statistical analysis and reporting domain addresses the appropriateness of the study's statistical analysis and completeness of reporting. A study will be considered to have low risk of bias if the statistical analysis is appropriate for the study design and data, statistical model building is based on a conceptual framework or model (rather than a data-driven approach), and all primary outcomes are reported.

Appendix 5. Guide to judge the quality of evidence for prognosis

Starting GRADE	Phase of investigation		
HIGH	<i>Phase 3 Explanatory Study:</i> Explanatory research aimed to understand prognostic pathways; or <i>Phase 2 Explanatory Study:</i> Explanatory research aimed to confirm independent associations between potential prognostic factor and the outcome		
MODERATE	<i>Phase 1 Explanatory Study:</i> Explanatory research aimed to identify associations between potential prognostic factors and the outcome, or Outcome prediction research providing evidence about prognostic factor associations		
<i>Downgrade if:</i>		<i>Upgrade if:</i>	
Study limitations	Serious limitations when most evidence is from studies with moderate or unclear risk of bias for most bias domains	Moderate or large effect	For meta-analysis: pooled effect is moderate or large.
	Very serious limitations when most evidence is from studies with high risk of bias for almost all bias do-		For narrative summary: moderate or large similar effect is reported by most studies

(Continued)

	mains		
Inconsistency	Unexplained heterogeneity or variability in results across studies with differences of results not clinically meaningful. This may be supported by:	Exposure-gradient response	For meta-analysis: gradient is present between analyses for factors measured at different doses
	- For meta-analysis: significant heterogeneity detected by test of heterogeneity and large I^2 value.		For narrative summary: possible gradient exists within and between primary studies
	- For narrative summary: variations in effect estimates across studies with points of effect on either side of the line of no effect, and confidence intervals showing minimal overlap		
Indirectness	The study sample, the prognostic factor, and/or the outcome in the primary studies do not accurately reflect the review question		
Imprecision	For meta-analysis: (1) insufficient sample size and (2) no precise estimate of the effect size in the meta-analysis: confidence interval is excessively wide and overlaps the value of no effect and contain values implying that the factor plays an important role in protecting or putting the individual at risk		
	For narrative summary: Within-study imprecision, (1) sample size justification is not provided and there are less than 10 outcome events for each prognostic variable (for dichotomous outcomes) OR there are less than 100 cases reaching endpoint (for continuous outcomes); and (2) no precision in the estimation of the effect size within each primary study, AND		
	Across study imprecision: there are few studies and small number of participants across studies		

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Publication bias:	We recommend downgrading unless the value of the risk/protective factor in predicting the outcome has been repetitively investigated, ideally by phase 2 and 3 studies		
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Table modified (with permission) from Table 4, [Huguet 2013](#)

CONTRIBUTIONS OF AUTHORS

Conception, design and drafting of the protocol: JA Hayden, ME Tougas

Critical revision of the protocol for important intellectual content: R Riley, R Iles, T Pincus

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DECLARATIONS OF INTEREST

None