

BMJ Open Prognostic factors for recovery and non-recovery in patients with non-specific neck pain: a protocol for a systematic literature review

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ABSTRACT

Introduction Neck pain is a common musculoskeletal disorder worldwide. It can result in significant disability and impaired quality of life. More than 50% of patients with neck pain still report symptoms 1 year later despite receiving different forms of non-pharmacological and pharmacological treatment. Identifying patient characteristics that are modifiable or predict recovery and non-recovery for an individual patient might identify ways of improving outcomes. This systematic review aims to comprehensively summarise the existing evidence regarding baseline patient characteristics associated with recovery and non-recovery, as defined by measures of pain intensity, disability and global perceived improvement.

Methods and analysis Six electronic databases, PubMed, CINAHL, PEDro Database, EMBASE, Cochrane Library and Web of Science, will be searched, with terms related to the review question such as neck pain, prognostic or predictive research, from inception to 28 September of 2018. Studies will be included if they have investigated an association between patient characteristics and outcomes, with at least one follow-up time point. Two independent reviewers will screen the titles and abstracts followed by a full-text review to assess papers regarding their eligibility. Data from included papers will be extracted using standardised forms, including study and participants' characteristics, outcomes, prognostic factors and effect size of the association. The risk of bias of each study will be assessed using the Quality in Prognostic Studies tool. A narrative synthesis will be conducted considering the strength, consistency of results and the methodological quality.

Ethics and dissemination This systematic review does not require ethical approval. The results will be disseminated through publication in a peer-review journal, as a chapter of a doctoral thesis and through presentations at national and international conferences.

PROSPERO registration number CRD42018091183.

INTRODUCTION

Rationale

Neck pain is one of the most common musculoskeletal disorders worldwide and may have a

Strengths and limitations of this study

- The planned systematic review aims to comprehensively synthesise the available evidence about prognostic factors for recovery and non-recovery in patients with non-specific neck pain.
- This protocol has been developed following the guidance of the Preferred Reporting Items for Systematic Review and Meta-analyses Protocols and has been registered with the Prospective Register of Systematic Reviews.
- Heterogeneity of the definition of recovery or non-recovery in terms of pain intensity, disability or global perceived improvement, may hamper the consistent conclusions.

significant impact on function and quality of life.^{1–4} In the general population, 30%–50% of adults will experience an episode of neck pain at least once in their lifetime,⁵ and the prevalence peaks in adults between 40 and 45 years of age.² According to the Global Burden of Disease Study 2016, neck pain is the second most common musculoskeletal condition after low back pain.⁴ Disability-adjusted life-years increased from 17 million (95% CI 11.4 million to 23.7 million) in 1990 to 24 million (95% CI 16.2 million to 33.4 million) in 2006, and increased again to 29 million (95% CI 19.5 million to 40.5 million) in 2016.⁴

Of those who experience acute neck pain, up to 50%–85% will report pain 1–5 years later.⁶ Neck pain is also often associated with other complaints such as low back pain and headache, and with poorer self-rated health.⁷ Neck pain presents an economic burden for society since it may result in extended periods of sick-leave from work and high use of health services.⁸

Most often a specific cause of neck pain symptoms cannot be identified and the label

of non-specific neck pain is given, defined as pain in the cervical region without an identifiable specific anatomopathological diagnosis.^{9–11} Patients with neck pain are commonly referred for non-pharmacological or pharmacological treatment, with considerable heterogeneity of outcomes and recovery rates.^{12–16}

The literature on recovery and non-recovery from neck pain has shown associations with clinical, sociodemographic and psychosocial patient characteristics, and some authors suggest that these prognostic factors are the key to explaining the outcomes achieved in these patients.^{17 18} Factors such as older age, female gender, the presence of low back pain, past history of neck symptoms and previous trauma have been associated with less favourable outcomes in terms of disability, pain intensity or global perceived improvement.^{11 19–22}

The knowledge of these prognostic factors may help clinicians to better distinguish between patients with a good versus less favourable prognosis, leading to provision of better advice about likely outcomes and better management decisions.^{17 23}

Despite the increasing number of primary studies published in recent years, the last systematic review on prognostic factors in patients with neck pain was published in 2009.^{11 19–21 24} This and other systematic reviews have examined risk factors for developing neck pain and prognostic factors for course and recurrence, but they have combined populations with traumatic and non-traumatic causes of neck pain and none of them has focused on prognosis for recovery or non-recovery.^{11 19–21 24}

Given its high rate of prevalence, the identification of prognostic factors for recovery and non-recovery in patients with non-specific neck pain is relevant for effective patient management. However, to our knowledge, no published systematic review has yet identified and synthesised the available evidence concerning prognostic factors for recovery and non-recovery, regarding pain intensity, disability and global perceived improvement, in adult patients with non-specific neck pain.

Objectives

The aim of this review is to identify, assess and synthesise the available evidence about prognostic factors for short-term and long-term recovery and non-recovery, in terms of pain intensity, disability and global perceived improvement in patients with non-specific neck pain.

METHODS AND ANALYSIS

This review protocol is registered with the International Prospective Register of Systematic Reviews by the Centre for Reviews and Dissemination at the University of York, with the number CRD42018091183.²⁵ The protocol and completed review will be reported following the guidance of the Preferred Reporting Items for Systematic Review and Meta-analyses Protocols,²⁶ and the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA),²⁵ respectively.

Eligibility criteria

Studies will be selected according to the criteria outlined below.

Participants and settings

Studies will be included in this review if they investigate adults (aged over 18 years of age) with non-specific neck pain, defined as pain in the cervical region without a specific anatomopathological diagnosis.^{9–11} The studies that include people with specific causes of neck pain (eg, nerve root compression, trauma, malignancy, infection), inflammatory arthritis (eg, rheumatoid arthritis, spondyloarthritis) or neurological diseases (eg, multiple sclerosis) will be excluded. No restrictions will be applied to the setting.

Exposure and outcome measures

This systematic review seeks to identify demographic, clinical and psychosocial factors assessed at baseline that examine the association with recovery or non-recovery in patients with non-specific neck pain.

The definition of demographic, clinical and psychosocial factors was established according to a theoretical framework, based on the following constructs:

Demographic factors: ‘Socioeconomic characteristics of a population expressed statistically, such as age, sex, education level, income level, marital status, occupation, religion, birth rate, death rate, average size of a family, average age at marriage’.²⁷

Clinical condition: signs and symptoms of the disease or clinical condition, presented or described by the patient or found in clinical evaluation, defined in Medical Subject Headings (MeSH) terms as ‘disease attribute—clinical characteristics of disease or illness’.

Psychosocial factors: Social factors include general factors at the level of human society concerned with social structure and social processes that impinge on the individual. Psychological factors include individual-level processes and meanings that influence mental states’.²⁸

Study participants might or might not be treated. If treated, the interventions may include any management and care of any duration, with an explicit description of treatment (eg, medication, exercise, manual therapy, acupuncture, surgery, etc).

The outcome of this systematic review is recovery and non-recovery regarding disability, pain intensity and global perceived improvement. The definition of recovery/non-recovery presented by the authors of original articles (eg, based on definition of ‘recovery’ or ‘complete remission’ or ‘functional recovery’ or ‘non-recovery’) will be accepted, if they are determined by at least one of the following outcome domains: disability, pain intensity and global perceived improvement.

Any recovery/non-recovery criterion presented by the authors of the original studies will be accepted. It can be based on a cut-off point (eg, recovery in disability: decrease at least 27% in Neck Disability Index; score higher than 5 in a Global Recovery Scale), established

by authors, or based on a recovery continuum. In the absence of a clear recovery/non-recovery criterion, the studies will be excluded.

All outcome measures of disability, pain intensity and global perceived improvement will be accepted if they correspond to validated instruments (appropriate for culture and language), specific for people with neck pain, and with at least one follow-up time point. Where several measures were used, all the measures will be extracted and classified according to the domain.

Outcomes will be considered at two time points from baseline defined as ≤ 6 months and > 6 months. If multiple data of disability, pain intensity or global perceived improvement are provided, data close to these time points will be prioritised.

Study designs

Eligible studies will be prospective cohort studies or randomised controlled trials (RCTs) with prognostic factor analysis, published in peer-reviewed journals. RCTs will only be included if information regarding prognostic factors for recovery and non-recovery are available in the published report. The studies will have to identify prognostic factors at baseline and report a statistical association (or lack of association) with an outcome (disability, pain intensity and/or global perceived improvement). Studies including people with pain elsewhere will be included provided if the data for the participants with non-specific neck pain are reported separately. Cross-sectional studies, case series, case reports, case-control studies, systematic reviews, conference proceedings and Masters or PhD theses will be excluded.

Language and time frame

No language or geographical restriction will be applied. The search in each database will be performed from inception to 28 September 2018.

Information sources and search strategy

Searches will be conducted in six electronic databases: PubMed, CINAHL (via EBSCO), PEDro Database; EMBASE (via Elsevier); Cochrane Library (via Wiley Online Library) and Web of Science (via Clarivate Analytics). Additionally, hand searches of the reference lists of all included studies and previously published systematic reviews of prognostic factors for non-specific neck pain will be conducted to ensure completeness of the search.^{11 19 21}

The search strategy will be developed in consultation with a medical librarian with expertise in systematic review searching. A variety of terms related to key subject areas of the review question such as neck pain, prognostic or predictive research will be used. Keywords or database-specific subject headings (eg, MeSH) and the Boolean operators 'OR' and 'AND' will be used to combine the search terms. The search terms will be adjusted to the specificities of the different databases. A draft of the PubMed search strategy is included in [table 1](#).

Table 1 Draft of search strategy in PubMed

Search strategy in PubMed database	
No	Search items
1	'neck pain'[MeSH Terms]
2	'neck'[All Fields] AND 'pain'[All Fields]
3	'neck pain'[All Fields]
4	1 or 2 or 3
5	predictor[All Fields]
6	predictors[All Fields]
7	Prognostic OR Prognosis[All Fields] OR 'Prognosis'[Mesh]
8	5 or 6 or 7
9	4 and 8
10	'therapy'[Subheading]
11	'therapy'[All Fields]
12	'treatment'[All Fields]
13	'therapeutics'[MeSH Terms]
14	'therapeutics'[All Fields]
15	'intervention'[All Fields]
16	10 or 11 or 12 or 13 or 14 or 15
17	9 and 16

Study selection

All potentially eligible articles will be retrieved and organised in the Mendeley reference manager software and duplicate publications will be deleted. Two independent reviewers will screen the titles and abstracts identified in the search to identify potentially eligible studies and will perform full-text review of all those identified to determine inclusion. Reasons for exclusion will be documented in tabular format. Any disagreements between reviewers will be resolved by consensus or by consulting a third independent reviewer if consensus cannot be reached.

The PRISMA flow diagram will document included and excluded studies with the reasons for exclusion.^{26 29} Reviewers will not be blind to the study authors, institutions or journals.

Data extraction

Two independent reviewers will extract relevant data from each selected study, using a piloted standardised data extraction form. To ensure consistency of data extraction, the form will be tested on a sample of five studies, prior to the main data extraction. Any discrepancies in data extraction will be resolved by consensus or discussion with a third reviewer if needed. Reviewers will not be blind to the study authors, institutions or journals.

The extracted data will consist of:

1. Study identification (authors, year of publication, volume, issue and pages);
2. Study characteristics (study setting, study design, sample size, type of intervention, follow-up length, drop-out rate, source of funding and country of origin);

3. Participants' characteristics (age, gender, duration of neck pain, pain intensity, disability);
4. Prognostic factors (any demographic, clinical and psychosocial factors defined according to a theoretical framework described in 'Exposure and outcome measures' section);
5. Outcomes (any measure of recovery or non-recovery in terms of pain intensity, disability and global perceived improvement, the cut-off point or the statistical analysis of clinical improvement to define recovery/non-recovery and rate of recovery, when available);
6. Effect size (measures of unadjusted and adjusted associations (with description of variables adjusted) reported between prognostic factors and outcomes).

If the studies have assessed multiple outcomes, only the information that is relevant to this systematic review research question will be extracted. If there are missing data about study characteristics, methods or measures of association, the study authors will be contacted and asked to provide these data with a maximum of three email attempts in a 2-month period.

If the same data have been reported in multiple study publications, the duplicated data will be presented only one time, to minimise the overrating of any prognostic factors investigated in the same sample.

Assessment of risk of bias

The risk of bias of the included studies will be assessed through the Quality in Prognostic Studies (QUIPS) tool.³⁰ This tool addresses six potential domains of bias: study participation, study attrition, prognostic factor measurement, outcome measurement, study confounding and statistical analysis and reporting.

Two independent reviewers will assess the risk of bias of each included study, following training in risk of bias assessment. The training will consist of application of the QUIPS tool to three articles, with either low, moderate or high risk of bias, investigating prognostic factors for recovery or non-recovery from low back pain. Inter-rater agreement for each domain will be evaluated by percentage of agreement (calculated as the number of agreement domains divided by the total number of domains). If <90% agreement is observed, a second training programme will be conducted.

The results of the risk of bias assessment for each included study will be presented in tabular format by each domain and overall. Reviewers will first assess the relevant risk of bias items in each domain and then produce an overall judgement based on these ratings. Each domain and overall risk of bias will be categorised as low, moderate or high risk of bias. An overall judgement of low risk of bias will require all six bias domains to be rated as low risk of bias. Any disagreements between reviewers will be resolved through discussion or consultation with a third reviewer if required.

Data synthesis

A formal meta-analysis is not planned for this systematic review as the populations, type of treatment received, definitions or prognostic factors, outcomes and methods/tools are anticipated to be too heterogeneous.^{31 32} Consequently, a narrative synthesis will be conducted taking into account risk of bias and the strength and consistency of significant associations.

We will extract and report all unadjusted and adjusted measures of association from included studies. Associations with outcome will be defined as a significant ($p < 0.2$) univariable association, a significant ($p < 0.05$) adjusted association (multivariable) or a significant ($p < 0.05$) association in other predictive analysis (linear or multiple regression).

Effect sizes will be represented as an OR or relative risk (RR) and considered as significant when the 95% CIs do not include 1, or as a coefficient of determination (R^2) and beta-coefficient (b) when the 95% CIs do not include 0. Results will be analysed using the levels of evidence proposed by Furlan *et al*.³³

- A. strong evidence, defined as consistent (>75%) findings among multiple (≥ 2) high-quality studies;
- B. moderate evidence, defined as findings in one high-quality study and consistent (>75%) findings in ≥ 2 low-quality studies;
- C. limited evidence, that is, findings in one high-quality study or consistent findings in ≥ 3 low-quality studies;
- D. conflicting or inconclusive evidence, that is, <75% of the studies reported consistent findings or the results were only based on one study.

To simplify the data presentation, the prognostic factors will be categorised into three main domains: demographic, clinical and psychosocial factors, according to the theoretical framework defined a priori. A tabular form for each category will be made with the discrimination of all the factors, with data of outcomes, effect size as well as the level of evidence.

Additionally, homogeneous subgroups will be defined according to pain duration (acute/subacute (0–12 weeks) and chronic (>12 weeks)), type of treatment (medication, exercise, manual therapy, acupuncture, surgery, etc) and outcome measurement (pain, functional limitations, global perceived improvement/recovery). Should we decide on any other categorisation, we will note this and provide a rationale.

To assess the robustness of our evidence synthesis, a sensitivity analysis will be carried out to examine the influence of the risk of bias whenever possible.

Patient and public involvement

This article reports a protocol of the systematic review. Therefore, patients and or public were not involved and individual patient data will not be collected.

ETHICS AND DISSEMINATION

A comprehensive systematic review to synthesise the available evidence about prognostic factors for recovery

and non-recovery in patients with non-specific neck pain is needed considering the multiplicity of the clinical, sociodemographic and psychosocial patient characteristics identified in the literature. Moreover, and given the expected clinical and/or methodological heterogeneity in the individual studies that will be included in this review, the review aims to provide possible directions for standardisation of participants, outcome measures, cut-off points and follow-up time points in future observational studies.

Formal ethical approval is not required, as individual patient data will not be collected. The results will be disseminated through a peer-reviewed publication and conference presentations and included in a chapter of a Doctoral thesis.

AMENDMENTS

If there are any amendments, we will register the date, describe the change and the rationale. Changes will not be incorporated into the protocol but in the PROSPERO register and will be identified in the systematic review.

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Contributors The manuscript protocol was drafted by LD and was revised by EBC, FPDs, JCB, SR, HD, JAH, RB and SRM. LD, EBC, FPDs, SR, JAH, RB, SRM and JCB contributed to the development of the selection criteria, the risk of bias assessment strategy and data extraction criteria. HD will develop the search strategy and manage the study records on Mendeley software. EBC and FPDs will screen the studies obtained in the search for their eligibility criteria. LD and SRM will extract data and assess risk of bias of included studies. JAH and RB will resolve any disagreements regarding eligibility for inclusion, data extraction and/or risk of bias. All authors have read, provided feedback and approved the final protocol. LD is the guarantor of this article.

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