Clinical utility and reproducibility of surface electromyography in individuals with chronic low back pain: a protocol for a systematic review and meta-analysis

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ABSTRACT
Introduction Chronic low back pain (CLBP) is one of the most common disorders presenting in primary healthcare. Kinematic studies of low lumbar pelvic mobility allied with surface electromyography (sEMG) may assist in the assessment and management of CLBP. However, the applicability in the use of sEMG in the clinical setting remains uncertain. In this protocol, we aim to review the clinical utility and reproducibility of the sEMG component of these kinematic studies in patients with CLBP.

Methods and analysis This protocol was informed by the Preferred Reporting Items for Systematic review and Meta-Analysis Protocols (PRISMA-P) and results will be reported in line with the PRISMA. Searches will be conducted on PubMed, Scopus, Web of Science, Embase, CINAHL and Google Scholar databases, along with a comprehensive review of grey literature. Two reviewers will conduct the searches and independently screen them, according to title and abstract. Two independent reviewers will then assess the full-text versions of those selected articles and assess the risk of bias using the defined protocol inclusion criteria. The risk of bias within the studies included will be assessed via the Quality Assessment of Diagnostic Accuracy Studies tool, V.2 and the Grading of Recommendations Assessment, Development and Evaluation guidelines will be used to assess certainty of evidence for recommendations based on the risk of bias findings. Meta-analysis will be conducted where appropriate on groups of studies with low heterogeneity. In instances of higher heterogeneity, meta-synthesis will instead be completed, comparing results in terms of increased or decreased clinical utility and/or reproducibility of sEMG.

Ethics and dissemination Ethics approval was not required for this research. It is anticipated that the results will influence the use, interpretation and further development of sEMG in management and assessment of these patients.

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INTRODUCTION
Rationale Chronic low back pain (CLBP) is one of the most common medical conditions globally, and in the vast majority of cases (>85%), no obvious structural cause can be found for the disorder.1 This has led to a myriad of pathways of management for these patients by various medical and paramedical professionals.2,3 Over the last two decades, much attention has focused on the role of paraspinal muscles in the generation of CLBP.4,5 There are several aetiological mechanisms by which muscle dysfunction could contribute to CLBP. One is arthrogenic muscle inhibition by which pain in a joint disrupts the motor control of the muscles that stabilise that joint.3,10,11 Persistent arthrogenic muscle inhibition may lead to muscle atrophy and weakness.12 Qualitative and quantitative imaging and histological studies in patients with CLBP have shown atrophy and fatty infiltration in the multifidus and erector spinae muscles, which are important for spinal stability and
The mechanisms underlying this change in tissue quality (defined as ‘sarcopenia’) are probably multifactorial since experimental and clinical studies after minimally invasive discectomy suggest that the multifidus muscle may undergo remodelling of muscle, fatty and connective tissue rather than simple atrophy.14–16 Although some clinical studies aimed at restoring multifidus function in patients with CLBP have shown little benefit,17–21 a novel neurostimulation therapy, using the Reactiv8 device to stimulate the multifidus muscle, has resulted in significant reductions in pain and disability at 12 and up to 48 months in a randomised control trial.22 23 In conjunction with such interventions, active exercise-based therapies have shown promise in reversing these changes in tissue quality, with a particular focus on motor control.24 25 Therefore, it is essential that methods to assess both the kinematics and also muscular activation patterns are evaluated according to reproducibility, clinical utility, validity and reliability.

For this research, we define ‘clinical utility’ as ‘the practical relevance of surface electromyography (sEMG) in either assessing patients or using sEMG as a guide to change after a therapeutic endeavour’. For this clinical relevance, changes have to be consistent, that is, reproducible, the tool (sEMG) has to be sensitive to, and specific for, changes in the patient’s clinical condition (as assessed by subjective self-report measures and/or clinical examination). Our definition of ‘reproducibility’ is consistent with that used by the National Library of Medicine.26 ‘The statistical reproducibility of measurements (often in a clinical context), including the testing of instrumentation or techniques to obtain reproducible results. The concept includes reproducibility of physiological measurements, which may be used to develop rules to assess probability or prognosis, or response to a stimulus; reproducibility of occurrence of a condition and reproducibility of experimental results’.

Functionally the consequences of CLBP can be measured by restrictions of lumbar and lumbar-pelvic movements. One difficulty with this approach, however, is that the relationships between LBP, posture and lumbar movement are complex and can be influenced by a range of modifiable and non-modifiable factors such as genotype, age, gender, body mass index, duration and intensity of pain and therapeutic endeavours.27–29 Nonetheless the use of non-invasive kinematic motion sensors linked to computer programmes can assist with easier quantifiability of lumbo-pelvic movements. Some of the more modern systems also combine wireless motion with sEMG recordings.30 Such systems, such as Vimove,31 can superimpose the motion activity and sEMG, enabling qualitative relationships between muscle activity and motion dynamics to be visualised. Furthermore, such systems have reasonable validity and reliability when compared with more established methods such as motion capture systems.31 The output of these systems can be used in the primary assessment of the patient and also to monitor patient responses to treatment.32 sEMG can also be used in experimental and clinical trial settings to evaluate biofeedback techniques for specific movements.33–35 sEMG can be quantified by amplitude over time and this activity represents the summed effect of neural integrity and the muscle motor unit activity and its firing frequency. The sEMG signal is influenced by a multitude of recording, processing, filtering, task-related and other variables that are independent of the muscle integrity.36–41 Currently, the effects of CLBP on lumbar muscle sEMG are unknown. A protocol for a systematic review of the literature on the effects of CLBP on sEMG, which included the effects of sEMG signal processing and high-density EMG, was outlined 2 years ago, and registered with PROSPERO, but no subsequent paper has appeared.42 We, therefore, felt that a focused systematic review and meta-analysis on the literature relating to the clinical utility and methodological aspects of the sEMG component of kinematic studies of lumbar movements in both CLBP patients and controls was important for clinicians and allied health professionals in view of the increasing facility for its use.

Objectives

Aims

The aim of this manuscript is to establish a protocol for a systematic review, which will evaluate studies investigating the clinical utility and reproducibility of sEMG for lumbar muscles in individuals with CLBP.

Furthermore, the primary aims are to:

1. Establish the clinical utility of the sEMG component of lumbar kinematic studies in patients with CLBP.
2. Establish the reproducibility (including sensitivity, specificity and reliability) of the sEMG component in patients with CLBP.
3. Determine the validity and reliability of the sEMG component in patients with CLBP.

The secondary aims are: (1) establish muscle activity markers associated with sEMG in patients with CLBP and (2) establish kinematic parameters associated with sEMG in patients with CLBP.

METHODS AND ANALYSIS

The protocol for this review was based on the Cochrane Back review Group Guidelines,43 44 Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) guidelines45 46 and methodology outlined in a previously published protocol in this field.42 This study commenced the 14 August 2021 and is anticipated to be ready for publication March 2022.

Eligibility criteria

Population

Inclusion criteria:

- Adults (>17 years) who have CLBP (as defined as ‘pain in the lower back persisting for more than 3 months’)47 and have undergone kinematic studies of lumbar spinal mobility that incorporates sEMG.
recording. ‘Low back’ is defined as the region between the ‘costal margins and the gluteal folds’.48

- Diagnosis of non-specific LBP confirmed by clinical examination and patient confirmation that the pain has lasted >12 weeks in the absence of any neurological signs.
- Control subjects (adults over 17 years) who have no history of CLBP and have undergone kinematic studies of the lumbar spine.
- Studies carried out with low back pain patients in various settings (eg, inpatient hospital-based or outpatient clinics, private clinics (sports or musculoskeletal subspecialties), primary care and research-based specialist university clinics).
- Patients from different backgrounds (eg, sports-based, workplace, home), already receiving some form of medical support for their pain.

Exclusion criteria:
- CLBP with pathoanatomical causes (eg, traumatic/stress/osteoporotic vertebral body fracture, significant disc prolapse with radicular pain, spondylolisthesis, symptomatic lumbar spinal canal stenosis).
- Individuals with prior surgical treatment to the lumbar spine and systemic conditions such as malignancies, inflammatory conditions and significant mental health disorders.

Duration of low back pain will be considered in analysis of EMG reproducibility (acute <4 weeks; Subacute >4 weeks but less than 12 weeks and chronic ≥12 weeks).49

The intervention
This review will consider studies that evaluate the clinical (diagnostic and therapeutic) utility, reliability, validity and reproducibility of sEMG for assessing muscle activity in kinematic studies of those with non-specific low back pain, ‘normal’ controls and specific active controls (patients receiving physiotherapy treatment and/or rehabilitative care).

The EMG study must be recorded by surface electrodes (ie, EMGs recorded by needles are excluded), contain descriptive methodology about recording technique, electrode site and recording conditions. The sEMG must contain amplitude and temporal domains.

Comparison
The control or comparator group will be individuals who are otherwise healthy with no previous history of low back pain. Studies that include both those with CLBP and those without pain will be included in the proposed review.

Outcomes
The main outcomes we wish to evaluate include a range of factors that are outlined in table 1.

Studies
Given initial searches thus far, it is anticipated that the level of evidence for this review is most likely to be based on observational (and some experimental studies), including cohort, case-control, cross-sectional and case study reports. The inclusion and exclusion criteria for this review are summarised in table 1.

Information sources
Information sources will be searched from inception to 15 February 2022. Specific search strategies using medical subject heading (MESH) terms were used are appropriate. The following databases will be used for searching: PubMed (OVID Interface), CINAHL (EBSCO interface), Web of Science (OVID Interface), EMBASE (OVID Interface), Scopus (ELSEVIER interface) and Google Scholar. The PRISMA-S extension50 will be used to guide the conduct of the search strategy.

Hand searching of key journals will be conducted, including BMC Musculoskeletal Disorders, the Journal of Electromyography and Kinesiology, Journal of Neuroscience Methods, Spine, Muscle & Nerve, Clinical Biomechanics and Clinical Neurophysiology. Authors who have published conference abstracts or are notable in the field will be contacted to identify relevant unpublished literature, not as yet published in such journals. Grey literature will be included in the search via Google search engine. Apart from the database and grey literature search, the reference lists of studies identified as eligible and relevant review papers will be hand searched (ie, via ‘snowballing’ methods) to ensure that none of the relevant studies is missed.

Search strategy
The search will be conducted by two authors (SS, AKR) and has been informed by subject-specific expertise (IRW and TL) and the completion of scoping searches. No limits will be placed on the search in terms of date, region, language and/or study design. The keyword search strategy was developed for PubMed and identified appropriate MESH keywords to ensure completeness of the search. If these did not add any further hits, for parsimony only the direct keyword was used. The specific search terms may have been modified to reflect differences across databases. The initial PubMed search strategy is included in the online supplemental material.

Two authors (SS, TL) under the guidance of the first author (TL) will conduct all information sources to identify suitable studies. All duplicates will be screened and removed as appropriate. These same two authors (SS, TL) will independently screen the full-text articles of all eligible studies.

Data management
The complete record for each eligible study (including citation and abstract) will be imported into Endnote 20 (Clarivate Analytics). Study citations will be imported during the search, and duplicate studies identified and removed prior to the screening process. Folders (under ‘group set’) will be set up for each reviewer, with individual folders (under ‘groups’) according to the six databases searched. The full text version for all included studies will be obtained and stored in Endnote V.20. Screening will
Selection process
The study selection process aims to reflect the best practice guidelines outlined in documentation produced by the Cochrane Back Review Group. Initial screening aims to only include studies readily identifiable from the title and abstract consistent with the inclusion criteria. Studies not to be included will be placed in folders (‘groups’) in Endnote 20 with each exclusion criteria reason clearly identified. Where eligibility is unclear the reviewers will obtain and review the full text of the article, using the predetermined screening template to ascertain inclusion. The form helps to clearly identify studies as eligible, ineligible or unclear in terms of the inclusion and exclusion criteria. Studies identified as unclear will be checked by a third reviewer (TL) to determine the eligibility of the study.

The review will not be discriminative in terms of study design, with both observational and experimental study designs being included.

Data collection process
Data will be extracted from studies by two independent reviewers (AKR, SS) using a standardised extraction form, based on the Cochrane data extraction template as a guide and entered into Microsoft Excel Sheet. The data extracted will include: specific details about populations, study methods, interventions and outcomes of significance to the review objective. Data extraction domains will involve: (1) Article Details, (2) Population, (3) Methods, (4) Results. The standardised extraction sheet will be piloted for completeness of data extraction on a sample of studies and any relevant updates made prior to full extraction of eligible studies. Information extracted (using a specified extraction template) will be completed by AKR, with accuracy checked by TL. There will be no blinding by author, research group and/or institution of the included studies. In cases where the required data are not clearly or completely reported, the authors of the study will be contacted for clarification. If no response is obtained from the authors (after two attempts), or if the authors could not provide the requested data, the study outcome will be excluded from further analysis.

Data items
A summary of data items to be extracted from included studies is included in Table 2. Where data are not identifiable or unclear, attempts will be made to contact the corresponding author for clarification. On attempts to
Risk of bias
The risk of bias within the studies included may be assessed via the Quality Assessment of Diagnostic Accuracy Studies tool-2, as recommended in the Cochrane Handbook, when carrying out reviews focused on diagnostic tests and strategies. This tool will be used in conjunction with System for the Unified Management, Assessment and Review of Information developed by Joanna Briggs Institute, Adelaide, Australia (JBI SUMARI software).

The four key domains are patient selection, index test, reference standard and flow of patients through the study and timing of the index test(s) and reference standard (‘flow and timing’). The tool is completed in four phases:

1. state the review question, (2) develop review specific guidance, (3) review the published flow diagram for the primary study or construct a flow diagram if none is reported, (4) judgement of bias and applicability. Each domain is assessed in terms of the risk of bias and the first three are also assessed in terms of concerns regarding applicability. To help reach a judgement on the risk of bias, signalling questions are included. These flag aspects of study design related to the potential for bias and aim to help reviewers make risk of bias judgements.

Data synthesis
In order to be considered for meta-analysis, the outcomes and the methodology of eligible studies must maintain homogeneity. The process for meta-analysis will be more clear pending data extraction, based on assumptions of homogeneity remaining true. The remainder of this section is based on such an assumption of homogeneity in outcomes and methodology of the studies; however, some changes may be needed following data extraction.

The heterogeneity of the eligible studies will be assessed according to the following outcome categories:

1. The sEMG-related measures (duration, amplitude, intensity) have been reported during kinematic activity

Table 2 Summary of items from eligible studies using the standardised extraction form

| Information area | Data extracted |
|------------------|----------------|
| **Background** | **Data extracted** |
| Authors | |
| Year of publication | |
| Title | |
| **Methodology** | **Data extracted** |
| Study design | Sample characteristics (sample size, age, demographic data) |
| Setting | LBP characteristics (duration, average pain, current pain, laterality) |
| | Dimension of movement (flexion-relaxation, extension-relaxation, lateral flexion-relaxation) |
| | Type of sEMG (bipolar, linear array, HDEMG) |
| | EMG processing (sampling frequency, filtering, offline processing) |
| | EMG processing of signal amplitude (RMS, ARV, integrated EMG) |
| | Muscles measured (longissimus, multifidus) |
| | Absolute or normalised activity values |
| **Results** | The kinematic study is considered normal or abnormal (eg, time to full flexion, lumbo-pelvic movement components in degrees); |
| | The sEMG is considered normal or abnormal (duration, amplitude, intensity); |
| | The sEMG has been evaluated for reproducibility (intra-rater; inter-rater); |
| | The kinematic and sEMG recording methodology is clearly described and adheres to the SENIAM guidelines; |
| | The subject of study has/has not LBP; |
| | The intensity and any disability associated with the LBP is recorded at the time of study (Visual Analogue Score, Numeric Pain Rating, recognised disability index score); |
| | The association between abnormal kinematic study and abnormal sEMG.; |
| | The usefulness of the study for clinical purposes (ie, did it facilitate diagnosis, planning or monitoring therapy); |
| | The differences in patterns of abnormality between kinematic and sEMG studies in patients with acute, subacute and chronic LBP; |
| | The consideration of anatomical status of the paravertebral lumbar muscles (eg, fatty infiltration of muscle, muscle atrophy) or associated medical conditions (eg, diabetes, BMI for obesity). |

ARV, average rectified value; BMI, body mass index; EMG, electromyography; HDEMG, high density electromyography; LBP, low back pain; RMS, root mean square; sEMG, surface electromyography; SENIAM, surface electromyography for the non-invasive measurement of muscles.
(eg, time to full flexion, lumbo-pelvic movement components in degrees), (2) The sEMG has been evaluated for reproducibility (intrarater; inter-rater), (3) the kinematic and sEMG recording methodology is clearly described and adheres to the surface EMG for non-invasive assessments of muscles (SENIAM) guidelines. (4) The subject of study has/has not LBP, (5) the intensity and any disability associated with the LBP is recorded at the time of study (Visuaal Analogue Score, Numeric Pain Rating, recognised disability index score), (6) the association between abnormal kinematic study and abnormal sEMG, (7) the usefulness of the study for clinical purposes (ie, did it facilitate diagnosis, planning or monitoring therapy), (8) the differences in patterns of abnormality between kinematic and sEMG studies in patients with acute, subacute and chronic LBP, (9) the consideration of anatomical status of the paravertebral lumbar muscles (eg, fatty infiltration of muscle, muscle atrophy) or associated medical conditions (eg, diabetes, body mass Index for obesity).

Where homogeneity is sufficient between groups within these categories, then inclusion within meta-analysis either as a large group or several subgroups will be determined by all reviewers. If the eligible studies are clearly homogenous or not clearly heterogeneous, then each reviewer will place studies into appropriate groups for analysis. This process will be done by each independently to determine which factors will allow the best and most accurate comparisons to be made. Relevant subgroupings are likely to be made based on the methodological factors listed in table 2. For example, subgroupings according to whether or not the patient group(s) have CLBP would be considered, as appropriate for the eligible studies. If suitable, reviewers can include studies in more than one subgroup (ie, pain and normality of EMG signal); however, in this instance, the subgroups will not be used in the same meta-analysis. Where reviewers agree on what is to be grouped for each meta-analysis, this process will be facilitated. If there is not broad agreement on groups, discussion will take place. If the relevant reviews disagree, the reviewers as a group will determine suitability of quantitative synthesis.

On a meta-analysis being deemed appropriate by the reviewers, a statistical test of heterogeneity will be carried out, providing an I² value in the heterogeneity of the sample. The I² value will be reported as a percentage and interpreted as suggested in the Cochrane Handbook for Systematic Reviews of Interventions. Significance in the measure of heterogeneity as calculated by the χ² test will be set at p≤0.10. Effect sizes (ES; Hedge’s g) will be calculated for each measure using means and SD from pretests and post-tests for each dependent variable. The effect size magnitudes will be interpreted using the following scale: <0.2, trivial; 0.2–0.6, small; >0.6–1.2, moderate; >1.2–2.0, large; >2.0–4.0, very large; >4.0, extremely large. In the event significance was reported, the I² statistic will be then explored to define the magnitude of heterogeneity about the finding, where 0–40, 30–60, 50–90 and 75+ are suggestive of low, moderate, substantial and considerable heterogeneity, respectively. As outlined in the previous reviews, the groupings of studies will be eligible for meta-analysis if an I² value of <50% (low heterogeneity) is calculated. In the instance of statistical heterogeneity, leave-one-out sensitivity analyses may be performed; however, groups considered to exceed the minimal value for heterogeneity will be ineligible for meta-analysis and hence considered for best-evidence synthesis instead. Comparisons in some of the categories (eg, changes in muscle activity between studies) may be challenging to assess due to differences in signal processing, muscles measured and amplitude as well as experimental design. Where meta-analysis has been decided as appropriate by the group, results will be extracted from the eligible studies and aggregated, with changes normalised and reported as percentage changes or standard mean differences in all studies. Where data are lacking, the authors of relevant studies will be contacted to provide further data. For variables of interest with binary outcomes, ORs will be used to investigate the relationship between EMG variables and binary outcomes (yes/no). Within subgroups, percentage changes in variables (eg, one-dimensional activity) will be correlated with additional outcomes (as above in table 2), including the level and duration of pain, sample characteristics and sEMG-specific characteristics, to investigate what impact these have on the clinical utility and reproducibility of sEMG in those contexts.

If the data are not sufficiently homogenous, a narrative synthesis will be focused from the data set with some binary elements of analysis also included. In this context, statements as to ‘increase’, ‘decrease’ or ‘no change’ in the clinical utility based on the set characteristics outlined will be described.

Confidence in cumulative evidence

The potential of non-reporting bias will be evaluated by using the Outcome Reporting Bias in Trials framework to investigate potential missing results. In addition, we plan to conduct a comprehensive search of unpublished studies, contacting respective authors in the field and including grey literature obtained via several additional methods (eg, ‘snowballing’ of primary and secondary article reference lists). Conference presentations not carried through to publication will also be reviewed, with authors contacted. Further statistical tests, such as the Begg and Mazumbar’s rank correlation test and Eggers linear regression model, may be applied to each category and overall analyses. On non-reporting bias being detected; Duval and Tweedie’s trim and fill correction may be applied and the result effect sizes and 95% CIs explored.

The pooled data will be assessed using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach to evaluate the overall quality and ‘certainty of recommendations’ from the literature. The GRADE approach will be used to determine the certainty and strength of evidence according
to the categories (methodological and outcome based) outlined in table 2 and carried out in accordance with set recommendations. For example, observational studies will be assigned a ‘low’ certainty of recommendation prior to then either being upgraded or downgraded from this point, based on the quality of the evidence. Studies will be upgraded for factors such as large effect sizes or dose–response relationships between CLBP, EMG characteristics and clinical utility/reproducibility of results. Potential downgrading of studies for certainty of evidence can occur for factors such as non-reporting bias, indirect relationships with results (unexplained confounding) or inconsistencies between studies. From this process, qualitative ratings for the certainty of evidence and recommendations will be listed as ‘high’, ‘moderate’, ‘low’ or ‘very low’, able to be interpreted according to the GRADE approach.75,59

**Patient and public involvement**

The topic of this review was identified through discussions between the respective collaborators in this research (The International Spine Centre and The University of Adelaide). Patients will not be involved in the analysis and data collection of the systematic review and meta-analysis.

**ETHICS AND DISSEMINATION OF RESULTS**

No ethical approval is required for this review due to this being a collation of previously published literature. The systematic review and meta-analysis will collect and compile results from several studies, which have included sEMG in the appraisal of one-directional movement, with various outlined characteristics of sEMG for the purpose of clinical utility and reproducibility of the results in measurement. While heterogeneity is anticipated, this review aims to succeed in identifying key features of sEMG and the various patient groups applied, which may impact on the primary outcomes of clinical utility and reproducibility. Consequently, the results of this review and any difference in characteristics in sEMG between individuals with or without LBP according to the various impacting factors have the potential to influence future approaches both clinically and in the research-supporting clinical practice. The results of this review will be submitted for publication in respective peer review journals and presented at appropriate domestic/international conferences.

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