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Evaluating the efficacy of wearable biofeedback on the outcomes of exercise interventions in people with chronic non-specific spinal pain: protocol for a systematic review and meta-analysis

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ABSTRACT

Introduction Wearable neuromuscular and biomechanical biofeedback technology has the potential to improve patient outcomes by facilitating exercise interventions. We will conduct a systematic review to examine whether the addition of wearable biofeedback to exercise interventions improves pain, disability and quality of life beyond exercise alone for adults with chronic non-specific spinal pain. Specific effects on clinical, physiological, psychological, exercise adherence and safety outcomes will also be examined.

Methods and analysis A systematic search will be conducted from inception to February 2024. Full articles in the English language will be included. MEDLINE, PubMed, CINAHL, EMBASE, Web of Science, PsycINFO, AMED, SPORTDiscus, CENTRAL databases, clinical trial registries and ProQuest (PQDT) will be used to search for eligible studies. Grey literature and conference proceedings (2022–2024) will be searched for relevant reports. Randomised controlled trials using wearable neuromuscular or kinematic biofeedback devices as an adjunct to exercise interventions for the treatment of chronic spinal pain will be included in this systematic review. The comparators will be wearable biofeedback with exercise versus exercise alone, or wearable biofeedback with exercise versus placebo and exercise. Risk of bias will be assessed using Cochrane Back Review Group criteria and the quality of evidence using Grading of Recommendations Assessment, Development and Evaluation recommendations.

Ethics and dissemination The systematic review will be based on published studies, and therefore, does not require ethical approval. The study results will be submitted for publication in an international, open-access, peer-reviewed journal and shared through conferences and public engagement.

PROSPERO registration number CRD42023481393.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This systematic review is designed to examine whether wearable biofeedback tools enhance the outcomes of exercise interventions in adults with chronic spinal pain.
⇒ To ensure high-quality reporting, this protocol complies with the Preferred Reporting Items for Systematic Review and Meta-Analysis for Protocols 2015.
⇒ Clinical, psychological and physiological outcomes will be examined in conjunction with exercise adherence and safety or potential for harm.
⇒ Subgroup analysis will be undertaken according to each spinal region (cervical, thoracic and lumbar) to examine the dose (intensity and frequency) of the intervention.
⇒ Databases in languages other than English will not be searched and studies reported in languages other than English will not be included.

INTRODUCTION

For the purposes of this systematic review, chronic spinal pain will be defined as chronic, non-specific pain that persists or recurs in the cervical, thoracic, lumbar, sacral or coccygeal spine area for more than 3 months with no clear underlying pathology.[1] The global point prevalence of chronic spinal pain is 7.3%.[2] This implies that approximately 540 million people experience chronic pain globally at any one time,[2] which with respect to low back pain, is projected to rise to 800 million by 2050.[3] In the UK, 28 million people experience chronic pain, 72% of which is attributed to chronic spinal pain,[4] forcing 262 272 people with spinal pain to leave work and 1 in 5 people to take more than 6 months leave from work.[5 6]

The current UK National Institute for Health and Care Excellence (NICE) guidance endorses exercise self-management and personalised care over pharmacological or surgical treatments for the management of chronic spinal pain.[1 7 8] However, there

are increasing concerns that if exercise interventions fail, patients will be referred for more invasive, harmful or costly treatments.[9] Given these concerns, the potential impact on patients, society and the economy of lost working days and predicted rises in this condition, it is a pressing priority to optimise health outcomes, such as pain and disability, to exercise interventions.

A recent Cochrane systematic review demonstrates that exercise can significantly change outcomes (pain and disability) in patients with chronic spinal pain when compared with conservative treatment, placebo or no treatment.[10] However, since the observed effect size of exercise remains small, authors endorse the use of technology as an adjunct to exercise as 'the best way forward' to optimise outcomes for people with chronic spinal pain.[10] This is a view with which NICE concurs, foreseeing the potential role that technology could play in expediting recovery and improving outcomes for people with spinal pain.[11]

Biofeedback is an example of technology used to personalise exercise by converting physiological data into auditory or visual feedback, which is then used to train or cue changes in physiology through operant conditioning.[12–14] This enables enhanced patient control over involuntary physiological processes that are often difficult to consistently or objectively interpret, permitting individualised training with therapist support.[12] Biofeedback has been shown to significantly improve patient outcomes for a range of musculoskeletal conditions associated with chronic pain, including low back pain, as part of a multimodal approach.[15 16] In 2017, a systematic review identified that technology-supported exercise therapy programmes can improve pain and disability for people experiencing low back pain and may be superior to usual care.[15] However, there were some limitations. First, this study by Matheve *et al* focused on the lumbar spine, and therefore, did not consider the entire spine.[15] Indeed, it was also beyond the scope of the study to consider chronicity, exercise adherence, psychological or potential safety effects.[15] Second, the biofeedback devices examined were not necessarily wearable, identification of which could support future clinical research translation within clinical and home environments.[15] Finally, Matheve *et al* agreed that it was difficult to draw firm conclusions since approximately half of the included studies had a high risk of bias and inadequate power, which limited the strength of their conclusions at that time.[15]

Therefore, we will provide an up-to-date evaluation of the effects of wearable spinal biofeedback tools, which will be defined as commercially available, wearable devices that could be used within a clinical context to improve pain and disability outcomes of exercise interventions. Since current NICE guidelines endorse self-management, personalised care and exercise for chronic spinal pain[17 18] and future UK research delivery aims to support patient-centred research enabled by digital tools,[19] it is timely to explore the effect of biofeedback exercise interventions on outcomes in this population.

This systematic review will be undertaken to answer the following overarching research question:

Does the addition of wearable biofeedback improve the outcomes of exercise interventions for adults with chronic spinal pain when compared with placebo biofeedback exercise interventions or exercise alone?

Objectives

To determine the effect of wearable biofeedback on:

1. Clinical outcomes of exercise interventions (disability, pain and quality of life).
2. Psychological outcomes of exercise interventions (depression and anxiety, beliefs, fear avoidance).
3. Physiological outcomes of exercise interventions (muscle activity and joint range of motion).
4. Exercise adherence and safety of exercise interventions (adverse events).

METHODS AND ANALYSIS

Criteria for considering studies for this review

The protocol for this systematic review was developed in line with current Preferred Reporting Items for Systematic Review and Meta-Analysis for Protocols (PRISMA-P) reporting guidelines and was registered with PROSPERO (CRD42023481393, date: 13 November 2023). The following PICOS framework will be used to determine the eligibility of the studies to be included in the systematic review.[20 21]

Participants

Adults (males and females aged ≥18 years) who have experienced chronic non-specific spinal pain (cervical, thoracic, lumbar, sacral or coccygeal spine pain of greater than or equal to 3 months duration),[22] irrespective of setting.

Interventions

We will use the Association for Applied Psychophysiology and Biofeedback's definition of biofeedback to make decisions regarding eligibility, that is, 'a process that enables an individual to learn how to change physiological activity for the purposes of improving health and performance'.[14] Biofeedback will include any wearable neuromuscular or biomechanical biofeedback device that monitors muscle activation and/or joint kinematics that could be used within a clinical context.

An exercise intervention will be any intervention (≥3 weeks duration) that incorporates prescribed exercise, excluding general physical activity (such as walking or gardening). Studies that use biofeedback and placebo biofeedback in addition to other exercise interventions will be included. Since exercise is rarely provided in isolation, the intervention may include other components (eg, cognitive behavioural therapy, advice, education), in

which case, this will need to be matched by the comparator in order to be reported.

Comparators

The comparators will be biofeedback and exercise intervention versus exercise intervention alone or placebo and exercise intervention.

Outcome measures

The outcomes selected are based on recommendations for core outcome measurement instruments for clinical trials in spinal pain,[23 24] previous research findings and patient and public involvement.

1. Clinical outcomes of exercise interventions (eg, disability, pain and quality of life).
2. Physiological outcomes of exercise interventions (eg, muscle activity and joint range of motion).
3. Psychological outcomes of exercise interventions (eg, depression and anxiety, beliefs, fear avoidance).
4. Exercise adherence and safety outcomes (eg, session attendance and adverse events).

Primary outcomes

The primary patient-centred outcome will include any measures of patient self-reported disability (eg, Oswestry Disability Index Version 2.1a (ODI)) and any change in patient self-reported pain frequency or intensity (eg, Numeric Rating Scale), (clinical outcomes).

Secondary outcomes

Potential secondary outcomes in order of priority will include any change in measures of neuromuscular data (eg, peak amplitude of muscle activation and kinematic data (eg, degrees of joint range of motion) (physiological outcome), health-related quality of life (eg, Short Form 12) (clinical outcome), self-reported psychological factors affecting patients (eg, Fear Avoidance Beliefs Questionnaire) (psychological outcome), exercise adherence (eg, the number of completed exercise sessions) and safety (eg, the number of adverse events) (exercise adherence and safety outcome).

Studies

Randomised controlled trials (RCTs) using wearable neuromuscular or kinematic biofeedback devices as an adjunct to exercise interventions for the treatment of chronic spinal pain will be included in this systematic review. All published parallel group or cross-over RCT studies (full reports) that compare wearable biofeedback and exercise intervention versus exercise intervention alone or placebo and exercise intervention will be included.

Search methods for identification of studies

Sources of information will include electronic databases, trial registries, the grey literature and guidance from expert authors in this field. The search will be conducted by MA from inception to February 2024. Full articles in the English language will be included. There will be no date limit. The databases will include MEDLINE (via Ovid), PubMed (via Ovid), CINAHL (via EBSCOhost), EMBASE (via Ovid), Web of Science, PsycINFO (via Ovid), AMED (via Ovid), SPORTDiscus (via EBSCO) and the Cochrane Central Register of Controlled Trials (CENTRAL). The search strategy will be defined and developed using medical subject heading (MESH) and keywords in MEDLINE. The same search strategy will then be applied to the other databases (see online supplemental material). The search strategy will be adapted to search Clinical trial registries (ClinicalTrials.gov), ICTRP (www.who.int/ictrp/clinical-trials-registry-platform) and ISRCTN Registry (www.isrctn.com). In addition, we will undertake handsearching of specific journals (Physiotherapy, Musculoskeletal Science and Practice, PLOS ONE, Journal of Electromyography and Kinesiology, Journal of Back and Musculoskeletal Rehabilitation, Journal of Neuroengineering and Rehabilitation and BMC Musculoskeletal Disorders). Unpublished and ongoing studies will be identified through the examination of the grey literature (OpenGrey); ProQuest (PQDT Open) will be searched for report literature and dissertation abstracts (https://pqdtopen.proquest.com/search.html). Proceedings from conferences (2022–2024) will be accessed using Web of Science and relevant websites (including proceedings from the International Federation of Orthopaedic Manipulative Physical Therapists, the World Congress of Physiotherapy, the Society for Back Pain Research Annual General Meeting, the World Congress of Biomechanics and the Congress of the International Society of Electrophysiology and kinesiology). The reference lists of included studies will be handsearched to ensure relevant studies are included.

This search strategy is informed by scoping searches and specific expertise in clinical biomechanics and electromyography. The strategy, developed in MEDLINE using MESH terms, will be adapted according to the requirements of each database (see online supplemental material). The search strategy will be performed consistently between databases, using the same keywords but without filters for date, language, sex, region or journal type.

MA will perform the searches to identify RCTs using the information sources described. At this point, duplicates will be removed. The selected studies will be screened independently by two reviewers (MA and JD) using screening forms summarising inclusion and exclusion criteria. Relevant data will be extracted from the studies that are deemed eligible. To ensure accuracy, the extracted data will be reviewed. In the case of disagreement, an independent researcher will act as arbiter.

Data extraction and management

During the literature search, relevant citations and abstracts will be imported into EndNote V.20.1 (Clarivate, Philadelphia, Pennsylvania, USA) and duplicates removed. The full text of each article will be stored within an EndNote file. This file will be made available to two authors for screening.

Data will be extracted independently by these authors and disagreements resolved by consensus. A standardised data extraction form will be piloted in advance of extraction. The data extraction form will be created to record information relevant to each of the included RCTs. The data extracted will be arranged according to the spinal region affected (cervical, thoracic or lumbar) and will include information relating to:

1. Methods (the design of each included study (eg, parallel, cross-over), method of sequence generation, allocation of sequence concealment, blinding of both researchers and participants).
2. Participants (sample size of each group (n), age, gender, setting (eg, primary care), duration of non-specific spinal pain, including associated clinical characteristics or reasons for pain and disability experienced.
3. Intervention (type of intervention (exercise, biofeedback or placebo), brief details of what this included, the duration and frequency. Details of any concurrent treatment will also be noted).
4. Comparison group (type of intervention and the number of groups).
5. Outcomes of exercise interventions
   - Clinical outcomes (disability, pain and quality of life): type, reported definition and validity, scoring (high or low score indicating poor or excellent outcome) and time points at which outcomes were recorded.
   - Physiological outcomes (neuromuscular and kinematic features): units of measurement, increase or decrease in objective measure (such as muscle activation or joint range of movement) and time points at which outcomes were recorded.
   - Psychological outcomes (depression and anxiety, beliefs, fear avoidance): type, reported definition and validity, scoring (high or low score indicating poor or excellent outcome) and time points at which outcomes were recorded.
   - Exercise adherence and safety outcomes: Exercise adherence: the number of and reasons for drop-outs (n) and incomplete sessions (n). Safety: Adverse events: the number of adverse events, in which group they occurred, and why.
6. Results

For each intervention group the following results will be extracted:

1. The number of participants for whom the outcome was measured (n).
2. The number of drop-outs recorded (n).
3. Baseline and postintervention means and SDs (short term (3–12 weeks), intermediate term (13–51 weeks) or long term (52 weeks)[13 15] to facilitate the calculation of absolute and relative differences.
4. P values and effect sizes including confidence intervals and, where possible, the minimal clinically important difference (ie, improvement in patient outcome that results in clinically important treatment effect).
5. Information relating to the assessment of 'Risk of Bias' (see below).

Assessment of risk of bias in included studies

The data extraction form will also include 'Risk of Bias' questions to examine internal validity of each RCT, including questions relating to the following domains: selection, performance, attrition, detection, reporting bias and other forms of bias. The 'Risk of Bias' questions will be informed by the Cochrane Back Review Group guidelines[25] and Cochrane Handbook for Systematic Reviews of Interventions.[26] These data will be extracted independently by the same two authors involved in the initial data extraction.

Each RCT will be determined as having an 'unclear,' 'low' or 'high' risk of bias based on the Cochrane Back Review Group criteria. For the purposes of this systematic review and in line with Cochrane recommendations,[25] the overall risk of bias will be determined by 'the least favourable assessment across the domains of bias'. This judgement may be overridden by our independent arbiter (MJ).

Study authors will be contacted if information is missing or requires further clarification. The final 'Risk of Bias' data will be entered into Review Manager (RevMan 2020, Review Manager (RevMan) (Computer program). V.5.4. The Cochrane Collaboration, 2020, UK). The Cochrane Collaboration, 2020 and 'Risk of Bias' tables will be created to indicate the biases of individual RCTs.

Measure of treatment effects

RevMan 2020 will be used to analyse the effects using a random-effects model for the meta-analysis. The average treatment effect of wearable biofeedback on the outcomes of exercise in adults with chronic spinal pain will be estimated.

For continuous outcomes, Hedge's g and 95% CI will be recorded. If the outcome measure scales are the same, an unbiased estimate of the mean difference (MD) will be determined. However, if studies measure the same outcome but outcome measure scales are different, standardised MD (SMD) will be used. Cohen's d cut-offs will be used to interpret SMDs (≤0.2 represents a small effect, ≤0.5 a moderate effect and ≥0.8 a large effect).[27]

For dichotomous outcomes, risk ratios (RRs) and risk difference will be calculated with 95% CI. An RR of less than one will favour the biofeedback intervention group over the control group for dichotomous outcomes.[28]

Reductions in pain intensity will be interpreted as per the Initiative on Methods, Measurement and Pain Assessment in Clinical Trials recommendations (15% no important change; ≥15% minimally important change, ≥30% moderately important change and ≥50% substantially important change).[29]

To facilitate further interpretation of results, a ≥30% change from baseline in pain, function and quality of life-related outcomes will be considered a clinically meaningful improvement.[30 31]

Unit of analysis issues

In order to address any unit of analysis issues, the intention will be to (1) split the control group for any multiple intervention arm trials, where intervention arms are not combined as part of the analysis and (2) where trials cited repeated participant observations, only one observation will be used (ie, if numerous adverse events are reported in relation to one participant, the total number of participants who experience adverse events will be recorded).[32]

Dealing with missing data

Missing data will be dealt with as recommended by the Cochrane Handbook for Systematic Reviews of Interventions.[26] If data are missing, authors will be contacted to request additional information. If data are missing due to random error (the data are missing for random reasons and do not reflect actual data), then this missing data will be ignored. If the data are missing due to non-random error, data will be extracted from graphs using open-source software (http://plotdigitizer.sourceforge.net/). The uncertainty of these estimates will be acknowledged. A sensitivity analysis, with and without the imputed values, will determine that such estimates are robust with or without this missing data.

Assessment of heterogeneity

A random effects model will be used to consider data heterogeneity in RevMan 2020. The random effects model assumes that the data are normal and that the pooled effect of biofeedback represents the average biofeedback effect across RCTs.

The I^2 statistic will be determined in RevMan 2020 and used to describe the heterogeneity of the RCTs included within this systematic review that is, the proportion of the total variance in the estimates of effects between studies due to heterogeneity. Visual inspection of forest plots and the χ^2 test will also be used to examine heterogeneity. The Cochrane's rough guide (V.6.3, 2022) will be employed to both grade and interpret heterogeneity[33]:

- Not important ((I^2=0%–40%).
- Moderate (I^2=30%–60%)
- Substantial (I^2=50%–90%).
- Considerable (I^2=75%–100%).

Assessment of reporting biases

The 'Risk of Bias' tables and graphs will be created by JD in RevMan 2020 and used to summarise the level of bias ('low', unclear', 'high') within each study as per Cochrane Back Review Group criteria. If there is adequate power (ie, at least 10 studies),[33] publication bias will be determined using funnel plots in RevMan 2020.

Data synthesis

The data will be analysed using a random effects model for each comparison since heterogeneity is expected within the population under investigation. In the event that there are insufficient data to undertake a meta-analysis, a narrative synthesis of the evidence will be conducted using GRADEpro (Grades of Recommendation, Assessment, Development and Evaluation, GRADEpro GDT: GRADEpro Guideline Development Tool (Software). McMaster University and Evidence Prime, 2024. Available from gradepro.org.).[34] The pooled effects for the outcomes and related GRADE assessments will be presented within a 'Summary of findings' table.

'Summary of findings' table(s)

'Summary of findings' tables, reflecting the findings for each outcome, will be created using GRADEpro software. Tables headings will include a description of the patient population (adults with chronic spinal pain), the intervention (neuromuscular or kinematic biofeedback only), comparison (no biofeedback or placebo or alternative treatment) and setting. The effect size and 95% CI (including the number of studies and participants that contributed towards the effect size) and the quality of evidence (GRADE) from the RCTs will be reported in relation to each outcome (eg, ODI).

Subgroup analysis and investigation of heterogeneity

It is anticipated that meaningful subgroup analysis will not be possible due to the insufficient data. However, if significant heterogeneity is observed (I^2>40%, p<0.1) and sufficient data are available, further subgroup analysis will be undertaken to examine the impact of potential confounders within the process, including the effect of sample size, risk of bias, the dose (intensity and frequency) of the intervention. Subgroup analysis and the investigation of heterogeneity will be undertaken according to each spinal region (cervical, thoracic and lumbar).

Sensitivity analysis

It is anticipated that there may be insufficient data to undertake a meaningful sensitivity analysis. However, in the event that sufficient data are available (more than two separate studies demonstrating an estimated effect),[33] the effect of the exclusion of studies with a high risk of bias will be examined. In addition, the effect of a random versus a fixed effects model will be determined.

Patient and public involvement

A core patient and public involvement group reviewed the plans for this systematic review, and it was determined that understanding the key effects of biofeedback is important to people with spinal pain. Although patients will not be involved in data collection and the analysis related to this review, patient and public involvement will inform future work resulting from this study.

ETHICS AND DISSEMINATION

Ethical approval is not required for the purposes of this systematic review, which is based on the analysis of previously published research. The study results will be submitted for publication in an international, open-access, peer-reviewed journal and shared through conferences and public engagement.

DISCUSSION

Current NICE guidelines endorse targeted and personalised exercise interventions for the treatment of chronic spinal pain. However, to our knowledge, there is no specific guidance as to how this should be supported by healthcare professionals or through self-management approaches. It is known that exercise alone is only moderately effective for chronic spinal pain and that wearable biofeedback may improve patient outcomes. This systematic review will evaluate whether the addition of wearable biofeedback technology (neuromuscular or biomechanical) to exercise interventions affects clinical, physiological and psychological outcomes, exercise adherence and safety. The findings will be used to inform clinical practice and the direction of future research.

To ensure high-quality reporting, this protocol complies with the PRISMA-P 2015. It is an accepted limitation of this systematic review that only English databases will be searched or included, which may lead to language bias. We have planned to undertake subgroup analyses to evaluate the effects of wearable biofeedback interventions according to spinal region (cervical, thoracic and lumbar) and dose (intensity and frequency of biofeedback), although we acknowledge that there may be insufficient homogeneous data to pool for meta-group and/or subgroup analyses.

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Competing interests In the previous 5 years, MJ's employer has received income for expert consultancy activities from GSK, TENSCare and LifeCare that lie outside the submitted work. MJ declares book royalties from Oxford University Press. All other authors declare no competing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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