i. Title, abstract, and key words;

Title

Self-management of musculoskeletal (MSK) conditions: what is most useful to patients? Protocol for a mixed methods systematic review

Abstract

Introduction

Musculoskeletal (MSK) conditions are the leading cause of disability in the United Kingdom, leading to ever-growing waiting lists. Clinical guidelines highlight that most musculoskeletal conditions resolve in time and with little clinical input, and so supporting people to self-manage is recommended to optimise healthcare resources. Despite this, the term self-management remains ambiguous and to date no systematic review has evaluated if self-management is a suitable, acceptable, and effective intervention/strategy for managing all MSK conditions.

Previous literature reviews evaluating self-management have sought to quantify the effectiveness of self-management interventions but few have explored subjective elements such as the patient's perspective regarding the intervention's suitability or acceptability. This review therefore aims to explore qualitative (QL), quantitative (QT) and mixed methods (MM) methods research to discover what self-management means to people with MSKD's, and whether the concept of self-management is an acceptable and useful intervention.

Aim

To evaluate if self-management is a suitable, acceptable and effective intervention/strategy for managing MSK conditions?

Methods

An advanced convergent qualitative meta-integration mixed studies design will be used aiming to evaluate data and evidence from QL, QT and MM studies. A comprehensive search strategy following the Population, Intervention, Control, Outcome and Study type (PICOS) format will be performed.

The Mixed Methods Appraisal Tool (MMAT) will be used to appraise the methodological quality and the risk of bias of the included studies.

Data from QT studies will be extracted from the QT studies. Studies' characteristics and outcome data will be tabulated. A narrative analysis of the QT evidence will be undertaken.

Data from MM studies will be transformed using a process of fractionation. Fractionation is defined as the process by which QL and QT data are divided into smaller quantities such that the parts can be analysed and synthesised based on their QL and QT. QL and QT data will be analysed following synthesis and then a process of 'mindful comparison' will be conducted throughout, whereby although at this point the data hasn't been integrated, a conscious and intentional consideration of the findings, commonalities and differences between the two datasets is made.

QL data from MM and QL studies will be synthesised using a thematic analytical approach. Data will be grouped into descriptive themes and then developed into analytical themes/sub-themes.

Confidence in the evidence synthesised from the review will be assessed using the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach for qualitative data and GRADE (Grading of Recommendations Assessment, Development and Evaluation) for the quantitative data.

Discussion

This systematic review will provide a detailed analysis and summary of self-management interventions for MSK conditions. If we are to truly understand self-management we need to understand what it means to the very people who are expected to use it as a strategy to manage their MSK condition. This review aims to plug this existing evidence gap by evaluating a much broader range of MSK conditions and study types, and clearly describing the quality and risk of bias of included studies. By reviewing data from mixed sources and purposefully maximising heteregenity it should cover a much broader range of data and evidence on this topic, and help patients and clinicians to make a more informed decision regarding which interventions to use.

Key words

Self-management, self-care, musculoskeletal, MSK, acceptability, acceptance.

ii. Main text;

Introduction

Rationale

Musculoskeletal (MSK) conditions are the leading cause of disability (adjusted life years) in the UK (Vos et al. 2017), accounting for 14% of all GP appointments (Jordan et al. 2010). This costs the UK National health Service (NHS) £5 billion per year and results in 10.8 million lost working days annually (Public Health England 2019). To compound matters, waiting lists for musculoskeletal (MSK) services are long, and continue to grow (NHS England 2017).

Clinical guidelines highlight that most MSK conditions resolve in time and with little clinical input, and so supporting people to self-manage is logical to reduce healthcare resource. Self-management is a concept that is now firmly established in healthcare policy and practice; however, the term remains ambiguous. Lorig and Holman (2003) define self-management as engaging in a health promoting activity such to enable day-to-day management of a health condition (Lorig and Holman, 2003). Other notable definitions include 'self-management can be defined as the day-today management by individuals of health conditions' (Grady and Gough 2018) and 'self-management includes all the actions taken by people to recognise, treat and manage their own healthcare independently of or in partnership with the healthcare system' (National Voices 2014).

Self-management has been recommended within MSK guidelines, policy, and clinical support tools to provide people with support and help them manage their condition independently (Arthritis 2020; Arthritis and Musculoskleletal Alliance and (ARMA) 2018; Greenhough 2017; Lin et al. 2020; National Institute for Care and Excellence 2014, 2015, 2017; NHS England 2019). Despite self-management being widely recommended, criticism of this approach centres around the lack of evidence supporting its effectiveness (Babatunde et al. 2017; Goodwin and Naylor 2010; National Voices 2014; Rodham 2020). In addition, guidelines draw on evidence across populations, with data from controlled trials with tight exclusion criteria that often explicitly exclude people with multi-morbidities and older people, and implicitly exclude people from diverse backgrounds. This bias against some sections of society and those with protected characteristics presents a significant problem, both ethically but also when attempting to translate research into the real world. Further, qualitative (QL) data are often not used to inform clinical guidelines leading to poor context specificity in the delivery of self-management interventions. Importantly, guidelines that are purely informed by efficacy data often do not reflect the complex psycho-social elements of injury or in complex pain experiences, or the complexities of human behaviour change needed to successfully promote self-manage for health problems (Lill, Copeland, and Rocca 2020).

Previous literature reviews evaluating self-management have sought to quantify the effectiveness of self-management interventions, but few have explored subjective elements such as the patient's perspective regarding the intervention's suitability or acceptability. It is well recognised that the exclusion of QL data informed evidence could limit the transferability of guidelines, as complex problems, such as self-management, require complex mixed methods evidence synthesis (Dixon-Woods et al. 2005; Gough, Thomas, and Oliver 2012; Ring, Jepson, and Ritchie 2011; Shepperd et al. 2009; Tricco et al. 2016).

In a review of 228 systematic reviews (National Voices 2014) investigating supported self-management across a broad range of healthcare conditions, only 11 reviews of MSK conditions were identified and none explored the patients perspective. Of the 11, there was significant variation in conditions (Arthritis N=4 RA N=4, Chronic MSK N=3) and outcomes studied, thus many MSK conditions were not represented. The quality and risk of bias of the included reviews was not reported formally, therefore it is difficult to draw robust recommendations to enhance clinical practice. Other reviews have focused on specific sub-groups, settings or factors and again have only focused on quantitative (QT) data: Babatunde et al (Babatunde et al. 2017) reviewed the evidence for self-management for MSK in primary care, but only included evidence from QT studies, and Martinez-Calderon et al (Martinez-Calderon et al. 2020) evaluated intervention effect on pain self-efficacy but only included data from randomised control trials (RCT's). Owing to the heterogeneity of the literature evaluating self-management, it is difficult to understand what might work best, for whom and in what context (Nicholl et al. 2017). If we are to truly understand self-management, we need to understand what it means to the very people who are expected to use it as a strategy to manage their MSK condition.

Acceptability has become a key consideration in the implementation of healthcare interventions, but it has not been considered during the design or evaluation of many studies of self-management interventions (Sekhon, Cartwright, and Francis 2017). The content, context and quality of self-management interventions will all impact on patient and clinician acceptability, which will have knock on effects to adherence and benefit (Sekhon et al. 2017). This review aims to plug the existing evidence gap, by evaluating a much broader range of MSK conditions and study types, and clearly describing the quality and risk of bias of included studies. It will explore QL, QT and mixed methods (MM) methods research to discover what self-management means to people with MSK conditions, and whether the concept of self-management is an acceptable and useful intervention. We will also explore clinicians' perspectives and what self-management interventions, if any, are effective at actually helping people better manage their condition.

Aim

To evaluate if self-management is a suitable, acceptable, and effective intervention/strategy for managing MSK conditions?

Objectives

1. To examine patient's and clinician's interpretation of the term self-management.
2. To assess which self-management strategies are acceptable and useful for patients with MSK conditions.
3. To identify, map and examine effective self-management resources for MSK conditions.

Methods

Design

An advanced convergent qualitative meta-integration mixed studies design (Frantzen and Fetters 2016; Hong et al. 2017; Pluye and Hong 2014) will be used, aiming to evaluate data and evidence from QL, QT and MM studies (Figure 1). Although other designs and frameworks exist (Creswell and Clark 2010; Heyvaert, Maes, and Onghena 2013; Sandelowski, Voils, and Barroso 2006) for

performing mixed studies reviews, the Pluye and Hong (Pluye and Hong 2014) framework draws some of these approaches together in a unified and simplified framework and Franzten and Fetters (Frantzen and Fetters 2016) give detailed guidance for the data synthesis and integration procedure.

The review will be conducted according to a pre-defined protocol (Frantzen and Fetters 2016; Hong et al. 2017; Pluye and Hong 2014) that aligns to the Cochrane Handbook for Systematic Review, an internationally recognised handbook used to guide the review process (Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ 2021). The review will be presented in line with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to ensure quality and minimise bias (Shamseer et al. 2015). PRISMA is an evidence-based minimum set of items for reporting in systematic reviews. It is registered on the PROSPERO database (CRD42021265391) for transparency and to reduce the risk of duplication (Prospero 2021). PROSPERO is an international database that provides a comprehensive listing of systematic reviews to avoid duplication and reduce opportunity for reporting bias by enabling comparison of the completed review with what was planned in the protocol.

Eligibility criteria

Studies will be selected to inform the review aim and objectives. Specific inclusion criteria will follow the Population, Intervention, Comparison, Outcome and Study type (PICOS) format as outlined in table 1. PICOS has been shown to be a reliable search strategy for mixed-methods (MM) reviews and is preferable over other strategies i.e SPIDER as it retains the Intervention category needed for the quantitative arm of this review (Methley et al. 2014).

Language
We will only include studies published or translated into English.

Timing
Only studies published in the last 15 years will be included. Self-management as a concept to manage MSK conditions has been around for many years but was very much been presented as supported self-management – whereby patients are supported to self-manage their conditions by clinicians (Rodham 2020). Only recently has self-management, in its truest sense i.e. patients managing their symptoms independently of clinical input, started to appear in guidelines and policy (4-11), we therefore aim to focus on these later studies and not the wealth of literature describing supported self-management.

Exclusion Criteria
Studies not written in English.

Information Sources

Authors will search the information sources detailed in table 2. In addition to research databases, relevant internet sites will be searched to capture a wider breadth of QT sources. To ensure key information sources are not missed, expert opinion will be sought, and hand searches of key journals and the reference lists of key studies and unpublished research will be completed.

Search strategy

A comprehensive search strategy following the PICOS (Methley et al. 2014) format as outlined in Figure 4 will be performed using the databases outlined in Figure 3. A snowballing strategy will be used to review reference lists of those texts included for full-text review to identify any potentially previously unidentified articles.

Study Records

Data management

Following the literature search, citations will be imported into a commercial data collection and synthesis tool (rayan.ai). Papers will be segregated and categorised into QL and QT and MM papers. A brief description of each study with information about purpose, number of participants, study design, methodology, analysis and results will be recorded within the platform (rayan.ai). This is to enable easy identification and provide an easily accessible summary of studies for the reviewers.

Selection process

Two reviewers will perform the title and abstract screening, and disagreements will be resolved by consensus or by a third reviewer. The full text of eligible records will be retrieved and assessed by both reviewers. Disagreement between the reviewers regarding the full text will be resolved initially by discussion and, if necessary, arbitration by a third reviewer. In case of insufficient or unclear information in a potentially eligible article, the authors will be contacted before article exclusion. The number of studies included at each stage will be demonstrated within a PRISMA flow diagram (Shamseer et al. 2015).

Data collection process

Pre-tested data extraction forms will be used to extract data. One reviewer (BW) will use commercial software (rayyan.ai) to extract data and a second reviewer (TN) will independently review data extraction by ensuring that all relevant data were extracted. Differences in opinion will be resolved at a consensus meeting (Higgins JPT, Thomas J, Chandler J, Cumpston M, Li T, Page MJ 2021). A third reviewer will check for consistency, clarity and will aid resolution throughout the process.

Qualititative

Data related to patients and clinicians' perceptions of the term self-management, and patients' views regarding the acceptability of self-management, will be extracted by the two reviewers (BW, TN) using a commercial data collection/synthesis tool (rayyan.ai).

Quantitative

Data related to the efficacy of self-management interventions for MSK conditions will be extracted from the quantitative studies using a commercial data collection/synthesis tool (rayyan.ai). Data extraction items regarding included interventions will be informed by the TIDieR checklist (TiDIER 2014.; Hoffmann et al. 2014). This is to ensure a complete description of the interventions that are evaluated is published, so other researchers can replicate or build on research findings (Hoffmann et al. 2014).

Mixed methods studies
QL and QT data from MM papers will be separated using a process of fractionation. Fractionation is defined as the process by which QL and QT data are divided into smaller quantities such that the parts can be analysed and synthesised based on their QL and QT form (Frantzen and Fetters 2016).

Data items and outcomes

The following data items will be extracted from included articles with equal priority: author, year, country, publication status, design, self-management definition (if included), data collection method, participant characteristics, type and description of the intervention, duration of follow up (if relevant), qualitative information (themes/sub-themes), discussion (if applicable), or annex/appendix sections.

Quality assessment

The Mixed Methods Appraisal Tool (MMAT) will be used to appraise the methodological quality and the risk of bias of the included studies (Hong et al. 2018). The MMAT differs from other quality assessment tools (i.e the Critical Appraisal Skills Programme (CASP 2019.)) as it considers all necessary elements for the different data sources, and provides guidelines for quality appraisal of the integration of the MM papers.

Two reviewers will assess the quality of each study independently. Discrepancies between will be resolved by discussion. A third investigator will be consulted for arbitration if necessary

Data analysis and synthesis

Stage 1: Mixed Methods data Fractionation

Data from MM studies will be transformed using a process of fractionation. Fractionation is defined as the process by which QL and QT data are divided into smaller quantities such that the parts can be analysed and synthesised based on their QL and QT form (Frantzen and Fetters 2016). Following fractionation, the synthesised QL and QT data will be analysed within the QL and QT data analysis stages (Frantzen and Fetters 2016).

Stage 2: Quantitative data

Data from QT studies assessing objective 3 (the efficacy of self-management), will be extracted from the QT studies. Studies' characteristics and outcome data will be tabulated. A narrative analysis of the QT evidence will be undertaken.

Stage 3: Qualitative data

QL data from MM and QL studies will be synthesised using a thematic analytical approach to answer the three objectives. One reviewer (BW) will undertake line-by-line coding of data (using commercial software). Data will be grouped into descriptive themes and then developed into analytical themes/sub-themes (Thomas and Harden 2008). Two reviewers (BW,TN) will review preliminary themes/sub-themes; and re-read all included studies to ensure that the identification of

all relevant data was complete (Thomas and Harden 2008). The themes/sub-themes will then be scrutinised by a panel of experts to agree upon the findings. Characteristics and outcomes of the included studies will be tabulated.

A process of 'mindful comparison' will be conducted throughout, whereby although at this point the data hasn't been integrated, a conscious and intentional consideration of the findings, commonalities and differences between the two datasets is made (Frantzen and Fetters 2016).

Stage 4: Integration

Data from all sources will then be integrated to evaluate level of agreement and identify any conflicts or gaps in the data before results are organised and presented before drawing conclusions.

Meta-bias(es)

Due to the pragmatic nature of this review and its primary focus on interpreting and explaining findings from heterogenous study types to maximise variability, reporting bias formally will be difficult. We will discuss any clear biases during meta-integration and interpretation of the results.

Confidence in cumulative estimate

Confidence in the evidence synthesised from the review will be assessed using the GRADE-CERQual (Confidence in the Evidence from Reviews of Qualitative research) approach for qualitative data and GRADE (Grading of Recommendations Assessment, Development and Evaluation) for the quantitative data (Schünemann H, Brożek J, Guyatt G, Oxman A 2013). A summary of findings will be presented with the GRADE ratings.

Discussion

This systematic review will provide a detailed analysis and summary of self-management interventions for MSK conditions. If we are to truly understand self-management we need to understand what it means to the very people who are expected to use it as a strategy to manage their MSK condition. This review aims to plug this existing evidence gap by evaluating a much broader range of MSK conditions and study types, and clearly describing the quality and risk of bias of included studies. By reviewing data from mixed sources and purposefully maximising heteregenity it should cover a much broader range of data and evidence on this topic., and help patients and clinicians to make a more informed decision regarding which interventions to use.

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iv. Tables

Table 1: Eligibility criteria

Population	Patients - Individuals with MSK injury or pain. Clinicians - Any healthcare professional working in an MSK setting.
Intervention	Self-management resources: Leaflets, PDF's, websites, digital apps/solutions Self-management interventions: group or 1:1 coaching in any setting.
Comparison	N/a
Outcome	Patients' and clinicians' interpretation of the term self-management Patients' acceptability and/or experience of engaging with self-management resources/tools/interventions. Identify, map and examine effectiveness of self-management resources for MSKD's.
Study type	Qualitative, quantitative and mixed-method studies.

Table 2: Information sources

Databases
CINAHL, EMBASE, MEDLINE, AMED, NICE, Medicines Complete, HMIC, ASSIA, Web of Science, PUBMED, and Turning Research into Practice
Internet sites
System for Information on Grey Literature, Google Scholar, RCGP, King's Fund, National Institute of Clinical Excellence, Department of Health, Chartered Society of Physiotherapy, Society of Chiropodists and Podiatrists, AHSN sites
Other sources
Expert opinion, unpublished research, hand searching of key journals and reference lists of key studies.

Table 3: Primary search strategy

Search	**Search Term**	**PICOS Domain**
S1	"Musculoskeletal" OR "musculoskeletal pain" OR "musculoskeletal con*" OR "musculoskeletal dis*" OR "musculoskeletal inj*" OR Musculoskel* OR Joint* OR Tendon* OR Muscle* OR "Ligament injury" OR "Soft-tissue injury" OR 'Minor Injur*"	Population concept 1
S2	Shoulder* OR elbow* OR hand* OR finger* OR "upper limb*" OR hip* OR knee* OR ankle* OR foot OR Feet OR "lower limb*" OR Lumbar OR "Low back" OR Back OR Thoracic OR Cervical OR Neck	Population concept 2
S3	S1 AND S2	Population concept
S4	"self manage*" OR "self-manage* OR "self care" OR "self monit$r*" OR "goal-setting" OR "behaviour" OR "behaviour change	Intervention concept
S5	Effectiveness OR efficacy OR self-efficacy OR success* OR improve* OR perception* OR view* OR feeling* OR impact OR work* OR "quality of life*" OR acceptable OR useful OR attitudes' OR values OR confidence	Outcome concept
S6	S3 AND S4 AND S5	

v. Figure legends;

Fig 1: Study design. An advanced convergent qualitative meta-integration (Franzten and Fetters 2015)