STUDY PROTOCOL

ADvAnced PhysioTherapy in MuSculosKeletal Triage: Investigating prognostic factors, healthcare utilisation and clinical outcomes (ADAPT MSK) - a cohort study protocol. [version 1; peer review: 1 approved, 2 approved with reservations]

Fiona Callan[1], Louise Keating[1], Sarah Casserley-Feeney[2], Helen P. French[1]

[1]School of Physiotherapy, Royal College of Surgeons in Ireland, Dublin, Ireland
[2]National Musculoskeletal Triage Initiative, National Clinical Programme for Trauma & Orthopaedic Surgery (NCPTOS), Royal College of Surgeons in Ireland, Dublin, Ireland

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Abstract

Background: Clinical specialist physiotherapist-led musculoskeletal triage clinics were introduced nationally in Ireland in 2011 to improve patient care and reduce waiting times for secondary care orthopaedics and rheumatology. Evidence has shown them to be effective in reducing waiting lists, however there are currently no data on longitudinal patient outcomes following clinic attendance. The primary aim of this cohort study is to identify predictors of pain and function outcomes up to one year following musculoskeletal triage review. Secondary aims include measuring self-reported use of healthcare resources over the 12-month follow-up period and to explore musculoskeletal phenotypes based on established prognostic factors for musculoskeletal pain. This is a prospective cohort study.

Methods: ADvAnced PhysioTherapy in MuSculosKeletal Triage (ADAPT MSK) will recruit a cohort of 252 adults through musculoskeletal triage clinics across five secondary care sites in Ireland. The STrengthening the Reporting of Observational studies in Epidemiology (STROBE) guidelines will be adhered to for future reporting. Adults (≥ 18 years old) attending physiotherapist-led musculoskeletal triage clinics with musculoskeletal pain, who do not require surgical or consultant-led medical care will be considered for participation. Participant demographics, health literacy, healthcare utilisation, and self-report questionnaires on pain, function, musculoskeletal health, musculoskeletal risk stratification, fear of movement, and psychological distress will be obtained at baseline, with follow-ups at

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	1	2	3
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1. **Subhash Aryal**, University of Pennsylvania, Philadelphia, USA
2. **Karin Samsson**, University of Gothenburg, Gothenburg, Sweden
3. **helen o'leary**, University of Limerick, Limerick, Ireland

Any reports and responses or comments on the article can be found at the end of the article.

three, six, and 12 months. Primary outcomes are pain intensity and function. Secondary outcomes include musculoskeletal risk stratification status, musculoskeletal health, healthcare utilisation, and work-related factors. Descriptive statistics will be used to profile the participants and predictors of outcome will be assessed using multivariable linear regression. Musculoskeletal phenotypes will be explored using latent class analysis.

Results: Results will be disseminated via peer-reviewed journal publication and presentation at national and international conferences. Engagement with a public patient involvement (PPI) panel will explore dissemination strategies for public and service user engagement.

Keywords
Musculoskeletal triage; physiotherapy; orthopaedic triage, rheumatology triage; predictors of outcome; musculoskeletal pain, healthcare utilisation, cohort study

Corresponding author: Fiona Callan (fionacallan@rcsi.com)

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Introduction

Musculoskeletal (MSK) pain, which includes conditions such as low back pain, neck pain or osteoarthritis is recognised as one of the leading causes of disability worldwide[1], resulting in increased healthcare expenditure and longer waiting times for orthopaedic and rheumatology outpatient services[2,3]. Adult orthopaedic services represent the largest waiting list in Ireland (June 2023) with a total of 64,867. Up to 25% of patients are waiting more than 12 months for orthopaedic (22%) and rheumatology (25%) appointments in secondary care[4].

In 2011, to reduce outpatient Orthopaedic and Rheumatology waiting times in Ireland, the Health Service Executive (HSE) National Clinical Programmes for Trauma and Orthopaedics (NCPTOS), and Rheumatology (NCPR) established the National MSK Triage Initiative, consisting of 24 clinical specialist physiotherapist (CSP) posts in 18 Acute Hospital sites nationwide. In these MSK Triage clinics, CSPs triage patients on outpatient orthopaedic and rheumatology waiting lists, who are unlikely to require consultant care, onto appropriate care pathways. In a national audit, over 80% of patients presenting to MSK-triage clinics in Ireland were managed independently by the CSP, with 71% discharged at their initial appointment[5] and 23% referred to physiotherapy[6]. From 2012 to 2018, 125,852 patients on orthopaedic and rheumatology waiting lists were managed through MSK triage services[7]. Access to primary care physiotherapy also presents a barrier to patients, with 56,200 on primary care waiting lists and 22% (12,502) waiting greater than one year to access primary care physiotherapy services in 2022[8]. Longer waiting times to access physiotherapy can negatively affect patients' quality of life, psychological wellbeing, healthcare utilisation, health outcomes and economics[3,9,10].

Whilst the National MSK Triage Initiative has been successful in reducing acute hospital outpatient orthopaedic and rheumatology waiting lists, the high discharge rate of 71% at initial appointment[5] warrants further examination to explore the patient journey and potential reasons why patients are not referred to the right service at the right time, in line with the Irish government health reform plan (Sláintecare)[11]. It is possible that suboptimal access to primary care services, may be influencing referrer behaviour and decision making.

Several predictors of pain and functional outcomes in MSK conditions have previously been identified, including baseline function, pain intensity, mental well-being, co-morbidities, age, body mass index (BMI), duration of symptoms, workers' sick leave, education level[12] and altered pain processing[13]; which can also predict non-response to physiotherapy[14]. Recently, MSK core outcome sets, and prognostic stratification tools (such as the Subgroups for Targeted Treatment Back (STarT Back) and Subgroups for Targeted Treatment MSK (STarT MSK)), have been developed, based on established prognostic factors[12,15], and validated to identify earlier, those at risk of developing persistent MSK pain[16,17]. Research to date has shown that MSK triage is an effective waiting list initiative with good service user and healthcare professional satisfaction[5,7,18–21]. However, currently, patient outcomes, prognostic stratification, and predictors of outcome up to 1-year later have not been consistently studied in patients attending MSK triage clinics in Ireland or internationally.

Objectives

The primary aim of this prospective, cohort study is to identify predictors of clinical outcome (pain and function) at three-, six-, and 12-months post MSK-triage appointment.

Secondary aims are to:

1. Measure self-reported use of healthcare resources over the 12-month follow-up period post MSK-triage appointment.

2. Explore MSK phenotypes based on common prognostic factors for MSK pain.

Methods

Study design

ADAPT MSK is a prospective, observational, cohort study. The STROBE standardised reporting guidelines will be used to guide the reporting of this study[22]. Adults with MSK pain attending CSP-led MSK triage clinics will be recruited from five sites across Ireland. Baseline assessment will consist of baseline demographics, work-related factors, healthcare utilisation and self-report questionnaires. Follow-up at 3, 6 and 12 months will involve repeat measurement of work-related factors, healthcare utilisation and self-report questionnaires.

Ethics

Ethical approval for this study was granted by the Research Ethics Committees in Beaumont Hospital (Ref: 22/34), Tallaght University Hospital (Ref: 2418), Merlin Park Hospital (Ref: C.A. 2870), Midlands Regional Hospital Tullamore (Ref: RRECB1022FC) and St Vincent's University Hospital (Ref: RS23-010). Written informed consent will be obtained from eligible participants prior to study recruitment, in line with the Data Protection Act 2018 (Section 36(2))[23].

Setting

This study will be based in MSK Triage clinics across five urban and regional secondary care sites in Ireland. These clinics are run by CSPs with more than five years clinical experience and the majority achieving a postgraduate MSc or PhD degree, in the field of MSK physiotherapy[5]. They provide expert assessment, diagnosis and education to patients and identify the most appropriate management pathway for patients with MSK disorders. Patients on orthopaedic and rheumatology waiting lists, deemed unlikely to require orthopaedic surgeon or rheumatology consultant care are triaged to these MSK triage clinics, which improves service efficiency by reducing secondary care waiting lists and directing patients towards the appropriate care pathway[7].

Participants

A consecutive sample of patients presenting to orthopaedic and rheumatology MSK-triage clinics with pain will be recruited. Participants will be eligible if they are aged 18 years or over,

are triaged for non-consultant care at one of the five participating MSK triage services across Ireland, and have sufficient English language proficiency for the completion of self-reported questionnaires.

Patients will be ineligible to participate if they've been triaged by the CSP for orthopaedic surgical or rheumatologist assessment, are unable to communicate in English (written and spoken word), along with those who present with clinical indicators of suspected 'red flag' pathology (e.g. recent trauma with significant injury; acute, red, hot, or swollen joints; suspected fracture; joint infection; cancer)[24]; or a diagnosed systemic inflammatory MSK condition (such as rheumatoid arthritis) or a diagnosis of dementia or terminal illness.

Sample size

The estimated sample size is based on our primary aim. Approximately 18 predictor variables will be included in univariate analysis and with 10 events required per predictor variable[25], a sample of 180 participants is required. An additional 40% has been added to allow for drop-out at the 12-month follow-up, resulting in a final sample size of 252.

Recruitment and data collection

The MSK triage physiotherapist will identify and screen prospective participants for eligibility. If eligible, they will provide a participant information leaflet, briefly explain the objective of the study, and obtain written consent to be contacted by the primary investigator (FC). This allows the primary investigator to contact prospective participants to answer any questions about the study and if interested in participating, obtain informed written or electronic consent.

Once recruited, each participant will undergo a baseline assessment with the primary investigator, capturing participant demographics and healthcare utilisation, via Microsoft Teams or telephone, depending on participant preference. Thereafter, participants will complete a number of self-report questionnaires based on established prognostic factors i.e., baseline function, pain intensity, mental wellbeing, symptom duration, fear avoidance/catastrophising, quality of life/self-efficacy, widespread pain, age, co-morbidities, work absence duration, and education level[15,26,27]. This data will be collected through Research Electronic Data capture (REDCap) software[28,29], hosted at RCSI, on their personal device, or via posted paper questionnaires.

Demographic information will include participant gender, age, level of education, presenting MSK complaint, duration of symptoms, number of MSK pain sites, previous physiotherapy/surgery for presenting complaint, and work-related factors (employment status, work classification and duration of any work absence). Co-morbidities will be identified from a list of 12 comorbid conditions, informed by the National Institute of Clinical Excellence (NICE) indicator for multi-morbidity in primary care[30]. Health literacy will be explored using the single-item literacy screener[31]. Healthcare utilisation will be recorded using a modified version of the Managing of OSteoArthritis In ConsultationS (MOSAICS) trial questionnaire[32], which captures advice and information received about their condition, self-management, prescribed medications, aids and appliances, private/public health services (e.g., physiotherapy, GP, nursing, occupational therapy, podiatry), treatments, and investigations.

Self-report questionnaires will include the Musculoskeletal Health Questionnaire (MSK-HQ)[33], STarT MSK tool[17], and Patient Specific Functional Scale (PSFS)[34] to assess functional and MSK health status; pain intensity through the Numerical Pain Rating Scale (NPRS)[35,36]; fear of movement through the 11-item Tampa Scale for Kinesiophobia[37] and psychological distress via the Hospital Anxiety and Depression scale (HADS)[38].

All participants recruited in two sites (Beaumont Hospital and Tallaght University Hospital) will be invited to participate in a once-off baseline physical examination, consisting of grip strength examination, neurological exam, and quantitative sensory testing (Table 1).

Pain hypersensitivity, measured by quantitative sensory testing, has been shown to be a predictor of worse outcome (pain and disability) at follow-up across multiple MSK conditions (e.g., osteoarthritis, low back pain, whiplash, post-operative pain) and different body sites (e.g., hip, knee, low back, shoulder and neck)[13]. Quantitative sensory testing uses standardised testing protocols of somatosensory nerve function, to investigate potential underlying pain mechanisms[39,40]. The International Association for the Study of Pain (IASP) task force clinical criteria and grading system for nociplastic pain involves a stepwise approach to differentiate between predominant nociceptive, neuropathic or nociplastic pain[41], which, in conjunction with the NeuPSIG guidelines on neuropathic assessment[42] will be used to categorise participants' dominant pain phenotype (Figure 1). A quantitative sensory testing protocol including pressure pain thresholds (PPT), dynamic mechanical allodynia, pinprick, temporal summation and cold pain thresholds will be used to assess pain sensitivity in accordance with IASP and NeuPSIG grading systems[41,42].

Grip strength is regarded as a biomarker of current health status and has been adopted as a singular indicator of overall body strength[43–45]. Grip strength will be assessed isometrically using a calibrated Jamar Plus Digital dynamometer following a standard protocol[46].

Follow-up assessment

The primary investigator will contact participants at three, six, and 12 months via Microsoft Teams or telephone to collect healthcare utilisation data and work-related factors (employment status, work classification and duration of any work absence). Self-report questionnaires (MSK-HQ, STarT MSK, Patient Specific Functional scale, and NPRS) will be sent electronically via REDCap software or via post. Any participant withdrawals or loss to follow-up will be recorded.

Outcomes

The primary outcomes of interest are pain intensity (NPRS) and function (PSFS). Secondary outcomes are musculoskeletal risk stratification status (STarT MSK), musculoskeletal health

Table 1. Overview of primary and secondary outcomes, predictor variables, and time of assessment.

Variables		Method	Baseline	3 months	6 months	12 months
Primary Outcomes						
Pain	Numerical pain rating scale Mean of: - Current - Worst in last 24 hours - Least in last 24 hours	RC		✓	✓	✓
Function	Patient specific functional scale (PSFS)	RC	✓	✓	✓	✓
Secondary Outcomes						
Employment	Work status Work absence Work absence duration	MT/T	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓	✓ ✓ ✓
MSK Health Status	Musculoskeletal Health Questionnaire (MSK-HQ) STarT MSK	RC	✓	✓	✓	✓
Healthcare Utilisation	Modified MOSAICS Questionnaire	MT/T	✓	✓	✓	✓
Predictor Variables						
Demographics	Age Gender Education	MT/T	✓ ✓ ✓			
Baseline Clinical Factors	Total number of MSK pain sites (number/11 on body chart) NICE multi-morbidity index Single item health literacy screener (SILS) Duration of symptoms Previous surgery Previous physiotherapy	MT/T	✓ ✓ ✓ ✓ ✓ ✓	✓	✓	✓
Employment	Work classification	MT/T	✓	✓	✓	✓
Fear of Movement	Tampa Scale for Kinesiophobia (TSK-11)	RC	✓			
Anxiety and Depression	Hospital anxiety and depression scale (HADS)	RC	✓			
Optional Physical Examination (Two Recruitment Sites)						
Pain Phenotype	Quantitative Sensory Testing - Pressure pain threshold - Dynamic mechanical allodynia - Heat pain threshold - Temporal summation Clinical Neurological Exam	Physical	✓ ✓			
Grip Strength	Hand-held dynamometer	Physical	✓			

MSK, Musculoskeletal; MT/T, Microsoft Teams/Telephone; RC, RedCap

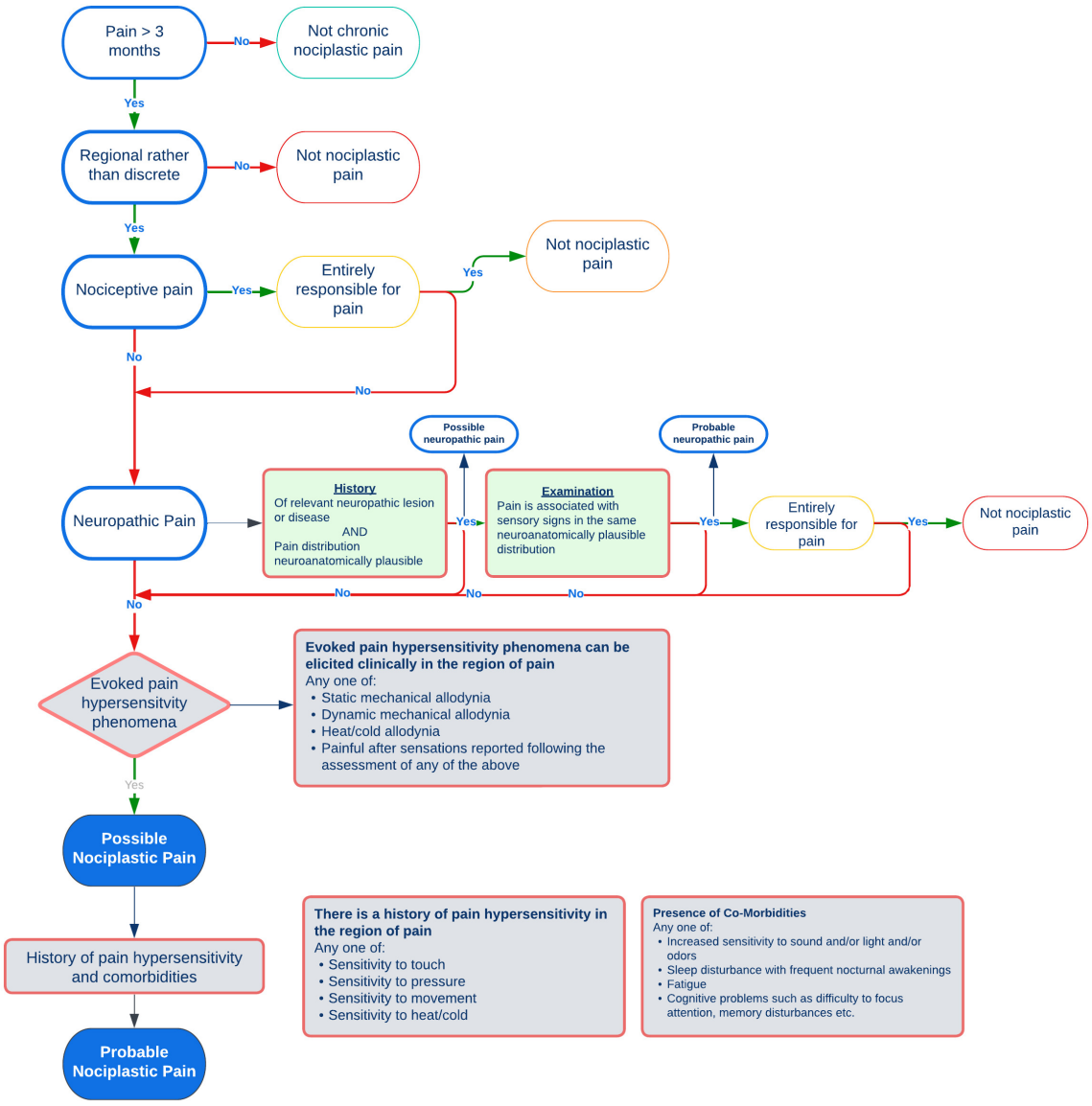

Figure 1. Screening process for pain classification based on IASP criteria for nociplastic pain[41] and NeuPSIG grading system for Neuropathic pain[42].

(MSK-HQ), healthcare utilisation and work-related factors (employment status, work classification, work absence ± duration).

Statistical analysis

Pseudonymised data will be stored in an encrypted and password protected folder on the study's SharePoint site in RCSI. Secure and encrypted access to the Microsoft SharePoint folder will be assigned to data controllers only. Descriptive statistics will be used to profile the characteristics of the cohort at baseline, three, six, and 12 months. Changes at three, six, and 12 months will be analysed using repeated measures multivariable regression. All models will be adjusted for potential confounding factors, checking for interactions and collinearity. Multivariable linear regression will be used to identify baseline predictors of pain and function outcomes at three, six, and the primary timepoint of 12 months. Variables included in the multivariable regression model will be selected if deemed clinically significant, or, if they have a univariable p-value of <0.2. Latent Class Analysis will be undertaken to explore underlying pain phenotypes within the cohort at baseline, three, six, and 12 months based on a range of observed categorical variables. Statistical significance will be inferred when the P value is <0.05. STATA 17 statistical software (StataCorp, College Station, Tx, USA) will be used for statistical analyses.

Dissemination

Findings from this study will be disseminated via peer-reviewed journal publication and presentation at national and international conferences. Engagement with a public patient

involvement (PPI) panel will explore dissemination strategies for public and service user engagement.

Study status

Data collection commenced in December 2022, with study completion anticipated in November 2024.

Discussion

The burden of MSK disorders is increasing exponentially worldwide, resulting in significant pressure on healthcare systems. People with MSK pain who present to their GP in Ireland are faced with difficulties accessing first-line public services, such as primary care physiotherapy and subsequently specialised orthopaedic and rheumatology services. To address secondary care waiting lists and improve service efficiency, the National MSK Triage Initiative, MSK triage clinics, run by CSPs under the clinical governance of Orthopaedic and Rheumatology Consultants commenced in Ireland in 2011, and has demonstrated success as a waiting list initiative. However, high discharge rates and onward referral to primary care physiotherapy following MSK triage suggest that these patients may have been managed more appropriately in primary care if sufficiently resourced. Currently, the patient journey and long-term outcomes following their MSK triage attendance are unknown. This longitudinal cohort study aims to identify predictors of pain and function outcomes up to 1 year following MSK triage attendance; measure individuals' self-reported use of healthcare resources and explore MSK phenotypes based on identified prognostic factors. This research has the potential to inform future needs within primary care for those with MSK conditions, as well as the implementation of pathways from primary to secondary care orthopaedics and rheumatology, ensuring that patients receive the 'right care, at the right place, at the right time' in line with SláinteCare principles[11].

Data availability

No data are associated with this article.

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✓ **helen o'leary**
University of Limerick, Limerick, County Limerick, Ireland

Introduction

Overall could include more information to expand on the gap this research is addressing/what is known already and why this research is important

While the background contains interesting info on the MSK triage initiative it's not clear from the Introduction why this is an important question? Why is knowing predictors of outcome for this particular patient cohort at 1 year is important? What are the implications of better predicting outcomes? Could it be used for early identification of those at risk of persistent pain and subsequent prioritisation by physiotherapy services? How will this information be used to improve or better current MSK services in Ireland? (some mention of this in Discussion)

Also, while the authors refer to previous SRs of predictors of pain and function in MSK conditions, it would be useful to know what type of patient population these relate to (primary care or secondary care). It is stated that MSK triage clinics have not been studied, which is true, however this cohort are essentially very similar to cohort attending secondary care elective othopaedic clinics, what are the main findings from these studies?

Methods
Study Design- Follow-up at 3, 6 and 12 months- is there a pre-specified primary end-point?

How many are estimated to undergo a baseline physical exam? Will there be sufficient data from these two sites to carry out the anticipated data analysis e.g. latent class analysis or multi-variable analysis? Or is this info solely to categorise the pain phenotype? Should make reference to this sub-group in the data analysis section.

Pain phenotyping- using IASP criteria and NeuPSIG based on baseline physical exam. Is this different to the Latent Class Analysis to explore underlying pain phenotypes "based on a range of

categorical variables”? Clarify this.

How soon will the physical exam be after the patient is recruited? What is the anticipated duration of this examination eg. 1 hour?

QST- Would have expected in a protocol to see more detail here in order that your testing procedures are reproducible. For example how do you intend to choose anatomical testing sites (related to the primary pain complaint?) What is the order of testing? Instruments- Device you are using for pressure pain algometry, what thermal testing devices?. What is pinprick testing? References (41, 42) provided are for grading systems and not for a QST protocol. Did the authors mean to reference the Rolke et al, 2006 (40)DFNS protocol here?

If DFNS Rolke 2006 protocol is what the researchers are using, are the researchers following a modified version of DFNS Rolke 2006 protocol or reproducing exactly. For example, this protocol uses testing of 1 pinprick versus 10 repeated pinpricks and repeats this procedure 5 times, this (55 pinpricks !) may be poorly tolerated by patients, esp hyperalgesic. Have the researcher’s modified this? How?

Perhaps Table 1 could include more detail on protocol or how differs to referenced protocol or include as supplementary info

Table 1- different QST info compared to text- pinprick omitted, heat pain threshold here instead of cold pain thresholds

Clinical Neurological Exam- indicate in Table 1 what will this entail? Is the main purpose to help with pain classification?

Patients attending Rheumatology MSK triage clinics are typically multi-site MSK pain, eg. Small joints of the hands plus other several painful area. It is not clear how it's decided which is the index site for the primary outcome pain NRS. Similarly for QST indicate how will select test site?

Is the rationale for, and objectives of, the study clearly described?

Partly

Is the study design appropriate for the research question?

Yes

Are sufficient details of the methods provided to allow replication by others?

Partly

Are the datasets clearly presented in a useable and accessible format?

Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: musculoskeletal pain, knee pain

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.

Reviewer Report 01 February 2024

https://doi.org/10.21956/hrbopenres.15061.r37424

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Karin Samsson
University of Gothenburg, Gothenburg, Sweden

This is an important aspect to address in research, to improve on the knowledge regarding the patients that are referred for MSK triage. Furthermore, to be able to screen patients prior to referral could reduce waiting times as well as improve care on the right level.

1. You state in the introduction that 71% of patients were discharged at their initial appointment and 23% referred to physiotherapy, which makes me wonder. The 71% who were discharged, do you think that they would have needed different care than what they received? And since this large number of patients were discharged, and not referred to physiotherapy, why do you think predictors of clinical outcome and prognostic factors for MSK pain. is important to investigate for this patients group?
2. The aims are not consistently reported throughout the paper.
3. You have a great number of predictors and outcomes, but I struggle to make them out clearly since they are inconsistently reported in introduction and various sections in the methods. It would be highly beneficial for the reader to have these clearly and consistently presented regarding what outcome you want to measure and what outcome measure you use. Furthermore, to use the same terms i.e. in some sections you use workers' sick leave, sick leave or work-related factors.

   Participants
4. Regarding patients included in the study - who is responsible for deciding which patients are "unlikely to require consultant care" and based on what?
5. Are the patients to be included in the study after the triage? When is the patient asked to participate? And why don’t you include the patients in need of orthopaedic surgeon to be able to investigate predictors of clinical outcome and prognostic factors for MSK pain for them as well? Considering that 71% are discharged, it would probably be quite beneficial to know if there is a difference between these two groups.

   Sample size
6. There is no formal sample size calculation.

   Recruitment and data collection
7. You state that the MSK triage physiotherapist will identify and screen prospective participants for eligibility – is this before the actual triage? I think this process needs to be

clearly described (as also addressed in previous question).
8. If I understand correctly you are collecting two written consents? What is the purpose of that?
9. Why did you chose to have a teams or telephone data collection as well as questionnaires?
10. Inconsistent reporting of outcomes collected and through what outcome measures, order and the use of abbreviations or not. Furthermore not clear which ones are collected via self-reported questionnaires vs telephone/teams. Furthermore, not all outcomes are included in the primary or secondary outcomes.
11. The outcome health literacy is not mentioned or described prior to data collection.
12. The whole section starting with "Pain hypersensitivity, measured by... / (Figure 1) seems more to belong in the introduction section.
Outcomes
13. Outcomes are not consistent with aims.

Is the rationale for, and objectives of, the study clearly described?
Partly

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Physiotherapist led orthopaedic triage. Have not focused on the statistics part as that is not my area of expertise.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Reviewer Report 16 January 2024

https://doi.org/10.21956/hrbopenres.15061.r37570

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Subhash Aryal
University of Pennsylvania, Philadelphia, Pennsylvania, USA

I focused on the statistical analysis component of the manuscript. Here are my specific concerns regarding this manuscript.

1) There is no formal sample size calculation. Rule of thumb of 10 events per variable is used. Software including PASS, SAS can actually provide a more formal sample size estimation.

2) The authors propose using repeated measures multivariable regression. I recommend being more specific in terms of whether it is random-effects model, covariance pattern model or marginal GEE model.

3) The authors have adjusted sample size to account for attrition. But missing data is not addressed in the statistical analysis plan.

4) If the authors are going to run separate models for baseline predictors of pain and function outcomes at three, six and the primary timepoint of 12 months, they should adjust the statistical significance level to adjust for inflated type I error rate.

5) There is no detail provided regarding the proposed Latent Class Analysis.

6) On page 4, column 2 the authors state "..... multiple MSK conditions (e.g., osteoarthritis, low back pain, whiplash, post-operative pain). It is quite possible that a large majority with post-operative pain may be lost to follow-up at 12 months. If the participant's pain is not chronic, they may drop-out of the study.

Is the rationale for, and objectives of, the study clearly described?
Yes

Is the study design appropriate for the research question?
Yes

Are sufficient details of the methods provided to allow replication by others?
Partly

Are the datasets clearly presented in a useable and accessible format?
Not applicable

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: Biostatist

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.