Full title: Musculoskeletal Conditions in Underserved Communities

Short title: MSK-UP

PROTOCOL VERSION NUMBER: V1.0 **ISSUE DATE: 17 Dec 2025**

RESEARCH REFERENCE NUMBERS

IRAS Number: 353549

ISRCTN Number: ISRCTN99466431

Sponsor Number: RG-0414-25

Funder Number: OBF/FR-000025814

VERSION CONTROL

Version	Issue date	Reasons for amendments; additional changes

SIGNATURE PAGE

For Keele University sponsored studies, the sponsor will confirm approval of the protocol by signing the IRAS form and therefore a signature on the protocol is not required. The sponsor must be notified of all amendments to the protocol, both substantial and non-substantial. Review of amendments by the sponsor will act as the confirmation that the sponsor confirms approval of the amended protocol.

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the research in compliance with the approved protocol, GCP guidelines, the Sponsor's SOPs, and other regulatory requirements as amended.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:

Date:
17.12.2025

.....

Name (please print):

Professor Ross Wilkie

.....

Sponsor statement:

Where Keele University takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the Sponsor will serve as confirmation of approval of this protocol.

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LIST OF ABBREVIATIONS

AB	Advisory Board
AHSN	Academic Health Science Network
ARC	Applied Research Collaboration
CI	Chief Investigator
CRLW	Community Research Link Workers
CTU	Clinical Trials Unit
HER	Electronic Health Records
GCP	Good Clinical Practice
HRA	Health Research Authority
ICS	Integrated Care System
MSK	Musculoskeletal
MSD	Musculoskeletal Disorders
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PAC	Patient and Community Group
PAG	Patient Advisory Group
PCN	Primary Care Network
PIL	Participant Information Leaflet
PPIE	Patient and Public Involvement and Engagement
REC	Research Ethics Committee
RR	Rapid Review
RUG	Research User Group
SDOH	Social Determinants of Health
SMF	Study Master File
SMG	Study Management Group
SOP	Standard Operating Procedure
WP	Work Package

KEY STUDY CONTACTS

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STUDY SUMMARY

Study Title	Musculoskeletal Conditions in Underserved Communities
Internal Ref. Number (or short title)	MSK-UP
Study Design	Cross sectional face to face survey
Study Participants	Adults living in CORE20 (most deprived 20%) areas of Stoke-on-Trent and Wolverhampton
Planned Sample Size	2,500 (face to face survey)
Follow up duration	Collection of Medical Record data between October 2026-September 2028
Planned Study Period	01/10/2025 – 30/09/2028

STUDY AIMS

Aim 1: To obtain person-centered data on musculoskeletal health, care and social determinants of health (SDOH) from underserved communities

Questions:

- What is the overall level of musculoskeletal health in the adult population in underserved communities?
- What is the nature and scale of inequalities in musculoskeletal health need within an underserved population?
- Objectives:
- To estimate the prevalence and severity of pain and musculoskeletal ill health in adults in underserved communities in North Staffordshire/Stoke-on-Trent and Wolverhampton
- To describe inequalities in musculoskeletal health need by age, sex, ethnicity, deprivation and financial strain.
- To estimate the strength and direction of association between the social determinants of health and consultation for musculoskeletal pain.
- To estimate the strength and direction of association between the social determinants of health and referral to NHS services from primary care.
- To estimate the impact of musculoskeletal disorders on work participation and how this differs by socio-demographic, comorbidity and work factors.
- To estimate the social gradients in the occurrence of musculoskeletal disorders, their impact and in risk factors across the adult life-course, and identify if the social gradients are most evident in comorbidity and more severe musculoskeletal disease
-

Aim 2: To identify themes and inform a conceptual framework to understand intersectional social influences on musculoskeletal health and co-produce interventions to develop better treatment and prevention strategies to improve musculoskeletal health in underserved populations.

Question:

- What are the key factors that explain variation in the prevalence of chronic pain and its impact? Of these factors which identify targets or target populations for reducing prevalence and impact?

Aim 3: To create multi-level datasets through extensive linkage to primary and secondary care electronic medical records and aggregate-level data on SDOH.

Questions:

- What proportion of people with musculoskeletal pain consult primary care for pain?
- What factors are associated with non-consultation to primary care?
- What factors are associated with referral from primary to secondary care in adults with musculoskeletal pain?

Aim 4: Contribute to policy development and disseminate findings through working with local and national stakeholders.

PLAIN ENGLISH SUMMARY

The number of people who have pain, from conditions like arthritis and back pain, and experience its effect on daily activities, is higher in communities that can be considered to be underserved. These are communities that often experience more poverty and more likely include people from a range of ethnic backgrounds and cultures. Whilst these communities have the greatest need and impact on healthcare use, we know less about them because they have not participated or been included in previous research studies. This means that healthcare is being planned for them without good information about these communities. This project will collect information in underserved communities that we will use to understand why higher levels of pain and its impact of daily lives occur and how we can work with people to reduce this.

To do this we will ask 2500 people living in underserved communities to complete a questionnaire and ask if we can link this with their health information. We will use this information to work with community groups to develop approaches that focus on reducing the number of people who experience pain and its impact in this community with greatest need. We will also speak to government organisations and other people interested in improving health for people with musculoskeletal conditions (e.g. Arthritis UK) to highlight our findings.

PATIENT AND PUBLIC INVOLVEMENT: This project builds on the work of the MIDAS Patient Advisory Group (PAG). In this work they:
• encouraged identification of the reasons for inequalities in health and care, with a focus on the social determinants of health
• suggested ways of raising awareness of the study, and making it easier for people to participate,
• reviewed the questionnaires and suggested ways of making it more relevant and easier to complete,
• highlighted ways to improve response and overcome barriers linked to low survey participation, including working on the development of the face-to-face survey.
This project will develop a Patient & Community Group (PAC), consisting of people from underserved communities, who will develop the questionnaire instrument and establish key questions for the analysis (WP1); this includes identifying reasons for inequalities linked to incidence, impact and use/non-interaction with healthcare and for what will provide the basis for community engagement in the development of interventions. The PAC will also contribute to the methodology for the qualitative interviews. Throughout the study the PAC will monitor study progress, contribute to interpretation of findings, and how best to share them with participants, the public, and other groups, to maximise our research making a real difference.
Our Race Equality Ambassador will advise on the NIHR Race Equality Framework for Public Involvement in Research. Southam and Sandhu (public co-applicants) will disseminate findings from the study, and we will work with community organisations (e.g. Expert Citizens) to further develop outputs and interventions. By active, ongoing Patient and Public Involvement and Engagement (PPIE), our research will be more relevant to the needs of people with lived experiences of musculoskeletal conditions and the ‘underserved’ community and conducted in a people/community-friendly manner, thus supporting study recruitment and retention. All PPIE activity will follow our Research Institute’s written framework for PPIE involvement that is based on INVOLVE and will be supported by our PPIE Research Administrator and user support worker.

SHARING OUR FINDINGS: We will look to produce:

- Press releases, briefings, articles, and interviews for local radio and newspapers
- Study specific website
- Presentations to stakeholder meetings
- Use of electronic media including a study website, institutional websites, social media including X and YouTube.
- Links with key local, national and international organisations including the Arthritis UK National MSK Health Data Group, West Midlands Academic Health Science Network (AHSN), Applied Research Collaboration (ARC), Office for Health Inequalities and Disparities, to contribute to and capitalise on their networks
- Publications including full report, executive summary and plain English summary, peer-reviewed journals, and local NHS and research newsletters
- Presentations at high-profile scientific and health policy conferences.
- Dissemination of findings in collaboration with community groups through participatory workshops.

1 BACKGROUND AND RATIONALE

The frequency and impact of musculoskeletal health is associated with socio-economic deprivation, ethnicity and the wider determinants of health. The issue this project will focus on is addressing the gap in understanding how inequalities occur and what could reduce these in underserved populations, including how to enhance community engagement. This project builds on the PRELIM and MIDAS projects. Both focused on pain, which musculoskeletal conditions are the largest cause of in adults PRELIM data highlighted why this project is important by identifying the high frequency of chronic and high impact chronic pain and that this varied significantly by area; prevalence of chronic pain and high impact chronic pain was five times higher in areas with greater socio-economic deprivation.

Data from MIDAS highlighted why this project is needed now as it identified that inequalities are increasing; initial findings indicate that inequalities have increased and that whilst prevalence of chronic and high impact chronic pain, between 2018 and 2023, have not increased in the most affluent 10% of the population, they have increased in the other 90% and more so in the most deprived. Whilst the relationships between musculoskeletal health and socio-economic deprivation and ethnicity have been reported, there is limited understanding of why this occurs in populations that can be considered underserved; these are communities with greatest need (and exert the greatest impact on population health and healthcare burden) but they are not well represented in research and is acknowledged as a clear gap. This project builds on the work of MIDAS in which we used face-to-face methods to collect data from 605 people who lived in the most deprived 20% of areas (i.e. Core20 areas) and were considered ethnically diverse; these are areas where response to survey methods is low (<10%) resulting in limited intelligence on health needs and determinants. The underserved population had a significantly different socio-demographic and health profile to those who responded to the MIDAS survey online or by mailed questionnaire, the underserved group were more ethnically diverse (e.g. White: 68.8% cf 95.0), younger and had higher levels of obesity, food bank use (7.7% cf 2.9%) and lower levels of social participation (no participation 86.1% cf 43.4%). To identify community needs and plan appropriate interventions for those who experience the greatest burden and are most in need, more intelligence is required on underserved populations. The MIDAS data indicated heterogeneity within the underserved group and the need for larger sample sizes to allow stratification by different demographic factors (e.g. ethnicity). It also indicated a need to further explore the reasons for

inequalities through quantitative methods and to increase the role of local communities in developing data collection, analysis and dissemination, in line with our commitment to democratic science. Building on linked qualitative work and approaches to implementation, this would form the basis for further exploration of inequalities and how to optimise community engagement.

2 AIMS AND OBJECTIVES

Our aim is to obtain musculoskeletal health intelligence in underserved populations that provides the basis for further community engagement and development of interventions to reduce inequalities and the burden of musculoskeletal conditions. This involves further development of data collection driven by public involvement, to obtain meaningful information on the social determinants of health (SDOH), risk factors and health states. This work will refer to SDOH models, including the PROGRESS framework. This will form the basis for a mixed methods approach; we aim to link information collected via surveys and qualitative interviews and explore the potential to link to high-quality primary and secondary data and environmental data. The objectives link to work packages are to:

1. Obtain person-centred data on musculoskeletal health, care and SDOH from underserved communities

2. Identify themes and inform a conceptual framework to understand intersectional social influences on musculoskeletal health and co-produce interventions to develop better treatment and prevention strategies to improve musculoskeletal health in underserved populations

3. Create multi-level datasets through extensive linkage to primary and secondary care electronic medical records and aggregate-level data on SDOH

4. Contribute to policy development and disseminate findings through working with local and national stakeholders

3 DESIGN

There is a work package (WP) linked to each objective.

WP1. TO OBTAIN PERSON-CENTERED DATA ON MUSCULOSKELETAL HEALTH, CARE AND SDOH FROM UNDERSERVED COMMUNITIES (Months 0-36)

Objective 1.1. The survey instrument has been developed in collaboration with public members (Months 0- 6) The development of a survey instrument used the model of working with a patient and community group (PAC) from the MIDAS study, in which we apply democratic science and where the public members have the power to ask questions for analysis. We have worked with existing community links to organise a new PAC, which include people from underserved communities, including new and established migrants and red-wall communities. The PAC will identify key constructs to measure in the survey instrument, that contribute to variation in levels of musculoskeletal health in underserved populations. Examples from previous discussions are the role of individual's sense of purpose and identity within a community, approaches to self-management and views of healthcare. The constructs for measurement were identified during a series of meetings (n=4 to 6). A research assistant then identified the instruments to measure the constructs that have previously undergone extensive testing and validation and, where possible, offer opportunities for internal or external comparison. Following this

the research team worked with the PAC to further develop and test the questionnaire (for face validity) for use in the survey.

Objective 1.2 To collect musculoskeletal health and SDOH data in underserved communities in Stoke-on-Trent (months 6-18) We will use face-to-face completion of surveys on the doorstop to collect information from the underserved communities. We will work with MEL research, a third-party market research company, who successfully collected data from 605 people in MIDAS to collect information from 2500 people from geographical areas linked to general practices where there are higher levels of deprivation and ethnic diversity. For each practice, we will use Ward or Lower Super Output Area-based sampling with CACI Insight software to identify clusters of houses with higher deprivation. Royal Mail Postcode address files will be used to create a stratified random sample. A random locational quota sampling method will be used to reflect the distribution of households across deprivation deciles whilst providing coverage across Lower Layer Super Output Areas (LSOAs). 7500 addresses will be identified with the aim of achieving 2500 questionnaire completions; this is based on the 30% of those contacted completing the questionnaire in the MIDAS population study. The sampling approach will be reviewed throughout the administration to review whether quotas for ethnic groups will be met; we will include quota sampling to collect data from 200 people each from Black African, Caribbean heritage, Indian, Bangladesh, Pakistan and middle eastern communities. A sample size of 200 will allow estimation of the extent of association between chronic pain and deprivation (for example, comparing the least and most deprived groups for deprivation on high impact chronic pain (80% power, 5% significance level).

In line with previous methods, interviews will be conducted face to face on residents' doorsteps using a Computer Aided Personal Interview (CAPI) approach (i.e. on a tablet). The tablet will be passed to the respondent for self-completion (to reduce potential interviewer bias). Whilst the survey is in English, the doorstep approach offers the potential for family members in the household as an option to translate. MEL Research will provide fieldworkers who speak the most common community languages (e.g. Punjabi, Urdu, Polish, Gujarati, Bengali). The survey data will be converted into an SPSS file to transfer to Keele University. Raw data will be exported to MEL Research's Microsoft 365 Business Software as a cloud-based solution and SharePoint Quality issues will be agreed with MEL Research (e.g. 80% of the questionnaire must be completed).

WP2. CREATING MULTI-LEVEL DATASETS THROUGH EXTENSIVE LINKAGE The purpose of creating multi-level datasets is to examine (i) patterns of healthcare use for those with chronic and high impact chronic pain and (ii) the relationship between general practice and neighbourhood characteristics and levels of chronic and high impact chronic pain in underserved communities. For respondents consenting to linkage, we will link survey information to 2.1 Primary care electronic health record (EHR) Records will be collated from 10 years prior and 12 months from survey completion. EHR will be accessed to obtain information on consultations, prescriptions and associated aspects. Analysis: Frequency of consultation, prescriptions and referral will be described for those with chronic and high impact chronic pain and compared to populations from non-Core20 areas (data collected in MIDAS; there is insufficient data to allow this for underserved populations in MIDAS). 2.2 NHS Digital datasets Linkage to Hospital Episode Statistics will be sought through the Data Access Review Service (DARS). Information will include hospital outpatient appointments, admissions, accident & emergency attendances (Hospital Episode Statistics) and diagnostic imaging (Diagnostic Imaging Dataset). Analysis: Building on that outlined in 2.1, in people who indicate that they have chronic pain and high impact chronic pain, we will stratify by access to care status (non-consulter/primary consulter only, secondary care user (including primary care). We will further stratify by wider determinants of health.

These will be described as crude risk differences (all binary indicators). Frequency of use of secondary care musculoskeletal care (e.g. orthopaedic referral), consultations to accident and emergency and further mapping will be described and compared to non-Core20 populations (using data from MIDAS). Regression modelling will be used to identify association between wider determinants and non-consultation of healthcare. We will also explore the outcomes of non-consultation to provide a basis of whether to target groups who may experience poor outcomes and don't engage with services.

2.3. Healthcare provider characteristics. Non-sensitive aggregate-level data (on general practices will be extracted from the freely available general practice workforce data (e.g. NHS Digital General Practice Data Hub). 2.4 Neighbourhood characteristics and assets Aggregate data on SDOH (e.g. labour market, housing, built environment) in local geographies (lower and middle super output areas) will be extracted from existing accessible sources NOMIS (labour market statistics); Office for Health Improvement & Disparities (OHID) Data Gateway and Local Health tools and linked to individual-level datasets above to create multi-level data. Analysis (2.3. & 2.4): Area-level analysis will be used to examine the associations between neighbourhood characteristics and assets and levels of chronic and high impact chronic pain. For example, we will examine the association between rates of did-not-attend, participation in health check programmes, screening programmes and NHS dental activity and pain outcomes.

WP3. WORKING WITH LOCAL AND NATIONAL STAKEHOLDERS TO CONTRIBUTE TO POLICY DEVELOPMENT AND DISSEMINATE FINDINGS. In addition to WP2.4 we will also work with local community groups, (e.g. Primary Care Networks,(Expert citizens http://expertcitizens.org.uk), national government (e.g. DHSC, NHE England Strategic Development Team and Prevention and Long Term Conditions strategy Team) and other stakeholders (Versus Arthritis) to identify and prioritise key potential interventions/targets to reduce musculoskeletal health inequalities in underserved populations (refer to Section D below). To ensure a focus on benefit to people and the public, we will determine the research direction, dissemination strategies, and interpret findings with input from the PAC. Through MIDAS and other projects, the research team meet regularly (approximately 1 meeting per month) with government departments (i.e. DHSC, NHS England) to discuss findings and linkage to intelligence gaps and policy development. The research team will continue to liaise with these departments, Nuffield Foundation and Versus Arthritis to (i) align data collection with policy needs and questions and (ii) disseminate findings and contribute to policy development and (iii) identify how to optimise the applicability of findings to underserved populations nationally. In addition to our routine meetings with government agencies, we will also hold biannual meetings to facilitate research development, provide a direct route for outputs to policymakers, and help steer knowledge creation for maximum relevance and impact. In year 3, we will hold two meetings that will focus on applicability of findings to other underserved populations; we will invite stakeholders from other underserved populations to discuss application of findings to their communities.

4 SETTING

Stoke-on-Trent and Wolverhampton.

5 ELIGIBILITY CRITERIA

For the population survey (WP1), a random sample of 7500 people aged 18 years and over who live in the six areas within Stoke on Trent and Wolverhampton with high levels of deprivation and ethnic diversity will be invited to participate.

5.1. Participants

Inclusion	Exclusion
People aged 18 years and over	
	Patients receiving palliative care, patients residing in a nursing home, patients with severe mental illness and patients who are recently bereaved.
Able to provide informed consent[a]	
[a] indicated through completion of the questionnaire and completed consent form	

6 STUDY PROCEDURES

6.1. Overview

We propose to conduct a cross-sectional survey of key patient-reported outcomes and 'psychosocial vital signs' at baseline in a random sample of adults aged 18 years and over registered with 6 practices in North Staffordshire and Stoke-on-Trent and Wolverhampton, which are in the most deprived quintile of the UK population. We will link the survey data collected to the primary and secondary care EHR data for those who provide written consent. The primary care EHR data will be anonymised, routinely recorded, information including reasons for consultation prescriptions, sickness certification, referrals and investigations, dating back 10 years and for 12 months following baseline. The secondary care data will be anonymised and include consultation with emergency services, outpatient and in-patient services. The following section refers to WS1 in which we will collect information on musculoskeletal health in underserved populations.

6.2. Strategies to improve inclusion and reduce bias

Participation rates in cohort studies have been declining over several years raising concerns over inefficiency and the potential for selection bias. The use of web-based data collection is increasingly being pursued as a low-cost solution to the former problem but may have lower response rates [11] and is still susceptible to selective participation. Internet access in UK households continues to increase year-on-year (96% in 2020[12]) but people most likely to be 'digitally excluded' are: older people, people in lower income groups, people without a job, people in social housing, people with disabilities, people with fewer educational qualifications, people living in rural areas, homeless people, people whose first language is not English[13]. These groups may be 'disadvantaged' or 'under-served'[14] and have more complex health needs and poorer outcomes and are more likely to be impacted by health inequalities.

The following strategies to improve inclusion and reduce bias are informed by discussions with our Patient and Community Group (PAC), previous synthesis of evidence on the effectiveness of different strategies for survey completion, NIHR INCLUDE[14] and NIHR INCLUDE Ethnicity[15] frameworks, previous experience within the research team, and considerations over what is feasible and affordable for our study.

- We will invite a random sample of people from the Stoke-on-Trent and Wolverhampton areas, living in areas with high deprivation and ethnic diversity.

- Collection of brief information in the questionnaire on important social characteristics (e.g. age, sex at birth, ethnicity, occupational class, financial strain) to help understand participation, care, and outcomes in under-served groups.

- Describing the characteristics, and patterns of care of the total eligible population of adults with musculoskeletal pain during the study period to enable evaluation and possible modelling of selective participation; this links with a latter part of the MSK-UP programme

- Interviewers will visit six areas within Stoke on Trent and Wolverhampton with higher rates of non-completion in MIDAS, diversity and ethnic diversity to offer doorstep face to face questionnaire completion.

- An information poster providing general information on the study will be displayed on the general practice website and social media of participating practices, where possible.

- Keeping questionnaire length to a minimum [11,18]; presenting questions in a logical order; minimising cognitive burden of questions; explaining where possible the purpose of questions.

- Offering a verbal translation service

- Seeking advice from a Race Equality Ambassador for Public Involvement in Research

6.3. Participant identification and recruitment

We will work with MEL Research, who successfully collected data from 605 people in MIDAS to collect information from 2500 people from geographical areas linked to general practices where there are higher levels of deprivation and ethnic diversity. For each practice, we will use Ward or Lower Super Output Area-based sampling with CACI Insight software to identify clusters of houses with higher deprivation. Royal Mail Postcode address files will be used to create a stratified random sample. A random locational quota sampling method will be used to reflect the distribution of households across deprivation deciles whilst providing coverage across Lower Layer Super Output Areas (LSOAs). 7500 addresses will be identified with the aim of achieving 2500 questionnaire completions; this is based on the 30% of those contacted completing the questionnaire in the MIDAS population study. The sampling approach will be reviewed throughout the administration to review whether quotas for ethnic groups will be met; we will include quota sampling to collect data from 200 people each from Black African, Caribbean heritage, Indian, Bangladesh, Pakistan and middle eastern communities. A sample size of 200 will allow estimation of the extent of association between chronic pain and deprivation (for example, comparing the least and most deprived groups for deprivation on high impact chronic pain (80% power, 5% significance level).

In line with previous methods, interviews will be conducted face to face on residents' doorsteps using a Computer Aided Personal Interview (CAPI) approach (i.e. on a tablet). First, the potential participant will be given the participant information sheet and asked if they would like to participate. If they do, the tablet will be passed to the respondent for self-completion (to reduce potential interviewer bias). Whilst

the survey is in English, the doorstep approach offers the potential for family members in the household as an option to translate. MEL Research will provide fieldworkers who speak the most common community languages (e.g. Punjabi, Urdu, Polish, Gujarati, Bengali). Quality issues will be agreed with MEL Research (e.g. 80%80% of the participants must consent to data linkage and have no missing data).

***Survey design and administration*:**

We will adopt several strategies to help minimise the threats to validity of the general national trend in declining response rates and selective nonresponse: (i) involve patients and members of the public from our PAC in finalising the survey and study documentation; (ii) offer a verbal translation service.

Pre-piloting:

We have checked the survey and study documentation with members of our Patient and Community Group, making any required amendments to the documentation as necessary, prior to regulatory approval submission.

6.4 Data collection

6.4.1 Survey administration

The survey administration offers face to face on the doorstep completion. The aim is to obtain 2500 responses from a geographical area linked to six practices where there are higher levels of deprivation and ethnic diversity and low response to the MIDAS POP study (600 in total). As outlined above, Ward or Lower Super Output Area-based sampling will be used with CACI Insight software to identify clusters of houses with higher deprivation. Royal Mail Postcode address files will be used to create a stratified random sample. A random locational quota sampling method will be used to reflect the distribution of households across deprivation deciles whilst providing coverage across Lower Layer Super Output Areas (LSOAs). 7500 addresses will be identified with the aim of achieving 2500 questionnaire completions.

Keele University will define the catchment area for each practice. This definition will be formed of postcodes/a list of Census Output Areas (COAs)/Lower Super Output Areas (LSOA).

MEL Research will access the Royal Mail's Postal Address File (PAF) to extract all residential addresses within each catchment.

MEL Research will summarise the counts of addresses per component part of each catchment e.g. the number of households per LSOA. Proportional interviewing targets per LSOA will then be agreed with the Keele University team to ensure a geographical spread of interviews per catchment.

It is envisaged that all addresses in each practice catchment will need to be visited to secure to volume of interviews required. Individual interviewers will be allocated a specific list of addresses to approach which will be accessible to them via their tablet computer. Return visits to addresses will be made on subsequent dates where initially no one answers the door, or when a participant requests more time to read the patient information leaflet.

During the pilot phase at household level an initial request will be made to speak to the person with the next birthday. The results of the pilot will determine how practicable this household level selection will be. Interviewer's will call at homes to complete the questionnaire on a tablet. Next birthday approach

would be fine for identifying an adult aged 18 and over in the household. Interviews will be conducted face to face on residents' doorsteps using a Computer Aided Personal Interview (CAPI) approach (i.e. on a tablet). The tablet can be passed to the respondent for self-completion (to reduce potential interviewer bias). Whilst the survey is in English, the doorstep approach offers the potential for family members in the household as an option to translate. We will also work with the third party to provide fieldworkers who speak the most common community languages (e.g. Punjabi, Urdu, Polish, Gujarati, Bengali).

Quality issues will be agreed with the third party who will administer the survey (for example, 80% of the questionnaire must consent to data linkage and have no missing data). The Contractor will adhere to the current Code of Conduct of the Market Research Society. The Contractor will be registered under the Data Protection Act and must confirm that they have not in the past been subject to any action under this Act. Confirm all intellectual property is of the MSK-UP team only; data from completed questionnaires will be kept by the Contractor for the time required (for transfer to Keele databases) and then destroyed.

6.4.2 Survey content

The content of the survey will include measures and items that have previously undergone extensive testing, validation, and application and, where possible, offer opportunities for internal or external comparison (e.g. with data from NHS Health Checks, NICE QOF indicators, GP Patient Survey, Health Survey for England, Office for National Statistics). The content of the survey includes validated measures and frameworks:

- Graded Chronic Pain Scale-Revised [19]
- Beliefs about pain (adapted from Kleinman's Explanatory Model) [20]
- 15-item Versus Arthritis MSK-HQ [24]
- General health, mental health and wellbeing: General health status (EQ-5D) [25], sleep quality [26], anxiety and depression (Patient Health Questionnaire 4) [27], resilience and sense of purpose and physical activity
- Perception of quality of health care, and trust in the healthcare system [28],
- Work loss, productivity and satisfaction [24]
- Core demographic, psychosocial and behavioural factors: date of birth, sex at birth, employment status, marital status, educational attainment, perceived adequacy of income, food and transport poverty, area-level deprivation score from postcode [29], height and weight and caregiving duties.
- Measures of social needs and aspects of social capital – a set of single items adapted from the Accountable Health Communities Health related social needs Screening Tool [30], questions on social/community interaction [29,30], and Lubben Social Network Scale [23],
- Brief measure of health literacy [31] and to identify additional healthcare use (NHS, private) and self-management (including over the counter medication)

All required permissions / licences have been obtained for all outcome measures.

Table 1: Content of MSK UP survey questionnaire

Domain	Construct	No. of items	Item/Instrument
Consent	Consent	7	Standard items; consent to survey, consent to electronic health record linkage
	NHS number	1	Standard item
	Date of Birth	1	Standard item
	Contact details	1	Standard item
Pain beliefs and communication	Views and communication of pain	4	Standard items adapted from Kleinman's Explanatory Model and Geiger-Davidhiziar's
Musculoskeletal Health	Chronic pain	1	Graded Chronic Pain-Scale Revised
	High impact chronic pain	1	Graded Chronic Pain-Scale Revised
	Pain duration	7	Von Korff single items for neck, shoulder, hand/wrist, back, hip, knee and foot/ankle pain
	Pain intensity and interference	3	Pain, Enjoyment of life and General activity (PEG) scale 3- Pain screening tool
	Musculoskeletal health	14 items	MSK-HQ. Items on Severity of pain/stiffness (in the day and night) Physical function (walking and dressing) Physical activity level Pain interference (work/daily routine) Difficulty with sleep Fatigue/low energy levels Emotional wellbeing (anxiety and mood) Understanding diagnosis and treatment Confidence to manage (pain self-efficacy) Independence Overall impact of symptoms
	Pain self-management (including those not captured by EHR)	1	Standard items (including over the counter medication, use of online resources)
	Use of musculoskeletal health care	7	Single items capturing engagement with NHS and private health care

	(including those not captured by EHR)		
	Perceived quality of healthcare service	3	Standard items from the MIDAS- GP survey
Mental health and psychological wellbeing	Anxiety	1	Patient Health questionnaire 4- containing the Generalized Anxiety Disorder Scale (GAD) 2
	Depression	1	Patient Health questionnaire 4- containing the Patient Health Questionnaire (PHQ) 2
	Resilience	6	Brief Resilience scale
	Sense of purpose	4	Purpose in Life test - short form
General health and wellbeing	General health	1	EQ VAS
	Mobility	1	EQ-5D-5L
	Self-care	1	EQ-5D-5L
	Limitation in usual activities	1	EQ-5D-5L
	Pain/discomfort	1	EQ-5D-5L
	Anxiety/depression	1	EQ-5D-5L
	BMI	2	Standard single items on height and weight
	Physical activity	1	Captured using MSK-HQ item
	Access to physical activities	1	Adapted from the Community and Engagement Survey
	Sleep/insomnia	4	Jenkins sleep questionnaire
	Health literacy	7	HLS-EU-6Q (European Health Literacy Survey Questionnaire-6 items) plus 1 single item
Socio-demographic characteristics	Sex at birth	1	Standard item
	Age	1	Standard item
	Ethnicity	1	Standard item
	Education	1	Standard item
	Marital status	1	Standard item
	Trust in healthcare	7	7 item- Medical Mistrust Index
	Financial resource: Adequacy of income	1	Standard item
	Housing needs/deprivation	2	Items adapted from the Accountable Health Communities Health related social needs Screening Tool

	Food poverty	3	Items adapted from the Accountable Health Communities Health related social needs Screening Tool
	Transport poverty	1	Single item adapted from the Accountable Health Communities Health related social needs Screening Tool
	Social/Community participation	2	Standard items
	Caring role status	1	Standard item
	Social connectedness	6	Lubben Social Network Scale- 6
	Loneliness	1	Standard item
Work factors	Employment status	1	Standard items
	Job title	4	Standard items
	Work loss due to pain	1	Standard item
	Full/part time work	1	Standard item
	Job activities	1	items from the Health and Employment After Fifty (HEAF) survey
	Work absence	2	Items from the Work Productivity and Activity Impairment (WPAI) questionnaire
	Work presenteeism	2	Items from the Work Productivity and Activity Impairment (WPAI) questionnaire
	Work demands	2	items from the Health and Employment After Fifty (HEAF) survey
	Workplace support	1	item from the Health and Employment After Fifty (HEAF) survey
	Work satisfaction	1	item from the Health and Employment After Fifty (HEAF) survey
	Job security	2	items from the Health and Employment After Fifty (HEAF) survey
	Work life Balance	4	Work Life balance Scale

6.4.3 Informed consent

MEL Research works on the basis of consent. Interviews can and will only happen where the respondent is willing to do so. If an individual wishes to take more time to consider the request/ undertake their own due diligence on the legitimacy of the research an appointment can be set for a return visit on another occasion.

A returned completed survey and consent form will be taken as written consent for the use of the survey data they provide and seeks consent to linkage of their responses to their medical record and use of their data in future studies and linkage to NHS Digital datasets. As part of the survey, a minimal set of participant identifiable data will be collected to ensure an individual is correctly identified. Access to identifiable information will be restricted to authorised members of the research team and managed in accordance with the UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

Contact details recorded on the consent form will be transferred to Keele Clinical Trials Unit (CTU) in a separate, data file. This file will contain only the minimum personal identifiers necessary for trial coordination and will be stored separately from participants' survey responses. Survey data will be pseudonymised prior to analysis, and no direct identifiers will be included in the dataset used for research purposes. Prior to seeking consent to study participation, all potential participants will have had the opportunity to access the Participant Information Leaflet and contact a member of the study team, should they wish to do so.

If participants have consented to be contacted about future studies, we ask will them to provide their name, address, telephone number and email address, in order that they can receive invitations to other research.

6.4.4 Data entry, storage

Data entry. Refer to 6.4.1 Survey Administration

Data storage. All personal data is stored in secure and dedicated client project folders using Microsoft 365 SharePoint architecture with access control and user authentication requirements. MEL systems have role-based access controls, set on a project-by-project basis. Only those staff working on a project, that require access to the data to perform their duties, have access to each unique client folder.

All personal data is logged in a Data Asset Register, which identifies the project folder and location of the data, legal basis for processing, as well as the project end date and secure destruction date.

MEL Research's standard approach for secure data transfer is to create a project specific SharePoint folder to which access would be limited to immediate project leads at Keele University. Data is typically the deleted from this location once file receipt is confirmed. Once project outputs i.e. the raw data file is securely shared with Keele University, data will be deleted by MEL Research as per contractual terms/ the terms of MEL Research's standard privacy policy - 90 days after project completion. Deletion is actioned from all locations including the Forsta platform. The details added to our Data Asset Register ensure that such deletions happen on time.

Responses will be stored on the Keele Clinical Trials Unit secure virtual network for 10 years in line with Keele CTU standard operating procedures.

Storage of personal details provided by participants who have consented to be contacted about future research will be kept for 5 years and securely stored on the CTU secure virtual network.

6.5. Data linkage and extraction

For respondents consenting to linkage, we will link survey information to other data sources, listed below -

6.5.1. Primary care electronic health record (EHR)

Data from consenting participant's primary care medical records will form a standalone study dataset, using a unique study ID as the identifier. The GP Practices will run the searches with support from Keele CTU. Keele CTU will provide the search criteria. Records will be collated from 10 years prior to the survey to 12 months from invitation mailing. Full general practice medical records of consenting participants will be accessed and securely downloaded to obtain information on consultations, prescriptions and associated aspects in the medical record, for the duration of the study requirements. We will adapt other publicly accessible code lists or use similar GP consensus approaches to derive code lists for identifying morbidities from the medical records. Similar approaches will be used to identify other information from the records (e.g. prescriptions and sickness certification).

Because recruitment is based on LSOA rather than GP registration, not all participants will necessarily be registered with the practices approached. Some may be registered elsewhere or may not have a registered GP at all. In such cases, medical record linkage will not be possible, but survey data will still be collected and included in the analysis.

6.5.2. NHS Digital datasets

Linkage to MSK-relevant hospital outpatient appointments, admissions, accident & emergency attendances (Hospital Episode Statistics) and diagnostic imaging (Diagnostic Imaging Dataset) outcomes held by NHS Digital will be sought through the Data Access Review Service (DARS).

6.5.3. Healthcare provider characteristics

Non-sensitive aggregate and global-level data on general practices and MSK services (e.g. staffing levels, Quality and Outcomes Framework (QOF) performance) will be extracted by the Research Assistant from the freely available general practice workforce data (NHS Digital General Practice Data Hub), OHID National General Practice Profiles, and GP Patient Survey data. During site initiation visits with participating general practices, we will clarify the current provision of selected recommended MSK services, e.g. First Contact Practitioner physiotherapists, vocational advice, stratified care for low back pain.

6.5.4. Neighbourhood characteristics and assets

Aggregate data on SDOH (e.g. labour market, housing, built environment) in local geographies (lower and middle super output areas) will be extracted from existing accessible sources NOMIS (labour market statistics); Office for Health Improvement & Disparities (OHID) Data Gateway and Local Health tools and linked to individual-level datasets above to create multi-level data.

6.6. Withdrawal criteria

Participants can withdraw from the study at any time by contacting and informing Keele CTU by telephone, email or letter. Withdrawal will mean no further contact. Any information provided up to the point the participant withdraws will be anonymised and retained unless the request is made for data to be destroyed.

6.7. Risk Mitigation

The survey questions do not cover sensitive topics, and we do not anticipate any distress arising from completion of the survey. The PAC Group have reviewed the questionnaire, and we have removed sensitive non-essential items from the questionnaire with their guidance.

Participant's personal data will only be accessible by authorised members of the research team during the data collection phase of the study unless the participant has consented to being contacted about future research studies then it will be securely stored and accessible for 5 years. All study data will be stored on Keele University storage services within the UK and protected by industry standard security tools.

Roles and permissions are applied to users within the network as well as within an application to restrict what data a user can access and operations they can perform. Once data collection has been completed, all data will be maintained in such a form that they cannot be linked with identifiable participants and will be anonymised in the reports and for archival deposit.

To ensure that consenting participants in the study are appropriately linked to the medical record data we will use the NHS number as the key link administrative processing variable.

General practices will receive payment for the time required to perform the retrospective searches for the Medical Record Review.

6.8. End of study

The end of the study will be when the end of study declaration is submitted, this will be once all relevant medical record data has been collected.

7. STATISTICS AND DATA ANALYSIS

7.1. Sample size calculation

The sample size is based on obtaining sufficient data to examine musculoskeletal health in different ethnic groups (we are using quota sampling to collect data from 200 people each from Black African, Caribbean heritage, Indian, Bangladesh, Pakistan and middle eastern communities). A sample size of 200 will allow estimation of the extent of association between pain and SDOH (e.g. comparing levels of health literacy on chronic pain (80% power, 5% significance level). Based on the frequency of other constructs in the MIDAS study our sample size is sufficient for our analysis of different constructs (e.g. frequency of no participation is 86%, financial strain 17.2%).

7.2. Statistical analysis plan

7.2.1 Analyses

7.2.1.1. Summary of baseline data and flow of patients

We will determine the percentage of eligible patients responding at baseline and descriptively compare responders to the general practice populations.

7.2.1.2 Analyses

The analysis plan will focus on -

1.To describe inequalities in musculoskeletal health by age, sex, ethnicity, deprivation and financial strain.

We will report summary statistics (mean and standard deviation, median and interquartile range or frequencies and percentages as appropriate) for each measure of musculoskeletal health (high impact chronic pain, musculoskeletal health, employment rate, absenteeism, presenteeism), overall and stratified by age, gender, ethnicity and deprivation. We will also weight responses by age, gender, ethnicity and deprivation distribution of eligible patients to assess the potential impact of non-response on our estimates. We will determine inequalities in health profiles by levels of health literacy, individual and neighbourhood measures of deprivation and occupational class, adjusting for potential confounders), again using appropriate regression models.

We will estimate the prevalence of high impact pain (i.e. pain that is severe and disabling) and describe the strength of associations with SDOHs/constructs identified by PAC. To ensure accurate and minimise response bias, weighted analyses will be employed, utilising the weights derived from LSOA population structure in the study region. Standardisation to population structure will be used to adjust for selection bias This approach accounts for potential selection bias and ensure representativeness of the target population (i.e. the aim is to provide estimates by ethnicity that can be considered representative). Multivariable regression models, with multiple imputation for missing data, will be used to estimate inequality gaps after adjustment for important confounders (age, sex, ethnicity, body mass index/obesity status, smoking status, and comorbidities will be included in the model to isolate the effects of SDOHs on outcomes). Weighted and imputed models will be applied to estimate the slope index of inequalities, providing a quantitative measurement of inequality within the population. In discussion with our AG and local decision makers, we will extend our analysis to other policy-relevant indicators of musculoskeletal health (for example work participation) (see Work Package 3). This will include subgroup analyses stratified by key demographic and socioeconomic factors to inform tailored interventions and highlight opportunities to address inequalities.

8. DATA HANDLING

8.1. Data collection tools and source document identification

In line with previous methods, interviews will be conducted face to face on residents' doorsteps using a Computer Aided Personal Interview (CAPI) approach (i.e. on a tablet). The tablet will be passed to the respondent for self-completion (to reduce potential interviewer bias). Whilst the survey is in English, the doorstep approach offers the potential for family members in the household as an option to translate. MEL Research will provide fieldworkers who speak the most common community languages (e.g. Punjabi, Urdu, Polish, Gujarati, Bengali). Quality issues will be agreed with MEL Research (e.g. 80% of the questionnaire must be completed).

The consenting process will be clearly outlined, and the potential participant will provide informed consent to take part in the study and to the sharing of data.

8.2. Data handling and record keeping

Data management will be carried out in accordance with Keele University Standard Operating Procedures (SOPs).

The study data will be stored on Keele University storage services within the UK and protected by industry standard security tools. All confidentiality arrangements adhere to relevant data protection regulations and guidelines (Data Protection Act 2018, UK General Data Protection Regulation (UKGDPR), Caldicott, General Medical Council (GMC), Medical Research Council (MRC) UK Policy), Confidentiality NHS Code of Practice, and the Chief Investigator and Study Statistician (Data Custodian) have responsibility to ensure the integrity of the data and that all confidentiality procedures are followed.

All information will be held securely and in strict confidence. Each person in this study will be given a unique study ID so that research data from the study will not contain any identifiable information, such as names and addresses. On this basis, these pseudonymised data will be kept electronically and may be used in other research studies.

The subset of pseudonymised, non-sensitive data from the locked, validated dataset used to generate the tables, figures, and results for the Final Report to Nuffield Foundation, together with the study protocol, statistical analysis plan, data dictionary, and analysis code, will be made available upon acceptance of the Final Report to the Nuffield Foundation. These datasets will be registered on Keele University's Research Data Repository with a unique digital object identifier (DOI), enhancing its discoverability.

8.3. Access to Data

Keele University is a member of the UK Reproducibility Network and committed to the principles of the UK Concordat on Open Research Data (https://www.ukri.org/wp-content/uploads/2020/10/UKRI-020920-ConcordatonOpenResearchData.pdf). The School of Medicine and Keele CTU have a longstanding commitment to sharing data from our studies to improve research reproducibility and to maximise benefits for patients, the wider public, and the health and care system.

Metadata, including study protocol, statistical analysis plan, data dictionaries and key study documents (Participant Information Leaflet, consent form) will be deposited on a publicly accessible repository. Anonymised individual participant data (IPD) that underlie the results from this trial will be securely stored on servers approved by a government-backed cyber security scheme and made available to bona-fide researchers upon reasonable request via our controlled access procedures. Unless there are exceptional circumstances, data will be available upon publication of main study findings or within 18 months of study completion (whichever is earlier) and with no end date. Data requests and enquiries should be directed to medicine.datasharing@keele.ac.uk. We encourage collaboration with those who collected the data, to recognise and credit their contributions.

Any requests for access to the data from anyone outside of the research team (e.g. collaboration, joint publication, data sharing requests from publishers) will follow the Keele CTU Standard Operating Procedure (SOP) Data Request Process.

8.4. Data Sharing Agreements

The data generated from this study will remain the responsibility of the Sponsor. Release of data will be subject to a data use agreement between the Sponsor and the third party requesting the data. Anonymised individual participant data will be encrypted on transfer.

The full Privacy Notice for Research Participants can be found at https://www.keele.ac.uk/legalgovernancecompliance/legalandinformationcompliance/informationgovernance/checkyourinformationisbeinghandledcorrectly/researchparticipants/#data-sharing.

8.5. Archiving

At the end of the study, data will be securely archived in line with the Keele CTU standard operating procedures for 10 years after end of study declaration and until the sponsor authorises destruction.

9 MONITORING & AUDIT

9.1. Study Management

The study Chief Investigator (CI) is responsible for the conduct of the study and will convene a Study Management Group (SMG) comprising members of the research team. Regular meeting of the SMG will take place throughout the study.

The SMG will oversee the protocol completion, obtaining regulatory approval and site set-up and software development. They will be responsible for the delivery of the study, data collection and the ongoing management. The SMG will monitor recruitment procedures, review against timelines and complete regulatory reporting requirements. In addition, they will also oversee the analyses and the interpretation of the results. The SMG will also ensure there is sufficient staffing support available for the study.

Our experience demonstrates that this combination of detailed plans with regular SMG meetings ensures successful research delivery. Good communication across the study will be facilitated by commonly shared study specific and protected drives on the University's network including MS Teams and SharePoint.

Study monitoring will be carried out in accordance with Keele University SOPs which lay out the procedures for monitoring the data collection, protocol compliance and data management procedures.

9.2. Independent Advisory Board

In accordance with funder requirements, independent oversight of the programme of research in general and this study in particular will be provided by an Expert Advisory Board comprising senior researchers and practitioners. The remit of the Expert Advisory Board covers the planning, conduct, and dissemination of the research as laid out in its written Terms of Reference. The Expert Advisory Board will convene initially to provide critical independent feedback on the study protocol and plans. After the initial meeting the Advisory Board will meet annually with the opportunity to schedule meetings at key timepoints in the programme and to agree any additional meetings as deemed necessary by the Chair of the Expert Advisory Board or the Chief Investigator.

9.3. Study Timeline

Activity	*Projected Timeline*
Finalise survey data collection instruments	Apr-Oct 2025
Database design, obtain approvals, site set up	Apr-Dec 2025
Develop survey instrument in collaboration with public member	Oct 2025–Mar 2026
Collect health data using a cross-sectional face to face survey	March 2026–Oct 2026
Submit DARS request for secondar care data	October 2025–Dec2025
Link individual survey data with primary care data	Oct 2026–Oct 2028
Dissemination activities	Mar 2027–Oct 2028
End of Study	Mar 2028

10 ETHICAL AND REGULATORY CONSIDERATIONS

Health Research Authority (HRA) approvals will be applied for and obtained before the study commences. HRA Approval is the process for the NHS in England that brings together the assessment of governance and legal compliance, with independent Research Ethics Committee opinion provided through the UK Health Departments' Research Ethics Service.

10.1. Research Ethics Committee (REC) review & reports

This study will be submitted for a favoured ethical opinion by an appropriate NHS Research Ethics Committee (REC).

- Substantial amendments that require review by REC will not be implemented until the REC grants a favourable opinion for the study (note that amendments may also need to be reviewed by NHS R&D departments before they can be implemented in practice at sites).
- All correspondence with the REC will be retained in the Sponsor Study Master File
- The Chief Investigator will notify the REC of the end of the study.
- If the study is ended prematurely, the Chief Investigator will notify the REC, including the reasons for the premature termination.
- Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

10.2. Peer review

This study protocol has been subject to internal peer review, external peer review by the funding body (Nuffield Foundation) and peer review by the Expert Advisory Board.

10.3. Public and Patient Involvement

The School of Medicine at Keele University has a strong Patient and Public Involvement and Engagement (PPIE) infrastructure, supported by the Impact Accelerator Unit (IAU), and which includes a large Research User Group (RUG) (n=180) advising on all studies within the school. For this study, more than seven patient representatives have been invited from the current RUG members to form a Patient and Community Group to contribute to the development of certain aspects of the study based on their lived experience of having a chronic painful musculoskeletal condition. The IAU has a dedicated Race Equality Ambassador who supports the implementation of the NIHR Race Equality Frameworks for Public Involvement in Research. The IAU Director (Dziedzic) is a member of the NIHR Race Equality Public Action Group.

Their key role will include:

- Responding to REC feedback and amendments
- The management of the survey
- To contribute to discussions on how to maximise inclusion and diversity in this research study
- To contribute to and review and interpretation of the findings
- To contribute to the dissemination strategy and publications, such as materials or talks with patient forums and practitioners

The Patient and Community Group has already contributed to the research design by:

- To provide the patient perspective on the design of the survey questionnaires, invitation letter, participant information leaflet and consent form
- Assessing the proposed research questions in terms of content, layout, style, order of questions, and overall length
- Reviewing the recruitment methods proposed for the study including providing advice on promoting and advertising the study to people
- Contributing to and review participant facing study documents and materials used in the study
- Reviewing the content and order of survey questions stressing the importance of looking seriously at inequalities in health and care
- Suggesting ways of raising awareness, maintaining interest in the study, and making it easier for a wide range of people to take part
- Discussing issues regarding inclusion and diversity of potential participant groups

The Public Community Group will continue to convene during the study contributing to oversight of the conduct of the study, interpreting findings, and our strategy for dissemination and pathways to achieving impact.

10.4. Regulatory Compliance

Participant data (in an electronic format) will be acquired, anonymised, transferred and stored according to the Data Protection Act 2018, UK General Data Protection Regulation (UKGDPR) (Regulation (EU) 2016/679);the Confidentiality NHS Code of Practice (https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice) and the Caldicott principles (https://www.gov.uk/government/publications/the-caldicott-principles)

Before any site can enrol participants into the study, the CI or designee will apply for HRA approval. For any amendment see section 10.9.

10.5. Protocol compliance

The study will be conducted in compliance with this protocol and GCP guidelines. Deviations from study protocols and GCP occur commonly in health and social care research. The majority of these instances are technical non-compliances that do not result in harm to the study subjects, do not compromise data integrity, or significantly affect the scientific value of the reported results of the study.

Non-compliance may be identified through any study activity but in particular through the use of central monitoring procedures such as consent form review or data management, and self-reporting by the study sites or participants. All deviations will be documented, and appropriate corrective and preventative actions will be taken by Keele CTU with responsibility being taken by the CI.

10.6. Notification of Serious Breaches to GCP and/or the protocol

All instances of protocol deviations will be assessed for severity by the CI (or their delegate), in accordance with the study protocol and using the Sponsor's GCP and Protocol Deviations FOR25.1 Initial Report.

10.7. Data protection and patient confidentiality

See section 8 Data Handling for details of how data is protected and patient confidentiality maintained throughout this study.

All information collected during the course of the study will be kept strictly confidential. Information will be held securely on paper and managed electronically by Keele University through Keele CTU. Keele CTU complies with data protection regulations:

- Appropriate storage, restricted access and disposal arrangements for participant personal and clinical details
- Consent from participants for access to their healthcare records by responsible individuals from the research staff or from regulatory authorities, where it is relevant to study participation
- Consent from participants for the data collected for the study to be used to evaluate safety and develop new research
- All data collection forms that are transferred to and from Keele CTU will be coded with a study number

All research staff/CTU operational staff involved in this study adhere to robust data security procedures and have explicit duties of confidentiality. These practices are written into their employment contracts and are equivalent to the duty placed on NHS staff.

10.8. Indemnity

The Sponsor is responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and research staff. The following arrangements are in place to fulfil the Sponsor's responsibilities:

· The Protocol has been designed by the Chief Investigator and researchers employed by the Sponsor and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

· Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The Sponsor requires individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

· Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity. Agreements between the Sponsor and participating NHS organisations detailing study conduct and the responsibilities to be honoured by each party will be fully executed before the study can start at the any participating site.

10.9. Amendments

The need for any potential protocol amendment will be raised with the CI and will be discussed with both the SMG and Sponsor prior to being agreed. Updated versions of the protocol will not be circulated for use until the appropriate regulatory parties have approved the amendment, at which point every effort will be made to implement this updated protocol as soon as is practicably possible, superseding the previous version and documenting the date at which the new protocol was implemented.

10.10. Access to the final dataset

See section 8.4 Data Sharing Agreements.

11. DISSEMINATION POLICY

11.1. Dissemination plan

The School of Medicine, Keele University has a dedicated infrastructure, linked to strong regional, national and international health care and academic networks, which facilitate dissemination of our research findings to key policy, commissioning clinical, health education and patient stakeholders. It hosts the Impact Accelerator Unit that has strong links with NHS England and NHS Improvement (NHSE&I) Musculoskeletal strategy. The research team will be able to access our dedicated infrastructure to identify and promote research outputs that lend themselves to translation by health providers.

Our approach to achieving impact from research

To maximise the impact of our research we will work closely with Keele University's dedicated Impact Accelerator Unit (IAU) which is part of the West Midlands Knowledge Mobilisation Collaboration. It brings access to local and national stakeholder networks, an experienced and extensive PPIE infrastructure and support, and experience and skills in closing the evidence-to-practice gap.

Public involvement

Our research project relies on strong patient and public participation across all stages from conception to dissemination. Our Patient and Community Group (PAC) meet on a regular (monthly) basis to discuss and advise on all aspects of the project. All PPIE activity follows our Institution's written framework for PPIE involvement that is based on INVOLVE and is supported by our PPIE Research Administrator and user support worker. We have been a pilot site for the NIHR Race Equality Framework for Public Involvement in Research. Members of our PAG have access to training resources (e.g. contributing assertively to meetings, INVOLVE resources) and we offer payment for PPIE activity according to INVOLVE guidelines.

Our commitment to open science

Keele University is a member of the UK Reproducibility Network and committed to the principles of the UK Concordat on Open Research Data. Specifically, we aim to:

- make research methods, software, outputs and data open, and available at the earliest possible point.
- ensure appropriately de-identified data are Findable, Accessible, Interoperable and Reusable.
- deposit outputs in open access repositories

Addressing equity concerns in communication

We are keen to ensure that important new knowledge arising from our research reaches disadvantaged and under-served communities. We will do this by bringing together our Patient and Community Group with our Race Equality Ambassador for Public Involvement in Research and exploring links to colleagues in the Keele Institute for Social Inclusion to engage organisations and individuals with existing close links in these communities (e.g. local social prescribers and charities/community organisations).

Expected main outcomes from this study include:

1. New data, information, and intelligence on inequalities and variations in musculoskeletal health outcomes, experiences and care
2. New insights into the feasibility, validity, and persuasiveness of new musculoskeletal health indicators and data visualisations

The key audiences for our research are:

a) patients with musculoskeletal conditions and the wider public.
b) healthcare professionals, with particular emphasis on general practitioners and first contact practitioners;
c) local health policymakers, including clinical commissioners and PCN leads.
d) external statutory bodies (e.g. NHS England, Office for Health Improvement and Disparities (OHID)), patient groups (e.g. The Arthritis and Musculoskeletal Alliance (ARMA)) and charities (e.g. Versus Arthritis);
e) Academia

Planned outputs:

• Press releases/briefings/articles for local radio and newspapers

• Oral presentation to local stakeholders

• Use of electronic media including a study website, institutional websites, social media including Twitter, YouTube video

• Links with key local, national and international organisations including the Versus Arthritis National MSK Health Data Group, Department for Health and Social Care, Office for Health Improvements and Disparities to contribute to and capitalise on their networks

• Publications including full report, executive summary and plain English summary, peer reviewed journals, and local NHS and research newsletters

• Presentations at high-profile scientific and health policy conferences In accordance with the Nuffield Foundation's guidance to grant holders we will submit and agree a communications plan in the event of successful award

11.2. Authorship eligibility guidelines and any intended use of professional writers

Authorship will be available to those who fulfil the International Committee of Medical Journal Editors (ICMJE) criteria (https://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html. No-one who fulfils the ICMJE criteria should be excluded from authorship credit and, of equal importance, no-one who fails to fulfil the four criteria should receive authorship credit. This includes academic staff and students as well as CTU, administrative, informatics, IT and nursing staff where they fulfil all four criteria above. However, individuals have the right to choose not to be an author on a particular paper.

Staff heavily involved in the practicalities of study operationalisation and delivery, including dedicated study co-ordinators, will be considered for co-authorship of protocol papers on the condition they can contribute to critical revision of drafts, approve the final version, and be accountable for the content.

There is no intention to use professional writers.

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