Full title: Multi-level Integrated Data for Musculoskeletal Health Intelligence and Actions: Population Survey

Short title: MIDAS-Population Study

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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:

..../...../.....

Name (please print):

Prof George Peat

.....

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
CI	Chief Investigator
CRN	Clinical Research Network
CTU	Clinical Trials Unit
EHR	Electronic Health Records
GCP	Good Clinical Practice
GPSoC	General Practice System of Choice
HRA	Health Research Authority
ICS	Integrated Care System
ISF	Investigator Site File
MSK	Musculoskeletal
MSD	Musculoskeletal disorders
NICE	The National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
PAG	Patient Advisory Group
PCN	Primary Care Network
PIL	Participant Information Leaflet
PPIE	Patient and Public Involvement and Engagement
REC	Research Ethics Committee
RUG	Research User Group
SMF	Study Master File
SMG	Study Management Group
SMS	Short Messaging Service
SOP	Standard Operating Procedure

KEY STUDY CONTACTS

Chief Investigator	Professor George Peat Sheffield Hallam University (Visiting Professor at Keele University), Robert Winston Building Sheffield Hallam University, Sheffield, S10 2BP Tel: 07851 330682 Email: g.peat@shu.ac.uk
Associate Investigator	Dr Ross Wilkie School of Medicine Keele University Staffordshire, ST5 5BG Tel: (01782) 733945 Fax: (01782) 733911 Email: r.wilkie@keele.ac.uk
Sponsor	Head of Project Assurance, Directorate of Research, Innovation and Engagement Innovation Centre 2 Keele University Staffordshire ST5 5NH Tel: 01782 732975 Email: research.governance@keele.ac.uk
Funder(s)	Nuffield Foundation 28 Bedford Square, London WC1B 3JS Edmund McKiernan, Grants Coordinator Tel: 020 7681 9614 Email: cdennison@nuffieldfoundation.org
Study Management	Keele Clinical Trials Unit (CTU) School of Medicine Keele University Staffordshire, ST5 5BG Tel: 01782 732916 Email: ctu.operations@keele.ac.uk
Key Protocol Contributors	Prof Krysia Dziedzic, Tel: 01782 733907, Email: k.s.dziedzic@keele.ac.uk Dr Jonathan Hill, Tel: 01782 733900, Email: j.hill@keele.ac.uk Prof Kelvin Jordan, Tel: 01782 733924, Email: k.p.jordan@keele.ac.uk Dr Emma Parry, Tel 01782 734929, Email e.parry@keele.ac.uk Dr Ross Wilkie, Tel: 01782 734845, Email: r.wilkie@keele.ac.uk Dr Dahai Yu, Tel: 01782 734891, Email: d.yu@keele.ac.uk Mrs Sarah A Lawton, Tel: 01782 734887, Email: s.a.lawton@keele.ac.uk Ms Stefannie Garvin, Tel: 01782 732950, Email: s.garvin@keele.ac.uk
Lead Statistician	Professor Kelvin Jordan School of Medicine, Keele University Staffordshire, ST5 5BG Tel: 01782 733924 Email: k.p.jordan@keele.ac.uk

Committees	**Study Management Group** Peat (Chair), Clarson, Dziedzic, Garvin, Hill, Jordan, Lawton S.A., Lawton S.L., Parry, Stevenson, Thompson, Wathall, Wilkie, Yu **Advisory Board** Peter Croft, Email: p.r.croft@keele.ac.uk Nicholas Steel, Email: N.Steel@uea.ac.uk Andrew Judge, Email: andrew.judge@bristol.ac.uk Andrew Bennett, Email: andrew.bennett9@nhs.net Nuzhat Ali, Email: nuzhat.ali@dhsc.gov.uk Amanda Hensman-Crook, Email: Amanda.Hensman-Crook@hee.nhs.uk Deborah Riley (Lay member) **Patient Advisory Group** Lindsey Brown, Stephen Dent, John Haines, Ruth Haines, Jane Hall, Sue Maddison, Kanta Sandu

STUDY SUMMARY

Study Title	Multi-level Integrated Data for Musculoskeletal Health Intelligence and Actions: Population Survey
Internal Ref. Number (or short title)	MIDAS-Population Study
Study Design	Observational Cohort Study; cross-sectional survey (hybrid online/postal administration) with individual-level linkage to primary care electronic health records
Study Participants	Adults aged 35 years and over
Planned Sample Size	4495
Follow up duration	12 months (Electronic Health Record outcomes)
Planned Study Period	Sep 2022 – Mar 2025

STUDY AIMS

Aim 1: To describe musculoskeletal health and inequalities in the adult population

Aim 2: To describe and compare the biopsychosocial context of adults with musculoskeletal health problems

Aim 3: To relate local estimates of musculoskeletal health need with use of healthcare services

PLAIN ENGLISH SUMMARY

This study is part of the MIDAS programme of research which is designed to get better evidence about health and care in local populations. Our focus is on trying to understand and reduce differences in musculoskeletal health between different groups of people.

BACKGROUND: Painful musculoskeletal conditions like back pain and osteoarthritis cause more disability in the general population than any other health conditions. Poorer communities and individuals are often the hardest hit. In order to have a suitably 'joined up' response to this challenge we need accurate and meaningful joined up information on musculoskeletal health, risk, and care in local populations. This is what our study will try to address.

DESIGN AND METHODS: We will invite adults aged 35 years and over in North Staffordshire and Stoke-on-Trent to complete a questionnaire that collects information on pain and its effects on people, with a particular focus on disability and work. We will examine the extent of health inequalities in these and in the key social and behavioural risk factors that are believed to determine them. People will have the option of completing the survey either online or by postal return. If people agree, we will link their questionnaire responses with information held in their medical records so that we can piece together information on the care that people are receiving. Potential participants will be registered with one of 30 participating general practices across North Staffordshire and Stoke-on-Trent, particularly those serving more deprived and ethnically diverse areas, that have preferably been part of a linked MIDAS-GP study. We will include methods to encourage participation from underserved populations where response has previously been low (e.g. translation service).

PATIENT AND PUBLIC INVOLVEMENT: We have a MIDAS Patient Advisory Group (PAG) who have already been involved in designing this study. They have:

- stressed the importance of looking seriously at inequalities in health and care,
- suggested ways of raising awareness, maintaining interest in the study, and making it easier for a wide range of people to take part,
- looked carefully at the questionnaires and suggested ways of making it more relevant and easier to complete.

We will continue to work with the PAG to monitor how the study is going, what the findings mean, and how best to share them with participants, the public, and other groups, to maximise our chances of this research making a real difference. We have access to a Race Equality Ambassador who can advise on the NIHR Race Equality Framework for Public Involvement in Research.

SHARING OUR FINDINGS: We will look to produce:

- Written summary reports and data visualisations for participating GP practices and community musculoskeletal services
- Press releases, briefings, articles, and interviews for local radio and newspapers
- Presentations to stakeholder meetings
- 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, West Midlands Academic Health Science Network (AHSN), Applied Research Collaboration (ARC), Office for Health Inequalities and Disparities, NICE, 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: NHS Evidence, Society for Academic Primary Care, Office for Health Improvement and Disparities

SUMMARY STUDY FLOW CHART

Cross-sectional survey of adults (n=13,500) aged ≥ 35 years with linked medical record review and data modelling

Identification of potential participants
The practice will identify a random sample of the GP practice (n=30) population aged 35 years and over (n=450 for each practice).

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All people for whom the practice have a mobile telephone number, and who have not opted out of receiving text message communication, will receive a text message with an invitation and link URL to complete the online survey and consent form via the Keele Health Survey platform.

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Approximately two weeks after, non-responders and people who their GP practice do not hold mobile numbers for will be mailed a postal invitation study pack, via Docmail, including a:-

- Letter of invitation (on GP letter headed paper, including a link URL, to the online survey)
- Participant Information Leaflet
- Paper Survey (for self-completion) including the Consent Form
- Pre-paid addressed return envelope

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Approximately two weeks after the postal invitation pack, non-responders will be mailed a repeat study pack as above but containing a minimum data collection survey in place of the full survey.

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Non-responders after approximately six weeks will not be contacted again.

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Data Entry

Returned surveys from consented participants will be entered onto a secure database either by scanning of survey by Keele CTU or online data entry by the participant

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A Medical Record Review will be conducted for participants who have provided Informed Consent, at 12 months from invitation mailing

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Data Analysis & modelling (cross-sectional and longitudinal analysis)

Writing and dissemination

1 BACKGROUND AND RATIONALE

Musculoskeletal disorders (MSD) are the main drivers of non-communicable disease disability burden in most countries and regions worldwide.[1] In England, they account for an estimated 21% of total years lived with disability,[2] 6.2 million working days lost,[3] 12-14% of all primary care consultations in people aged 15 years and over,[4,5] and the third largest programme budget for NHS healthcare expenditure.[6] The need for better information for chronic disease surveillance of MSK disorders has been highlighted by the Chief Medical Officer[7] and in successive Global Burden of Disease reports for England.[8,9] Public Health England's 5-year strategy for musculoskeletal health (2019-2024) includes a commitment to "high quality, accessible data and intelligence tools to support surveillance and reduce unwarranted variation of musculoskeletal conditions across the population pathway."[10]

Our MIDAS programme of research, made up of three components and funded by the Nuffield Foundation and Versus Arthritis, seeks to develop and evaluate a place-based system for population musculoskeletal health intelligence across North Staffordshire and Stoke-on-Trent (https://www.nuffieldfoundation.org/project/enriched-data-integration-for-population-musculoskeletal-health-intelligence).

This MIDAS-Population Study – a cross-sectional survey of the general population – is the second component of the programme (other components being surveys administered to patients as they present to general practice and to community musculoskeletal services). It addresses an important priority for population health, which is to contribute to a system of musculoskeletal health intelligence in the West Midlands that provides useful, timely, sustainable, trustworthy evidence for policymakers, practitioners, and the public. The aim of this study is to provide a detailed description of musculoskeletal health (including information on pain intensity and work participation), key comorbidity (e.g. anxiety, depression, obesity), the impact of health inequalities and care in the general population within one geographical area by linking the survey to local, high-quality, primary care Electronic Health Record (EHR) data and other publicly available sources of data using robust epidemiological approaches.

The data collected in this study will be collected from a self-report questionnaire completed by participants; the questionnaire will measure pain severity and impact, lifestyle and behavioural factors and wider social determinants.

This data will be linked to:

(1) EHR data (where consent has been provided): for recorded care (e.g. prescriptions, referrals, imaging, Fit Notes, repeat GP visits) and comorbidities; and

(2) publicly available data on neighbourhood health, assets and deprivation, and on healthcare service characteristics.

By linking these sources of data we are seeking to create multi-level data that enable us to better understand variations in, and determinants of, musculoskeletal outcomes in adults in the general population and in those that present to primary care with common painful MSDs. Our intention is for this study to impact on decisions about what information may be most useful and how it might be collected, linked, analysed, and disseminated within routine care.

2 AIMS AND OBJECTIVES

The aim of this study is to provide new research evidence to inform efforts to reduce variation in musculoskeletal health at a population level. Through a cross-sectional survey of key participant-reported outcomes and social determinants of health, of the adult population and with linkage to high-

quality EHR data among consenting respondents. Our proposal will provide a detailed description of health, key comorbidity, the wider determinants and care among the general population, with a particular focus on musculoskeletal health and those with musculoskeletal conditions. The survey will address the following aims, questions and objectives:

Aim 1: To describe musculoskeletal health and inequalities in the adult population

Questions:

What is the nature and scale of inequalities in musculoskeletal health in the adult population in North Staffordshire and Stoke-on-Trent?

Primary Objective:

- To describe inequalities in musculoskeletal health by age, sex, ethnicity, deprivation, occupational class, educational attainment, and financial strain.

Secondary objectives:

- To estimate the prevalence and severity of pain and musculoskeletal ill health in adults in North Staffordshire and Stoke-on-Trent in 2022
- To estimate the strength and direction of association between the social determinants of health and consultation for musculoskeletal pain
- To explore change over time by comparing with similar estimates obtained in a previous survey (PRELIM) in 2017 (i.e. before and after COVID-19); for example, we will estimate high impact chronic pain by Lower super output area and compare with 2017 estimates.
- 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 and their impact
- To identify if the social gradients in musculoskeletal health are most evident with comorbidity and more severe musculoskeletal disease

Aim 2: To describe and compare the biopsychosocial context of adults with musculoskeletal health problems

Questions:

What are the comorbidities, mental health, living conditions and social circumstances of adults with a musculoskeletal health problem? How do these compare with adults who report no musculoskeletal health problem?

Primary objective:

- To identify the most common and disabling patterns of comorbidity (i.e. musculoskeletal conditions plus one or more additional morbidities) in the local population, and how these differ by socio-demographic distribution.

Secondary objectives:

- To identify if people with low literacy are more at risk of more severe musculoskeletal pain and impact
- To understand whether individual level or household data performs better at predicting outcomes linked to social determinants of health compared to neighbourhood or area level

data at estimating certain musculoskeletal health outcomes (pain intensity, musculoskeletal health and work participation)

Aim 3: To relate local estimates of musculoskeletal health need with use of healthcare services

Questions:

Within an Integrated Care System (ICS) can local population survey data yield meaningful estimates of the size and nature of musculoskeletal health need? Do these suggest large differences in need between local authorities, primary care networks, and individual GP practices? Are differences in need reflected in (a) differences in the numbers accessing primary care for a musculoskeletal problem, (b) workforce and service provision?

Primary objective:

- To produce estimates of the prevalence and distribution of musculoskeletal health among adults for each (a) GP practice and (b) Primary Care Network

Secondary objective:

- To correlate practice-level estimates of musculoskeletal need and consultation rates for musculoskeletal problems

3 DESIGN

Observational cohort study: cross-sectional survey (postal and online data collection) with linkage (with participant consent) to longitudinal primary care EHR data.

4 SETTING

General practices in North Staffordshire and Stoke-on-Trent.

5 ELIGIBILITY CRITERIA

A random sample of 450 people aged 35 years and over and registered from each of the 30 general practices (total sample 13,500) in North Staffordshire and Stoke-on-Trent that are preferably also participating in the MIDAS-GP study, will be invited to participate.

5.1. General practices

Inclusion	Exclusion
Located in North Staffordshire or Stoke-on-Trent	GPSoC SystmOne or Vision practices
Uses the General Practice System of Choice (GPSoC) EMIS, together with a compatible bulk messaging (Short Messaging Service (SMS)) service (e.g. MJog)	

5.2. Participants

Inclusion	Exclusion
People aged 35 years and over	Has declined to be contacted about research studies recorded in their EHR.
Registered with a participating general practice during the study period	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 return of the questionnaire and completed consent form	

6 STUDY PROCEDURES

6.1. Overview

We propose to conduct a cross-sectional survey of key participant-reported outcomes and 'psychosocial vital signs' at baseline in a random sample of adults aged 35 years and over registered with one of the participating 30 practices in North Staffordshire and Stoke-on-Trent. We will link the survey data collected, to the primary care EHR data for those who provide written consent. The EHR data will be anonymised, routinely recorded information including reasons for consultation, prescriptions, sickness certification, referrals and investigations, dating back 10 years and for the 12 months following invitation mailing.

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 MIDAS Patient Advisory Group (PAG), 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 30 practices who are part of the linked MIDAS-GP study. These practices are situated across North Staffordshire and Stoke-on-Trent, including areas with high deprivation and ethnic diversity, and representing all 13 PCNs.

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

- Use of a mixed-model approach for survey completion. Those unable or unwilling to complete online questionnaires are offered conventional pen-and-paper self-complete questionnaires.[16]

- 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

- Raising awareness of the survey among the practice and registered population prior to going live; using reminders to encourage questionnaire completion[11,18]

- 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. Better information on relevant social characteristics was a unanimous recommendation from our independent Advisory Board

- 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 MIDAS programme

- Consider an additional process of doorstep survey participation for reaching under-served communities in deprived and ethnically diverse areas of Stoke-on-Trent and North Staffordshire (if feasible, this will be submitted separately to REC for their consideration)

The offer of monetary and non-monetary incentives and the full (validated) written translation of questionnaires and other participant-facing documentation was not feasible within the budget and time constraints of our project.

6.3. Participant identification and recruitment

The survey will be sent to a random sample of the registered practice population. This will be a representative sample of all adults fulfilling the age and registration criteria at the practices and may include those who are part of the MIDAS-GP study. The age cut-off is based on the PRELIM pilot study where it was found that the response rate was so low in the 25 to 35 year old age group to vastly reduce overall response and the representativeness of the data (overall as well as the 25-25 age group in the target population).

Notification of general practices:

The NIHR Clinical Research Network: West Midlands (CRN:WM) will facilitate engagement with the general practices currently participating in the MIDAS-GP Study. The CRN:WM have a high-level objective to engage with at least 45% of GP practices in the region. They actively contact those practices who are not currently research active and ‘hard to reach’ to encourage interest in research studies. They provide advice on the Research Site Initiative (RSI) scheme which provides financial incentives for practices to be involved in research. Each participating practice will receive a Site Initiation Visit (SIV) and be provided with a Site Pack containing the essential study documentation. GP practice consent to participate will be formalised through HRA standard agreements.

***Survey design and administration*:**

We will adopt a number of 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 PAG in finalising the survey and study documentation; (ii) undertake pre-pilot testing; (iii) offer the option of paper and web-based survey completion; (iv) offer a telephone support to answer questions about the survey or complete the questionnaire over the phone; (v) offer a verbal translation service.

Pre-piloting:

We have checked the survey and study documentation with members of our Patient Advisory Group, making any required amendments to the documentation as necessary, prior to regulatory approval submission. We will also check the design of the online platform with members of our Patient Advisory Group to check that it is user friendly.

6.4 Data collection

6.4.1 Survey administration

The survey administration offers both online and pen-and-paper completion.

The sample for the study consists of a random sample of 450 adults aged 35 years and over from each of the 30 participating practices (total sample: 13,500). Potential participants will be identified by conducting a search of the practice GPSoC. Keele CTU will be provided with the following data from the search at each practice: Practice Code, NHS Number, Anonymised Identifier along with the date and method of each invite.. To characterise the random sample for each practice, and facilitate analysis of non-response bias, non-identifiable sample demographic data (including practice code, anonymised identifier, age and sex at birth, ethnicity and lower-layer super output area (LSOA) deprivation score) will be provided to the research team. This will allow any evidence of response bias to be assessed.

The survey administration will offer questionnaire completion using online or postal questionnaires. The online data will be collected using an advanced online questionnaire development tool, 'Keele Health Survey' (KHS), which provides a secure platform for online data capture.

The invitation administration will progress through the following stages:

Stage 1:

People with a mobile telephone number recorded on the general practice EHR, and who have not opted out of receiving text message communication, will be sent a text message (SMS) from their general practice containing a link URL to the online survey. The online survey will include a link to the Participant Information Leaflet. People without a mobile telephone number recorded on the general practice EHR will be invited to join the study at stage 2. If people invited by SMS do not respond, they will be invited to enter the study again at stage 2.

Stage 2:

Keele CTU staff will download an Excel file for each practice, which will contain a list of non-responders from stage 1, from the management application approximately 2 weeks after their initial SMS invitation. This Excel file will consist of a list of NHS numbers of those patients who have not responded to the invitation by completing and consenting to the online survey. This Excel file will be sent via NHS secure email to the appropriate practice.

Non-responders to the invitation SMS at 2 weeks and those who do not have a mobile telephone number recorded with the general practice, will be invited to participate by post. They will be sent a Study

Invitation Pack containing a paper survey, Participant Information Leaflet and an invitation letter from their General Practice inviting them to participate in the study. The invitation letter will provide them with the option of completing their questionnaire either online or by completing and returning the enclosed questionnaire in the prepaid envelope, also provided. Potential participants will be provided with a freephone telephone number for the research team at Keele University, should they have any queries about the study. They can also request to use the translation service (provided over the telephone by Stoke-on-Trent City Council and facilitated by Keele CTU) or the help of a CTU administrator to help complete the questionnaire.

The postal invitation will be performed by Docmail. Docmail is a standards-compliant hybrid mail service, providing document management and ISO 27001 secure mailings. Data from the search will be emailed from the GP Practice to Docmail via a secure email service that is accredited to the NHS Digital secure email standard DCB1596.

Stage 3:

Keele CTU staff will download an Excel file for each practice, which will contain a list of non-responders from stage 2, from the management application approximately 2 weeks after the postal invitation. This Excel file will consist of a list of NHS numbers of those patients who have not responded to the invitation by completing and consenting to the online or postal survey. This Excel file will be sent via NHS secure email to the appropriate practice.

Non-responders to stage 2 will be sent a repeat Study Pack by post, which will include a Minimum Data Collection survey in place of the full survey. Potential participants will again be asked to either complete this online or via post, returning it in the prepaid envelope also provided.

Non responders to stages 1, 2 and 3 will be assumed to have declined participation. People are notified in the Participant Information Leaflet that they can contact Keele Clinical Trials Unit to decline any reminder invitations. People who indicate they do not wish to take part in the study in the initial recruitment stage will have this recorded in the study management application and will not receive any further mailings.

Return of completed survey and consent form will be taken as consent for the use of the survey data they provide. Additional consents are outlined in section 6.4.3.

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). Please refer to Table 1 for the content of the population survey questionnaire and Table 2 for the content of the minimum data collection questionnaire. The content of the survey includes validated measures:

- Graded Chronic Pain Scale-Revised [19]
- 15-item Versus Arthritis MSK-HQ [20]
- General health status (EQ-5D) [21], sleep quality [22], anxiety and depression [23]
- Work loss, productivity and satisfaction [24]
- Core demographic, psychosocial and behavioural factors: date of birth, sex at birth, employment status, marital status, educational attainment, occupational class, perceived adequacy of income, poverty (food, transport), area-level deprivation score from postcode [25], physical activity, 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 [28] and questions on social/community interaction [29,30]
- 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 MIDAS population survey questionnaire

Domain	Construct	No. of items	Item/Instrument
Musculoskeletal Health	High impact chronic pain	6	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	7	Von Korff single items for neck, shoulder, hand/wrist, back, hip, knee and foot/ankle pain
	Musculoskeletal health	14 items (physical activity item included below)	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 self-manage (pain self-efficacy) Independence Overall impact of symptoms
	Use of musculoskeletal health care not captured by EHR	4	Single items capturing engagement with NHS, private health care and self-management (including over the counter medication)
Mental health	Anxiety	7	Hospital Anxiety and Depression Scale
	Depression	7	Hospital Anxiety and Depression Scale
General health	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
	Work absence	2	Standard items
	Work presenteeism	2	Standard items
	Work satisfaction	1	Standard items
	BMI	2	Standard single items on height and weight
	Physical activity	1	Captured using MSK-HQ item
	Sleep/insomnia	4	Jenkins sleep questionnaire
	Health literacy	7	HLS-EU-6Q (6 items) plus 1 single item
	Resilience	6	Brief Resilience scale
Socio-demographic characteristics	Sex at birth	1	Standard single item
	Age	1	Standard single item
	Ethnicity	1	Standard single item
	Education	1	Standard items
	Marital status	1	Standard single item
	Occupational socio-economic status	4	Standard single items on job title
	Financial resource: Adequacy of income	1	Single item
	Employment status	1	Standard single items on employment status
	Caring role status	1	Standard single item
	Housing needs/deprivation	2	Single items adapted from the Accountable Health Communities Health related social needs Screening Tool
	Food poverty	3	Single items
	Fuel poverty	1	Single item
	Transport poverty	1	Single item
	Community participation	1	Single item
	Trust and community engagement	6	Single items
	Emotional support	4	Single items
	Loneliness	1	Single item
Work factors	Job characteristics	2	Single items adapted from the HEAF survey
	Workplace support	1	Single items adapted from the HEAF survey
	Work demands	2	Single items adapted from the HEAF survey
	Job security	2	Single items adapted from the HEAF survey

Table 2: Content of MIDAS population survey minimum data collection questionnaire

	Construct measured	Number of items	Instrument
Musculoskeletal health	Health-related quality of life	6	EQ-5D-5L
	Physical activity	1	Single item from MSK-HQ
	High impact chronic pain	5 (pain impact on work not included)	Graded Chronic Pain Scale-revised
	Employment status	1	Single item
	Absenteeism and Presenteeism	4	Work Productivity and Activity impairment questionnaire
Socio-demographic factors	Age	1	Single item
	Sex at birth	1	Single item
	Perceived adequacy of income	1	Single item
	Ethnicity	1	Single item

6.4.3 Informed consent

A returned completed survey and consent form will be taken as written consent for the use of the survey data they provide and also 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. Optional permission will be sought for contact for further studies. In the online and postal survey formats, informed consent from willing participants will be obtained at the end of survey completion. For the online survey this will be e-consent through the secure web-based interface hosted by Keele University; for the postal it will be written consent.

As part of the survey, a minimal set of participant identifiable data will be collected in order to ensure an individual is correctly identified. Both consent formats cannot be altered by the participant and will be dated either automatically by the web-based system for online completion or by the participant for manual completion. If the consent date is missing from the postal consent form, the date the questionnaire was received will be added upon entry to the database by an administrator. If the participant's signature is missing from the postal consent form this will be sought by following the incomplete consent procedure.

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. Participants who contact Keele CTU and provide consent over the telephone will be posted a hard copy of the Participant Information Leaflet.

If potential participants decline the e-consent to take part in the study, they will receive an onscreen notification thanking them for considering participation and explaining that all of their responses to the survey will be deleted.

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, cleaning, storage

Data entry. Each participant will have a unique study ID. The paper version of the survey will be designed in TeleForm which will allow data to be scanned into a database specifically designed for this study.

Prior to data entry, this database will be tested using a set of dummy data. Logging of response and consent in the study management application will be performed by the Study Administrator. Data from participants completing their survey online by the participant, will be entered directly into the database. Personal data received on the consent form will be held separately from the research data entry databases. All study data will be stored on Keele University storage services within the UK and protected by industry standard security tools. Prior to data cleaning, the TeleForm data will be held on a Keele Clinical Trials Unit secure virtual network which requires two factor authentication in order to access it. All databases will conform to current data protection laws.

Data cleaning. All scanned data, from the paper version of the survey, is machine read within the TeleForm software and any anomalies detected by the software require real-time manual verification. Following this first stage of data cleaning, data from the paper and online surveys will be amalgamated. All verified data is then cleaned, under the supervision of the study statistician.

Data storage. Surveys completed by pen-and-paper will be pseudonymously stored by the Keele Clinical Trials Unit for 10 years in line with Keele CTU standard operating procedures. Data from surveys completed online will to be housed with the Keele Clinical Trials Unit (CTU) secure virtual network. Completed consent forms will be securely stored separate to research data.

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. 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).

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 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 wider determinants of health (e.g. healthy diet, obesity, labour market, housing, built environment, journey time statistics) in local geographies (lower and middle super output areas, CCG, unitary authority) 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. This includes modelled estimates of the underlying population prevalence of MSK pain and disability from our previously conducted PRELIM survey IRAS: 187604 which investigated population health in North Staffordshire.

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 Patient Advisory 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. The CTU Secure Network has been independently audited and achieved level one of the Government backed Cyber Essentials Scheme. 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.

There are secure physical storage arrangements for the hard copy at the Keele CTU within lockable filing cabinets and/or in strictly restricted access rooms. Completed consent forms will be securely stored separate to research data. In addition, any hard copy research data that has been printed for checking will be destroyed by shredding. Surveys completed by pen-and-paper will be stored without names and addresses for 10 years in accordance with Keele CTU standard operating procedures.

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 additional time required to set-up the study and for the retrospective searches they perform.

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 have been collected.

7. STATISTICS AND DATA ANALYSIS

7.1. Sample size calculation

We will invite 13,500 people to take part. Based on a previous survey undertaken by the Keele research team, we are anticipating a 33% response to the survey administration which will provide 4495 responders, of whom 85% will provide consent to medical record review and linkages (this is based on response to the Hill Study response and consent; the Hill study was a population survey which used the same methodology outlined for this survey and involved practices from across the West Midlands).

Receiving 4495 responses will allow us to determine the overall prevalence of high impact chronic pain with a margin of error of less than ±150 per 10,000 (at the 95% confidence level) for any level of prevalence. It is also sufficient to compare between socio-economic groups; based on PRELIM data, this sample size will allow us to estimate the extent of association between high impact 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). If response rates are lower than expected, further general practice registered people may be contacted. If response rates are higher than expected, recruitment will not be cut off as these responses will enrich the data collection and will not incur any extra costs.

We will use a mixed mode approach to collecting information in that we will offer potential responders the choice to complete the questionnaire using conventional postal or online; this is in line with the recommendations of an expert review from the National Centre for Research Methods[14]. Despite increasing access and coverage to the internet, the representativeness of online response is often low. The mixed-mode approach affords both the reassurance of conventional methods but also the opportunity to critically evaluate patterns of uptake of the online survey option and the data quality arising from such an approach. Stage 1 of the survey administration now uses the Keele Health Survey platform which provides a direct link from a text message to the online survey. Preliminary testing of the platform indicates higher response than in PRELIM, with response around 10%. With the survey being conducted within the registered practice population non-response bias can be evaluated and corrected.

Selection and non-response bias to the survey will be adjusted for using weights derived from the age, sex and deprivation structure of the North Staffordshire and Stoke-on-Trent CCG population (from who the 30 practices are from).

7.2. Statistical analysis plan

7.2.1. Summary of baseline data and flow of participants

We will determine the percentage of eligible people responding at baseline and descriptively compare responders to the study sample and general population of North Staffordshire and Stoke-on-Trent by age, gender, general practice and PCN.

7.2.2 Analyses

The analysis plan will focus on the three primary objectives, outlined in section 2.

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 (MSK-HQ), 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 people 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), using appropriate regression models.

2. To identify the most common and disabling patterns of comorbidity (i.e. musculoskeletal conditions plus one or more additional morbidities) in the local population, how these differ by socio-demographic distribution and how such individuals are currently being managed

We will summarise the patterns and frequency of comorbidity (for example high impact chronic pain and depression) and disability within the local population and describe this by age, gender, ethnicity and deprivation. We will then use explore the management profile of patterns of comorbidity stratifying by individual and area level deprivation. Multi-level modelling will be used to examine the association of comorbidity with individual and area level deprivation adjusting for potential confounders.

3. To explore the role of area-level and individual-level social determinants of health on likelihood of consulting primary care among adults with a musculoskeletal health condition

We will determine population profiles of high impact chronic pain, musculoskeletal health (MSK-HQ score) and work participation among respondents by specified populations linked to healthcare use (for example, consulters to primary care for musculoskeletal condition compared to people with musculoskeletal pain who do not consult), using summary measures (for example, percentage, mean (SD)). Weighting will be used to take into account any selective non-response by age, gender, ethnicity, deprivation and practice. Multiple imputation will be used if there is missing data in respondents on the health profile indicators. We will compare the health profiles between the different consulter/non-consulter groups, using multilevel logistic, linear, or negative binomial regression models as appropriate, adjusting for age and gender and other confounders.

To understand the role of area-level and individual-level social determinants of health on consultation for musculoskeletal pain/conditions, multilevel logistic models will be derived separately, to estimate population-level of consultation and compare the predictive abilities of area-level and individual-level social determinants. Data visualisation (map) on the distribution of population-level general health, musculoskeletal health and consultation frequency in local small-areas (MSOA/LSOA) with most predictive social determinant will be produced. Results will be presented and discussed at a PPIE meeting.

8 DATA HANDLING

8.1. Data collection tools and source document identification

Participant-reported data are to be captured through a secure online platform (Keele Health Survey) ensuring that all regulatory requirements are met, including the Data Protection Act 2018, UK General Data Protection Regulation (UKGDPR), NHS Information Governance, and Good Clinical Practice (GCP). Data will also be collected via paper questionnaires; these data will be entered via TeleForm (OMR scanning and verification) platform by a Keele CTU administrator. Paper questionnaires will be sent to potential participants via DOCMAIL. DOCMAIL is a standards-compliant hybrid mail service, providing document management and ISO 27001 secure mailings.

Participant-reported data will be collected at baseline. Following a retrospective search at the GP practice, eligible people with an active mobile telephone number registered at the GP practice and who have not opted out of receiving text message communication, will be sent a SMS text containing a link URL to an online questionnaire. All people sent a SMS invite text will be sent a reminder text approximately 48 hours after the initial text was sent. People who do not have an active mobile telephone number at the GP practice will be sent an invitation pack through the post including an invite letter (including a link URL to complete the survey online), a Participant Information Leaflet, a paper survey, and a pre-paid return envelope two weeks later along with those people who did not respond to the SMS invitation. If there is no response, people will be sent a further pack containing a Minimal Data Collection Questionnaire, there will be no further contact after this.

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 a Study Data Management Plan, 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 will be managed by Keele CTU in accordance with Keele University Health and Social Care (HSCR) SOPs, together with Keele CTU SOPs. 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.

The NIHR CRN: WM, will co-ordinate the general practice identification process and co-ordinate local implementation and study set-up for the research team.

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 Study Monitoring and Data Management Plans and 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 Advisory Board comprising senior researchers and practitioners as well as a patient/public representative. The remit of the Advisory Board covers the planning, conduct, and dissemination of the research as laid out in its written Terms of Reference. The 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 Advisory Board or the Chief Investigator.

9.3. Study Timeline

Activity	***Projected Timeline***
Set up Docmail process	Jun-Sep 2022
Management Web Application & Database design **Management Web Application & Database testing** **Management Web Application & Database sign-off**	Apr-Sep 2022 Jun-Sep 2022 Aug-Sep 2022
Finalise survey instruments and study documentation (PIL, letters, reminders)	Apr-May 2022
Submit to sponsor review **Sponsor review complete**	Jun-Jul 2022 Jun-Jul 2022
Site recruitment and set up	Jun 2022-Dec2022
Submit to HRA/Ethics review **HRA/Ethics approval received**	Jul-Aug 2022 Jul-Aug 2022
Retrospective download begins at first practice	Sep-Oct 2022
First participant recruited	Sep-Oct 2022
Collecting and extracting GP data	Sep 2023-Mar 2024
Survey data cleaning process	Jan 2023-Jun 2023
NHS Digital data requests	2023-2024
Data linkage to practice recruitment data	2023-2024
Data linkage to NHS data	2023-2024
Analysis	2023-2025
End of Study	Mar 2025

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 approval by an appropriate NHS Research Ethics Committee (REC). It will also be submitted for inclusion within the National Institute for Health Research (NIHR) Clinical Research Network (CRN) Portfolio.

- 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/local Investigator Site File.
- An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended.
- It is the Chief Investigator's responsibility to produce the annual reports as required.
- 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 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 Advisory 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 Advisory 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 Patient Advisory 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

Data within the Keele Health Survey is to be captured through secure online forms that meet NHS Information Governance requirements. 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

Keele University has in place Clinical Trials indemnity which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the study and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

The NHS has a duty of care to patients treated, whether or not the patient is taking part in a clinical trial, and the NHS organisation (GP practice) remain liable for clinical negligence and other negligent harm to patients under this duty of care.

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 local NHS Trust.

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.

Overarching principles of our dissemination plan

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. Dziedzic (IAU Director) and Stevenson (Senior Knowledge Mobilisation Fellow and NHSE&I West Midlands Region MSK Lead) are co-investigators on MIDAS-GP study and members of the Project Management Team that meets regularly.

Public involvement

Our research project relies on strong patient and public participation across all stages from conception to dissemination. Our Patient Advisory Group (PAG) meets on a regular (monthly) basis to discuss and advise on all aspects of the MIDAS 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 Advisory 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:

- Written aggregate-level reports and data visualisations to participating GP practices and PCNs (a,b)
- Press releases, briefings, articles, and interviews for local radio and newspapers (a,b,c)
- Written and oral presentation to local policy/planning meetings
- Use of electronic media including a study website, institutional websites, social media including Twitter, YouTube video (all)
- Links with key local, national and international organisations including the Versus Arthritis National MSK Health Data Group, West Midlands Academic Health Science Network, West Midlands Applied Research Collaboration, OHID, NICE, to contribute to and capitalise on their networks (all)
- Publications including full report, executive summary and plain English summary, peer-reviewed journals, and local NHS and research newsletters (all)
- Presentations at high-profile scientific and health policy conferences: NHS Evidence, Society for Academic Primary Care, Chartered Society of Physiotherapy, OHID (b,c,d,e)

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.

12 REFERENCES

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