End of Research Summary Report to Research Ethics Committee

Details of Research

Study Acronym	**MIDAS-GP**
Full Study Title	**Real World Pain Outcomes and Experiences of care (MIDAS GP)**
Sponsor Protocol Ref no.	**RG-0327-21**
REC reference	**292109**
EudracT number	**N/A**
ISRCTN	**18132064**
Sponsor name	**Keele University**

Commencement and termination dates

Date of favourable ethical opinion	**10th August 2021**
Date of MHRA notification of no objection	**N/A**
Start date	**27/09/2022**
End date	**08/07/2024**

Chief Investigator Details

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1. Brief Summary

Recruitment
Consecutive eligible patients consulting a participating general practice during the study period were invited to take part.

Patients
Patients aged 18 years and over who are registered with a participating general practice and consulted with a painful, non-inflammatory musculoskeletal disorder during the study period.

Safety
This was an observational study involving completion of questionnaires that did not cover sensitive topics. No safety risks were highlighted.

Data Collection
Patient reported data was collected at baseline and every month for six months. Patient reported data was collected through a secure online platform (Keele Health Survey) and via paper questionnaires.
The consenting process was clearly outlined, and the participants had to agree to take part in the study and to what information (and to whom) would be shared.

Randomisation
Not applicable to this study.

Contents

1. Introduction to the research

Musculoskeletal (MSK) conditions are the main drivers of non-communicable disease disability burden in most countries and regions worldwide. In England, they account for an estimated 21% of total years lived with disability, 6.2 million working days lost, 12-14% of all primary care consultations in people aged 15 years and over, and the third largest programme budget for NHS healthcare expenditure Our MIDAS programme of research, 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.

The overall aim of this prospective cohort study was to investigate variation and inequalities in patient-reported outcomes and experiences of care and the type of care received by adults presenting to general practice with a non-inflammatory musculoskeletal (MSK) pain condition.

Primary objectives:

- To estimate the magnitude and direction of differences between potentially 'disadvantaged' and 'advantaged' groups of patients in their reported MSK outcomes up to 6-months after consultation.
- To estimate the magnitude of between-practice variation in rates of primary care (re)consultation, secondary care referral, opioid prescribing, and musculoskeletal imaging for adults consulting with a MSK pain condition.

Secondary:

- To estimate differences between potentially 'disadvantaged' and 'advantaged' groups of patients in their experiences of primary care MSK consultation.
- To explore within-practice change in consultation prevalence and recorded management of MSK pain among adults presenting to general practice over time, including comparing current levels with those before COVID (i.e., pre-2020)
- To plot the flow of patients along different MSK care pathways and to define MSK service organisation characteristics for participating general practices and Primary Care Networks (PCNs)
- To produce new benchmarked data on processes and outcomes of care for MSK pain conditions at GP practice and PCN levels and to provide new insights into the credibility, validity, and persuasiveness of new visualisations of this MSK health intelligence and present these for feedback from key stakeholders.
- To explore the relationships between identified variations and inequalities in patient care, outcomes, and experiences and their association with wider determinants and organisational characteristics.
- To test case-mix adjustment methods for identifying outliers for recorded processes of care.
- To evaluate patterns of non-response and non-participation and their implications for bias in the above estimates

2. Methods

2.1. Design of the trial

Observational cohort study of adults presenting to general practice with a musculoskeletal pain condition, with 6-month (self-reported outcomes) and 12-month (electronic health record outcomes) follow-up.

2.2. Outcome measures

Primary outcome: Musculoskeletal health based on the validated MSK-HQ questionnaire: score (0-56) across post-consultation, 3- and 6-months
Key secondary outcomes:

- Overall experience rated “fairly poor” or “very poor” on post-consultation questionnaire.
- Opioid prescription recorded in primary care electronic health record within 14 days of index MSK consultation.
- MSK pain consultation rates

2.3. Eligibility criteria

For General Practices

Inclusion	***Exclusion***
Located in North Staffordshire or Stoke on Trent	
Uses compatible IT systems.	
Uses compatible SMS messaging systems.	
Willing and able to undertake regular anonymised medical record audits of MSK consultations during the study period.	

For Patients

Inclusion	***Exclusion***
Aged 18 years and above	Inflammatory musculoskeletal disease
Registered with a participating GP practice during the study period	Has indicated in their record that they do not consent to be approached about research studies
Consulting any primary healthcare professional in the general practice for a painful, non-inflammatory musculoskeletal disorder during the study period	
Able to provide informed consent	

2.4. Assessment procedure

Shortly after consulting the GP practice for a musculoskeletal pain condition all eligible potential participants were sent a SMS (or letter if no valid mobile number was registered with the practice) inviting them to take part in the MIDAS-GP study. Information about the study was provided on a written Participant Information Sheet. Participation involved completing some short questionnaires and permitting linkage to electronic health records. Consent was sought and completed at entry to the study. Participants had an option to complete the questionnaires online or by pen-and-paper. Questionnaires containing items on musculoskeletal symptoms, their impact on daily life, healthcare use, and experiences of care. Main follow-up points were at 3- and 6-months, with a brief question on pain intensity administered at intermediate points at 1, 2, 4, and 5 months.

2.5. Sample size & Analysis

Based on estimates of the number of participating practices, average practice size and proportion aged 18+ years, duration of recruitment, MSK pain consultation prevalence, 25% response at baseline, 50% follow-up at 6-months, and 80% consent to further contact and record linkage, we anticipated a minimum 1424 baseline respondents (1139 consenting to further contact and record linkage) and 569 responders at 6-month follow-up.

This was sufficient to detect a difference on the follow-up MSK-HQ of 3 or more points (assuming standard deviation of 10), with 80% power at the 5% significance level, for groups defined by a dichotomous covariate. This is based on a covariate with a prevalence of 10%, 2 follow-up time points (3m and 6m), adjustment for baseline MSK-HQ score, and assumed correlations of 0.5 between the two follow-up scores and between the follow-up and baseline. We will, however, use repeated measures multilevel models to ensure all patients responding at baseline can be included in the analysis. The length of the recruitment period was allowed to vary between practices in an attempt to reach a minimum of 50 baseline participants per practice and 100-150 per PCN.

3. Recruitment

End date of recruitment	= 29/07/2022
Recruitment period	= 10 months
Total recruitment	= 2008 (of whom 1875 gave consent to follow-up and record linkage)
Number of participant withdrawals	= 25

30 general practices (at least 1 practice for each of 13 PCNs in North Staffordshire & Stoke-on-Trent) took part in the study, recruiting for a median of 4 months.

4. Comparability of baseline characteristics

This is an observational cohort study, so baseline characteristics for all participants consenting to follow-up and record linkage are provided below.

Key characteristics	**N (%) except where stated**	**Valid N**
Age (years): mean (SD)	58 (16)	1875
Female	1233 (66)	1875
Living in most deprived quintile of neighbourhoods in England	530 (28)	1875
Black, Asian, Multiple, or Mixed ethnic background	87 (5)	1875
Mode of questionnaire completion: online	1593 (85)	1875
Time from index consultation to baseline questionnaire completion: mean (SD)	9 (11)	1875
Clinical characteristics		
≥3 pain sites	549 (29)	1875
Duration of symptoms: > 3 years	371 (20)	1875

Previous episodes: 10+	862 (46)	1875
Previous MSK surgery	238 (13)	1875
Days of moderate physical activity over past week: mean (SD)	2.2 (2.4)	1875
Comorbidity count: ≥3	140 (7)	1875
MSK-HQ (0-56): mean (SD)	25.8 (10.6)	1875
Overall experience rated “fairly poor” or “very poor”	119 (6)	1875
Prescribed opioid analgesia within 14 days of index MSK consultation	493 (26)	1875

5. Follow-up

5.1. Response rate

	Total eligible	Respondents	Response rate
	n	n	%
Baseline	13447	2008	14.9
1-month follow-up	1875	1379	73.5
2-month follow-up	1875	1336	71.3
3-month follow-up	1875	1369	73.0
6-month follow-up	1875	1240	66.1

5.2. Primary outcome completion rates

Not relevant by treatment arm - this is an observational cohort study.

Overall completion rate: 945 (50%) had complete MSK-HQ data at baseline, 3m, and 6m

5.3. Primary end-point analysis (Primary outcome measure)

Not relevant by treatment arm - this is an observational cohort study.

The following table provides primary outcome by main exposure of interest (deprivation):

	Index of Multiple Deprivation† (1=most deprived; 5=least deprived)				
	1 (n=530)	2 (n=383)	3 (n=398)	4 (n=320)	5 (n=244)
MSK-HQ: mean (SD)					
Baseline	22.8 (10.4)	26.1 (10.7)	26.5 (10.5)	27.2 (10.7)	27.6 (10.1)
3 months	26.9 (13.1)	29.2 (12.5)	31.6 (12.7)	31.5 (11.9)	32.9 (12.4)
6 months	27.0 (12.8)	30.9 (13.4)	33.2 (13.8)	32.8 (12.5)	34.3 (12.9)

Opioid prescription within 14 days of index consultation: N (%)	158 (30)	99 (26)	114 (29)	75 (23)	47 (19)
Overall experience “fairly poor” or “very poor”: N (%)	47 (9)	23 (6)	22 (6)	13 (4)	14 (6)
† Based on residential postcode of participant					

6. Safety

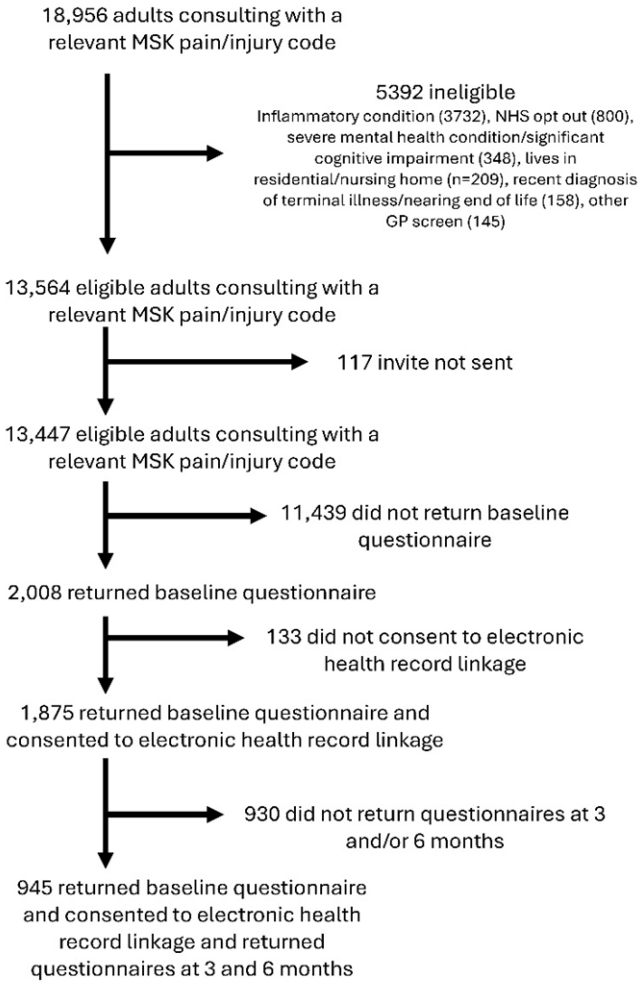
There were no recorded serious adverse events or adverse events.

7. External validity

Baseline characteristics of trial participants and non-participants:

	Baseline responders	Baseline responders + consent to EHR linkage	Baseline responders + consent to EHR linkage + responded at 3 and 6 months
N =	2008	1875	945
Age, Mean (SD)	57.7 (15.5)	57.7 (15.5)	61.1 (13.8)
Female	1322 (66)	1233 (66)	628 (66)
Deprivation			
IMDq1 (Most)	562 (29)	530 (28)	227 (24)
IMDq2	388 (20)	383 (20)	187 (20)
IMDq3	419 (21)	398 (21)	211 (22)
IMDq4	343 (17)	320 (17)	184 (20)
IMDq5 (Least)	249 (13)	244 (13)	136(14)
Ethnicity, White	1919 (96)	1788 (95)	921 (97)
IMDq Index of Multiple Deprivation quintile			

8. CONSORT Flow diagram



9. Conclusions

The study exceeded the target number of general practices and the number of individual participants consulting with a MSK pain condition. It succeeded in including practices across all 13 target Primary Care Networks. The initial proportion of all potentially eligible patients who responded was below expectations, but follow-up was higher. The vast majority of potentially eligible patients had a mobile phone registered with the practice. Of those participating, very few chose pen-and-paper questionnaire completion.

Our initial findings suggest that:

1. Consultation rates for musculoskeletal pain conditions vary two-fold between practices within the same Integrated Care System. Consultation rates are not closely related to underlying estimates of the prevalence of MSK conditions or chronic pain, raising the possibility that differences in accessibility, perceived usefulness, and availability of alternative sources of care may play a role.
2. Deprivation is strongly associated with presenting with more severe, complex problems with a poorer prognosis. Inequalities in MSK health outcomes do not appear to reduce following consultation and may even widen slightly. Patients from more

deprived neighbourhoods appear more likely to be offered an opioid analgesic, and to report dissatisfaction with the consultation (although only a small proportion reported dissatisfaction on our measure).

Although data collection is complete, we are still undertaking further analyses of these data to address the study's secondary objectives, including understanding selective participation at baseline, and research questions proposed by our Patient Advisory Group.

10. Dissemination plan

We have presented our initial findings to scientific, clinical, and lay audiences at the national MSK data meeting and to our Patient Advisory Group who have helped us produce Plain Language Summaries of our findings.

We will not feedback results individually to participants, but we will be posting a lay summary of the results on our publicly available study website. We are also working with colleagues in Keele's Impact Accelerator Unit to explore other channels to disseminate our findings to the public.

The following original research articles have been submitted to open-access scientific journals at the time of writing this report:

Peat et al. **Local variation in musculoskeletal pain consultation rates in primary care: findings from an ecologic study in Staffordshire.** Manuscript submitted to *Prim Health Care Res Develop*

Peat et al. **Socioeconomic inequalities in outcomes, experiences, and treatment among adults consulting primary care for a musculoskeletal pain condition: a prospective cohort study.** Manuscript submitted to *BMJ Open*

Braybrooke et al. **Estimating the cost and carbon output of the primary care management of musculoskeletal conditions: A retrospective electronic health care record analysis.** *Int J Health Planning Manage (In press)*

Mathew et al. **Sequence Analysis to Phenotype Healthcare Patterns in Adults with Musculoskeletal Conditions Using Primary Care Electronic Health Records.** Manuscript submitted to *Arthritis Care Res*

In addition, we have shared our protocol, codes lists and other meta-data, and anonymised, aggregated datasets via Open Science Framework (https://osf.io/e542w/)

11. Acknowledgements

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12. Appendices

None