

BMJ Open Child and adolescent musculoskeletal pain (CAM-Pain) feasibility study: testing a method of identifying, recruiting and collecting data from children and adolescents who consult about a musculoskeletal condition in UK general practice

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ABSTRACT

Objectives Test a method of identifying, recruiting and collecting data from children and adolescents who consult their general practitioner about a musculoskeletal condition.

Design Prospective cohort feasibility study.

Setting 13 general practices in West Midlands of England.

Participants Patients aged 8–19 years who consult their general practice about a musculoskeletal condition. Patients were identified via a relevant musculoskeletal Read code entered at the point of consultation.

Outcome measures Feasibility was assessed in terms of *study processes* (recruitment rates), *data collection procedures* (duration, response variability), *resource utilisation* (mail-outs) and *ethical considerations* (acceptability).

Results From October 2016 to February 2017, an eligible musculoskeletal Read code was entered on 343 occasions, 202 patients were excluded (declined, n=153; screened not suitable, n=49) at the point of consultation. The remaining 141 patients were mailed an invitation to participate (41.1%); 46 patients responded to the invitation (response rate: 32.6%), of which 27 patients consented (consent rate: 19.1%). Participants mean age was 13.7 years (SD 2.7) and current pain intensity was 2.8 (SD 2.7). All participants completed the 6-week follow-up questionnaire. All participants found the interview questions to be acceptable and would consider participating in a similar study in the future. The majority of general practitioners/nurse practitioners, and all of the research nurses reported to be adequately informed about the study and found the study processes acceptable.

Conclusion The expected number of participants were identified and invited, but consent rate was low (<20%) indicating that this method is not feasible (eg, for use in a large prospective study). Recruiting children and adolescents with musculoskeletal conditions in a primary care setting currently presents a challenge for researchers. Further work is needed to identify alternative ways to

Strengths and limitations of this study

- This is the first prospective cohort study to assess the feasibility of identifying, recruiting and collecting data from children and adolescents who consult their general practitioner about a musculoskeletal condition in the UK.
- This study was developed with extensive patient and participant involvement and engagement with young people, clinical specialists and study staff, but the perspectives of parents/guardian was not incorporated.
- This study captured the level of assistance given by parents/guardians to help their child/adolescent complete the baseline interview.
- At the time of inviting consulting patients to take part, a significant proportion 'declined', more work is needed to understand the reasons for decline and what can be changed to make participation more appealing.
- There was a significant delay between each stage of the study (ie, patient identification, invitation and recruitment into the study), which may have resulted in selection bias (ie, some children and adolescents may have not taken part because their pain had resolved). However, the population recruited in this study are comparable to previous studies.

conduct studies in this population in order to address the current knowledge gap in this field.

INTRODUCTION

Musculoskeletal conditions such as foot, knee and back pain are common across the life course and lead many to seek healthcare in primary care. From childhood through to

adulthood, musculoskeletal pain is recognised as a leading cause of years lived with disability and has a substantial impact on the individual and society, including time off school and/or work, psychological status, healthcare and medication use.¹⁻⁴ Research that has considered the longitudinal course or trajectories of adult musculoskeletal pain (in particular back pain) overtime has shown relatively stable patterns. For example, trajectory research has shown that those who start off with high levels of pain tend to stay on a trajectory of high pain, similarly those with low levels of pain or no pain tend to stay within that trajectory, with little evidence that people 'change' trajectories, even over the long term.⁵⁻⁸ However, the patterns or trajectories of musculoskeletal pain measured in children and adolescents are different, with evidence to suggest greater variability and change, indicating that childhood and adolescence may be a critical period to investigate the development of long-term pain trajectories, and potentially identify longitudinal markers predictive of persistent pain in adulthood.⁹⁻¹¹ Existing evidence shows childhood predictors of persistent pain in adults, as well as an association between persistent pain in childhood and persistent pain in adulthood. However, at present this evidence is mainly cross-sectional or measured using few time points (eg, baseline and follow-up). As a result, knowledge of change or development in pain status, or the factors that associate with that change over time is limited.¹²⁻¹⁵ Only evidence from prospective longitudinal cohort studies with multiple follow-up stages offers the opportunity to characterise the development of musculoskeletal pain in childhood and identify periods of susceptibility or vulnerability linked to future adult chronic pain. Understanding influences and determinants of these periods has potential to identify targets for prevention or amelioration of such conditions.

At present, much of the information about childhood musculoskeletal conditions is drawn from general population and specialist care settings; however, a significant gap exists in the literature from children who seek healthcare from primary care, in particular general practice settings. Investigating childhood musculoskeletal symptoms among those that seek treatment in primary care is the ideal location for such research, as between 4% and 8% of consultations annually are for musculoskeletal conditions in children and adolescents, and this is where most of the assessment and management of such problems occurs.¹⁶⁻¹⁸ Compared with the amount of literature on musculoskeletal pain in adults, there are currently very few published cross-sectional or cohort studies of children who seek healthcare with musculoskeletal conditions, in the UK or elsewhere.¹⁶⁻²³ This is a substantial omission, particularly considering the high burden of such conditions in primary care and the potential for such problems to influence later adult patterns of pain.

The aim of this feasibility study was to test a method of identifying, recruiting and collecting data from children and adolescents who consult their general practitioner (GP) about a musculoskeletal condition.

Following the general guidance on the conduct of feasibility studies,^{24,25} this study specifically aimed to assess and report on factors related to study processes, data collection, resource utilisation and ethical considerations.

METHODS

Study design and setting

This prospective cohort feasibility study recruited children and adolescents seeking healthcare (consulting) for a musculoskeletal condition from 13 UK primary care general practices within the National Institute for Health Research (NIHR) Clinical Research Network: West Midlands. Participating practices operated under the research incentive scheme, whereby practices are provided with funding to support infrastructure within primary care organisations to enable them to become or continue to be 'research active'. Participants who consented to take part were asked to complete a face-to-face baseline interview and 6-week follow-up questionnaire. The identification of eligible patients via a relevant musculoskeletal Read code entered at the point of consultation occurred from October 2016 to February 2017. Data were collected from participants from November 2016 to May 2017 and, post patient recruitment from research nurses, GPs and nurse practitioners (NPs) from May 2017 to July 2017. No financial incentives or remuneration were provided to participants; however, participants could opt to receive a certificate at the end of the study that acknowledged their participation.

Eligibility criteria, participant identification and recruitment procedure

Eligibility criteria

Children and adolescents were eligible to participate in this study if they were aged between 8 and 19 years and consulted their GP or NP about a musculoskeletal condition. The term musculoskeletal condition referred to any diagnosis (eg, ankle sprain) as well as presenting signs (eg, limp) or symptoms (eg, pain, stiffness) suggestive of a musculoskeletal problem. The lower age range (8 years) was selected based on evidence of the capability of children to understand, comprehend and independently report their pain.^{3,26,27} In further support of this choice, epidemiological evidence shows that children below the age of 8 years only account for a small percentage (<10%) of the child/adolescent consultations for musculoskeletal pain in primary care within the UK.^{16,18,28} The upper age range (19 years) was chosen based on the WHO definition of an adolescent being people aged between 10 and 19 years.²⁹

Patients were excluded if they declined the GP/NP invitation to participate, there was an indication of a serious diagnosis (eg, cancer, meningitis), the patient was judged to be vulnerable (eg, child at risk, recent trauma) by their GP or NP, were unable to respond to the initial study invitation (eg, severe learning difficulties, unable to speak/

read English) or the consultation was not face-to-face (eg, telephone triage).

Patient identification

Consecutive children and adolescents who consulted their GP or NP about a musculoskeletal condition were identified by the Read code entered by the GP/NP on their practice computer at the time of consultation. Read codes are a standardised set of clinical terms that allow the recording of patient findings, procedures and morbidity in UK primary care IT systems, and have been shown as suitable for epidemiological studies.³⁰ Musculoskeletal Read codes included symptom and diagnosis codes from Chapter N 'Musculoskeletal and connective tissue diseases', R 'Symptom, signs and ill-defined conditions', S 'Injury and poisoning' and I 'History/symptoms' as outlined in previous methodology.¹⁸ The list of eligible musculoskeletal Read codes are freely available and can be accessed at <https://www.keele.ac.uk/mrr/>. In order to identify Read codes describing benign musculoskeletal conditions relevant to children and adolescents, the available list of musculoskeletal Read codes was independently reviewed by two GPs and a physiotherapist familiar with paediatric conditions. Musculoskeletal Read codes were excluded if they were related to specific diseases or health conditions (eg, osteoporosis, inflammatory condition such as rheumatoid arthritis or infections such as osteomyelitis) or were the result of severe injury or trauma (eg, fractures). Any disagreements on the inclusion/exclusion of a Read code were first discussed between two reviewers (GP and physiotherapist) and if consensus could not be achieved the code was reviewed and discussed with the second GP. The revised list of musculoskeletal Read codes relevant to children and adolescents is also freely available and can be requested through the URL address reported above. This revised list of musculoskeletal Read codes was used to trigger an electronic prompt (screen pop up) that was installed in all computer systems at participating practices (see online supplementary appendix 1 for screenshots of the electronic prompts used). Each time a Read code indicating an eligible musculoskeletal condition was entered into the medical record of a child within the age range (see the 'Eligibility criteria' section), an electronic prompt was triggered (the prompt was only triggered once per patient, ie, did not trigger again on subsequent consultations). This prompt reminded the GP or NP that the patient is eligible for the study, to briefly mention the study to the child/adolescent patient and their parent/guardian (if applicable) and give them a study information card. The information card let the patient know that they were eligible for the study and to expect to receive a study pack in the post. Patients could be excluded from the study by either declining the invitation to participate, or at the discretion of the GP/NP for reasons listed above in the exclusion criteria. If the patient was excluded by the GP/NP, a reason for exclusion was requested from a standardised list of options (vulnerable, serious diagnosis, inability to speak or read English, severe learning

difficulty, patient declined invite). On a fortnightly basis, NIHR Clinical Research Network staff downloaded the contact details of eligible patients, and mailed prepared study packs to potential participants on behalf of participating GP practices.

Recruitment procedure

Eligible child/adolescent patients or their parent/guardian (if aged <16 years) received a participant study pack in the post from their GP practice. The participant study pack contained a letter of invitation, participant information booklet, reply slip and prepaid envelope. To assist younger people, or those who are less proficient in written English, to understand the main aims of the study and study procedures, the participant information was available online as a YouTube video. To ensure patient confidentiality, the online version of the participant information was set as unlisted (ie, the video cannot be found by searching on a web browser), which means that only people who were provided the web address in the invitation letter and participant information booklet could access the video and verbal explanation of the study. The child/adolescent and their parent/guardian (if aged <16 years) were encouraged to read the enclosed documents carefully, or watch the online information and respond to the invitation to participate by postal mail, email or telephone. A response to the invitation could either be positive expressing interest in the study or decline of the invitation in which case a reason for decline was requested. On receipt of a positive response, a research nurse (experienced in research with children/adolescents) contacted the adolescent (if aged 16 years or older) or their parent/guardian (if aged <16 years) to arrange a time to visit the child/adolescent to obtain consent and complete the baseline interview at their home or registered GP practice. For patients aged <16 years, it was stipulated by the research nurse over the phone and in the 'confirmation of appointment' letter that a parent/guardian must be present at the time of the interview; this was to ensure that the parent/guardian could provide written co-consent for their child's participation in the study and to assist their child complete the interview as required. The participant was considered to be recruited into the study at the baseline interview once written informed assent/consent had been obtained from both the child/adolescent and parent/guardian (if aged <16 years) or from the adolescent themselves (if aged 16 years or older). Consent in this study extended to participants agreeing to receive the follow-up questions 6 weeks after the baseline interview. Participants could withdraw from the study at any time without reason and participation did not change the care they received.

To maximise response rates, a reminder procedure was used for both the initial mail-out and follow-up stage. Patients who did not respond to the initial invitation included in the study pack were sent a reminder study

pack after 4 weeks. Similarly, follow-up reminders were sent at 2 and 4 weeks of the first follow-up questions being sent.

Outcomes

Assessment of feasibility

Feasibility of participant identification, recruitment and data collection procedures was assessed in terms of *study processes*, *data collection procedures*, *resource utilisation* and *ethical considerations*.

Study processes assessed the flow of participants through the study in particular the number of patients identified as eligible to participate (ie, number of times an eligible musculoskeletal Read code was entered), the number of patients invited and excluded (including reasons for exclusion), the number of patients who responded to the invitation (ie, response rate: of those invited, the number who responded (accepted or declined the invitation) and the number who provided consent to participate in the study (ie, consent rate: of those invited, the number who gave written informed consent to participate). Participants' follow-up preferences and response to follow-up was described, and potential for bias from loss to follow-up analysed by comparing participants who responded to those who did not (ie, baseline comparison). The duration between each of the study stages was calculated and reported, that is, time between the index consultation and, being invited to participate in the study, response to the invitation and baseline interview with the research nurse as well as the time between the baseline interview and completion of follow-up.

Data collection procedures assessed the content of the interview in terms of time taken to complete the baseline interview, whether assistance was provided by parents/guardians to complete each section of the questionnaire and the amount of missing baseline and follow-up data. Patient-reported outcomes measures collected at the baseline interview and follow-up were reported descriptively to assess participant responses and variability.

Resource utilisation evaluated the workload on study staff in terms of the number of postal mail, emails sent and received and phone calls made.

Ethical considerations assessed participants, GP/NP and research nurses' involvement in the study in terms of content, practicality and acceptability. Acceptability of study processes for participants was assessed at the end of the baseline interview by questions related to question difficulty, interview length and willingness to participate in future research. The acceptability of study procedures for GPs/NPs and research nurses was assessed at the end of the recruitment period using a short evaluation (7 questions for GP/NP; 11 questions for research nurses who conducted interviews; 5 min to complete). Questions included level of awareness of the study, content and acceptability of study procedures and electronic study prompts (GP/NP) or interview (research nurse), time required to participate and willingness to participate in future studies in children and adolescents.

Participant baseline and follow-up outcome measures

Baseline interview

Information about participants musculoskeletal conditions were collected using validated or widely accepted instruments for this population.^{27 31 32} Data collected at baseline are reported in [table 1](#) and covers demographic information, information about the consultation for the musculoskeletal condition, pain outcomes, psychological outcomes, questions on function and activity limitation, quality of life and questions about the study processes (eg, interview acceptability, timings, contact preferences for follow-up). Please note, only a selected number of outcomes from this list are reported in the results to facilitate comparisons with other studies. For a full description of baseline data, please see online supplementary appendix 2.

Follow-up

The 6-week follow-up consisted of three questions (global perceived effect scale,³³ pain intensity^{27 34} and pain bothersomeness (over the past 7 days)).³⁵

Patient and participant involvement and engagement

The child and adolescent musculoskeletal pain study protocol (see online supplementary appendix 3) and processes received extensive patient and parent input from the NIHR Rheumatology Clinical Studies Group whose role is to assist researchers with refining the research question, assess feasibility, facilitate patient and parent input, comment on recruitment and study design. In light of the feedback received, the inclusion/exclusion criteria and terminology were refined. The study also received significant input from the GenerationR Young Person's Advisory Group (YPAG) in Liverpool (a group of child/adolescent users), specifically for review and feedback on study processes and materials including the participant information booklet and questions that we planned to use. Feedback received from the YPAG resulted in a number of changes, for example, revision of the wording to make it more child friendly and development of age-specific participant information booklets (8–12 years, 13–15 years, 16–19 years versions, and a parent version which accompanied the 8–12 years and 13–15 years booklets). Prior to commencement of the study, the study procedures and baseline interview were piloted in full with three children/adolescents aged 8–12 years.

Study sample size

Based on sample size recommendations for pilot and feasibility designs,^{36 37} the study aimed to recruit 50 participants to ensure sufficient variability for feasibility analysis (study processes, data collection, demographics). Previous research of local consultation records indicated that approximately 9% of children/adolescents visit their GP practice with musculoskeletal conditions each year.^{18 28 38} This translates to approximately 60 consultations per year at an average GP practice (average population size 7000,

Table 1 Baseline data collection

Demographics	
Date of birth	Open response
Gender	Male/female
Ethnic category national coding ⁵⁶	Select most appropriate response option(s)
School/work situation (three questions: school/training, part-time/full-time work, not in any type of work or education)	Yes/no response
Satisfaction with school/work/college	Four response options ('very satisfied' to 'very dissatisfied')
Screen time ⁵⁷	Six response options ('none' to '>5 hours')
Physical activity. ⁵⁷ In the past week, the number of times per day you have done a total of 30 min or more of physical activity	Five response options ('<1 time/day' to '>5 times/day')
Comorbidities: Other health problems/illnesses (12 conditions and 2 open response)	Location of other bodily pains recorded on body chart
Details about the consultation for the musculoskeletal condition	
Location of pain for consultation ⁵⁸	Body chart
Is this pain still present?	Yes/no response
Duration of other bodily pains	Four response options ('<1 week' to '>12 weeks')
Is this the first episode of pain?	Yes/no response
Mechanism of injury	Four response options (accident/injury; gradual onset with no injury; sudden onset with no injury; do not know/unable to recall)
Treatment provided: medications, advice/education, referral to healthcare professional, imaging referral (yes/no with free text to capture details)	Yes/no response+additional open response
Pain outcomes	
Pain intensity: Current pain ³⁴ Usual pain intensity over last 7 days ³⁴	NRS (0–10 scale)
Bothersomeness ³⁵	Five response options ('not at all' to 'extremely')
Visual pain trajectories ⁵⁹	Seven graphical response options indicating differing pain patterns. Select option that best reflects their pain experience.
Psychological outcomes	
Child self-efficacy scale ⁶⁰	Seven items, five responses ('very sure' to 'very unsure')
Single items from Fear of Pain Questionnaire ⁶¹	Three items, three responses ("I do not agree", "I am not sure", "I agree with this")
Functional/activity limitation	
Paediatric pain screening tool ⁶²	Nine items, eight items ('agree' or 'disagree'), one item five response options ('not at all' to 'a whole lot')
FDI ⁶³	Fifteen items, five response options ('no trouble' to 'impossible')
Chronic pain grade scale: 0–10 interference with usual activities ^{64 65}	Numerical rating scale (0–10 scale)
Sleep: Duration Quality: trouble falling asleep, waking in the night, trouble staying asleep, waking feeling tired and worn out ⁶⁶	Usual bed/wake time Four items, three response options ('not at all', 'on some nights', 'on most nights')
Health-related quality of life (HRQoL)	
KIDSCREEN-27 ⁴⁰ : five domains: physical activities and health, general mood and feelings about yourself, family and free time, friends, school and learning	Twenty-seven items, five response options ('not at all' to 'extremely'). Higher score=higher HRQoL

Continued

Table 1 Continued

Interview acceptability	
Ease of interview	Five response options ('very difficult' to 'very easy')
Acceptability of interview duration	Three response options ('too short', 'just right', 'too long')
Willingness to participate in future research	Three response options ('yes', 'maybe', 'no')
Preferences for research involvement: Frequency of contact Method of contact, seven options	Six response options ('daily' to 'monthly', option of free text) Yes/no response to each
CAM-Pain 6-week follow-up preferences	
Follow-up preferences	Three response options ('phone', 'email', 'mail')

CAM-Pain, child and adolescent musculoskeletal pain; FDI, functional disability inventory; NRS, numerical rating scale.

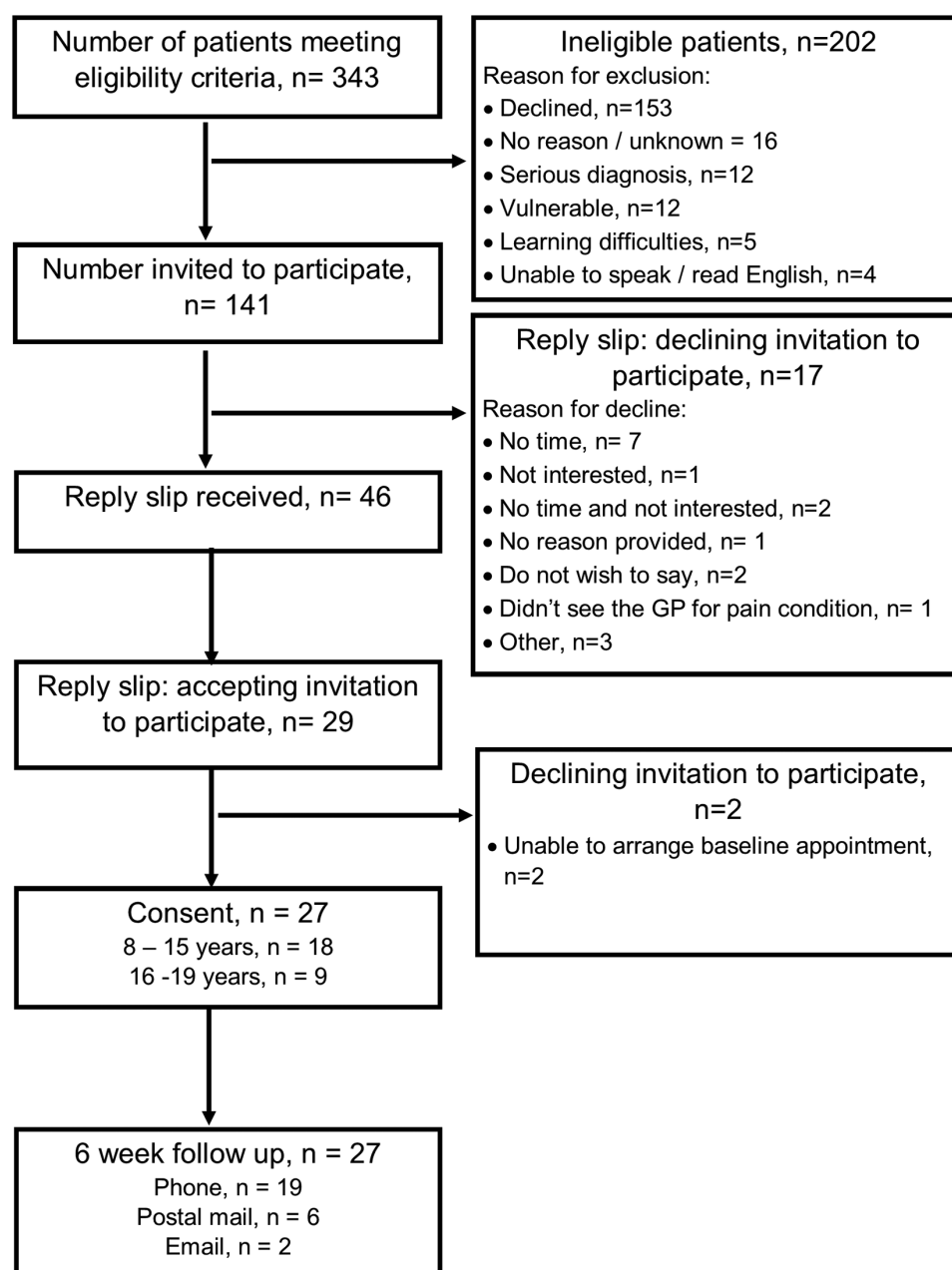
**Figure 1** Participant flow diagram and reasons for exclusion at each stage of the study. GP, general practitioner.

Table 2 Days taken between each stage of the study

Stage of study	Median	Mean	SD	Range
Index consultation to the postal date of invitation*	22.0	19.7	9.6	2–42
Index consultation to the baseline interview*	56.0	61.3	23.0	28–122
Postal date of invitation to receipt of the reply slip (accept or decline invitation) (n=46)	23.5	22.1	16.4	3–68
Declined invitation (n=19)	30.0	26.3	17.3	3–68
Consent (n=27)	12.0	19.2	15.4	3–51
Postal date of invitation to the baseline interview (n=27)	37.0	41.6	18.8	18–80
Receipt of reply slip to baseline interview (n=27)	22.0	22.4	8.0	7–38

*n=23, consultation date was not available for four participants.

NHS 2012). Based on an estimated participation rate of 30% over a recruitment time scale of 4 months, we estimated the need to approach 170 patients from approximately 15 GP practices in order to recruit the required sample (n=50).

Data analysis

The focus of this study is on feasibility which was assessed in terms of study processes, data collection, resources utilisation and ethical considerations, details of which can be found under the outcome subheading. All data were analysed descriptively, with continuous variables expressed as means, SD and range and categorical variables as frequency counts and percentages. Data were analysed using SPSS Statistics Package V.24.

RESULTS

Feasibility outcomes

Study processes

From the 13 general practices, the electronic study prompt was triggered on at least one occasion by 78 GPs/NPs. An eligible musculoskeletal Read code was entered on 343 occasions indicating 343 potentially eligible patients, with a total of 202 patients (58.9%) excluded at the point of consultation, either because they declined the invitation to participate (n=153) or were screened as not suitable by the GP/NP (n=59). The remaining 141 patients (41.1% of those deemed eligible) were mailed participant information packs and invited to participate. A total of 46 (32.6% of those invited) responded to the invitation, and within that group of responders 29 (63.0%) indicated a wish to take part, and 17 (37.0%) declined. Of the 29 patients who indicated a wish to take part in the study, 2 patients later declined the invitation following multiple attempts by the research nurse to schedule a baseline appointment. Consent was obtained from 27 participants; this indicated a consent rate of 19.1% from those patients invited, and represents 7.9% of those deemed eligible within the consulting population. Participant flow diagram and reasons for exclusion at each stage are reported in [figure 1](#). Investigation of the timescale to participate at each stage is reported in [table 2](#).

Response at follow-up was 100% with all 27 participants completing the 6-week follow-up questionnaire in its entirety. Participant's follow-up response preferences were phone (n=19, 70.4%), postal mail (n=6, 22.2%) and email (n=2, 7.4%). The mean time from baseline assessment to completion of the 6-week follow-up was 47.4 days (SD 8.5, range 42–74 days).

On average, the baseline interview (obtaining consent and completing the interview) took 49 min (SD 15 min, range 22–74 min). Stratified by age group, the average baseline interview was 51 min (SD 14 min, range 27–74 min) for those aged 8–15 years (n=18) and 45 min (SD 16 min, range 22–74 min) for those aged 16–19 years (n=9), no statistical tests to compare age group differences were conducted due to the small sample size per group. The majority of participants (70.4%, 8–15 years, n=17; 16–19 years, n=2) received assistance from a parent/guardian to complete one or more sections of a questionnaire during the baseline interview (a section could represent a single question or subsection of a questionnaire). Parents/guardians assisted with an average of 5.3 of the total 42 sections (SD 4.5, median 3.0, range 0–14 individual questionnaire items) during the interview. In terms of item completion, missing data were low with a total of 10 individual questionnaire items missing from all interviews.

Data collection

Reported in [table 3](#) are selected baseline participant characteristics and patient-reported outcome measures. The mean age of participants was 13.7 years (SD 2.7, range 9–18 years) and approximately equal numbers of boys (48%) and girls (52%) participated. Participants predominantly consulted their GP/NP for musculoskeletal conditions affecting the lower limb (ie, knee) followed by back (ie, low back) and upper limb. Participants reported current pain intensity to be 2.8 (SD 2.7) and usual pain intensity over the previous week to be 4.3 (SD 2.1). A significant proportion (85%) of participants reported no-to-moderate pain bothersomeness, and almost two-thirds of participants (63%) reported no/mild levels of disability (functional disability index (FDI)).³⁹ The majority of participants

Table 3 Baseline characteristics, n=27

Baseline characteristics	
Age (years)	
Mean (SD), range	13.7 (2.7), 9–18
8–15, n (%)	18 (66.6%)
16–19, n (%)	9 (33.3%)
Sex, n (%)	
Boys	13 (48.1)
Girls	14 (51.9)
Ethnicity	
White British, n (%)	26 (96.3)
Other white background	1 (3.7)
Current status	
School, n (%)	27 (100)
Part-time/full-time work, n (%)	5 (18.5)
Body region consulted about (>1 site could be reported)	
Head	0
Face	0
Chest pain	1
Spine (eg, cervical, thoracic, lumbar spine), n	7
Cervical	1
Thoracic	2
Low back	4
Lower limb	23
Hip	2
Gluteal region	2
Hip/knee/ankle	2
Hip/foot	1
Thigh	1
Knee	7
Knee/ankle	3
Ankle	1
Foot	3
Foot/ankle	1
Upper limb	4
Elbow	1
Wrist	1
Hand+wrist	1
Hand	1
Duration of current pain, n (%) (weeks)	
<1	1 (4.2)
1–6	1 (4.2)
>12	22 (91.7)
Taken time off school for current MSK condition	
Yes, n (%), duration (%)	7 (25.9), <1 week 100%

Continued

Table 3 Continued

Baseline characteristics	
Current pain intensity (0–10 NRS), mean (SD), range	2.8 (2.7), 0–8
Usual pain intensity over last 7 days (0–10 NRS), mean (SD), range	4.3 (2.1), 0–7
Bothersomeness, n (%): not at all	7 (25.9)
Slightly	2 (7.4)
Moderately	14 (51.9)
Very much	4 (14.8)
Extremely	0 (0)
FDI*, mean (SD), range	10.7 (8.2), 0–29
No/mild disability (score≤12)	17 (63)
Moderate disability (score 13–29)	10 (37)
Severe disability (score≥30)	0 (0)
KIDSCREEN-27†*	
Physical well-being, mean T-value (SD)	43.3 (7.9)
Psychological well-being, mean T-value (SD)	45.8 (6.8)
Autonomy and parent relations, mean T-value (SD)	50.8 (8.3)
Social support and peers, mean T-value (SD)	50.4 (12.0)
School environment, mean T-value (SD)	48.5 (8.2)

*FDI scores range from 0 to 60, with higher scores indicating greater functional disability.

†UK National Norm data mean 50 (SD 10). High, average or low quality of life for each subscale was determined by mean of the reference group±half the reference SD as described in the KIDSCREEN manual.

FDI, functional disability index; MSK, musculoskeletal; NRS, numerical rating scale.

(>90%) reported experiencing their current pain for >12 weeks, with just over 25% having time off school due to their pain. Participants were within normative ranges for all quality of life subscales except for physical well-being, which recorded lower physical functioning than the UK population norms.⁴⁰ In terms of ethnicity, no children of black or ethnic minority status participated, but we do not have the information of the ethnicity breakdown of the source consulting population.

Follow-up data are reported in table 4, all participants completed the follow-up and no data were missing. Compared with when patients consulted their GP/NP about a musculoskeletal condition, 59.3% of patients considered themselves better, much better or completely recovered, 25.9% felt that their pain had not changed and 14.8% reported that their pain had become worse. Usual 7-day pain score for participants at follow-up was 3.5 (SD 2.3, range 0–7) and for majority of patients (n=20, 74%) this pain was either not, or only slightly bothersome.

Table 4 Six-week follow-up responses, n=27

Outcome	
Global perceived effect scale, n (%)	
Completely recovered	3 (11.1)
Much better	1 (3.7)
Better	12 (44.4)
No change	7 (25.9)
Worse	3 (11.1)
Much worse	1 (3.7)
Worse than ever	0 (0)
Pain over last week (NRS), mean (SD), range	3.5 (SD 2.3), 0–7
Bothersomeness, n (%)	
Not at all	7 (25.9)
Slightly	13 (48.1)
Moderately	5 (18.5)
Very much	2 (7.4)
Extremely	0 (0)

Resource utilisation

The number of resources including mail outs, phone calls and emails is reported in [table 5](#). Majority of participants (84.1%) did not respond to the initial invitation to participate and were sent a reminder study pack after 4 weeks. On average, staff were required to make two calls in order to contact participants by phone.

Ethical considerations

Participants

All participants found the interview questions to be acceptable and would consider participating in a similar study in the future. The majority (n=26) of participants found the duration of the interview to be acceptable with only one participant (aged 16 years) indicating that it was 'too long'. No adverse events were reported. In order to determine acceptable study parameters for future research studies in this population, participants were asked about their most preferred frequency and method of contact, these findings are reported in [table 6](#). In addition to interview questions, 85.2% of participants indicated that they would be willing to complete a physical assessment if required.

General practitioner/nurse practitioner

Study evaluations were sent to the 78 GP/NP who entered an eligible musculoskeletal Read code on at least one occasion, and 15 evaluations were returned (19.2% response rate). Majority of GP/NP reported being adequately informed about the study (60.0%) and found the study processes acceptable (66.7%), also the time required to participate in the study (66.6%) and content of the prompts were reported as acceptable (73.3%). The electronic prompts were seen by most GPs/NPs to be a helpful reminder about the study (73.3%), and they did not feel that use of the electronic prompt interfered with the consultation. The majority

(80.0%) of GPs/NPs indicated that they would participate in a study recruiting children and adolescents again in the future.

Research nurse

Three research nurses conducted baseline interviews. All the research nurses reported that they felt well prepared for their role in terms of the training that was provided, and their ability to respond to the questions asked by participants and parents/guardians. Study procedures including scheduling, completing, duration and content of interviews were all deemed by the research nurses to be appropriate and acceptable. The time required to travel to home visits in specific regions was reported to be a challenge, especially as many of the interviews had to be conducted outside of school hours. At no point did the research nurses have any concerns about their own safety or security during the home visits and all would participate in a study recruiting children and adolescents again.

DISCUSSION

This feasibility study evaluated a method of identifying, recruiting and collecting data from children and

Table 5 Resources used at each stage of the study

Resources used at each stage of the study	Count
Invitation packs sent	
No. of initial invitations sent	141
No. of 4-week reminder invitations sent	116
Nurse call sheets	
Nurse visit sheets	
Nurse phone calls to book baseline appointment, n=29	
Total calls	51
Calls per patient, mean (SD), range	1.8 (0.9), 1–4
Written correspondence	
GP notification of participation	27
Confirmation of appointment letter	27
Certificates	27
Follow-up	
Phone calls, n=19	
Total number of phone calls	32
Calls per participant, mean (SD), range	1.7 (0.9), 1–4
Postal mail, n=6	
Total number of letters sent	10
No. of participants sent a reminder: 2 weeks	2
4 weeks	2
Emails, n=2: total number of emails sent	2

Table 6 Participants most preferred frequency and method of contact for future studies

Preferences	Frequency
Frequency of contact (able to select >1 option)	
Daily, n (%)	5 (18.5)
Weekly, n (%)	14 (51.9)
Every 2 weeks, n (%)	22 (81.5)
Every month, n (%)	22 (81.5)
Do not know, n (%)	1 (3.7)
Preferences for method of contact (able to select >1 option)	
Email link to online survey, n (%)	21 (77.8)
Direct response to email, n (%)	16 (59.3)
Study app, n (%)	20 (74.1)
Direct response by text message, n (%)	20 (74.1)
Face-to-face interview, n (%)	21 (77.8)
Paper questionnaire by post, n (%)	26 (96.3)
Over the phone, n (%)	18 (66.7)
Most preferred method of contact (select only one option)	
Email link to online survey, n (%)	2 (7.4)
Study app, n (%)	6 (22.2)
Direct response by text message, n (%)	3 (11.1)
Face-to-face interview, n (%)	7 (25.9)
Paper questionnaire by post, n (%)	3 (11.1)
Over the phone, n (%)	2 (7.4)
Missing, n (%)	4 (14.8)

adolescents who consulted in primary care about a musculoskeletal condition. Feasibility was assessed in terms of study processes, data collection procedures, resource utilisation and ethical considerations. The number of consultations was in line with our estimations, but the response (32.6%) and consent rate was low (19.1%) indicating a lack of feasibility for recruitment. However, it should be noted that participants recruited into the study found data collection procedures acceptable, and all participants completed the 6-week follow-up. In addition, study processes, resource utilisation and ethical considerations were reported to be acceptable for participants, GPs/NPs and research nurses.

Strengths and limitations

This feasibility study has a number of strengths in its development, design and conduct that can be considered for inclusion by future studies. First, this study received quite extensive patient and participant involvement and engagement from the NIHR Rheumatology Clinical Studies Group and child and adolescent members of GenerationR Young Persons' Advisory Group. Furthermore, study processes were developed in collaboration with key study members including research nurses, GPs, administration staff and Clinical Research Network Staff and interview questionnaire piloted with children and

adolescents. Collectively, this input resulted in the development of high-quality, visually appealing and age-appropriate study materials (including an online participant information video) and a baseline and follow-up questionnaire that was acceptable for use in this population. Second, this study reports on the number of children and adolescents who consult for a musculoskeletal condition in the UK, and the flow and timing of participants through each stage of the study. Third, this study is the first, to the authors' knowledge, which has attempted to capture and quantify the amount of assistance Parents/guardians provided to child and adolescent participants. The amount of parent input is an important consideration in child and adolescent research as parent proxy has been found to not be an accurate representation of children's pain experiences.^{27 41} Therefore, in children and young people who are able to communicate, the most valid and reliable approach to measuring pain is through the use of self-report measures.^{27 41} The results of this study suggest that by using carefully selected, age-appropriate outcome measures, children as young as 8 years can participate in a research interview and self-report their pain experience with minimal support from a parent/guardian. Lastly, this study captured information about patients who declined the invitation to participate and reasons for their decision, although this was restricted to those who actively responded. Findings reported by those who declined show similarities to paediatric studies in other health conditions, for example, 'no longer has the health condition of interest', 'a lack of time' and 'lack of interest in taking part' were the main reasons given, and are factors that need to be addressed by future studies.⁴²

The current study also illustrates a number of limitations in the study design that are likely to have had a significant impact on the identification and recruitment of young people. While study processes appeared to be acceptable to GPs/NPs, the response rate from GPs/NPs was low (<20%) and therefore the majority view is actually unknown. The low response rate may be an indication of GPs/NPs poor recollection about the study and possibly low engagement. In addition, a significant proportion of patients were screened as ineligible (n=202, 58.9%) with 'patient declined' the main reason provided (n=153) and the remainder judged by GPs/NPs as not suitable (n=59). While we have a breakdown of the information on suitability (eg, patients judged as vulnerable, having serious diagnosis, learning difficulties), due to study design constraints, we could not collect information for reasons of decline. Clearly with almost half (44.6%) of the eligible population declining at the point of consultation there is a need to better understand the reasons why this was the case, the context in which this occurred and the potential impact these exclusions had on the external validity and generalisability of study findings.^{43–45} While the study received significant Patient and Public Involvement and Engagement (PPIE) input from clinicians, study staff (some of whom are parents) and a group of child and adolescent health users, we did not specifically seek the

opinions and perspectives of parents/guardians. This is an important oversight as parents/guardians are considered the gatekeepers and decision makers on whether their child/adolescent may take part in a research study.^{46 47}

Comparable studies in the literature

A key factor that impacted on feasibility in this study was the duration between patient identification, response to invitation and recruitment into the study. The duration between each of the three stages was ~20 days (table 2), and from the index consultation to the baseline interview a total of approximately 60 days. This is a significant delay in recruiting patients and may have resulted in selection bias (ie, patients whose pain is still present or impactful choosing to participate, while those who have recovered no longer seeing the relevance of participating). There is some evidence to support this, as participants in the majority (>90%) reported pain duration of >12 weeks at baseline, and 40.7% of participants indicated either no change or actual worsening of their pain at 6-week follow-up. This therefore may not be a true representation of all children and adolescents who consult in primary care for musculoskeletal conditions. However, while selection bias cannot be ruled out, our cohort is comparable to the few other studies that have reported on children and adolescents who seek healthcare in primary care in terms of age, pain intensity (current and usual), disability (FDI) and duration of symptoms.^{20 22 23} Interestingly, a significant proportion (range from 30% to 92%) of patients from this and the other previous studies report symptoms for >3 months' duration. Rather than this being an issue of selection bias, it may signify that many young people delay seeking healthcare for musculoskeletal conditions, and that primary care clinicians are mainly managing persistent pain problems.^{20 22 23} Furthermore, the higher proportion of participants reporting pain for >3 months in this study may be explained by differences in the study design (previous studies recruiting only incident patients vs this study identifying all patients who consulted about a musculoskeletal condition regardless if they have consulted previously), or differences in healthcare setting and/or providers (physiotherapy vs general practice).^{20 22 23} In addition, while the response rate of this study is low (19.1%) it may reflect the realities of current research in the 21st century, with evidence of a reduction in volunteerism and social participation, and changes in privacy laws, all contributing to a general downward trend.⁴⁷

Future research

Participant recruitment is inherently one of the most challenging aspects of health research, with the challenges seemingly compounded in research involving children and adolescents. As demonstrated by this and a previous study by Swain *et al* 2016, the feasibility of conducting a longitudinal cohort study in children and adolescents who consult in primary care with musculoskeletal conditions is limited by the ability (or inability)

to recruit these patients.²⁰ However, this assessment may be based on 'traditional' approaches to recruitment (eg, mail out, opportunistic in-consultation methods). Perhaps new, novel and likely multiple approaches are needed in order to engage and recruit young people into research.⁴² Qualitative research approaches involving children, adolescents and their parents may be a positive initial step of inquiry in order to better understand, identify and define research parameters that are acceptable and appealing to young people such as study methods (eg, interview, text message, online), frequency of contact, integration of technology (eg, tablets, activity monitors) and positive reinforcements (eg, incentives, rewards). In other fields of paediatric research, participant recruitment and screening are moving towards including online approaches, which may be inherently more appealing (and relevant) to young people especially when considering 92% report going online daily, and over 97% report using social media.^{48 49} Online recruitment strategies include the use of social media such as Facebook (including advertisements), Twitter, Google+ and youth-focused blog sites (eg, 'Teenology101'),⁴⁹⁻⁵² and study or recruitment websites (eg, www.callforparticipants.com,⁵³ Institute of Translational Health Sciences: Child health).⁵⁴ To date, very few studies have directly compared the effectiveness of online and 'traditional' methods used to recruit children and adolescents, in terms of the number of participants recruited and retained, costs involved and generalisability or comparability of populations.^{49 50 52} While these few studies suggest that online approaches are currently more expensive per participant recruited, compared with 'traditional' recruitment methods, the success of each appears to be influenced by population of interest and whether targeted approaches are needed. For example, a study by Close *et al* found online methods were more successful in recruiting young people with a rare genetic syndrome compared with in-person recruitment, while Moreno *et al*, recruiting adolescents from a general population, did not find one method to be clearly superior.^{42 49 52} Each approach however provides opportunities and challenges that researchers need to consider when developing and designing studies including staff time, costs (eg, study materials, advertisements), study access, safety and security (eg, internet access and connectivity, blocked content, 'hackers', legitimacy of websites and emails) and the ability to reach socioeconomically and educationally disadvantaged groups or those from culturally diverse populations.^{49 51 52} The results of this study show that there was a wide range of preferences for future research engagement from the participants, with preferred methods involving electronic data capture (eg, online survey, phone app, text message). However, over 25% indicated 'face to face' as most preferred in this current study, suggesting variability in methods of recruitment (providing choice) may be beneficial. More research is needed to optimise the recruitment and engagement of young people in healthcare research. In

reality however, it is likely future studies need to incorporate multiple recruitment strategies to ensure representativeness and completion in a timely and efficient manner.^{42 55}

CONCLUSION

This feasibility study provides realistic estimates for the identification and recruitment of children and adolescents with musculoskeletal conditions from general practice setting in the UK. This information was previously not known and is important in the design of future studies in this setting. Further research is needed to identify the most effective and feasible ways of identifying and recruiting children and adolescents with musculoskeletal pain from primary care into longitudinal research.

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