

Study protocol

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## The North Staffordshire Osteoarthritis Project – NorStOP: Prospective, 3-year study of the epidemiology and management of clinical osteoarthritis in a general population of older adults

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### Abstract

**Background:** The clinical syndrome of joint pain and stiffness in older people is the commonest cause of disability and health care consultation in this age group. Yet there have been few prospective studies of its course over time and its impact on personal and social life. We plan a cohort study in the general population aged 50 years and over to determine the course and prognosis of hand, hip, knee and foot pain, and the impact of these syndromes on participation levels and health care use.

**Methods:** All patients aged 50 years and over registered with 3 local general practices are to be recruited to a population-based cohort study through the use of a two-stage mailing process. Participants will initially complete a "Health Survey" questionnaire. This will collect information on several areas of life including socio-demographics, general health, physical function, participation, and bodily pain. Those who state that they have experienced any hand problem or any pain in their hands, hips, knees, or feet in the previous 12 months, and also give permission to be re-contacted, will be mailed a "Regional Pains Survey" questionnaire which collects detailed information on the four selected body regions (hand, hips, knees, feet). Follow-up data for the three-year period subsequent to cohort recruitment will be collected through two sources: i) general practice medical records and ii) repeat mailed survey.

### Background

Osteoarthritis is the commonest cause of chronic pain in older people, and the single most frequent reason for restricted activity in this age-group [1]. Osteoarthritis of the knee and hip have the greatest impact on individuals; the hand and foot are also commonly affected.

in which cartilage is lost, subchondral bone alters, and new bone is formed around the joint. The typical radiographic features of joint space narrowing, bony sclerosis and osteophytosis are considered to reflect this dynamic process of degeneration and repair. Second is the clinical syndrome of joint pain and stiffness in older people.

The term "osteoarthritis" refers to two different but overlapping syndromes. First is the disease of synovial joints

Population studies have established that these two syndromes are not equivalent. Although people with severe

radiographic osteoarthritis of the hip or knee, for example, are more likely to have hip or knee pain, a substantial proportion do not have symptoms [2]. By contrast, only a minority of older people with knee pain, for example, have definite radiographic changes of osteoarthritis, and the severity of their restricted lower limb function is more closely related to quadriceps strength and depression than to the severity of the radiographic changes [3].

Such observations suggest that clinical osteoarthritis should be regarded as a syndrome of chronic pain in older people, in much the same way as chronic back pain is now regarded as a condition in its own right, with the presence of radiographic changes defining a subgroup [4]. It is this symptomatic syndrome that is common in the general population and which is presented to primary care. Indeed joint pain is the commonest chronic condition in the elderly for which primary care is sought and provided [5]. Yet there is remarkably little evidence about the occurrence, natural history, and prognostic characteristics of joint pain in older people as it occurs in the community and presents to primary care.

Chronic joint pain occurs in the context of the everyday lives of older people, and its impact is not only to be measured in terms of pain experience or restricted function of the affected joints, but the influence which it has on the life that the sufferer wishes to live. The World Health Organisation has identified the term "participation" to represent this level of social functioning [6]. The extent to which chronic joint pain in older people might affect participation, and the way in which this may change over time and influence consultation in primary care, has not been investigated.

We are initiating a three-year cohort study of the clinical syndrome of osteoarthritis in a general population sample of older people. The areas under scrutiny are the hand, knee, hip and foot, and the general aims are (i) to determine the impact these syndromes have on activity and participation levels in older people, (ii) to determine factors which predict prognosis over time with respect to change in pain, activity and participation, and (iii) to determine frequency and predictors of health care use by sufferers of these syndromes through prospective linkage of self-completion survey instruments with primary care records.

## Methods

### Design

A population-based cohort study in three phases in a sample of patients, aged 50 years and over, registered with three local general practices. Ethical approval for all phases of the study has been obtained from the North Staffordshire Local Research Ethics Committee.

*Phase 1:* Baseline two-stage mailed survey to recruit the cohort for the study

*Phase 2:* Three-year prospective follow-up of general practice medical records

*Phase 3:* Repeat mailed survey at three years

### Phase 1 – Cohort recruitment

#### Sampling frame

Three practices from the North Staffordshire Primary Care Research Consortium are to be recruited to the study and contact details of all adults aged 50 years and over will be taken from each practice list ( $n = 11309$ ). In the United Kingdom (UK), about 98% of the population are registered with a general practitioner (GP) and so practice registers provide a convenient frame for sampling a local population [7]. The samples obtained will then be checked by the GPs for exclusions (for example, severe psychiatric or terminal illness) prior to the mailing procedure.

The baseline phase of the study is a two-stage mailed survey. Firstly, the study population will be mailed a "Health Survey" questionnaire which collects information on several areas of life including socio-demographics, general health, physical function, participation, and bodily pain. Responders to this questionnaire who give permission to be re-contacted and who report experiencing, in the previous 12 months, a hand problem or pain in either their hands, hips, knees, or feet will be mailed a "Regional Pains Survey" questionnaire which focuses on these four regional sites. At each stage, questionnaires will be mailed with a letter from the GP practice and a study information leaflet, with reminders to be sent to non-responders after two and four weeks.

#### "Health Survey" questionnaire

Details of the information to be collected by the "Health Survey" questionnaire are presented in Table 1. On receipt by the Research Centre, the date of birth and gender information given on the questionnaire will be compared with that obtained from the general practice lists to ensure that the respondent is the intended participant.

Participants to this first stage (*Phase 1*) will be eligible to take part in the second mailing stage if they:

- a) Consent to further contact by the Research Centre
- b) Respond positively to at least one of the questions relating to regional sites (hands, hips, knees, or feet)

If respondents satisfy both of these criteria, they will be mailed the "Regional Pains Survey" questionnaire.

**Table 1: Content of "Health Survey" questionnaire**

Concept	Measurement method	Details
Perceived general health	MOS SF-12 [8]	physical and mental component summary scores
Participation	Keele Assessment of Participation (KAP) [9]	11 item measure of person-perceived, performance-based participation
Social isolation	- Berkman-Syme Social Network Index [10]  - presence and frequency of contact with confidante [11]	4 levels of social connection: 'Most integrated' to 'Most isolated'  "Is there any one special person you know that you feel very close to; someone you can share confidences and feelings with?"
Access to material goods and services		car, public transport, telephone, GP, bank, chemist, advice about income, education, work
Anxiety and depression	Hospital anxiety and depression scale (HADs) [12]	anxiety and depression sub-scales
Causes of illness	Illness perceptions questionnaire (IPQ(R)) [13]	causes sub-scale
Demographic characteristics	- date of birth, gender - marital status - living arrangements - ethnic origin	single, married, divorced, widowed, cohabiting, single alone, not alone white, afro caribbean, chinese, asian, african, other
Occupational characteristics	- current employment status  - current/recent job title - socio-economic classification - educational attainment	employed, not working due to ill health, seeking employment, retired, housewife, other  SOC 2000 [14,15] age when left school, completed higher education, gained qualifications as adult
Anthropometric characteristics	-self-reported height -self-reported weight	
Lifestyle characteristics	-alcohol intake - smoking status - adequacy of income	daily, weekly, monthly, annually, never current, previous, never strain, need to be careful, can manage, comfortably well off
Co-morbidities	chest problems, heart problems, deafness, eyesight, raised blood pressure, diabetes	
Symptoms	falls, memory difficulties, cough with spit, breathless when walking, dizziness, weakness in arms/legs	occurred in past 3 months
Cognition	Functional Limitations Profile (FLP) [16]	alertness sub-scale score
Sleep problems	[17]	4 item sub-scale
Bodily pain	- self-completed manikin  - specific sites questions	"In the past 4 weeks have you had pain that has lasted for one day or longer in any part of your body?" "Have you had any problems in your hands or pain in your hands/knees/hips/feet in the last year?"
Medication use	Painkillers, creams, natural medicine, glucosamine/ chondroitin sulphate	usage in past 4 weeks – daily, most days, some days, few days, no days
Physical function	MOS Short Form-36 [18]	physical functioning sub-scale
Consent	- further contact - access to GP records	

**"Regional Pains Survey" questionnaire**

Details of the information collected by the "Regional Pains Survey" questionnaire are presented in Table 2.

**Phase 2: Follow-up using general practice medical records**

All participants to Phase 1 who give permission for their GP records to be accessed will have their computerised medical records tagged by a member of the Centre's Health Informatics Specialist team. All consultations for the 12-month period prior to cohort recruitment and all consultations for the three-year period following recruit-

ment will be identified. The three practices participating in this research are fully computerised and all practice staff enter a code for each contact. These codes are part of the READ classification of morbidity and event coding which is widely used in the National Health Service in the UK and can be mapped to the International Classification of Diseases. The practices undergo annual audits completed by the Centre's Health Informatics team to assess the quality and completeness of the data entry at the practices.

**Table 2: Content of "Regional Pain Survey" questionnaire**

Concept	Measurement method	Details
<i>HAND PAIN/PROBLEMS SECTION</i>		
Characteristic of complaint	- hand dominance	right, left, both
Pain and symptoms	- side of pain	right, left, both
	- duration of pain in past 12 months	<7 days, 1–4 weeks, 1–3 months, 3+ months
Physical features	- AIMS 2 [19]	pain sub-scale
	- individual symptoms in past month	stiffness, aching, tenderness, weakness, clumsiness, burning, tingling, numbness
Aesthetics	- hand drawings	painful areas
Function	hand drawing	self-reported nodes
	Michigan Hand Outcomes Questionnaire [20]	appearance sub-scale
Illness perceptions	- AIMS 2 [19]	hand and finger function sub-scale arm function sub-scale
	AUSCAN [21]	pain, stiffness, physical function sub-scales
Health care	Illness Perceptions Questionnaire Revised (IPQ(R)) [13]	9 dimensions: illness coherence, treatment control, personal control, timeline (acute/chronic), timeline (cyclical), consequences, emotional representation, identify, causes
	- AIMS 2 [19]	medication sub-scale
Occupational impact	- consulted with GP	past 12 months
	- any hand operations	ever
Past-times and hobbies	- NHS & private services [22]	past 12 months
	Self-reported excessive use of hands in occupation	ever
Impact of symptoms	Self-reported excessive use of hands in past-times/hobbies	ever
	AIMS 2 [19]	impact sub-scale
<i>HIP PAIN SECTION</i>		
Characteristic of complaint	- side of pain	right, left, both
Previous injury	- duration of pain in past 12 months	<7 days, 1–4 weeks, 1–3 months, 3+ months
	Consulted with GP	ever
Complaint specific functioning	Western Ontario and McMaster Universities OA index (WOMAC LK3.0) [23]	pain (0–20), stiffness (0–8), physical function (0–68) subscales
<i>KNEE PAIN SECTION</i>		
Characteristic of complaint	- side of pain	right, left, both
Previous injury	- duration of pain in past 12 months	<7 days, 1–4 weeks, 1–3 months, 3+ months
	Consulted with GP	ever
Complaint specific functioning	Western Ontario and McMaster Universities OA index (WOMAC LK3.0) [23]	pain (0–20), stiffness (0–8), physical function (0–68) subscales
<i>FOOT PAIN SECTION</i>		
Characteristic of complaint	- side of pain	right, left, both
Previous injury	- duration of pain in past 12 months	<7 days, 1–4 weeks, 1–3 months, 3+ months
	Consulted with GP	ever
Complaint specific functioning	Foot Disability Index (FDI) [24]	pain, appearance, physical function subscales

The practice-held information will provide the basic data for analysis of health care utilisation. This will include all consultations, medications, and referrals to other health care professionals both within primary care and on to sec-

ondary care. All sensitive data (name, contact details) will be removed from the medical records data and the consultation data will be linked to the survey data through the unique survey identifier.

**Table 3: Content of 3-year follow-up questionnaire**

Concept	Measurement method	Details
<i>GENERAL SECTION</i>		
Perceived general health Participation	MOS SF-12 [8] Keele Assessment of Participation (KAP) [9]	physical and mental component summary scores 11 item measure of person-perceived, performance-based participation
Demographic characteristics	- date of birth, gender - marital status	single, married, divorced, separated, widowed
Occupational characteristics	Current employment status	employed, not working due to ill health, seeking employment, retired, housewife, other
Bodily pain	- self-completed manikin  - specific sites questions	In the past 4 weeks have you had pain that has lasted for one day or longer in any part of your body? "Have you had any problems in your hands or pain in your hands/knees/ hips/feet in the last year?"
<i>HAND PAIN/PROBLEMS SECTION</i>		
Characteristic of complaint	- hand dominance - side of pain - duration of pain in past 12 months	right, left, both right, left, both <7 days, 1-4 weeks, 1-3 months, 3+ months
Pain	- AIMS 2 [19] - hand drawings	pain sub-scale painful areas
Physical features	- hand drawing	self-reported nodes
Function	- AIMS 2 [19] - AUSCAN [21]	hand and finger function sub-scale pain, stiffness, physical function sub-scales
Illness perceptions	Illness Perceptions Questionnaire Revised (IPQ(R)) [13]	9 dimensions: illness coherence, treatment control, personal control, timeline (acute/chronic), timeline (cyclical), consequences, emotional representation, identify, causes
Health care	NHS & private services [22]	past 3 years
<i>HIP PAIN SECTION</i>		
Characteristic of complaint	- side of pain - duration of pain in past 12 months	right, left, both <7 days, 1-4 weeks, 1-3 months, 3+ months
Health care seeking	consulted with GP	ever
Complaint specific functioning	Western Ontario and McMaster Universities OA index (WOMAC) [23]	pain, stiffness, physical function
<i>KNEE PAIN SECTION</i>		
Characteristic of complaint	- side of pain - duration of pain in past 12 months	right, left, both <7 days, 1-4 weeks, 1-3 months, 3+ months
Health care seeking	Consulted with GP	ever
Complaint specific functioning	Western Ontario and McMaster Universities OA index (WOMAC) [23]	pain, stiffness, physical function
<i>FOOT PAIN SECTION</i>		
Characteristic of complaint	- side of pain - duration of pain in past 12 months	right, left, both <7 days, 1-4 weeks, 1-3 months, 3+ months
Health care seeking	Consulted with GP	ever
Complaint specific functioning	Foot Disability Index (FDI) [24]	pain, appearance, physical function

**Phase 3: Follow-up using repeat mailed survey**

A follow-up survey, at three-years post-cohort recruitment, will be mailed to all those participants in the baseline phase who gave permission for re-contact. This questionnaire will focus on current problems and changes occurring since recruitment. Details of the information to be collected by this questionnaire are presented in Table 3.

**Sample size**

The size of the sample chosen for this study reflects the need to ensure that a cohort of sufficient size is identified in *Phase 1* to enable follow-up analysis to be adequately powered. The three participating practices have a total of 11309 registered patients who are suitable to take part in the study. From pilot work we have estimated that the response to the "Health Survey" questionnaire would be approximately 73% (n = 8300) and 70% of those completing this questionnaire (n = 5800) would give permission for re-contact and access to medical records. Moreover, of those who give permission for re-contact, 71% (n = 4100) will have hand problems or pain in at least one of the four specified pain regions and be mailed the "Regional Pains Survey" questionnaire, with an estimated 90% (n = 3700) who will complete it.

Three-year follow-up, in terms of survey and general practice data, will then be collected on those responders to the "Health Survey" who are alive and registered at the study practices at the time of follow-up and who gave permission for re-contact and access to medical records. Based on data from a recently conducted three-year follow-up survey in an older population (Jinks, personal communication) it is anticipated that 90% (n = 5220) of those who complete the "Health Questionnaire" will be alive and registered at the same study practices at the time of follow-up. Moreover, it is estimated that approximately 77% (n = 4000) will complete the follow-up survey.

**Statistical analysis**

The data collected in *Phase 1* will be examined for cross-sectional relationships. The data collected in *Phase 2* will be linked to *Phase 1* data to determine predictors of consultation for joint pain sufferers. The data collected at *Phase 3* will be linked to *Phase 1* data to determine changes occurring between the two surveys.

**Conclusions**

This protocol describes a prospective observational cohort study which aims to determine the frequency and natural history of joint pain at four common sites in the general population aged over 50 years, and the patterns and predictors of outcome as measured by participation levels and primary health care use. The results of this study, along with other work in this research programme, will

form the basis for the development and piloting of randomised controlled trials of primary care management of osteoarthritis symptoms in primary care. The results of this study will be published as soon as they are available.

**Competing interests**

None declared.

**Authors' contributions**

All authors participated in the design of the study, baseline data collection, and drafting the manuscript. All authors read and approved the final manuscript.

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