

BMJ Open

Clinical and health-economic outcome following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study.

Journal:	BMJ Open
Manuscript ID	bmjopen-2016-011735
Article Type:	Research
Date Submitted by the Author:	29-Feb-2016
Complete List of Authors:	Roddy, Edward; Keele University, Research Institute for Primary Care and Health Sciences; Keele University Jordan, Kelvin; Keele University, Arthritis Research UK Primary Care Centre Oppong, Ray; University of Birmingham, Health Economics Unit Chen, Ying; Keele University, Primary Care Sciences Jowett, Sue; University of Birmingham, Health Economics Unit Dawes, Peter; Haywood Hospital, Staffordshire Rheumatology Centre Hider, Samantha; Keele University, Arthritis Research UK Primary Care Centre; Packham, Jonathan; Haywood Hospital, Staffordshire Rheumatology Centre Stevenson, Kay; University Hospital of North Midlands, Physiotherapy Zwierska, Irena; Keele University, Research Institute for Primary Care and Health Sciences Hay, Elaine; Arthritis Research Primary Care Centre
Primary Subject Heading:	Rheumatology
Secondary Subject Heading:	General practice / Family practice, Health services research
Keywords:	RHEUMATOLOGY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Rheumatology < INTERNAL MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

SCHOLARONE™
Manuscripts

TITLE: Clinical and health-economic outcome following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study.

AUTHORS:
Edward Roddy^{1,2}, Kelvin P Jordan¹, Raymond Oppong³, Ying Chen¹, Sue Jowett³, Peter Dawes², Samantha L Hider^{1,2}, Jon Packham², Kay Stevenson^{1,2,4}, Irena Zwierska¹, Elaine M Hay^{1,2}

AFFILIATIONS:
¹Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK
²Staffordshire Rheumatology Centre, Haywood Hospital, High Lane, Burslem, Stoke-on-Trent, ST6 7AG, UK
³Health Economics Unit, School of Health and Population Sciences, University of Birmingham, Birmingham B15 2TT, UK
⁴Physiotherapy Department, University Hospital of North Midlands, Stoke-on-Trent, UK

CORRESPONDING AUTHOR:
Dr Edward Roddy, Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK.
Tel: 00 44 1782 734715 Fax: 00 44 1782 734719
e-mail: e.rodgy@keele.ac.uk

KEYWORDS: Primary-secondary care interface, Musculoskeletal, Outcome, Pain, Healthcare costs

WORD COUNT: 3505 words

ABSTRACT

Objectives: To determine (1) re-consultation frequency, (2) change in self-reported health status, (3) baseline factors associated with re-consultation and change in health status, and (4) associated healthcare costs and quality-adjusted life-years (QALYs), following assessment at a musculoskeletal Clinical and Assessment Treatment Service (CATS).

Design: Prospective cohort study

Setting: Single musculoskeletal CATS at the primary-secondary care interface

Participants: 2166 CATS attenders followed-up by postal questionnaires at 6 and 12 months and review of medical records.

Outcome measures: Primary outcome was consultation in primary care with the same musculoskeletal problem within twelve months. Secondary outcome measures were consultation at the CATS with the same musculoskeletal problem within twelve months, physical function and pain (SF36), anxiety and depression (Hospital Anxiety and Depression Scale), time off work, healthcare costs and quality-adjusted life-years (QALYs).

Results: Over 12 months, 507 (38%) re-consulted for the same problem in primary care and 345 (26%) at the CATS. Primary care re-consultation in the first 3 months was associated with pain interference (relative risk ratio 5.33; 95%CI 3.23, 8.80) and spinal pain (1.75; 1.09, 2.82), and after 3-6 months with baseline assessment by a hospital specialist (2.06; 1.13, 3.75). Small mean improvements were seen in physical function (1.88; 95%CI 1.44, 2.32) and body pain (3.86; 3.38, 4.34) at 6 months. Poor physical function at 6 months was associated with obesity, chronic pain, and poor baseline physical function. Mean (SD) 6-month cost and QALYs per patient were £422.40 (660.11) and 0.257 (0.144) respectively.

Conclusions: Whilst most patients are appropriate for a "one-stop shop" model, those with troublesome, disabling pain commonly re-consult and have ongoing problems. Services should be configured to identify and address such clinical complexity.

ARTICLE SUMMARY SECTION

Strengths and Limitations of this Study

- The largest study to date of outcome following treatment in a musculoskeletal CATS.
- The participation rate at baseline was high and use of routinely-collected consultation data ensured high completion rates for the primary outcome.
- Response to the postal follow-up questionnaires was poor, particularly at 12 months.
- Questionnaire length permitted inclusion of only generic measures of pain and physical function rather than body region-specific measures which might have been more sensitive to improvement.
- The study population was derived from a single geographical region and did not include a comparator cohort which might limit the generalisability of our findings.

INTRODUCTION

Musculoskeletal problems such as osteoarthritis (OA) and back pain are highly prevalent and present frequently to primary care. One-third of adults experience low back pain annually whereas 53% of older adults have symptomatic OA.[1,2] Annually in the UK, one-fifth of people consult their GP for a musculoskeletal condition and 4% of older adults consult for OA.[3] Musculoskeletal disorders account for 21% of years-lived-with-disability globally, second only to mental and behavioural disorders.[4]

Most of these people are managed entirely in primary care, with only a minority requiring specialist referral, traditionally to hospital-based orthopaedic and rheumatology services. Recently, patients requiring referral are increasingly managed in multidisciplinary Clinical Assessment and Treatment Services (CATS) at the primary-secondary care interface.[5,6] CATS act as a one-stop shop, providing rapid access to assessment, diagnostic investigations, treatment by appropriately-skilled healthcare practitioners, and onward referral pathways, aiming to provide more integrated care, and prevent chronicity, disability, and a cycle of reconsultation and referral to multiple services across primary and secondary care.[5-7] We have previously shown that chronic pain, physical disability, anxiety, depression, and work disability are prevalent amongst patients attending a musculoskeletal CATS, suggesting that these patients often already have chronic pain and are not being referred early, emphasising the need for appropriate early referral pathways to suitably skilled clinicians.[8] Little is known about patient outcome following treatment in this setting and if and how patients subsequently re-consult.

The objectives of this prospective study were (1) to determine the proportion of patients re-consulting in primary care and in a musculoskeletal CATS in the 12 months following baseline assessment at the CATS, (2) to assess baseline factors associated with re-consultation, (3) to determine change in self-reported health status at 6 and 12 months, (4) to assess baseline factors associated with change in self-reported health status, and (5) to estimate the health care costs and quality-adjusted life-years (QALYs) over 6 months

associated with CATS attendance and determine whether these costs and QALYs differed by follow-up plan at baseline.

METHODS

This was a prospective observational study set within a musculoskeletal CATS in North Staffordshire, UK. The methods and baseline cross-sectional findings have been described previously.[8,9]

Study setting

At the time of baseline data collection, Stoke-on-Trent Primary Care Trust (PCT) served a population of more than 270,000 people. Referrals to secondary care musculoskeletal, rheumatology and orthopaedic services are triaged to a multidisciplinary, musculoskeletal CATS at the primary-secondary care interface following clinical review of referral letters, so that musculoskeletal conditions requiring non-surgical interventions are managed in the community, whilst appropriate cases are directed to rheumatology or orthopaedic services. The CATS is the preferred provider for patients with non-surgical, non-inflammatory musculoskeletal problems. Patients are triaged to unselected general musculoskeletal clinics within the CATS, where the type of healthcare professional patient seen and the clinic in which they are seen are not determined by the index referred condition. The sole exception to this is a physiotherapist-led back pain clinic. A greater proportion of patients with back pain therefore see a physiotherapist compared to other conditions.

Data collection

All adults aged ≥18 years seen at the CATS between February 2008 and June 2009 were invited to participate. Those who consented to take part completed a health questionnaire prior to their CATS appointment. Participants were also asked to provide consent for the research team to review their medical records.

Baseline measures

The questionnaire included physical functioning and body pain scales from the the Short Form-36 (SF-36) version 2 (general population mean = 50; scores <50 represent worse health).[10] Anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS, range 0-14; scores ≥8 on either scale representing possible or probable anxiety or depression).[11] The presence of pain that interfered with daily activities was measured using one item from the SF-36: 'During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?'.[10] Respondents answering 'moderately', 'quite a bit' or 'extremely' were defined as having pain interference, whilst responding 'quite a bit' or 'extremely' represented severe pain interference.[12-14] Cohabitation status, self-reported height/weight, musculoskeletal pain duration and work absence in the preceding 6 months because of musculoskeletal problems were also collected. The EQ-5D 3L was included, in order to calculate QALYs.[15]

The clinician conducting the CATS consultation completed a brief proforma but did not see the patient's completed questionnaire. The clinician proforma recorded the location of pain addressed in the consultation (used to group participants into four mutually exclusive categories: upper limb or neck alone, spine alone, lower limb alone or multiple sites), investigations, interventions, referrals and follow-up plan. Participants were regarded as having pain in multiple sites if the clinician recorded locations from two or more of the upper limb/neck, spine, or lower limb, or recorded a diagnosis of fibromyalgia, chronic widespread pain, generalised osteoarthritis, or polymyalgia rheumatica. Follow-up was categorised as referral to other services (eg rheumatology, orthopaedics, physiotherapy), CATS follow-up, discharge to the GP, or to be decided following investigations. If the follow-up plan was dependent upon investigation results, follow-up information for those participants who consented to medical record review was extracted from CATS records. The clinician profession (physiotherapist, rheumatologist, rehabilitation medicine specialists, GPwSI) was also recorded. Due to the low number of rehabilitation medicine specialists, we combined

these with rheumatologists (referred to hereafter as hospital specialists). We also recorded whether patients were attending a general musculoskeletal clinic or the physiotherapist-led back pain clinic described above.

Follow-up questionnaires

A self-administered questionnaire containing the same measures as at baseline was mailed at 6 and 12 months to all consenting participants. Non-responders were sent a postcard reminder after 2 weeks and a repeat questionnaire after 4 weeks.

Medical record review

In participants consenting to medical record review, information was extracted from primary care records for the 12 months following baseline. Due to the large number of general practices ($n=114$ including 49 with fewer than 10 patients), it was unfeasible to examine the records of all patients and so a pragmatic decision was made to extract records from 57 accessible practices. Records were downloaded electronically where possible but where software was incompatible with the practice, information was extracted manually using a proforma. The information extracted was date of any musculoskeletal consultation in primary care, and date of a musculoskeletal consultation for the same body location (neck, shoulder, elbow, hand/wrist, spine, hip, knee, foot/ankle) as recorded by the clinician at baseline. Musculoskeletal consultations were identified using the Read code system which is commonly used to record morbidity in UK primary care.[16] We identified the date of any further attendance at the CATS for the same body location in all participants who consented to medical record review through manual review of CATS records.

Sample size

At the time of baseline data collection, approximately 3500 patients were seen in the CATS annually. Based on previous studies, we expected 75% of these to participate at baseline ($n=2625$), and 75% of these to separately consent to further postal contact and medical

record review (n=2000 each). Whilst we aimed to review records of as many patients as feasible, as an example, a sample size of 1125 is sufficient to determine the percentage making a repeat primary care consultation during 12 months follow-up with a margin of error of 3% and a 95% confidence level, based on an estimate of 50%.

Statistical analysis

We compared baseline responders with extracted medical record data with all other baseline responders on baseline socio-demographic, pain characteristics, and general health. The percentage consulting for a musculoskeletal problem in the 12 months after baseline was determined. The primary analysis was based on the time to consulting in primary care about the same body location which was addressed at the baseline CATS consultation. We split time to first consultation to primary care into no consultation during 12-month follow-up, first consultation within 3 months (early), between 3-6 months, and between 6-12 months after baseline clinic assessment (late). We used these categories rather than actual time as it was evident that the baseline factors associated with first primary care attendance changed over the 12-month time-period, and it was considered that attendance to primary care within 3 months may be at the request of the CATS clinician. Multinomial logistic regression was used to determine the association of follow-up plan and clinician profession with time of consultation to primary care adjusted for self-reported (age, gender, cohabitation, pain interference and duration, body mass index, anxiety and depression) and clinician-reported (body region, musculoskeletal or back pain clinic) factors. No repeat consultation was treated as the reference category. Results are reported as adjusted relative risk ratios (RRR) with 95% confidence intervals (95%CI).

Secondary outcomes were re-consultation at the CATS during 12 months follow-up and self-reported health (physical function, body pain, anxiety and depression, and time off work in those employed at baseline) at 6 months and 12 months. Binary logistic regression was used to assess association of clinician profession and follow-up plan with re-consultation at

the CATS about the same body location as at the baseline clinic at any point during the 12 months, adjusting for the same factors included in the primary outcome analysis. Results are presented as odds ratios (OR) with 95%CI. Multiple linear regression was used to assess the association of clinician profession and follow-up plan with physical function score at follow-up adjusted for baseline score and for the same baseline self-reported and clinician-reported factors as included in the analysis of primary care consultation (except pain interference as it was highly correlated with baseline physical function).

Two sensitivity analyses were performed. Firstly, as primary care medical record information was not available for everyone, we performed multiple imputation with 50 imputations and again repeated the analysis. Secondly, because of the attrition at follow-up, the analysis of self-reported physical function at 6 months was repeated using multiple imputed data for those not responding at follow-up.

Analysis of health care costs and quality-adjusted life-years

The health economic analysis was conducted from a healthcare perspective and focused on estimating the costs and QALYs arising from attending the CATS. Resource use data were collected from the clinician proforma and 6-month questionnaire. The proforma recorded investigations and interventions that patients received, whilst the questionnaire asked about the number and type of health professionals seen, medication taken, and the number of interventions. Unit costs for individual resource use items were obtained from sources such as the British National Formulary (BNF), Personal Social Services Research Unit, and NHS reference costs.[17-19] The analysis was limited to those who completed the questionnaire. In order to value the resource use items, we multiplied resource use by unit costs and estimated a total cost per patient by summing up the costs associated with each resource use item. The area under the curve approach was used to estimate QALYs using EQ-5D responses at baseline and 6 months. Multiple regression was used to estimate mean total cost and QALYs by follow-up plan controlling for body region, age, BMI, anxiety and

depression, pain interference and baseline EQ-5D. Bootstrapping (1000 replications) was used to estimate bias-corrected confidence intervals around differences in mean costs and QALYs between groups using patients who were referred to other specialities as the reference category.

RESULTS

As reported previously,[8] 3429 patients were mailed the baseline questionnaire of whom 453 (13%) did not attend their CATS appointment. 2166 consented to participate at baseline, from whom 2116 clinician proformas were completed (adjusted response 71%). Of these, 1453 (69%) had their medical records reviewed and did not have a primary care musculoskeletal consultation on the same day as their CATS appointment (**supplementary figure**). Compared to those responding but not undergoing record review, these participants were older (mean difference 2.6 years, 95%CI 1.3,4.0) and had slightly worse levels of pain, but no differences on gender, anxiety, depression, physical functioning, pain duration, pain interference, employment status or time off work (**supplementary table**).

Consultation in primary care during 12-month follow-up

Of the 1453 for whom record data were collected, 1342 were included in the primary outcome analysis as the remainder received other diagnoses such as gout, inflammatory arthritis, and joint hypermobility, and hence a specific body region was not available to link subsequent consultations to (**supplementary figure**). Of these, 507 (38%, 95%CI 35%,40%) consulted primary care during 12 months follow-up for the same body region as addressed at the baseline clinic assessment. Median number of days to consulting primary care was 69 (IQR 27,159): 289 (22%) consulted within 3 months and 403 (30%) within 6 months. There was no association between the type of professional seen at baseline and consulting in the first 3 months but those seeing a hospital specialist were more likely to first return to primary care between 3 and 6 months after their CATS visit (adjusted RRR 2.06; 95%CI 1.13,3.75 compared to GPwSI) and between 6 and 12 months (2.08; 1.12,3.88)

(table 1). The strongest association with consulting within the first six months was with severe pain interference at baseline (within 3 months: 5.33; 3.23,8.80 compared to no pain interference; 3-6 months 2.26; 1.25,4.09). Those consulting with a spine problem were more likely to consult primary care in the first 3 months (1.75; 1.09,2.82) or after 6-12 months (2.17; 1.06,4.47) compared to having an upper limb or neck problem. Those with anxiety or depression were less likely to first consult primary care between 6 and 12 months (0.60; 0.38, 0.95). There was no association of gender, cohabitation status, follow-up plan, pain duration, or BMI with primary care consultation.

Analysis based on multiple imputation data yielded similar estimates and CIs to those from the analysis for those whose records were reviewed.

Table 1 - Associations with time after baseline assessment of first primary care consultation for musculoskeletal problem in same body location as at baseline CATS consultation

		0-3m (early)	3-6m	6-12m (late)
Total consulting (% consulting)	507 (38)	289 (22)	114 (8)	104 (8)
	<i>n</i> (% consulting)	Adjusted RRR ^a (95% CI)		
Male	586 (37)	1.00	1.00	1.00
Female	756 (38)	1.05 (0.79, 1.42)	0.96 (0.64, 1.46)	0.78 (0.51, 1.20)
Age (years)	18-44	1.00	1.00	1.00
	45-64	1.11 (0.80, 1.55)	1.11 (0.68, 1.81)	1.03 (0.63, 1.70)
	≥65	0.92 (0.60, 1.41)	1.33 (0.75, 2.36)	1.38 (0.77, 2.48)
Living alone:	No	1.00	1.00	1.00
	Yes	0.76 (0.49, 1.18)	1.33 (0.79, 2.23)	1.40 (0.80, 2.45)
Professional seen: GPwSI	309 (29)	1.00	1.00	1.00
	Hospital specialist	1.25 (0.82, 1.92)	2.06 (1.13, 3.75) ^b	2.08 (1.12, 3.88) ^b
	Physiotherapist	1.16 (0.77, 1.73)	1.58 (0.88, 2.84)	1.40 (0.76, 2.60)
Region at clinic:	Upper limb/neck	1.00	1.00	1.00
	Spine	1.75 (1.09, 2.82) ^b	1.12 (0.56, 2.24)	2.17 (1.06, 4.47) ^b
	Lower limb	0.87 (0.60, 1.28)	0.86 (0.53, 1.41)	1.38 (0.81, 2.36)
	Multiple regions	1.16 (0.66, 2.04)	0.97 (0.44, 2.14)	1.77 (0.78, 4.02)
Follow-up plan:	Referred	1.00	1.00	1.00
	Followed-up	1.28 (0.80, 2.06)	1.28 (0.65, 2.50)	0.86 (0.36, 2.10)
	Discharged	0.95 (0.69, 1.30)	0.75 (0.48, 1.17)	1.39 (0.87, 2.21)
	Unknown	1.40 (0.71, 2.75)	1.29 (0.53, 3.13)	1.87 (0.79, 4.46)

Pain duration:	<12months	603 (37)	1.00	1.00	1.00
	>12months	738 (38)	0.80 (0.60, 1.07)	0.91 (0.60, 1.37)	1.28 (0.82, 1.98)
Pain interference:	No/little bit	300 (22)	1.00	1.00	1.00
	Moderately	295 (29)	2.38 (1.37, 4.14) ^b	1.07 (0.54, 2.13)	0.72 (0.38, 1.37)
	Quite a bit/extremely	746 (47)	5.33 (3.23, 8.80) ^b	2.26 (1.25, 4.09) ^b	1.35 (0.78, 2.33)
BMI:	Normal	382 (35)	1.00	1.00	1.00
	Overweight	484 (36)	1.18 (0.82, 1.71)	0.77 (0.46, 1.30)	1.07 (0.61, 1.86)
	Obese	439 (42)	1.28 (0.88, 1.87)	1.16 (0.70, 1.93)	1.63 (0.95, 2.82)
	Unknown	37 (38)	0.89 (0.35, 2.23)	1.37 (0.47, 3.94)	0.86 (0.19, 3.97)
Anxious/depressed:	No	606 (34)	1.00	1.00	1.00
	Yes	736 (41)	1.02 (0.75, 1.40)	0.97 (0.62, 1.50)	0.60 (0.38, 0.95) ^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; RRR, relative risk ratios

^a Multinomial logistic regression $n=1340$ (2 participants omitted due to missing data). Relative risk ratios adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), reference group is no musculoskeletal consultation, ^b $p<0.05$

Re-consultation at the CATS during 12-month follow-up

345 (26%) re-consulted at the CATS during 12-months follow-up for a musculoskeletal problem in the same body location as assessed at baseline. The clinician stating they would follow-up the patient (adjusted OR 9.97; 95%CI 6.36,15.62) was most strongly associated with re-consultation at the CATS whilst being discharged (1.54; 1.13,2.10) was also significantly associated (**table 2**). Patients seeing a hospital specialist were more likely to re-consult in the CATS (OR 1.68; 95%CI 1.14,2.49 compared to GPwSI). Severe pain interference and shorter pain duration were also associated with re-consultation.

Table 2 - Associations with return to interface clinic during 12-month follow-up for musculoskeletal problem in same body location as baseline CATS consultation

	Total <i>n</i> (% with appointment)	OR (95% CI)	Adjusted OR ^a (95% CI)
Total	1342 (26)		
Male	586 (25)	1.00	1.00
Female	756 (26)	1.07 (0.84, 1.28)	1.10 (0.83, 1.45)
Age (years) 18-44	424 (23)	1.00	1.00
45-64	633 (27)	1.23 (0.93, 1.64)	1.35 (0.98, 1.86)
≥65	285 (27)	1.21 (0.86, 1.71)	1.41 (0.95, 2.09)
Living alone: No	1140 (26)	1.00	1.00
Yes	202 (23)	0.83 (0.58, 1.18)	0.89 (0.60, 1.32)
Professional seen: GPwSI	309 (23)	1.00	1.00
Hospital specialist	359 (26)	1.15 (0.81, 1.64)	1.68 (1.14, 2.49) ^b
Physiotherapist	674 (27)	1.20 (0.88, 1.64)	0.91 (0.62, 1.34)
Region at clinic: Upper limb/neck	436 (27)	1.00	1.00
Spine	347 (35)	1.48 (1.09, 2.01) ^b	0.84 (0.53, 1.35)
Lower limb	454 (17)	0.54 (0.39, 0.75) ^b	0.59 (0.41, 0.83) ^b
Multiple regions	105 (30)	1.14 (0.71, 1.83)	1.05 (0.63, 1.77)
Follow-up plan: Referred	492 (17)	1.00	1.00
Followed-up	145 (68)	10.61 (6.96, 16.17) ^b	9.97 (6.36, 15.62) ^b
Discharged	637 (23)	1.50 (1.12, 2.03) ^b	1.54 (1.13, 2.10) ^b
Unknown	68 (21)	1.28 (0.68, 2.41)	1.19 (0.62, 2.29)

Pain duration:	<12months	603 (27)	1.00	1.00
	>12months	738 (24)	0.85 (0.66, 1.09)	0.75 (0.57, 0.99) ^b
Pain interference:	No/little bit	300 (19)	1.00	1.00
	Moderately	295 (25)	1.49 (1.00, 2.20) ^b	1.53 (1.00, 2.35)
	Quite a bit/extremely	746 (29)	1.75 (1.26, 2.44) ^b	1.64 (1.11, 2.42) ^b
BMI	Normal	382 (25)	1.00	1.00
	Overweight	484 (26)	1.03 (0.76, 1.41)	1.10 (0.78, 1.55)
	Obese	439 (26)	1.06 (0.77, 1.44)	1.12 (0.79, 1.58)
	Unknown	37 (16)	0.57 (0.23, 1.40)	0.45 (0.17, 1.22)
Anxious/depressed:	No	606 (25)	1.00	1.00
	Yes	736 (26)	1.06 (0.83, 1.36)	0.92 (0.68, 1.23)

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; OR, odds ratio

^a Binary logistic regression $n=1340$ (2 participants omitted due to missing data). Adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), referent group is no follow-up appointment

^b $p < 0.05$

Self-reported health and time-off work

1143 (54%) of the 2116 baseline responders with a completed clinician proforma completed the follow-up questionnaire at 6 months and 762 (36%) at 12 months. 6-month responders were older (mean age 54.9 vs 46.4) compared to non-responders and had lower levels of anxiety and depression. However, they did not differ according to pain, physical function, or the type of clinician seen at baseline. Responders showed some improvement at 6 months on physical functioning (mean change 1.88; 95%CI 1.44,2.32; effect size equivalent 0.16) and body pain (mean change 3.86; 95%CI 3.38,4.34; effect size equivalent 0.47) (**table 3**). The percentage with severe pain interference fell from 54% to 40% at 6 months, whilst the percentage taking time off work due to their musculoskeletal problem fell from 42% to 33%. However, there was no change in anxiety or depression levels, nor was there any further change in any of these measures at 12 months. Given the high attrition at 12 months, and the lack of change at the population level between 6 and 12 months, the remainder of the self-reported analysis concentrated on the 6-month time-point.

Type of clinician seen and follow-up plan did not associate with physical function at 6 months (**table 4**). Females, older adults, those who were obese, those with pain duration of more than 12 months, and those with worse physical function at baseline had the worst outcomes at 6 months. Sensitivity analysis based on multiple imputation data made little difference to these estimates and CIs.

Table 3 – Self-reported change in physical and mental health status, time off work and pain interference at 6 and 12 months

	Baseline ^a	6 months	12 months
	Mean (SD)	Mean change ^b (95% CI)	Mean change ^b (95% CI)
HADS depression	6.1 (4.2)	-0.02 (-0.20, 0.16)	-0.13 (-0.35, 0.09)
HADS anxiety	7.5 (4.6)	0.03 (-0.16, 0.22)	-0.02 (-0.26, 0.22)
SF36 physical function	36.4 (11.9)	1.88 (1.44, 2.32)	1.82 (1.24, 2.39)
SF36 body pain	34.5 (8.3)	3.86 (3.38, 4.34)	4.19 (3.55, 4.83)
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Time off work ^c	219 (42)	169 (33)	110 (33)
Anxious / depressed	588 (53)	591 (53)	390 (52)
Pain interference			
Not at all / a little	258 (23)	429 (38)	284 (38)
Moderately	261 (23)	247 (22)	178 (24)
Quite a bit / extremely	606 (54)	449 (40)	289 (38)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SD, standard deviation; SF-36, Short Form-36

^a in those responding at 6 months

^b positive mean change indicates improvement

^c in those currently employed at baseline *n*=519. At 6 and 12 months, time off work includes those no longer employed

Number in analysis for baseline & 6 months: 1118 (depression), 1115 (anxiety), 1124 (physical function), 1109 (body pain), 519 (time off work), 1115 (anxiety/depression), 1125 (interfering pain)

Number in analysis for 12 months: 748 (depression), 748 (anxiety), 754 (physical function), 745 (body pain), 332 (time off work), 748 (anxiety/depression), 751 (interfering pain)

Table 4 – 6-month follow-up Physical Functioning (PF) score by baseline factors

	Adjusted for baseline PF score only Coeff (95% CI)	Adjusted for all variables Coeff (95% CI)
Female (referent: male)	-0.84 (-1.73, 0.06)	-0.90 (-1.80, 0.00) ^b
Age (years) (referent: 18-44)		
45-64	-1.41 (2.50, -0.33)	-1.27 (-2.36, -0.17) ^b
≥65	-2.94 (-4.21, -1.67) ^b	-2.87 (-4.19, -1.55) ^b
Living alone (referent: not living alone)	-1.14 (-2.37, 0.09)	-0.53 (-1.77, 0.72)
Professional seen (referent: GPwSI)		
Hospital specialist	0.05 (-1.17, 1.27)	-0.24 (-1.45, 0.97)
Physiotherapist	0.69 (-0.40, 1.77)	-0.32 (-1.48, 0.84)
Region at clinic (referent: upper limb/neck)		
Spine	2.02 (0.82, 3.21) ^b	0.52 (-1.02, 2.05)
Lower limb	-0.05 (-1.20, 1.10)	-0.47 (-1.62, 0.68)
Multiple regions	-0.34 (-1.89, 1.20)	-0.58 (-2.13, 0.96)
Other	0.07 (-2.10, 2.23)	-0.72 (-2.87, 1.43)
Follow-up plan (referent: Referred)		
Followed-up	0.05 (-1.45, 1.56)	-0.91 (-2.45, 0.63)
Discharged	0.23 (-0.75, 1.21)	0.12 (-0.85, 1.09)
Unknown	-0.48 (-2.26, 1.30)	-0.58 (-2.33, 1.17)
Pain duration >12months (referent <12months)	-1.99 (-2.90, -1.09) ^b	-1.93 (-2.83, -1.03) ^b
BMI (referent: normal BMI)		
Overweight	0.30 (-0.77, 1.36)	0.17 (-0.89, 1.22)
Obese	-1.59 (-2.75, -0.43) ^b	-1.58 (-2.74, -0.43) ^b
Unknown	-1.65 (-4.38, 1.08)	-1.09 (-3.80, 1.63)
Anxious/depressed (referent: not anxious/depressed)	-0.65 (-1.59, 0.29)	-0.81 (-1.75, 0.12)
Baseline PF score ^a	0.87 (0.82, 0.92) ^b	0.79 (0.75, 0.84) ^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest,
PF, physical function;
Positive mean change indicates improvement
Complete data only, n=1124
^a per unit PF score at baseline
^b p<0.05

Health care costs and QALYs

The overall mean (SD) cost per patient incurred by attending the CATS was £422.40 (660.11) over the 6-month period. Patients who were referred to other specialities had the highest cost whilst those who were discharged were associated with the lowest cost (**table 5**). The mean cost associated with patients who were discharged was significantly lower than those who were referred to other specialities (mean difference £-132.57; 95%CI: -226.78,-49.54). Costs associated with patients in the other groups (followed up and unknown) were not significantly different from costs associated with patients who were referred (**table 5**).

Across all participants, the mean (SD) QALYs per patient over the 6-month period was 0.257 (0.144). There was no significant difference in mean QALYs between patients who were referred to other specialities and any other group.

Table 5 – Mean costs and quality-adjusted life-years (QALYs) over 6 months according to follow-up plan

	Mean cost ^a	Mean difference (95% CI) ^b	Mean QALYs ^a	Mean difference (95% CI) ^b
Referred (n=405)	£497.55		0.2572	
Followed up (n=124)	£437.18	£-60.37 (-172.68, 67.36) ^c	0.2566	-0.001 (-0.014, 0.014) ^c
Discharged (n=526)	£364.98	£-132.57 ^d (-226.78, -49.54) ^c	0.2591	0.002 (-0.006, 0.009) ^c
Unknown (n=82)	£397.23	£-100.32 (-227.19, 93.92) ^c	0.2498	-0.007 (-0.020, 0.005) ^c

^a Values are predicted means obtained from multiple regression controlling for body region, age, body mass index, anxiety, depression, pain interference and baseline EQ-5D

^b Compared to patients who were referred

^c Bootstrapped confidence interval

^d p<0.05

DISCUSSION

After assessment in a musculoskeletal CATS, nearly 40% of people consulted primary care about the same problem within 12 months, with over half of these consulting within three months. Similarly, a quarter of patients re-consult in the CATS within 12 months. The explanations for this are likely to be multifactorial, and our study design cannot elucidate these. It may be that patients were advised to visit their GP for change in medication, or they re-consulted to obtain a repeat prescription, and/or the CATS consultation failed to adequately address patients' concerns. The observation that patients assessed by hospital specialists were more likely to re-consult could be explained by specialists advising further consultation in primary care, for example to change medication, rather than this reflecting poor outcome. The findings that people with pain interference were more likely to consult in either setting and worse functional outcome was associated with older age, obesity, chronicity and pre-existing physical impairment suggest that the current model-of-care does not meet the needs of those with the most troublesome symptoms. Nevertheless, over 6 months, small improvements were seen in body pain and physical function, and in the proportion reporting pain interference and taking time off work because of their musculoskeletal problem. An unexpected finding that we find difficult to explain was that people with anxiety or depression were less likely to first consult primary care between 6 and 12 months. The cost-outcome description found that follow-up plan to see again in the CATS or to refer to another specialty attracted higher mean costs.

There are few suitable cohorts to compare our findings to. In a study undertaken in a physiotherapist-led CATS, small improvements were reported in pain and general health (EQ-5D) over 12 months but no change was seen in the SF-36.[20] Most improvement occurred within 3 months but was less likely in people with spinal pain and chronic symptoms. Repeat consultation was not examined. Several studies have found similar rates of repeat musculoskeletal consultations in primary care following an initial primary care consultation. One-third to one-half of primary care shoulder pain consulters in Scandinavia re-consult within 12 months.[21,22] We have previously shown that 34% of knee pain

consulters and 22% of foot pain consulters consult again in primary care with the same problem over 18 months.[23,24]

This is the largest study to date of outcome following treatment in musculoskeletal CATS. Strengths of the study are the high participation rate at baseline (73%) and use of routinely-collected consultation data to ensure high completion rates for the primary outcome. Several limitations are, however, worthy of further discussion. Firstly, the response to the postal follow-up questionnaires was poor, particularly at 12 months. However, questionnaire data were used to answer the secondary objectives rather than the primary objective which utilised data from consultation records, available for 69% of baseline responders. Furthermore, a sensitivity analysis using multiple imputation to account for loss to follow-up did not significantly alter our findings. Secondly, pain and physical function were measured using generic health status instruments, finding only small changes over time. Owing to questionnaire length, we could not include body region-specific questionnaires which might have been more sensitive to improvement. Thirdly, the study population was derived from a single geographical region which might limit the generalisability of our findings. Finally, we did not include a comparator cohort to allow a direct comparison to patients managed in other settings such as primary care, orthopaedics or rheumatology.

Our findings suggest that musculoskeletal CATS should be configured to address troublesome disabling pain which might not be best achieved by a “one-stop shop” model-of-care. We have previously highlighted the complexity of patients referred from primary care to musculoskeletal CATS, showing chronic pain, major physical limitation, anxiety, depression and work disability to be highly prevalent.[8] Our finding that poor outcome is associated with pain interference, obesity, pain duration and physical impairment raises the possibility that targeting specific treatments at people with certain modifiable risk factors might improve outcome, as has been shown to be the case in other settings, for example, stratified care for low back pain in primary care.[25] However, further research is needed to determine how to identify people at risk of poor outcome from musculoskeletal problems and evaluate what targeted treatment should consist of. Notwithstanding this important future research agenda,

we suggest that musculoskeletal services need to be resourced to provide a biopsychosocial model of care, with appropriately trained clinical staff, and that services need the flexibility and resource to offer follow-up appointments, where clinically indicated, in order to monitor progress, tailor treatment to the individual and address clinical complexity.

For peer review only

ACKNOWLEDGEMENTS

The authors would like to thank the following people who contributed to the management and/or administration of the study either at the Arthritis Research UK Primary Care Centre or Stoke-on-Trent PCT: Joanne Bailey, Helen Duffy, Tina Gilbert, Rhian Hughes, Zoë Mayson, Janet Ough, Diane Stanyer, Vicki Taylor and Sue Weir. Professor Andrew Hassell led the funding application. The authors would also like to acknowledge the contribution of the research nurse teams at the Arthritis Research UK Primary Care Centre and Haywood Hospital, and the clinicians within Stoke-on-Trent PCT musculoskeletal and back pain interface services to data acquisition.

COMPETING INTERESTS

“All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) [initials of relevant authors] have support from [name of company] for the submitted work; (2) [initials of relevant authors] have [no or specified] relationships with [name of companies] that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have [specified] financial relationships that may be relevant to the submitted work; and (4) [initials of relevant authors] have no [or specified] non-financial interests that may be relevant to the submitted work.”

FUNDING

This work is supported by an Arthritis Research UK Integrated Clinical Arthritis Centre Grant (17684), the Arthritis Research UK Primary Care Centre Grant (18139), funding secured from Stoke-on-Trent Primary Care Trust (PCT), and service support through the West Midlands North CLRN. The study funders had no role in study design; in data collection, analysis, or interpretation; in the writing of the paper; or in the decision to submit the paper for publication. KS is part-funded by a NIHR Knowledge Mobilisation Fellowship (KMF-

2012-01-35). EH is a NIHR Senior Investigator. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

CONTRIBUTORSHIP STATEMENT

PD, EH and KS conceived of the study and secured funding. All authors participated in the design of the study and drafting of the manuscript, and read and approved the final manuscript. ER, IZ, PD, SH, JP, KS and EH participated in acquisition of data. Analysis was undertaken by YC, KJ, RO, and SJ. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. EH is guarantor.

ETHICAL APPROVAL

The study was approved by South Staffordshire Local Research Ethics Committee (REC reference number: 07 / H1203 / 86).

DATA SHARING

Data sharing: requests for further detail on the dataset and queries relating to data sharing arrangements may be submitted to the corresponding author. Participants did not give informed consent for data sharing although the presented data are anonymised and risk of identification is low.

REFERENCES

- [1] Papageorgiou AC, Croft PR, Thomas E et al. Influence of previous pain experience on the episode incidence of low back pain: results from the South Manchester Back Pain Study. *Pain* 1996;66:181-5.
- [2] Thomas E, Peat G, Croft P. Defining and mapping the person with osteoarthritis for population studies and public health. *Rheumatology (Oxford)* 2014;53:338-45.
- [3] Jordan KP, Jöud A, Bergknut C et al. International comparisons of the consultation prevalence of musculoskeletal conditions using population-based healthcare data from England and Sweden. *Ann Rheum Dis* 2014;73:212-8.
- [4] Vos T, Flaxman AD, Naghavi M et al. Years lived with disability (YLDs) for 1160 sequelae of 289 diseases and injuries 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet* 2012;380:2163-96.
- [5] Department of Health. The Musculoskeletal Services Framework. 2006. Published: 12/07/2006.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4138412.pdf
- [6] Maddison P, Jones J, Breslin A et al. Improved access and targeting of musculoskeletal services in northwest Wales: targeted early access to musculoskeletal services (TEAMS) programme. *BMJ* 2004;329:1325-7.
- [7] Dixey J, Bamji A. What is a rheumatologist for? *Rheumatology (Oxford)* 2007;46:377-378.
- [8] Roddy E, Zwierska I, Jordan KP et al. Musculoskeletal clinical assessment and treatment services at the primary-secondary care interface: an observational study. *Br J Gen Pract* 2013;63:e141-8.
- [9] Roddy E, Zwierska I, Dawes P et al. The Staffordshire Arthritis, Musculoskeletal, and Back Assessment (SAMBA) Study: a prospective observational study of patient outcome following referral to a primary-secondary care musculoskeletal interface service. *BMC Musculoskeletal Disorders* 2010;11:67.

[10] Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30:473-83.

[11] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70

[12] Blyth FM, March LM, Brnabic AJ et al. Chronic pain in Australia: a prevalence study. *Pain* 2001;89:127-34.

[13] Thomas E, Peat G, Harris L et al. The prevalence of pain and pain interference in a general population of older adults: cross-sectional findings from the North Staffordshire Osteoarthritis Project (NorStOP). *Pain* 2004;110:361-8.

[14] Jordan KP, Thomas E, Peat G et al. Social risks for disabling pain in older people: a prospective study of individual and area characteristics. *Pain* 2008;137:652-61.

[15] The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. *Health Policy* 1990;16:199-208.

[16] NHS Information Authority. The clinical terms version 3 (The Read Codes). Birmingham: NHS Information Authority, 2000.

[17] BMJ Group. British National Formulary (BNF) 63. London: BMJ Group and RPS Publishing. 2012.

[18] Curtis L. Unit Costs of Health and Social Care 2012 PSSRU (Personal Social Services Research Unit). University of Kent: Canterbury. 2010.

[19] Department of Health. NHS Reference Costs. 2010/11. <https://www.gov.uk/government/publications/2010-11-reference-costs-publication>

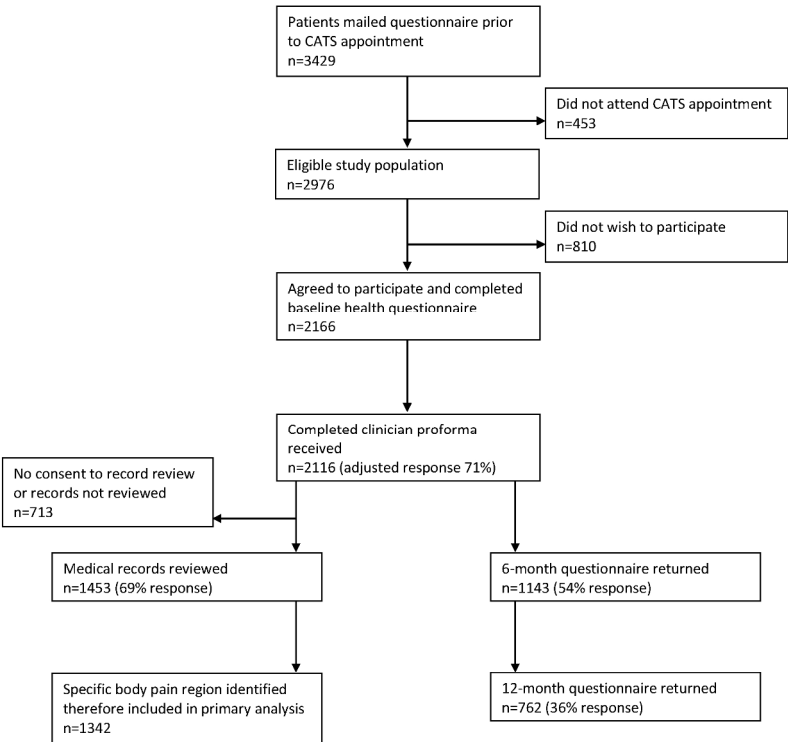
[20] Sephton R, Hough E, Roberts SA et al. Evaluation of a primary care musculoskeletal clinical assessment service: a preliminary study. *Physiotherapy* 2010;96:296-302.

[21] Tekavec E, Jöud A, Rittner R et al. Population-based consultation patterns in patients with shoulder pain diagnoses. *BMC Musculoskeletal Disord* 2012;13:238.

- [22] Paloneva J, Koskela S, Kautiainen H et al. Consumption of medical resources and outcome of shoulder disorders in primary health care consulters. BMC Musculoskeletal Disord 2013;14:348.
- [23] Jordan K, Jinks C, Croft P. A prospective study of the consulting behaviour of older people with knee pain. Br J Gen Pract 2006;56:269-76.
- [24] Menz HB, Jordan KP, Roddy E et al. Musculoskeletal foot problems in primary care: what influences older people to consult? Rheumatology (Oxford) 2010;49:2109-16.
- [25] Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011;378:1560-71.

Peer review only

Supplementary Figure – Flow of participants through the study



210x297mm (300 x 300 DPI)

Supplementary table 1 - comparison of baseline characteristics between those included and excluded from primary care record analysis

		Included	Excluded	Difference ^a (95% CI)
n		1453	713	
Female	n (%)	824 (57)	414 (58)	-1.4 (-5.8, 3.1)
Age	Mean (SD)	52.0 (14.9)	49.0 (15.8)	2.6 (1.3, 4.0) ^d
HADS depression	Mean (SD)	6.4 (4.4)	6.2 (4.3)	0.2 (-0.1, 0.6)
HADS anxiety	Mean (SD)	7.9 (4.7)	7.6 (4.6)	0.3 (-0.1, 0.7)
SF36 physical function	Mean (SD)	36.1 (12.1)	37.2 (11.9)	-1.1 (-2.1, 0.03)
SF36 body pain	Mean (SD)	34.1 (8.5)	35.1 (8.8)	-1.1 (-1.8, -0.3) ^d
Pain duration > 1year	n (%)	803 (55)	399 (56)	-0.8 (-5.2, 3.7)
Severe pain interference ^b	n (%)	819 (56)	370 (52)	4.4 (-0.02, 8.9)
Currently employed	n (%)	750 (52)	386 (55)	-2.7 (-7.2, 1.8)
Time off work ^c	n (%)	341 (46)	175 (45)	0.2 (-5.9, 6.3)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form-36; SD, standard deviation

^a difference in means or proportions as appropriate; ^b quite a bit or extremely; ^c due to musculoskeletal problem in the last 6 months in those currently employed; ^d p<0.05

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4,5
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	5,7
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	8,9
Study size	10	Explain how the study size was arrived at	7,8
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6-8
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-10
		(b) Describe any methods used to examine subgroups and interactions	8,9
		(c) Explain how missing data were addressed	9
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10, Suppl figure
		(c) Consider use of a flow diagram	Suppl figure
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Suppl table, Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 3, 4

		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 1, 2
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables 1, 2 & 4
		(b) Report category boundaries when continuous variables were categorized	6-8, Table 1
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not given
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-21
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22-23

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

BMJ Open

Re-consultation, self-reported health status, and costs following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study



Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2016-011735.R1
Article Type:	Research
Date Submitted by the Author:	28-Jun-2016
Complete List of Authors:	Roddy, Edward; Keele University, Research Institute for Primary Care and Health Sciences; Keele University Jordan, Kelvin; Keele University, Arthritis Research UK Primary Care Centre Oppong, Ray; University of Birmingham, Health Economics Unit Chen, Ying; Keele University, Primary Care Sciences Jowett, Sue; University of Birmingham, Health Economics Unit Dawes, Peter; Haywood Hospital, Staffordshire Rheumatology Centre Hider, Samantha; Keele University, Arthritis Research UK Primary Care Centre; Packham, Jonathan; Haywood Hospital, Staffordshire Rheumatology Centre Stevenson, Kay; University Hospital of North Midlands, Physiotherapy Zwierska, Irena; Keele University, Research Institute for Primary Care and Health Sciences Hay, Elaine; Arthritis Research Primary Care Centre
Primary Subject Heading:	Rheumatology
Secondary Subject Heading:	General practice / Family practice, Health services research
Keywords:	RHEUMATOLOGY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Rheumatology < INTERNAL MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

SCHOLARONE™
Manuscripts

TITLE: Re-consultation, self-reported health status, and costs following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study

AUTHORS:

Edward Roddy^{1,2}, Kelvin P Jordan¹, Raymond Oppong³, Ying Chen¹, Sue Jowett³, Peter Dawes², Samantha L Hider^{1,2}, Jon Packham², Kay Stevenson^{1,2,4}, Irena Zwierska¹, Elaine M Hay^{1,2}

AFFILIATIONS:

¹Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK

²Staffordshire Rheumatology Centre, Haywood Hospital, High Lane, Burslem, Stoke-on-Trent, ST6 7AG, UK

³Health Economics Unit, School of Health and Population Sciences, University of Birmingham, Birmingham B15 2TT, UK

⁴Physiotherapy Department, University Hospital of North Midlands, Stoke-on-Trent, UK

CORRESPONDING AUTHOR:

Dr Edward Roddy, Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK.
Tel: 00 44 1782 734715 Fax: 00 44 1782 734719 e-mail: e.rodgy@keele.ac.uk

KEYWORDS: Primary-secondary care interface, Musculoskeletal, Outcome, Pain, Healthcare costs

WORD COUNT: 3505 words

ABSTRACT

Objectives: To determine (1) re-consultation frequency, (2) change in self-reported health status, (3) baseline factors associated with re-consultation and change in health status, and (4) associated healthcare costs and quality-adjusted life-years (QALYs), following assessment at a musculoskeletal Clinical and Assessment Treatment Service (CATS).

Design: Prospective cohort study

Setting: Single musculoskeletal CATS at the primary-secondary care interface

Participants: 2166 CATS attenders followed-up by postal questionnaires at 6 and 12 months and review of medical records.

Outcome measures: Primary outcome was consultation in primary care with the same musculoskeletal problem within twelve months. Secondary outcome measures were consultation at the CATS with the same musculoskeletal problem within twelve months, physical function and pain (SF36), anxiety and depression (Hospital Anxiety and Depression Scale), time off work, healthcare costs and quality-adjusted life-years (QALYs).

Results: Over 12 months, 507 (38%) re-consulted for the same problem in primary care and 345 (26%) at the CATS. Primary care re-consultation in the first 3 months was associated with pain interference (relative risk ratio 5.33; 95%CI 3.23, 8.80) and spinal pain (1.75; 1.09, 2.82), and after 3-6 months with baseline assessment by a hospital specialist (2.06; 1.13, 3.75). Small mean improvements were seen in physical function (1.88; 95%CI 1.44, 2.32) and body pain (3.86; 3.38, 4.34) at 6 months. Poor physical function at 6 months was associated with obesity, chronic pain, and poor baseline physical function. Mean (SD) 6-month cost and QALYs per patient were £422.40 (660.11) and 0.257 (0.144) respectively.

Conclusions: Whilst most patients are appropriate for a "one-stop shop" model, those with troublesome, disabling pain and spinal pain commonly re-consult and have ongoing problems. Services should be configured to identify and address such clinical complexity.

ARTICLE SUMMARY SECTION

Strengths and Limitations of this Study

- The largest study to date of outcome following treatment in a musculoskeletal CATS.
- The participation rate at baseline was high and use of routinely-collected consultation data ensured high completion rates for the primary outcome.
- Response to the postal follow-up questionnaires was poor, particularly at 12 months.
- Questionnaire length permitted inclusion of only generic measures of pain and physical function rather than body region-specific measures which might have been more sensitive to improvement.
- The study population was derived from a single geographical region and did not include a comparator cohort which might limit the generalisability of our findings.

INTRODUCTION

Musculoskeletal problems such as osteoarthritis (OA) and back pain are highly prevalent and present frequently to primary care. One-third of adults experience low back pain annually whereas 53% of older adults have symptomatic OA.[1,2] Annually in the UK, one-fifth of people consult their GP for a musculoskeletal condition and 4% of older adults consult for OA.[3] Musculoskeletal disorders were the largest cause of disability globally in 2013.[4]

Most of these people are managed entirely in primary care, with only a minority requiring specialist referral, traditionally to hospital-based orthopaedic and rheumatology services. Recently, patients requiring referral are increasingly managed in multidisciplinary Clinical Assessment and Treatment Services (CATS) at the primary-secondary care interface.[5,6] CATS act as a one-stop shop, providing rapid access to assessment, diagnostic investigations, treatment by appropriately-skilled healthcare practitioners, and onward referral pathways, aiming to provide more integrated care, and prevent chronicity, disability, and a cycle of reconsultation and referral to multiple services across primary and secondary care.[5-7] We have previously shown that chronic pain, physical disability, anxiety, depression, and work disability are prevalent amongst patients attending a musculoskeletal CATS, suggesting that these patients often already have chronic pain and are not being identified early, emphasising the need for appropriate early referral pathways to suitably skilled clinicians.[8] Little is known about patient outcome following treatment in this setting and if and how patients subsequently re-consult.

The objectives of this prospective study were (1) to determine the proportion of patients re-consulting in primary care and in a musculoskeletal CATS in the 12 months following baseline assessment at the CATS, (2) to assess baseline factors associated with re-consultation in primary care and at the CATS, (3) to determine change in self-reported health status at 6 and 12 months, (4) to assess baseline factors associated with change in self-reported health status, and (5) to estimate the health care costs and quality-adjusted life-years (QALYs) over 6 months associated with CATS attendance and determine whether these costs and QALYs differed by follow-up plan at baseline.

METHODS

This was a prospective observational study set within a musculoskeletal CATS in North Staffordshire, UK. The methods and baseline cross-sectional findings have been described previously.[8,9]

Study setting

At the time of baseline data collection, Stoke-on-Trent Primary Care Trust (PCT) served a population of more than 270,000 people. Referrals to secondary care musculoskeletal, rheumatology and orthopaedic services are triaged by clinicians to a multidisciplinary, musculoskeletal CATS at the primary-secondary care interface following review of referral letters, so that musculoskeletal conditions requiring non-surgical interventions are managed in the community, whilst appropriate cases are directed to rheumatology or orthopaedic services. The CATS is the preferred provider for patients with non-surgical, non-inflammatory musculoskeletal problems. Patients are triaged to unselected general musculoskeletal clinics within the CATS, where the type of healthcare professional patient seen (physiotherapist, rheumatologist, rehabilitation medicine specialist, or GP with a special interest (GPwSI)) and the clinic in which they are seen are not determined by the index referred condition. The sole exception to this is a physiotherapist-led back pain clinic. A greater proportion of patients with back pain therefore see a physiotherapist compared to other conditions.

Data collection

All adults aged ≥18 years seen at the CATS between February 2008 and June 2009 were invited to participate. Those who consented to take part completed a health questionnaire prior to their CATS appointment. Participants were also asked to provide consent for the research team to review their medical records.

Baseline measures

The questionnaire included physical functioning and body pain scales from the the Short Form-36 (SF-36) version 2 (general population mean = 50; scores <50 represent worse health).[10] Anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS, range 0-14; scores ≥ 8 on either scale representing possible or probable anxiety or depression).[11] The presence of pain that interfered with daily activities was measured using one item from the SF-36: 'During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?'.[10] Respondents answering 'moderately', 'quite a bit' or 'extremely' were defined as having pain interference, whilst responding 'quite a bit' or 'extremely' represented severe pain interference.[12-14] Cohabitation status, self-reported height/weight, musculoskeletal pain duration and work absence in the preceding 6 months because of musculoskeletal problems were also collected. The EuroQoL-3L (EQ-5D 3L) was included, in order to calculate QALYs.[15]

The clinician conducting the CATS consultation completed a brief proforma but did not see the patient's completed questionnaire. The clinician proforma recorded the location of pain addressed in the consultation (used to group participants into four mutually exclusive categories: upper limb or neck alone, spine alone, lower limb alone or multiple sites), investigations, interventions, referrals and follow-up plan. Participants were regarded as having pain in multiple sites if the clinician recorded locations from two or more of the upper limb/neck, spine, or lower limb, or recorded a diagnosis of fibromyalgia, chronic widespread pain, generalised osteoarthritis, or polymyalgia rheumatica. Follow-up was categorised as referral to other services (eg rheumatology, orthopaedics, physiotherapy), CATS follow-up, discharge to the GP, or to be decided following investigations. If the follow-up plan was dependent upon investigation results, follow-up information for those participants who consented to medical record review was extracted from CATS records. The clinician profession was also recorded. Due to the low number of rehabilitation medicine specialists,

we combined these with rheumatologists (referred to hereafter as hospital specialists). We also recorded whether patients were attending a general musculoskeletal clinic or the physiotherapist-led back pain clinic described above.

Follow-up questionnaires

A self-administered questionnaire containing the same measures as at baseline was mailed at 6 and 12 months to all consenting participants. Non-responders were sent a postcard reminder after 2 weeks and a repeat questionnaire after 4 weeks.

Medical record review

In participants consenting to medical record review, information was extracted from primary care records for the 12 months following baseline. Due to the large number of general practices ($n=114$ including 49 with fewer than 10 patients), it was unfeasible to examine the records of all patients and so a pragmatic decision was made to extract records from the 57 most accessible practices with the highest number of participants. Records were downloaded electronically where possible but where software was incompatible with the practice, information was extracted manually using a proforma. The information extracted was date of any musculoskeletal consultation in primary care, and date of a musculoskeletal consultation for the same body location (neck, shoulder, elbow, hand/wrist, spine, hip, knee, foot/ankle) as recorded by the clinician at baseline. Musculoskeletal consultations were identified using the Read code system which is commonly used to record morbidity in UK primary care.[16] Free-text narrative data were not extracted from the medical record. We identified the date of any further attendance at the CATS for the same body location in all participants who consented to medical record review through manual review of CATS records.

Sample size

At the time of baseline data collection, approximately 3500 patients were seen in the CATS annually. Based on previous studies, we expected 75% of these to participate at baseline (n=2625), and 75% of these to separately consent to further postal contact and medical record review (n=2000 each). Whilst we aimed to review records of as many patients as feasible, as an example, a sample size of 1125 is sufficient to determine the percentage making a repeat primary care consultation during 12 months follow-up with a margin of error of 3% and a 95% confidence level, based on an estimate of 50%.

Statistical analysis

We compared baseline responders with extracted medical record data with all other baseline responders on baseline socio-demographic, pain characteristics, and general health. The percentage consulting for a musculoskeletal problem in primary care in the 12 months after baseline was determined. The primary analysis was based on the time to consulting in primary care about the same body location which was addressed at the baseline CATS consultation. We split time to first consultation to primary care into no consultation during 12-month follow-up, first consultation within 3 months (early), between 3-6 months, and between 6-12 months after baseline clinic assessment (late). We used these categories rather than actual time as it was evident that the baseline factors associated with first primary care attendance changed over the 12-month time-period, and it was considered that attendance to primary care within 3 months may be at the request of the CATS clinician. Multinomial logistic regression was used to determine the association of follow-up plan and clinician profession with time of consultation to primary care adjusted for self-reported (age, gender, cohabitation, pain interference and duration, body mass index, anxiety and depression) and clinician-reported (body region, musculoskeletal or back pain clinic) factors. No repeat consultation was treated as the reference category. Results are reported as adjusted relative risk ratios (RRR) with 95% confidence intervals (95%CI).

Secondary outcomes were re-consultation at the CATS during 12 months follow-up and self-reported health (physical function, body pain, anxiety and depression, and time off work in those employed at baseline) at 6 months and 12 months. Binary logistic regression was used to assess association of clinician profession and follow-up plan with re-consultation at the CATS about the same body location as at the baseline clinic at any point during the 12 months, adjusting for the same factors included in the primary outcome analysis. Results are presented as odds ratios (OR) with 95%CI. Multiple linear regression was used to assess the association of clinician profession and follow-up plan with physical function score at follow-up adjusted for baseline score and for the same baseline self-reported and clinician-reported factors as included in the analysis of primary care consultation (except pain interference as it was highly correlated with baseline physical function).

Two sensitivity analyses were performed. Firstly, as primary care medical record information was not available for everyone, we performed multiple imputation with 50 imputations and again repeated the analysis. Secondly, because of the attrition at follow-up, the analysis of self-reported physical function at 6 months was repeated using multiple imputed data for those not responding at follow-up.

Analysis of health care costs and quality-adjusted life-years

The health economic analysis was conducted from a healthcare perspective and focused on estimating the costs and QALYs arising from attending the CATS. Resource use data were collected from the clinician proforma and 6-month questionnaire. The proforma recorded investigations and interventions that patients received, whilst the questionnaire asked about the number and type of health professionals seen, medication taken, and the number of interventions. Unit costs for individual resource use items were obtained from sources such as the British National Formulary (BNF), Personal Social Services Research Unit, and NHS reference costs.[17-19] The analysis was limited to those who completed the questionnaire. In order to value the resource use items, we multiplied resource use by unit costs and

estimated a total cost per patient by summing up the costs associated with each resource use item. The area under the curve approach was used to estimate QALYs using EQ-5D responses at baseline and 6 months. Multiple regression was used to estimate mean total cost and QALYs by follow-up plan controlling for body region, age, BMI, anxiety and depression, pain interference and baseline EQ-5D. Bootstrapping (1000 replications) was used to estimate bias-corrected confidence intervals around differences in mean costs and QALYs between groups using patients who were referred to other specialities as the reference category.

RESULTS

As reported previously,[8] 3429 patients were mailed the baseline questionnaire of whom 453 (13%) did not attend their CATS appointment. 2166 consented to participate at baseline, from whom 2116 clinician proformas were completed (adjusted response 71%). Of these, 1453 (69%) had their medical records reviewed and did not have a primary care musculoskeletal consultation on the same day as their CATS appointment (**supplementary figure**). Compared to those responding but not undergoing record review, these participants were older (mean difference 2.6 years, 95%CI 1.3,4.0) and had slightly worse levels of pain, but no differences on gender, anxiety, depression, physical functioning, pain duration, pain interference, employment status or time off work (**supplementary table**).

Consultation in primary care during 12-month follow-up

Of the 1453 for whom record data were collected, 1342 were included in the primary outcome analysis as the remainder received other diagnoses such as gout, inflammatory arthritis, and joint hypermobility, and hence a specific body region was not available to link subsequent consultations to (**supplementary figure**). Of these, 507 (38%, 95%CI 35%,40%) consulted primary care during 12 months follow-up for the same body region as addressed at the baseline clinic assessment. Median number of days to consulting primary care was 69 (IQR 27,159): 289 (22%) consulted within 3 months and 403 (30%) within 6

months. There was no association between the type of professional seen at baseline and consulting in the first 3 months but those seeing a hospital specialist were more likely to first return to primary care between 3 and 6 months after their CATS visit (adjusted RRR 2.06; 95%CI 1.13,3.75 compared to GPwSI) and between 6 and 12 months (2.08; 1.12,3.88) (**table 1**). The strongest association with consulting within the first six months was with severe pain interference at baseline (within 3 months: 5.33; 3.23,8.80 compared to no pain interference; 3-6 months 2.26; 1.25,4.09). Those consulting with a spine problem were more likely to consult primary care in the first 3 months (1.75; 1.09,2.82) or after 6-12 months (2.17; 1.06,4.47) compared to having an upper limb or neck problem. Those with anxiety or depression were less likely to first consult primary care between 6 and 12 months (0.60; 0.38, 0.95). There was no association of gender, cohabitation status, follow-up plan, pain duration, or BMI with primary care consultation.

Analysis based on multiple imputation data yielded similar estimates and CIs to those from the analysis for those whose records were reviewed.

Table 1 - Associations with time after baseline assessment of first primary care consultation for musculoskeletal problem in same body location as at baseline CATS consultation

		0-3m (early)	3-6m	6-12m (late)
Total consulting (% consulting)	507 (38)	289 (22)	114 (8)	104 (8)
	<i>n</i> (% consulting)	Adjusted RRR ^a (95% CI)		
Male	586 (37)	1.00	1.00	1.00
Female	756 (38)	1.05 (0.79, 1.42)	0.96 (0.64, 1.46)	0.78 (0.51, 1.20)
Age (years)	18-44	1.00	1.00	1.00
	45-64	1.11 (0.80, 1.55)	1.11 (0.68, 1.81)	1.03 (0.63, 1.70)
	≥65	0.92 (0.60, 1.41)	1.33 (0.75, 2.36)	1.38 (0.77, 2.48)
Living alone:	No	1.00	1.00	1.00
	Yes	0.76 (0.49, 1.18)	1.33 (0.79, 2.23)	1.40 (0.80, 2.45)
Professional seen: GPwSI	309 (29)	1.00	1.00	1.00
	Hospital specialist	1.25 (0.82, 1.92)	2.06 (1.13, 3.75)^b	2.08 (1.12, 3.88)^b
	Physiotherapist	1.16 (0.77, 1.73)	1.58 (0.88, 2.84)	1.40 (0.76, 2.60)
Region at clinic:	Upper limb/neck	1.00	1.00	1.00
	Spine	1.75 (1.09, 2.82) ^b	1.12 (0.56, 2.24)	2.17 (1.06, 4.47)^b
	Lower limb	0.87 (0.60, 1.28)	0.86 (0.53, 1.41)	1.38 (0.81, 2.36)
	Multiple regions	1.16 (0.66, 2.04)	0.97 (0.44, 2.14)	1.77 (0.78, 4.02)
Follow-up plan:	Referred	1.00	1.00	1.00
	Followed-up	1.28 (0.80, 2.06)	1.28 (0.65, 2.50)	0.86 (0.36, 2.10)
	Discharged	0.95 (0.69, 1.30)	0.75 (0.48, 1.17)	1.39 (0.87, 2.21)
	Unknown	1.40 (0.71, 2.75)	1.29 (0.53, 3.13)	1.87 (0.79, 4.46)

Pain duration:	<12months	603 (37)	1.00	1.00	1.00
	>12months	738 (38)	0.80 (0.60, 1.07)	0.91 (0.60, 1.37)	1.28 (0.82, 1.98)
Pain interference:	No/little bit	300 (22)	1.00	1.00	1.00
	Moderately	295 (29)	2.38 (1.37, 4.14)^b	1.07 (0.54, 2.13)	0.72 (0.38, 1.37)
	Quite a bit/extremely	746 (47)	5.33 (3.23, 8.80)^b	2.26 (1.25, 4.09)^b	1.35 (0.78, 2.33)
BMI:	Normal	382 (35)	1.00	1.00	1.00
	Overweight	484 (36)	1.18 (0.82, 1.71)	0.77 (0.46, 1.30)	1.07 (0.61, 1.86)
	Obese	439 (42)	1.28 (0.88, 1.87)	1.16 (0.70, 1.93)	1.63 (0.95, 2.82)
	Unknown	37 (38)	0.89 (0.35, 2.23)	1.37 (0.47, 3.94)	0.86 (0.19, 3.97)
Anxious/depressed:	No	606 (34)	1.00	1.00	1.00
	Yes	736 (41)	1.02 (0.75, 1.40)	0.97 (0.62, 1.50)	0.60 (0.38, 0.95) ^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; RRR, relative risk ratios

^a Multinomial logistic regression $n=1340$ (2 participants omitted due to missing data). Relative risk ratios adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), reference group is no musculoskeletal consultation, ^b $p<0.05$

Percentages are row percentages

Re-consultation at the CATS during 12-month follow-up

345 (26%) re-consulted at the CATS during 12-months follow-up for a musculoskeletal problem in the same body location as assessed at baseline. The clinician stating they would follow-up the patient (adjusted OR 9.97; 95%CI 6.36, 15.62) was most strongly associated with re-consultation at the CATS whilst being discharged (1.54; 1.13, 2.10) was also significantly associated (**table 2**). Patients seeing a hospital specialist were more likely to re-consult in the CATS (OR 1.68; 95%CI 1.14, 2.49 compared to GPwSI). Severe pain interference and shorter pain duration were also associated with re-consultation.

Table 2 - Associations with return to interface clinic during 12-month follow-up for musculoskeletal problem in same body location as baseline CATS consultation

	Total <i>n</i> (% with appointment)	OR (95% CI)	Adjusted OR ^a (95% CI)
Total	1342 (26)		
Male	586 (25)	1.00	1.00
Female	756 (26)	1.07 (0.84, 1.28)	1.10 (0.83, 1.45)
Age (years) 18-44	424 (23)	1.00	1.00
45-64	633 (27)	1.23 (0.93, 1.64)	1.35 (0.98, 1.86)
≥65	285 (27)	1.21 (0.86, 1.71)	1.41 (0.95, 2.09)
Living alone: No	1140 (26)	1.00	1.00
Yes	202 (23)	0.83 (0.58, 1.18)	0.89 (0.60, 1.32)
Professional seen: GPwSI	309 (23)	1.00	1.00
Hospital specialist	359 (26)	1.15 (0.81, 1.64)	1.68 (1.14, 2.49)^b
Physiotherapist	674 (27)	1.20 (0.88, 1.64)	0.91 (0.62, 1.34)
Region at clinic: Upper limb/neck	436 (27)	1.00	1.00
Spine	347 (35)	1.48 (1.09, 2.01)^b	0.84 (0.53, 1.35)
Lower limb	454 (17)	0.54 (0.39, 0.75)^b	0.59 (0.41, 0.83)^b
Multiple regions	105 (30)	1.14 (0.71, 1.83)	1.05 (0.63, 1.77)
Follow-up plan: Referred	492 (17)	1.00	1.00
Followed-up	145 (68)	10.61 (6.96, 16.17)^b	9.97 (6.36, 15.62)^b
Discharged	637 (23)	1.50 (1.12, 2.03)^b	1.54 (1.13, 2.10)^b
Unknown	68 (21)	1.28 (0.68, 2.41)	1.19 (0.62, 2.29)

Pain duration:	<12months	603 (27)	1.00	1.00
	>12months	738 (24)	0.85 (0.66, 1.09)	0.75 (0.57, 0.99)^b
Pain interference:	No/little bit	300 (19)	1.00	1.00
	Moderately	295 (25)	1.49 (1.00, 2.20)^b	1.53 (1.00, 2.35)
	Quite a bit/extremely	746 (29)	1.75 (1.26, 2.44)^b	1.64 (1.11, 2.42)^b
BMI	Normal	382 (25)	1.00	1.00
	Overweight	484 (26)	1.03 (0.76, 1.41)	1.10 (0.78, 1.55)
	Obese	439 (26)	1.06 (0.77, 1.44)	1.12 (0.79, 1.58)
	Unknown	37 (16)	0.57 (0.23, 1.40)	0.45 (0.17, 1.22)
Anxious/depressed:	No	606 (25)	1.00	1.00
	Yes	736 (26)	1.06 (0.83, 1.36)	0.92 (0.68, 1.23)

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; OR, odds ratio

^a Binary logistic regression $n=1340$ (2 participants omitted due to missing data). Adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), referent group is no follow-up appointment

^b $p < 0.05$

Percentages are row percentages

Self-reported health and time-off work

1143 (54%) of the 2116 baseline responders with a completed clinician proforma completed the follow-up questionnaire at 6 months and 762 (36%) at 12 months. 6-month responders were older (mean age 54.9 vs 46.4) compared to non-responders and had lower levels of anxiety and depression. However, they did not differ according to pain, physical function, or the type of clinician seen at baseline. Responders showed some improvement at 6 months on physical functioning (mean change 1.88; 95%CI 1.44,2.32; effect size equivalent 0.16) and body pain (mean change 3.86; 95%CI 3.38,4.34; effect size equivalent 0.47) (**table 3**). The percentage with severe pain interference fell from 54% to 40% at 6 months, whilst the percentage taking time off work due to their musculoskeletal problem fell from 42% to 33%. However, there was no change in anxiety or depression levels, nor was there any further change in any of these measures at 12 months. Given the high attrition at 12 months, and

the lack of change at the population level between 6 and 12 months, the remainder of the self-reported analysis concentrated on the 6-month time-point.

Type of clinician seen and follow-up plan did not associate with physical function at 6 months (**table 4**). Females, older adults, those who were obese, those with pain duration of more than 12 months, and those with worse physical function at baseline had the worst outcomes at 6 months. For example, those with pain duration longer than 12 months at baseline had a mean PF score at 6 months around 2 points worse than those with shorter pain duration (adjusted mean difference -1.93; 95% CI -2.83, -1.03). Sensitivity analysis based on multiple imputation data made little difference to these estimates and CIs.

Table 3 – Self-reported change in physical and mental health status, time off work and pain interference at 6 and 12 months

	Baseline ^a	6 months	12 months
	Mean (SD)	Mean change ^b (95% CI)	Mean change ^b (95% CI)
HADS depression	6.1 (4.2)	-0.02 (-0.20, 0.16)	-0.13 (-0.35, 0.09)
HADS anxiety	7.5 (4.6)	0.03 (-0.16, 0.22)	-0.02 (-0.26, 0.22)
SF36 physical function	36.4 (11.9)	1.88 (1.44, 2.32)	1.82 (1.24, 2.39)
SF36 body pain	34.5 (8.3)	3.86 (3.38, 4.34)	4.19 (3.55, 4.83)
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Time off work ^c	219 (42)	169 (33)	110 (33)
Anxious / depressed	588 (53)	591 (53)	390 (52)
Pain interference			
Not at all / a little	258 (23)	429 (38)	284 (38)
Moderately	261 (23)	247 (22)	178 (24)
Quite a bit / extremely	606 (54)	449 (40)	289 (38)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SD, standard deviation; SF-36, Short Form-36

^a in those responding at 6 months

^b positive mean change indicates improvement

^c in those currently employed at baseline *n*=519. At 6 and 12 months, time off work includes those no longer employed

Number in analysis for baseline & 6 months: 1118 (depression), 1115 (anxiety), 1124 (physical function), 1109 (body pain), 519 (time off work), 1115 (anxiety/depression), 1125 (interfering pain)
Number in analysis for 12 months: 748 (depression), 748 (anxiety), 754 (physical function), 745 (body pain), 332 (time off work), 748 (anxiety/depression), 751 (interfering pain)

Table 4 – 6-month follow-up Physical Functioning (PF) score by baseline factors

	Adjusted for baseline PF score only Coeff (95% CI)	Adjusted for all variables Coeff (95% CI)
Female (referent: male)	-0.84 (-1.73, 0.06)	-0.90 (-1.80, 0.00)^b
Age (years) (referent: 18-44)		
45-64	-1.41 (2.50, -0.33)	-1.27 (-2.36, -0.17)^b
≥65	-2.94 (-4.21, -1.67)^b	-2.87 (-4.19, -1.55)^b
Living alone (referent: not living alone)	-1.14 (-2.37, 0.09)	-0.53 (-1.77, 0.72)
Professional seen (referent: GPwSI)		
Hospital specialist	0.05 (-1.17, 1.27)	-0.24 (-1.45, 0.97)
Physiotherapist	0.69 (-0.40, 1.77)	-0.32 (-1.48, 0.84)
Region at clinic (referent: upper limb/neck)		
Spine	2.02 (0.82, 3.21)^b	0.52 (-1.02, 2.05)
Lower limb	-0.05 (-1.20, 1.10)	-0.47 (-1.62, 0.68)
Multiple regions	-0.34 (-1.89, 1.20)	-0.58 (-2.13, 0.96)
Other	0.07 (-2.10, 2.23)	-0.72 (-2.87, 1.43)
Follow-up plan (referent: Referred)		
Followed-up	0.05 (-1.45, 1.56)	-0.91 (-2.45, 0.63)
Discharged	0.23 (-0.75, 1.21)	0.12 (-0.85, 1.09)
Unknown	-0.48 (-2.26, 1.30)	-0.58 (-2.33, 1.17)
Pain duration >12months (referent <12months)	-1.99 (-2.90, -1.09)^b	-1.93 (-2.83, -1.03)^b
BMI (referent: normal BMI)		
Overweight	0.30 (-0.77, 1.36)	0.17 (-0.89, 1.22)
Obese	-1.59 (-2.75, -0.43)^b	-1.58 (-2.74, -0.43)^b
Unknown	-1.65 (-4.38, 1.08)	-1.09 (-3.80, 1.63)
Anxious/depressed (referent: not anxious/depressed)	-0.65 (-1.59, 0.29)	-0.81 (-1.75, 0.12)
Baseline PF score ^a	0.87 (0.82, 0.92)^b	0.79 (0.75, 0.84)^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest, PF, physical function;

Coefficient is adjusted mean difference in PF score at follow-up compared to referent, with positive coefficient indicating higher (better) PF score Complete data only, $n=1124$

^a per unit PF score at baseline

^b $p<0.05$

Health care costs and QALYs

The overall mean (SD) cost per patient incurred by attending the CATS was £422.40 (660.11) over the 6-month period. Patients who were referred to other specialities had the highest cost whilst those who were discharged were associated with the lowest cost (**table 5**). The mean cost associated with patients who were discharged was significantly lower than those who were referred to other specialities (mean difference £-132.57; 95%CI: -226.78,-49.54). Costs associated with patients in the other groups (followed up and unknown) were not significantly different from costs associated with patients who were referred (**table 5**).

Across all participants, the mean (SD) QALYs per patient over the 6-month period was 0.257 (0.144). There was no significant difference in mean QALYs between patients who were referred to other specialities and any other group.

Table 5 – Mean costs and quality-adjusted life-years (QALYs) over 6 months according to follow-up plan

	Mean cost ^a	Mean difference (95% CI) ^b	Mean QALYs ^a	Mean difference (95% CI) ^b
Referred (n=405)	£497.55		0.2572	
Followed up (n=124)	£437.18	£-60.37 (-172.68, 67.36) ^c	0.2566	-0.001 (-0.014, 0.014) ^c
Discharged (n=526)	£364.98	£-132.57 ^d (-226.78, -49.54) ^c	0.2591	0.002 (-0.006, 0.009) ^c
Unknown (n=82)	£397.23	£-100.32 (-227.19, 93.92) ^c	0.2498	-0.007 (-0.020, 0.005) ^c

^a Values are predicted means obtained from multiple regression controlling for body region, age, body mass index, anxiety, depression, pain interference and baseline EQ-5D

^b Compared to patients who were referred

^c Bootstrapped confidence interval

^d $p<0.05$

DISCUSSION

After assessment in a musculoskeletal CATS, nearly 40% of people consulted primary care about the same problem within 12 months, with over half of these consulting within three months. Similarly, a quarter of patients re-consult in the CATS within 12 months. People with pain interference and spinal pain were more likely to re-consult. Over 6 months, only small improvements were seen in body pain and physical function, and in the proportion reporting pain interference and taking time off work because of their musculoskeletal problem. Functional outcome was worst in those with older age, obesity, chronicity and pre-existing physical impairment. The cost-outcome description found that follow-up plan to see again in the CATS or to refer to another specialty attracted higher mean costs.

The explanations for frequent reconsultation are likely to be multifactorial, and our study design cannot elucidate these. It may be that patients were advised to visit their GP for change in medication, they re-consulted to obtain a repeat prescription, the CATS consultation failed to adequately meet patients' expectations, and/or their symptoms did not improve. The observation that patients assessed by hospital specialists were more likely to re-consult could be explained by specialists advising further consultation in primary care, for example to change medication, rather than this reflecting poor outcome. The findings that people with pain interference (either setting) and spinal pain (primary care) were more likely to consult and worse functional outcome was associated with older age, obesity, chronicity and pre-existing physical impairment suggest that the current model-of-care does not meet the needs of those with the most troublesome symptoms. An unexpected finding that we find difficult to explain was that people with anxiety or depression were less likely to first consult primary care between 6 and 12 months.

There are few suitable cohorts to compare our findings to. In a study undertaken in a physiotherapist-led CATS, small improvements were reported in pain and general health (EQ-5D) over 12 months but no change was seen in the SF-36.[20] Most improvement occurred within 3 months but was less likely in people with spinal pain and chronic symptoms. Repeat consultation was not examined. Several studies have found similar rates

of repeat musculoskeletal consultations in primary care following an initial primary care consultation. One-third to one-half of primary care shoulder pain consultants in Scandinavia re-consult within 12 months.[21,22] We have previously shown that 34% of knee pain consultants and 22% of foot pain consultants consult again in primary care with the same problem over 18 months.[23,24]

This is the largest study to date of outcome following treatment in musculoskeletal CATS. Strengths of the study are the high participation rate at baseline (73%) and use of routinely-collected consultation data to ensure high completion rates for the primary outcome. Several limitations are, however, worthy of further discussion. Firstly, the response to the postal follow-up questionnaires was poor, particularly at 12 months. However, questionnaire data were used to answer the secondary objectives rather than the primary objective which utilised data from consultation records, available for 69% of baseline responders. Furthermore, a sensitivity analysis using multiple imputation to account for loss to follow-up did not significantly alter our findings. Secondly, pain and physical function were measured using generic health status instruments, finding only small changes over time. Owing to questionnaire length, we could not include body region-specific questionnaires which might have been more sensitive to improvement. Thirdly, the study population was derived from a single geographical region and participants recruited from a single CATS which might limit the generalisability of our findings. Finally, we did not include a comparator cohort to allow a direct comparison to patients managed in other settings such as primary care, orthopaedics or rheumatology.

Our findings suggest that musculoskeletal CATS should be configured to address troublesome disabling pain since it is patients with the most bothersome symptoms who are most likely to re-consult either in primary care or at the CATS and to experience poor functional outcome. We have previously highlighted the complexity of patients referred from primary care to musculoskeletal CATS, showing chronic pain, major physical limitation, anxiety, depression and work disability to be highly prevalent.[8] Our finding that poor outcome is associated with pain interference, obesity, pain duration and physical impairment

1
2
3 raises the possibility that targeting specific treatments at people with certain modifiable risk
4 factors might improve outcome, as has been shown to be the case in other settings, for
5 example, stratified care using the STarT Back tool in people with low back pain in primary
6 care.[25] However, further research is needed to determine how to identify people at risk of
7 poor outcome from musculoskeletal problems and evaluate what targeted treatment should
8 consist of. Notwithstanding this important future research agenda, we suggest that
9 musculoskeletal services need to be resourced to provide a biopsychosocial model of care,
10 with appropriately trained clinical staff, and that services need the flexibility and resource to
11 offer follow-up appointments, where clinically indicated, in order to monitor progress, tailor
12 treatment to the individual and address clinical complexity.
13
14
15
16
17
18
19
20
21
22
23
24
25
26
27
28
29
30
31
32
33
34
35
36
37
38
39
40
41
42
43
44
45
46
47
48
49
50
51
52
53
54
55
56
57
58
59
60

ACKNOWLEDGEMENTS

The authors would like to thank the following people who contributed to the management and/or administration of the study either at the Arthritis Research UK Primary Care Centre or Stoke-on-Trent PCT: Joanne Bailey, Helen Duffy, Tina Gilbert, Rhian Hughes, Zoë Mayson, Janet Ough, Diane Stanyer, Vicki Taylor and Sue Weir. Professor Andrew Hassell led the funding application. The authors would also like to acknowledge the contribution of the research nurse teams at the Arthritis Research UK Primary Care Centre and Haywood Hospital, and the clinicians within Stoke-on-Trent PCT musculoskeletal and back pain interface services to data acquisition.

COMPETING INTERESTS

“All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) [initials of relevant authors] have support from [name of company] for the submitted work; (2) [initials of relevant authors] have [no or specified] relationships with [name of companies] that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have [specified] financial relationships that may be relevant to the submitted work; and (4) [initials of relevant authors] have no [or specified] non-financial interests that may be relevant to the submitted work.”

FUNDING

This work is supported by an Arthritis Research UK Integrated Clinical Arthritis Centre Grant (17684), the Arthritis Research UK Primary Care Centre Grant (18139), funding secured from Stoke-on-Trent Primary Care Trust (PCT), and service support through the West Midlands North CLRN. The study funders had no role in study design; in data collection, analysis, or interpretation; in the writing of the paper; or in the decision to submit the paper for publication. KS is part-funded by a NIHR Knowledge Mobilisation Fellowship (KMF-

2012-01-35). EH is a NIHR Senior Investigator. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

CONTRIBUTORSHIP STATEMENT

PD, EH and KS conceived of the study and secured funding. All authors participated in the design of the study and drafting of the manuscript, and read and approved the final manuscript. ER, IZ, PD, SH, JP, KS and EH participated in acquisition of data. Analysis was undertaken by YC, KJ, RO, and SJ. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. EH is guarantor.

ETHICAL APPROVAL

The study was approved by South Staffordshire Local Research Ethics Committee (REC reference number: 07 / H1203 / 86).

DATA SHARING

Data sharing: requests for further detail on the dataset and queries relating to data sharing arrangements may be submitted to the corresponding author. Participants did not give informed consent for data sharing although the presented data are anonymised and risk of identification is low.

REFERENCES

- [1] Papageorgiou AC, Croft PR, Thomas E et al. Influence of previous pain experience on the episode incidence of low back pain: results from the South Manchester Back Pain Study. *Pain* 1996;66:181-5.
- [2] Thomas E, Peat G, Croft P. Defining and mapping the person with osteoarthritis for population studies and public health. *Rheumatology (Oxford)* 2014;53:338-45.
- [3] Jordan KP, Jöud A, Bergknut C et al. International comparisons of the consultation prevalence of musculoskeletal conditions using population-based healthcare data from England and Sweden. *Ann Rheum Dis* 2014;73:212-8.
- [4] Global Burden of Disease Study 2013 Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;22;386(9995):743-800. doi: 10.1016/S0140-6736(15)60692-4. Epub 2015 Jun 7
- [5] Department of Health. The Musculoskeletal Services Framework. 2006. Published: 12/07/2006.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4138412.pdf
- [6] Maddison P, Jones J, Breslin A et al. Improved access and targeting of musculoskeletal services in northwest Wales: targeted early access to musculoskeletal services (TEAMS) programme. *BMJ* 2004;329:1325-7.
- [7] Dixey J, Bamji A. What is a rheumatologist for? *Rheumatology (Oxford)* 2007;46:377-378.
- [8] Roddy E, Zwierska I, Jordan KP et al. Musculoskeletal clinical assessment and treatment services at the primary-secondary care interface: an observational study. *Br J Gen Pract* 2013;63:e141-8.
- [9] Roddy E, Zwierska I, Dawes P et al. The Staffordshire Arthritis, Musculoskeletal, and Back Assessment (SAMBA) Study: a prospective observational study of patient

outcome following referral to a primary-secondary care musculoskeletal interface service. BMC Musculoskeletal Disorders 2010;11:67.

[10] Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.

[11] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-70

[12] Blyth FM, March LM, Brnabic AJ et al. Chronic pain in Australia: a prevalence study. Pain 2001;89:127-34.

[13] Thomas E, Peat G, Harris L et al. The prevalence of pain and pain interference in a general population of older adults: cross-sectional findings from the North Staffordshire Osteoarthritis Project (NorStOP). Pain 2004;110:361-8.

[14] Jordan KP, Thomas E, Peat G et al. Social risks for disabling pain in older people: a prospective study of individual and area characteristics. Pain 2008;137:652-61.

[15] The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. Health Policy 1990;16:199-208.

[16] NHS Information Authority. The clinical terms version 3 (The Read Codes). Birmingham: NHS Information Authority, 2000.

[17] BMJ Group. British National Formulary (BNF) 63. London: BMJ Group and RPS Publishing. 2012.

[18] Curtis L. Unit Costs of Health and Social Care 2012 PSSRU (Personal Social Services Research Unit). University of Kent: Canterbury. 2010.

[19] Department of Health. NHS Reference Costs. 2010/11. <https://www.gov.uk/government/publications/2010-11-reference-costs-publication>

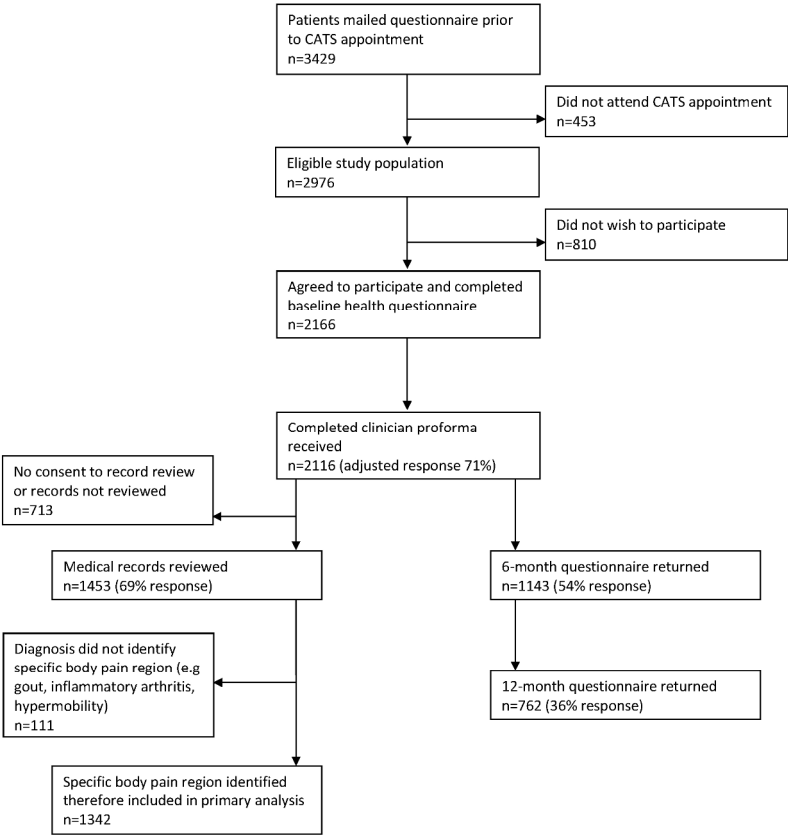
[20] Sephton R, Hough E, Roberts SA et al. Evaluation of a primary care musculoskeletal clinical assessment service: a preliminary study. Physiotherapy 2010;96:296-302.

[21] Tekavec E, Jöud A, Rittner R et al. Population-based consultation patterns in patients with shoulder pain diagnoses. BMC Musculoskeletal Disord 2012;13:238.

- [22] Paloneva J, Koskela S, Kautiainen H et al. Consumption of medical resources and outcome of shoulder disorders in primary health care consulters. BMC Musculoskeletal Disord 2013;14:348.
- [23] Jordan K, Jinks C, Croft P. A prospective study of the consulting behaviour of older people with knee pain. Br J Gen Pract 2006;56:269-76.
- [24] Menz HB, Jordan KP, Roddy E et al. Musculoskeletal foot problems in primary care: what influences older people to consult? Rheumatology (Oxford) 2010;49:2109-16.
- [25] Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011;378:1560-71.

Peer review only

Supplementary Figure – Flow of participants through the study



210x297mm (300 x 300 DPI)

Supplementary table 1 - comparison of baseline characteristics between those included and excluded from primary care record analysis

		Included	Excluded	Difference ^a (95% CI)
n		1453	713	
Female	n (%)	824 (57)	414 (58)	-1.4 (-5.8, 3.1)
Age	Mean (SD)	52.0 (14.9)	49.0 (15.8)	2.6 (1.3, 4.0) ^d
HADS depression	Mean (SD)	6.4 (4.4)	6.2 (4.3)	0.2 (-0.1, 0.6)
HADS anxiety	Mean (SD)	7.9 (4.7)	7.6 (4.6)	0.3 (-0.1, 0.7)
SF36 physical function	Mean (SD)	36.1 (12.1)	37.2 (11.9)	-1.1 (-2.1, 0.03)
SF36 body pain	Mean (SD)	34.1 (8.5)	35.1 (8.8)	-1.1 (-1.8, -0.3) ^d
Pain duration > 1year	n (%)	803 (55)	399 (56)	-0.8 (-5.2, 3.7)
Severe pain interference ^b	n (%)	819 (56)	370 (52)	4.4 (-0.02, 8.9)
Currently employed	n (%)	750 (52)	386 (55)	-2.7 (-7.2, 1.8)
Time off work ^c	n (%)	341 (46)	175 (45)	0.2 (-5.9, 6.3)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form-36; SD, standard deviation

^a difference in means or proportions as appropriate; ^b quite a bit or extremely; ^c due to musculoskeletal problem in the last 6 months in those currently employed; ^d p<0.05

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6,7
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	8,9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-10
		(b) Describe any methods used to examine subgroups and interactions	8,9
		(c) Explain how missing data were addressed	9
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10, Suppl figure
		(c) Consider use of a flow diagram	Suppl figure
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Suppl table, Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 3, 4

		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 1, 2
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Tables 1, 2 & 4 6-7, Table 1 Not given
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-21
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22-23

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

BMJ Open

Re-consultation, self-reported health status, and costs following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study



Journal:	BMJ Open
Manuscript ID	bmjopen-2016-011735.R2
Article Type:	Research
Date Submitted by the Author:	19-Sep-2016
Complete List of Authors:	Roddy, Edward; Keele University, Research Institute for Primary Care and Health Sciences; Keele University Jordan, Kelvin; Keele University, Arthritis Research UK Primary Care Centre Oppong, Ray; University of Birmingham, Health Economics Unit Chen, Ying; Keele University, Primary Care Sciences Jowett, Sue; University of Birmingham, Health Economics Unit Dawes, Peter; Haywood Hospital, Staffordshire Rheumatology Centre Hider, Samantha; Keele University, Arthritis Research UK Primary Care Centre; Packham, Jonathan; Haywood Hospital, Staffordshire Rheumatology Centre Stevenson, Kay; University Hospital of North Midlands, Physiotherapy Zwierska, Irena; Keele University, Research Institute for Primary Care and Health Sciences Hay, Elaine; Arthritis Research Primary Care Centre
Primary Subject Heading:	Rheumatology
Secondary Subject Heading:	General practice / Family practice, Health services research
Keywords:	RHEUMATOLOGY, Organisation of health services < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Rheumatology < INTERNAL MEDICINE, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY

SCHOLARONE™
Manuscripts

TITLE: Re-consultation, self-reported health status, and costs following treatment at a Musculoskeletal Clinical Assessment and Treatment Service (CATS): a twelve-month prospective cohort study

AUTHORS:

Edward Roddy^{1,2}, Kelvin P Jordan¹, Raymond Oppong³, Ying Chen¹, Sue Jowett³, Peter Dawes², Samantha L Hider^{1,2}, Jon Packham², Kay Stevenson^{1,2,4}, Irena Zwierska¹, Elaine M Hay^{1,2}

AFFILIATIONS:

¹Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK

²Staffordshire Rheumatology Centre, Haywood Hospital, High Lane, Burslem, Stoke-on-Trent, ST6 7AG, UK

³Health Economics Unit, School of Health and Population Sciences, University of Birmingham, Birmingham B15 2TT, UK

⁴Physiotherapy Department, University Hospital of North Midlands, Stoke-on-Trent, UK

CORRESPONDING AUTHOR:

Dr Edward Roddy, Arthritis Research UK Primary Care Centre, Research Institute for Primary Care and Health Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK.
Tel: 00 44 1782 734715 Fax: 00 44 1782 734719 e-mail: e.rodny@keele.ac.uk

KEYWORDS: Primary-secondary care interface, Musculoskeletal, Outcome, Pain, Healthcare costs

WORD COUNT: 3505 words

ABSTRACT

Objectives: To determine (1) re-consultation frequency, (2) change in self-reported health status, (3) baseline factors associated with re-consultation and change in health status, and (4) associated healthcare costs and quality-adjusted life-years (QALYs), following assessment at a musculoskeletal Clinical and Assessment Treatment Service (CATS).

Design: Prospective cohort study

Setting: Single musculoskeletal CATS at the primary-secondary care interface

Participants: 2166 CATS attenders followed-up by postal questionnaires at 6 and 12 months and review of medical records.

Outcome measures: Primary outcome was consultation in primary care with the same musculoskeletal problem within twelve months. Secondary outcome measures were consultation at the CATS with the same musculoskeletal problem within twelve months, physical function and pain (SF36), anxiety and depression (Hospital Anxiety and Depression Scale), time off work, healthcare costs and quality-adjusted life-years (QALYs).

Results: Over 12 months, 507 (38%) re-consulted for the same problem in primary care and 345 (26%) at the CATS. Primary care re-consultation in the first 3 months was associated with baseline pain interference (relative risk ratio 5.33; 95%CI 3.23, 8.80) and spinal pain (1.75; 1.09, 2.82), and after 3-6 months with baseline assessment by a hospital specialist (2.06; 1.13, 3.75). Small mean improvements were seen in physical function (1.88; 95%CI 1.44, 2.32) and body pain (3.86; 3.38, 4.34) at 6 months. Poor physical function at 6 months was associated with obesity, chronic pain, and poor baseline physical function. Mean (SD) 6-month cost and QALYs per patient were £422.40 (660.11) and 0.257 (0.144) respectively.

Conclusions: Whilst most patients are appropriate for a "one-stop shop" model, those with troublesome, disabling pain and spinal pain commonly re-consult and have ongoing problems. Services should be configured to identify and address such clinical complexity.

ARTICLE SUMMARY SECTION

Strengths and Limitations of this Study

- The largest study to date of outcome following treatment in a musculoskeletal CATS.
- The participation rate at baseline was high and use of routinely-collected consultation data ensured high completion rates for the primary outcome.
- Response to the postal follow-up questionnaires was poor, particularly at 12 months.
- Questionnaire length permitted inclusion of only generic measures of pain and physical function rather than body region-specific measures which might have been more sensitive to improvement.
- The study population was derived from a single geographical region and did not include a comparator cohort which might limit the generalisability of our findings.

INTRODUCTION

Musculoskeletal problems such as osteoarthritis (OA) and back pain are highly prevalent and present frequently to primary care. One-third of adults experience low back pain annually whereas 53% of older adults have symptomatic OA.[1,2] Annually in the UK, one-fifth of people consult their GP for a musculoskeletal condition and 4% of older adults consult for OA.[3] Musculoskeletal disorders were the largest cause of disability globally in 2013.[4]

Most of these people are managed entirely in primary care, with only a minority requiring specialist referral, traditionally to hospital-based orthopaedic and rheumatology services. Recently, patients requiring referral in the UK are increasingly managed in multidisciplinary Clinical Assessment and Treatment Services (CATS) at the primary-secondary care interface.[5,6] CATS act as a one-stop shop, providing rapid access to assessment, diagnostic investigations, treatment by appropriately-skilled healthcare practitioners, and onward referral pathways, aiming to provide more integrated care, and prevent chronicity, disability, and a cycle of reconsultation and referral to multiple services across primary and secondary care.[5-7] We have previously shown that chronic pain, physical disability, anxiety, depression, and work disability are prevalent amongst patients attending a musculoskeletal CATS, suggesting that these patients often already have chronic pain and are not being identified early, emphasising the need for appropriate early referral pathways to suitably skilled clinicians.[8] Little is known about patient outcome following treatment in this setting and if and how patients subsequently re-consult.

The objectives of this prospective study were (1) to determine the proportion of patients re-consulting in primary care and in a musculoskeletal CATS in the 12 months following baseline assessment at the CATS, (2) to assess baseline factors associated with re-consultation in primary care and at the CATS, (3) to determine change in self-reported health status at 6 and 12 months, (4) to assess baseline factors associated with change in self-reported health status, and (5) to estimate the health care costs and quality-adjusted life-years (QALYs) over 6 months associated with CATS attendance and determine whether these costs and QALYs differed by follow-up plan at baseline.

METHODS

This was a prospective observational study set within a musculoskeletal CATS in North Staffordshire, UK. The methods and baseline cross-sectional findings have been described previously.[8,9]

Study setting

At the time of baseline data collection, Stoke-on-Trent Primary Care Trust (PCT) served a population of more than 270,000 people. Referrals to secondary care musculoskeletal, rheumatology and orthopaedic services are triaged by clinicians to a multidisciplinary, musculoskeletal CATS at the primary-secondary care interface following review of referral letters, so that musculoskeletal conditions requiring non-surgical interventions are managed in the community, whilst appropriate cases are directed to rheumatology or orthopaedic services. The CATS is the preferred provider for patients with non-surgical, non-inflammatory musculoskeletal problems. Patients are triaged to unselected general musculoskeletal clinics within the CATS, where the type of healthcare professional patient seen (physiotherapist, rheumatologist, rehabilitation medicine specialist, or GP with a special interest (GPwSI)) and the clinic in which they are seen are not determined by the index referred condition. The sole exception to this is a physiotherapist-led back pain clinic. A greater proportion of patients with back pain therefore see a physiotherapist compared to other conditions.

Data collection

All adults aged ≥18 years seen at the CATS between February 2008 and June 2009 were invited to participate. Those who consented to take part completed a health questionnaire prior to their CATS appointment. Participants were also asked to provide consent for the research team to review their medical records, which provided data to answer the primary

outcome of consultation in primary care with the same musculoskeletal problem within twelve months.

Baseline measures

The questionnaire included physical functioning and body pain scales from the the Short Form-36 (SF-36) version 2 (general population mean = 50; scores <50 represent worse health).[10] Anxiety and depression were measured using the Hospital Anxiety and Depression Scale (HADS, range 0-14; scores ≥ 8 on either scale representing possible or probable anxiety or depression).[11] The presence of pain that interfered with daily activities was measured using one item from the SF-36: 'During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?'.[10] Respondents answering 'moderately', 'quite a bit' or 'extremely' were defined as having pain interference, whilst responding 'quite a bit' or 'extremely' represented severe pain interference.[12-14] Cohabitation status, self-reported height/weight, musculoskeletal pain duration and work absence in the preceding 6 months because of musculoskeletal problems were also collected. The EuroQoL-3L (EQ-5D 3L) was included, in order to calculate QALYs.[15]

The clinician conducting the CATS consultation completed a brief proforma but did not see the patient's completed questionnaire. The clinician proforma recorded the location of pain addressed in the consultation (used to group participants into four mutually exclusive categories: upper limb or neck alone, spine alone, lower limb alone or multiple sites), investigations, interventions, referrals and follow-up plan. Participants were regarded as having pain in multiple sites if the clinician recorded locations from two or more of the upper limb/neck, spine, or lower limb, or recorded a diagnosis of fibromyalgia, chronic widespread pain, generalised osteoarthritis, or polymyalgia rheumatica. Follow-up was categorised as referral to other services (eg rheumatology, orthopaedics, physiotherapy), CATS follow-up, discharge to the GP, or to be decided following investigations. If the follow-up plan was

dependent upon investigation results, follow-up information for those participants who consented to medical record review was extracted from CATS records. The clinician profession was also recorded. Due to the low number of rehabilitation medicine specialists, we combined these with rheumatologists (referred to hereafter as hospital specialists). We also recorded whether patients were attending a general musculoskeletal clinic or the physiotherapist-led back pain clinic described above.

Follow-up questionnaires

A self-administered questionnaire containing the same measures as at baseline was mailed at 6 and 12 months to all consenting participants. Non-responders were sent a postcard reminder after 2 weeks and a repeat questionnaire after 4 weeks.

Medical record review

In participants consenting to medical record review, information was extracted from primary care records for the 12 months following baseline. Due to the large number of general practices ($n=114$ including 49 with fewer than 10 patients), it was unfeasible to examine the records of all patients and so a pragmatic decision was made to extract records from the 57 most accessible practices with the highest number of participants. Records were downloaded electronically where possible but where software was incompatible with the practice, information was extracted manually using a proforma. The information extracted was date of any musculoskeletal consultation in primary care, and date of a musculoskeletal consultation for the same body location (neck, shoulder, elbow, hand/wrist, spine, hip, knee, foot/ankle) as recorded by the clinician at baseline. Musculoskeletal consultations were identified using the Read code system which is commonly used to record morbidity in UK primary care.[16] Free-text narrative data were not extracted from the medical record. We identified the date of any further attendance at the CATS for the same body location in all participants who consented to medical record review through manual review of CATS records.

Sample size

At the time of baseline data collection, approximately 3500 patients were seen in the CATS annually. Based on previous studies, we expected 75% of these to participate at baseline (n=2625), and 75% of these to separately consent to further postal contact and medical record review (n=2000 each). Whilst we aimed to review records of as many patients as feasible, as an example, a sample size of 1125 is sufficient to determine the percentage making a repeat primary care consultation during 12 months follow-up with a margin of error of 3% and a 95% confidence level, based on an estimate of 50%.

Statistical analysis

We compared baseline responders with extracted medical record data with all other baseline responders on baseline socio-demographic, pain characteristics, and general health. The percentage consulting for a musculoskeletal problem in primary care in the 12 months after baseline was determined. The primary analysis was based on the time to consulting in primary care about the same body location which was addressed at the baseline CATS consultation. We split time to first consultation to primary care into no consultation during 12-month follow-up, first consultation within 3 months (early), between 3-6 months, and between 6-12 months after baseline clinic assessment (late). We used these categories rather than actual time as it was evident that the baseline factors associated with first primary care attendance changed over the 12-month time-period, and it was considered that attendance to primary care within 3 months may be at the request of the CATS clinician. Multinomial logistic regression was used to determine the association of follow-up plan and clinician profession with time of consultation to primary care adjusted for self-reported (age, gender, cohabitation, pain interference and duration, body mass index, anxiety and depression) and clinician-reported (body region, musculoskeletal or back pain clinic) factors. No repeat consultation was treated as the reference category. Results are reported as adjusted relative risk ratios (RRR) with 95% confidence intervals (95%CI).

Secondary outcomes were re-consultation at the CATS during 12 months follow-up and self-reported health (physical function, body pain, anxiety and depression, and time off work in those employed at baseline) at 6 months and 12 months. Binary logistic regression was used to assess association of clinician profession and follow-up plan with re-consultation at the CATS about the same body location as at the baseline clinic at any point during the 12 months, adjusting for the same factors included in the primary outcome analysis. Results are presented as odds ratios (OR) with 95%CI. Multiple linear regression was used to assess the association of clinician profession and follow-up plan with physical function score at follow-up adjusted for baseline score and for the same baseline self-reported and clinician-reported factors as included in the analysis of primary care consultation (except pain interference as it was highly correlated with baseline physical function).

Two sensitivity analyses were performed. Firstly, as primary care medical record information was not available for everyone, we performed multiple imputation with 50 imputations and again repeated the analysis. Secondly, because of the attrition at follow-up, the analysis of self-reported physical function at 6 months was repeated using multiple imputed data for those not responding at follow-up.

Analysis of health care costs and quality-adjusted life-years

The health economic analysis was conducted from a healthcare perspective and focused on estimating the costs and QALYs arising from attending the CATS. Resource use data were collected from the clinician proforma and 6-month questionnaire. The proforma recorded investigations and interventions that patients received, whilst the questionnaire asked about the number and type of health professionals seen, medication taken, and the number of interventions. Unit costs for individual resource use items were obtained from sources such as the British National Formulary (BNF), Personal Social Services Research Unit, and NHS reference costs.[17-19] The analysis was limited to those who completed the questionnaire.

In order to value the resource use items, we multiplied resource use by unit costs and estimated a total cost per patient by summing up the costs associated with each resource use item. The area under the curve approach was used to estimate QALYs using EQ-5D responses at baseline and 6 months. Multiple regression was used to estimate mean total cost and QALYs by follow-up plan controlling for body region, age, BMI, anxiety and depression, pain interference and baseline EQ-5D. Bootstrapping (1000 replications) was used to estimate bias-corrected confidence intervals around differences in mean costs and QALYs between groups using patients who were referred to other specialities as the reference category.

RESULTS

As reported previously,[8] 3429 patients were mailed the baseline questionnaire of whom 453 (13%) did not attend their CATS appointment. 2166 consented to participate at baseline, from whom 2116 clinician proformas were completed (adjusted response 71%). Of these, 1453 (69%) had their medical records reviewed and did not have a primary care musculoskeletal consultation on the same day as their CATS appointment (**supplementary figure**). Compared to those responding but not undergoing record review, these participants were older (mean difference 2.6 years, 95%CI 1.3,4.0) and had slightly worse levels of pain, but no differences on gender, anxiety, depression, physical functioning, pain duration, pain interference, employment status or time off work (**supplementary table**).

Consultation in primary care during 12-month follow-up

Of the 1453 for whom record data were collected, 1342 were included in the primary outcome analysis as the remainder received other diagnoses such as gout, inflammatory arthritis, and joint hypermobility, and hence a specific body region was not available to link subsequent consultations to (**supplementary figure**). Of these, 507 (38%, 95%CI 35%,40%) consulted primary care during 12 months follow-up for the same body region as addressed at the baseline clinic assessment. Median number of days to consulting primary

care was 69 (IQR 27,159): 289 (22%) consulted within 3 months and 403 (30%) within 6 months. There was no association between the type of professional seen at baseline and consulting in the first 3 months but those seeing a hospital specialist were more likely to first return to primary care between 3 and 6 months after their CATS visit (adjusted RRR 2.06; 95%CI 1.13,3.75 compared to GPwSI) and between 6 and 12 months (2.08; 1.12,3.88) (**table 1**). The strongest association with consulting within the first six months was with severe pain interference at baseline (within 3 months: 5.33; 3.23,8.80 compared to no pain interference; 3-6 months 2.26; 1.25,4.09). Those consulting with a spine problem were more likely to consult primary care in the first 3 months (1.75; 1.09,2.82) or after 6-12 months (2.17; 1.06,4.47) compared to having an upper limb or neck problem. Those with anxiety or depression were less likely to first consult primary care between 6 and 12 months (0.60; 0.38, 0.95). There was no association of gender, cohabitation status, follow-up plan, pain duration, or BMI with primary care consultation.

Analysis based on multiple imputation data yielded similar estimates and CIs to those from the analysis for those whose records were reviewed.

Table 1 - Associations with time after baseline assessment of first primary care consultation for musculoskeletal problem in same body location as at baseline CATS consultation

		0-3m (early)	3-6m	6-12m (late)	
Total consulting (% consulting)		507 (38)	289 (22)	114 (8)	104 (8)
		<i>n</i> (% consulting)	Adjusted RRR ^a (95% CI)		
Male		586 (37)	1.00	1.00	1.00
Female		756 (38)	1.05 (0.79, 1.42)	0.96 (0.64, 1.46)	0.78 (0.51, 1.20)
Age (years)	18-44	424 (37)	1.00	1.00	1.00
	45-64	633 (38)	1.11 (0.80, 1.55)	1.11 (0.68, 1.81)	1.03 (0.63, 1.70)
	≥65	285 (38)	0.92 (0.60, 1.41)	1.33 (0.75, 2.36)	1.38 (0.77, 2.48)
Living alone:	No	1140 (38)	1.00	1.00	1.00
	Yes	202 (39)	0.76 (0.49, 1.18)	1.33 (0.79, 2.23)	1.40 (0.80, 2.45)
Professional seen: GPwSI		309 (29)	1.00	1.00	1.00
Hospital specialist		359 (39)	1.25 (0.82, 1.92)	2.06 (1.13, 3.75)^b	2.08 (1.12, 3.88)^b
Physiotherapist		674 (41)	1.16 (0.77, 1.73)	1.58 (0.88, 2.84)	1.40 (0.76, 2.60)
Region at clinic:	Upper limb/neck	436 (32)	1.00	1.00	1.00
	Spine	347 (52)	1.75 (1.09, 2.82) ^b	1.12 (0.56, 2.24)	2.17 (1.06, 4.47)^b
	Lower limb	454 (31)	0.87 (0.60, 1.28)	0.86 (0.53, 1.41)	1.38 (0.81, 2.36)
	Multiple regions	105 (42)	1.16 (0.66, 2.04)	0.97 (0.44, 2.14)	1.77 (0.78, 4.02)
Follow-up plan:	Referred	492 (38)	1.00	1.00	1.00
	Followed-up	145 (47)	1.28 (0.80, 2.06)	1.28 (0.65, 2.50)	0.86 (0.36, 2.10)
	Discharged	637 (35)	0.95 (0.69, 1.30)	0.75 (0.48, 1.17)	1.39 (0.87, 2.21)
	Unknown	68 (46)	1.40 (0.71, 2.75)	1.29 (0.53, 3.13)	1.87 (0.79, 4.46)

Pain duration:	<12months	603 (37)	1.00	1.00	1.00
	>12months	738 (38)	0.80 (0.60, 1.07)	0.91 (0.60, 1.37)	1.28 (0.82, 1.98)
Pain interference:	No/little bit	300 (22)	1.00	1.00	1.00
	Moderately	295 (29)	2.38 (1.37, 4.14)^b	1.07 (0.54, 2.13)	0.72 (0.38, 1.37)
	Quite a bit/extremely	746 (47)	5.33 (3.23, 8.80)^b	2.26 (1.25, 4.09)^b	1.35 (0.78, 2.33)
BMI:	Normal	382 (35)	1.00	1.00	1.00
	Overweight	484 (36)	1.18 (0.82, 1.71)	0.77 (0.46, 1.30)	1.07 (0.61, 1.86)
	Obese	439 (42)	1.28 (0.88, 1.87)	1.16 (0.70, 1.93)	1.63 (0.95, 2.82)
	Unknown	37 (38)	0.89 (0.35, 2.23)	1.37 (0.47, 3.94)	0.86 (0.19, 3.97)
Anxious/depressed:	No	606 (34)	1.00	1.00	1.00
	Yes	736 (41)	1.02 (0.75, 1.40)	0.97 (0.62, 1.50)	0.60 (0.38, 0.95) ^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; RRR, relative risk ratios

^a Multinomial logistic regression $n=1340$ (2 participants omitted due to missing data). Relative risk ratios adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), reference group is no musculoskeletal consultation, ^b $p<0.05$

Percentages are row percentages

Re-consultation at the CATS during 12-month follow-up

345 (26%) re-consulted at the CATS during 12-months follow-up for a musculoskeletal problem in the same body location as assessed at baseline. The clinician stating they would follow-up the patient (adjusted OR 9.97; 95%CI 6.36, 15.62) was most strongly associated with re-consultation at the CATS whilst being discharged (1.54; 1.13, 2.10) was also significantly associated (**table 2**). Patients seeing a hospital specialist were more likely to re-consult in the CATS (OR 1.68; 95%CI 1.14, 2.49 compared to GPwSI). Severe pain interference and shorter pain duration were also associated with re-consultation.

Table 2 - Associations with return to interface clinic during 12-month follow-up for musculoskeletal problem in same body location as baseline CATS consultation

	Total <i>n</i> (% with appointment)	OR (95% CI)	Adjusted OR ^a (95% CI)
Total	1342 (26)		
Male	586 (25)	1.00	1.00
Female	756 (26)	1.07 (0.84, 1.28)	1.10 (0.83, 1.45)
Age (years) 18-44	424 (23)	1.00	1.00
45-64	633 (27)	1.23 (0.93, 1.64)	1.35 (0.98, 1.86)
≥65	285 (27)	1.21 (0.86, 1.71)	1.41 (0.95, 2.09)
Living alone: No	1140 (26)	1.00	1.00
Yes	202 (23)	0.83 (0.58, 1.18)	0.89 (0.60, 1.32)
Professional seen: GPwSI	309 (23)	1.00	1.00
Hospital specialist	359 (26)	1.15 (0.81, 1.64)	1.68 (1.14, 2.49)^b
Physiotherapist	674 (27)	1.20 (0.88, 1.64)	0.91 (0.62, 1.34)
Region at clinic: Upper limb/neck	436 (27)	1.00	1.00
Spine	347 (35)	1.48 (1.09, 2.01)^b	0.84 (0.53, 1.35)
Lower limb	454 (17)	0.54 (0.39, 0.75)^b	0.59 (0.41, 0.83)^b
Multiple regions	105 (30)	1.14 (0.71, 1.83)	1.05 (0.63, 1.77)
Follow-up plan: Referred	492 (17)	1.00	1.00
Followed-up	145 (68)	10.61 (6.96, 16.17)^b	9.97 (6.36, 15.62)^b
Discharged	637 (23)	1.50 (1.12, 2.03)^b	1.54 (1.13, 2.10)^b
Unknown	68 (21)	1.28 (0.68, 2.41)	1.19 (0.62, 2.29)

Pain duration:	<12months	603 (27)	1.00	1.00
	>12months	738 (24)	0.85 (0.66, 1.09)	0.75 (0.57, 0.99)^b
Pain interference:	No/little bit	300 (19)	1.00	1.00
	Moderately	295 (25)	1.49 (1.00, 2.20)^b	1.53 (1.00, 2.35)
	Quite a bit/extremely	746 (29)	1.75 (1.26, 2.44)^b	1.64 (1.11, 2.42)^b
BMI	Normal	382 (25)	1.00	1.00
	Overweight	484 (26)	1.03 (0.76, 1.41)	1.10 (0.78, 1.55)
	Obese	439 (26)	1.06 (0.77, 1.44)	1.12 (0.79, 1.58)
	Unknown	37 (16)	0.57 (0.23, 1.40)	0.45 (0.17, 1.22)
Anxious/depressed:	No	606 (25)	1.00	1.00
	Yes	736 (26)	1.06 (0.83, 1.36)	0.92 (0.68, 1.23)

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest; OR, odds ratio

^a Binary logistic regression $n=1340$ (2 participants omitted due to missing data). Adjusted for all presented variables and type of clinic attended (general musculoskeletal or physiotherapist-led back pain clinic), referent group is no follow-up appointment

^b $p < 0.05$

Percentages are row percentages

Self-reported health and time-off work

1143 (54%) of the 2116 baseline responders with a completed clinician proforma completed the follow-up questionnaire at 6 months and 762 (36%) at 12 months. 6-month responders were older (mean age 54.9 vs 46.4) compared to non-responders and had lower levels of anxiety and depression. However, they did not differ according to pain, physical function, or the type of clinician seen at baseline. Responders showed some improvement at 6 months in body pain (mean change 3.86; 95%CI 3.38,4.34; effect size equivalent 0.47) whereas a smaller change was seen in physical functioning (mean change 1.88; 95%CI 1.44,2.32; effect size equivalent 0.16) (**table 3**). The percentage with severe pain interference fell from 54% to 40% at 6 months, whilst the percentage taking time off work due to their musculoskeletal problem fell from 42% to 33%. However, there was no change in anxiety or depression levels, nor was there any further change in any of these measures at 12 months. Given the high attrition at 12 months, and the lack of change at the population level between

6 and 12 months, the remainder of the self-reported analysis concentrated on the 6-month time-point.

Type of clinician seen and follow-up plan did not associate with physical function at 6 months (**table 4**). Females, older adults, those who were obese, those with pain duration of more than 12 months, and those with worse physical function at baseline had the worst outcomes at 6 months. For example, those with pain duration longer than 12 months at baseline had a mean PF score at 6 months around 2 points worse than those with shorter pain duration (adjusted mean difference -1.93; 95% CI -2.83, -1.03). Sensitivity analysis based on multiple imputation data made little difference to these estimates and CIs.

Table 3 – Self-reported change in physical and mental health status, time off work and pain interference at 6 and 12 months

	Baseline ^a	6 months	12 months
	Mean (SD)	Mean change ^b (95% CI)	Mean change ^b (95% CI)
HADS depression	6.1 (4.2)	-0.02 (-0.20, 0.16)	-0.13 (-0.35, 0.09)
HADS anxiety	7.5 (4.6)	0.03 (-0.16, 0.22)	-0.02 (-0.26, 0.22)
SF36 physical function	36.4 (11.9)	1.88 (1.44, 2.32)	1.82 (1.24, 2.39)
SF36 body pain	34.5 (8.3)	3.86 (3.38, 4.34)	4.19 (3.55, 4.83)
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Time off work ^c	219 (42)	169 (33)	110 (33)
Anxious / depressed	588 (53)	591 (53)	390 (52)
Pain interference			
Not at all / a little	258 (23)	429 (38)	284 (38)
Moderately	261 (23)	247 (22)	178 (24)
Quite a bit / extremely	606 (54)	449 (40)	289 (38)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SD, standard deviation; SF-36, Short Form-36

^a in those responding at 6 months

^b positive mean change indicates improvement

^c in those currently employed at baseline *n*=519. At 6 and 12 months, time off work includes those no longer employed

Number in analysis for baseline & 6 months: 1118 (depression), 1115 (anxiety), 1124 (physical function), 1109 (body pain), 519 (time off work), 1115 (anxiety/depression), 1125 (interfering pain)
Number in analysis for 12 months: 748 (depression), 748 (anxiety), 754 (physical function), 745 (body pain), 332 (time off work), 748 (anxiety/depression), 751 (interfering pain)

Table 4 – 6-month follow-up Physical Functioning (PF) score by baseline factors

	Adjusted for baseline PF score only Coeff (95% CI)	Adjusted for all variables Coeff (95% CI)
Female (referent: male)	-0.84 (-1.73, 0.06)	-0.90 (-1.80, 0.00)^b
Age (years) (referent: 18-44)		
45-64	-1.41 (2.50, -0.33)	-1.27 (-2.36, -0.17)^b
≥65	-2.94 (-4.21, -1.67)^b	-2.87 (-4.19, -1.55)^b
Living alone (referent: not living alone)	-1.14 (-2.37, 0.09)	-0.53 (-1.77, 0.72)
Professional seen (referent: GPwSI)		
Hospital specialist	0.05 (-1.17, 1.27)	-0.24 (-1.45, 0.97)
Physiotherapist	0.69 (-0.40, 1.77)	-0.32 (-1.48, 0.84)
Region at clinic (referent: upper limb/neck)		
Spine	2.02 (0.82, 3.21)^b	0.52 (-1.02, 2.05)
Lower limb	-0.05 (-1.20, 1.10)	-0.47 (-1.62, 0.68)
Multiple regions	-0.34 (-1.89, 1.20)	-0.58 (-2.13, 0.96)
Other	0.07 (-2.10, 2.23)	-0.72 (-2.87, 1.43)
Follow-up plan (referent: Referred)		
Followed-up	0.05 (-1.45, 1.56)	-0.91 (-2.45, 0.63)
Discharged	0.23 (-0.75, 1.21)	0.12 (-0.85, 1.09)
Unknown	-0.48 (-2.26, 1.30)	-0.58 (-2.33, 1.17)
Pain duration >12months (referent <12months)	-1.99 (-2.90, -1.09)^b	-1.93 (-2.83, -1.03)^b
BMI (referent: normal BMI)		
Overweight	0.30 (-0.77, 1.36)	0.17 (-0.89, 1.22)
Obese	-1.59 (-2.75, -0.43)^b	-1.58 (-2.74, -0.43)^b
Unknown	-1.65 (-4.38, 1.08)	-1.09 (-3.80, 1.63)
Anxious/depressed (referent: not anxious/depressed)	-0.65 (-1.59, 0.29)	-0.81 (-1.75, 0.12)
Baseline PF score ^a	0.87 (0.82, 0.92)^b	0.79 (0.75, 0.84)^b

BMI, body mass index; CI, confidence interval; GPwSI, general practitioner with a special interest, PF, physical function;

Coefficient is adjusted mean difference in PF score at follow-up compared to referent, with positive coefficient indicating higher (better) PF score Complete data only, $n=1124$

^a per unit PF score at baseline

^b $p<0.05$

Health care costs and QALYs

The overall mean (SD) cost per patient incurred by attending the CATS was £422.40 (660.11) over the 6-month period. The mean cost associated with patients who were discharged was significantly lower than those who were referred to other specialities (mean difference £-132.57; 95%CI: -226.78,-49.54) (**table 5**). Costs associated with patients in the other groups (followed up and unknown) were not significantly different from costs associated with patients who were referred (**table 5**).

Across all participants, the mean (SD) QALYs per patient over the 6-month period was 0.257 (0.144). There was no significant difference in mean QALYs between patients who were referred to other specialities and any other group.

Table 5 – Mean costs and quality-adjusted life-years (QALYs) over 6 months according to follow-up plan

	Mean cost ^a	Mean difference (95% CI) ^b	Mean QALYs ^a	Mean difference (95% CI) ^b
Referred (n=405)	£497.55		0.2572	
Followed up (n=124)	£437.18	£-60.37 (-172.68, 67.36) ^c	0.2566	-0.001 (-0.014, 0.014) ^c
Discharged (n=526)	£364.98	£-132.57 ^d (-226.78, -49.54) ^c	0.2591	0.002 (-0.006, 0.009) ^c
Unknown (n=82)	£397.23	£-100.32 (-227.19, 93.92) ^c	0.2498	-0.007 (-0.020, 0.005) ^c

^a Values are predicted means obtained from multiple regression controlling for body region, age, body mass index, anxiety, depression, pain interference and baseline EQ-5D

^b Compared to patients who were referred

^c Bootstrapped confidence interval

^d $p<0.05$

DISCUSSION

After assessment in a musculoskeletal CATS, nearly 40% of people consulted primary care about the same problem within 12 months, with over half of these consulting within three

months. Similarly, a quarter of patients re-consult in the CATS within 12 months. People with pain interference and spinal pain were more likely to re-consult. Over 6 months, only small changes were seen in body pain and physical function, and in the proportion reporting pain interference and taking time off work because of their musculoskeletal problem. Functional outcome was worst in those with older age, obesity, chronicity and pre-existing physical impairment. The cost-outcome description found that follow-up plan to see again in the CATS or to refer to another specialty attracted higher mean costs.

The explanations for frequent reconsultation are likely to be multifactorial, and our study design cannot elucidate these. It may be that patients were advised to visit their GP for change in medication, they re-consulted to obtain a repeat prescription, the CATS consultation failed to adequately meet patients' expectations, and/or their symptoms did not improve. The observation that patients assessed by hospital specialists were more likely to re-consult could be explained by specialists advising further consultation in primary care, for example to change medication, rather than this reflecting poor outcome. The findings that people with pain interference (either setting) and spinal pain (primary care) were more likely to consult and worse functional outcome was associated with older age, obesity, chronicity and pre-existing physical impairment suggest that the current model-of-care does not meet the needs of those with the most troublesome symptoms. An unexpected finding that we find difficult to explain was that people with anxiety or depression were less likely to first consult primary care between 6 and 12 months.

There are few suitable cohorts to compare our findings to. In a study undertaken in a physiotherapist-led CATS, small improvements were reported in pain and general health (EQ-5D) over 12 months but no change was seen in the SF-36.[20] Most improvement occurred within 3 months but was less likely in people with spinal pain and chronic symptoms. Repeat consultation was not examined. Several studies have found similar rates of repeat musculoskeletal consultations in primary care following an initial primary care consultation. One-third to one-half of primary care shoulder pain consultants in Scandinavia re-consult within 12 months.[21,22] We have previously shown that 34% of knee pain

1
2
3 consulters and 22% of foot pain consulters consult again in primary care with the same
4
5 problem over 18 months.[23,24]
6

7 This is the largest study to date of outcome following treatment in musculoskeletal
8
9 CATS. Strengths of the study are the high participation rate at baseline (73%) and use of
10
11 routinely-collected consultation data to ensure high completion rates for the primary
12
13 outcome. Several limitations are, however, worthy of further discussion. Firstly, the response
14
15 to the postal follow-up questionnaires was poor, particularly at 12 months. However,
16
17 questionnaire data were used to answer the secondary objectives rather than the primary
18
19 objective which utilised data from consultation records, available for 69% of baseline
20
21 responders. Furthermore, a sensitivity analysis using multiple imputation to account for loss
22
23 to follow-up did not significantly alter our findings. Secondly, pain and physical function were
24
25 measured using generic health status instruments, finding only small changes over time.
26
27 Owing to questionnaire length, we could not include body region-specific questionnaires
28
29 which might have been more sensitive to improvement. Thirdly, the study population was
30
31 derived from a single geographical region and participants recruited from a single CATS
32
33 which might limit the generalisability of our findings. Finally, we did not include a comparator
34
35 cohort to allow a direct comparison to patients managed in other settings such as primary
36
37 care, orthopaedics or rheumatology.
38

39 Our findings suggest that musculoskeletal CATS should be configured to address
40
41 troublesome disabling pain since it is patients with the most bothersome symptoms who are
42
43 most likely to re-consult either in primary care or at the CATS and to experience poor
44
45 functional outcome. We have previously highlighted the complexity of patients referred from
46
47 primary care to musculoskeletal CATS, showing chronic pain, major physical limitation,
48
49 anxiety, depression and work disability to be highly prevalent.[8] Our finding that poor
50
51 outcome is associated with pain interference, obesity, pain duration and physical impairment
52
53 raises the possibility that targeting specific treatments at people with certain modifiable risk
54
55 factors might improve outcome, as has been shown to be the case in other settings, for
56
57 example, stratified care using the STarT Back tool in people with low back pain in primary
58
59
60

care.[25] However, further research is needed to determine how to identify people at risk of poor outcome from musculoskeletal problems and evaluate what targeted treatment should consist of. Notwithstanding this important future research agenda, we suggest that musculoskeletal services need to be resourced to provide a biopsychosocial model of care, with appropriately trained clinical staff, and that services need the flexibility and resource to offer follow-up appointments, where clinically indicated, in order to monitor progress, tailor treatment to the individual and address clinical complexity.

ACKNOWLEDGEMENTS

The authors would like to thank the following people who contributed to the management and/or administration of the study either at the Arthritis Research UK Primary Care Centre or Stoke-on-Trent PCT: Joanne Bailey, Helen Duffy, Tina Gilbert, Rhian Hughes, Zoë Mayson, Janet Ough, Diane Stanyer, Vicki Taylor and Sue Weir. Professor Andrew Hassell led the funding application. The authors would also like to acknowledge the contribution of the research nurse teams at the Arthritis Research UK Primary Care Centre and Haywood Hospital, and the clinicians within Stoke-on-Trent PCT musculoskeletal and back pain interface services to data acquisition.

COMPETING INTERESTS

“All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that (1) [initials of relevant authors] have support from [name of company] for the submitted work; (2) [initials of relevant authors] have [no or specified] relationships with [name of companies] that might have an interest in the submitted work in the previous 3 years; (3) their spouses, partners, or children have [specified] financial relationships that may be relevant to the submitted work; and (4) [initials of relevant authors] have no [or specified] non-financial interests that may be relevant to the submitted work.”

FUNDING

This work is supported by an Arthritis Research UK Integrated Clinical Arthritis Centre Grant (17684), the Arthritis Research UK Primary Care Centre Grant (18139), funding secured from Stoke-on-Trent Primary Care Trust (PCT), and service support through the West Midlands North CLRN. The study funders had no role in study design; in data collection, analysis, or interpretation; in the writing of the paper; or in the decision to submit the paper for publication. KS is part-funded by a NIHR Knowledge Mobilisation Fellowship (KMF-

2012-01-35). EH is a NIHR Senior Investigator. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

CONTRIBUTORSHIP STATEMENT

PD, EH and KS conceived of the study and secured funding. All authors participated in the design of the study and drafting of the manuscript, and read and approved the final manuscript. ER, IZ, PD, SH, JP, KS and EH participated in acquisition of data. Analysis was undertaken by YC, KJ, RO, and SJ. All authors had full access to all of the data (including statistical reports and tables) in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. EH is guarantor.

ETHICAL APPROVAL

The study was approved by South Staffordshire Local Research Ethics Committee (REC reference number: 07 / H1203 / 86).

DATA SHARING

Data sharing: requests for further detail on the dataset and queries relating to data sharing arrangements may be submitted to the corresponding author. Participants did not give informed consent for data sharing although the presented data are anonymised and risk of identification is low.

REFERENCES

- [1] Papageorgiou AC, Croft PR, Thomas E et al. Influence of previous pain experience on the episode incidence of low back pain: results from the South Manchester Back Pain Study. *Pain* 1996;66:181-5.
- [2] Thomas E, Peat G, Croft P. Defining and mapping the person with osteoarthritis for population studies and public health. *Rheumatology (Oxford)* 2014;53:338-45.
- [3] Jordan KP, Jöud A, Bergknut C et al. International comparisons of the consultation prevalence of musculoskeletal conditions using population-based healthcare data from England and Sweden. *Ann Rheum Dis* 2014;73:212-8.
- [4] Global Burden of Disease Study 2013 Collaborators. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: a systematic analysis for the Global Burden of Disease Study 2013. *Lancet*. 2015;22;386(9995):743-800. doi: 10.1016/S0140-6736(15)60692-4. Epub 2015 Jun 7
- [5] Department of Health. The Musculoskeletal Services Framework. 2006. Published: 12/07/2006.
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4138412.pdf
- [6] Maddison P, Jones J, Breslin A et al. Improved access and targeting of musculoskeletal services in northwest Wales: targeted early access to musculoskeletal services (TEAMS) programme. *BMJ* 2004;329:1325-7.
- [7] Dixey J, Bamji A. What is a rheumatologist for? *Rheumatology (Oxford)* 2007;46:377-378.
- [8] Roddy E, Zwierska I, Jordan KP et al. Musculoskeletal clinical assessment and treatment services at the primary-secondary care interface: an observational study. *Br J Gen Pract* 2013;63:e141-8.
- [9] Roddy E, Zwierska I, Dawes P et al. The Staffordshire Arthritis, Musculoskeletal, and Back Assessment (SAMBA) Study: a prospective observational study of patient

outcome following referral to a primary-secondary care musculoskeletal interface service. BMC Musculoskeletal Disorders 2010;11:67.

[10] Ware JE, Jr., Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473-83.

[11] Zigmond AS, Snaith RP. The hospital anxiety and depression scale. Acta Psychiatr Scand 1983;67:361-70

[12] Blyth FM, March LM, Brnabic AJ et al. Chronic pain in Australia: a prevalence study. Pain 2001;89:127-34.

[13] Thomas E, Peat G, Harris L et al. The prevalence of pain and pain interference in a general population of older adults: cross-sectional findings from the North Staffordshire Osteoarthritis Project (NorStOP). Pain 2004;110:361-8.

[14] Jordan KP, Thomas E, Peat G et al. Social risks for disabling pain in older people: a prospective study of individual and area characteristics. Pain 2008;137:652-61.

[15] The EuroQol Group. EuroQol - a new facility for the measurement of health-related quality of life. Health Policy 1990;16:199-208.

[16] NHS Information Authority. The clinical terms version 3 (The Read Codes). Birmingham: NHS Information Authority, 2000.

[17] BMJ Group. British National Formulary (BNF) 63. London: BMJ Group and RPS Publishing. 2012.

[18] Curtis L. Unit Costs of Health and Social Care 2012 PSSRU (Personal Social Services Research Unit). University of Kent: Canterbury. 2010.

[19] Department of Health. NHS Reference Costs. 2010/11. <https://www.gov.uk/government/publications/2010-11-reference-costs-publication>

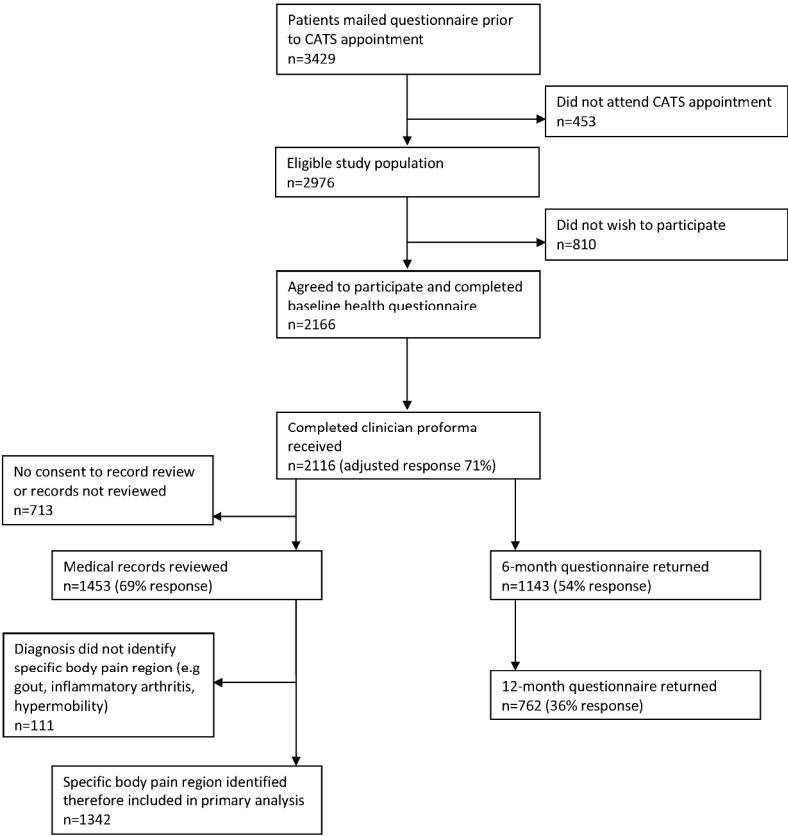
[20] Sephton R, Hough E, Roberts SA et al. Evaluation of a primary care musculoskeletal clinical assessment service: a preliminary study. Physiotherapy 2010;96:296-302.

[21] Tekavec E, Jöud A, Rittner R et al. Population-based consultation patterns in patients with shoulder pain diagnoses. BMC Musculoskeletal Disord 2012;13:238.

- [22] Paloneva J, Koskela S, Kautiainen H et al. Consumption of medical resources and outcome of shoulder disorders in primary health care consulters. BMC Musculoskeletal Disord 2013;14:348.
- [23] Jordan K, Jinks C, Croft P. A prospective study of the consulting behaviour of older people with knee pain. Br J Gen Pract 2006;56:269-76.
- [24] Menz HB, Jordan KP, Roddy E et al. Musculoskeletal foot problems in primary care: what influences older people to consult? Rheumatology (Oxford) 2010;49:2109-16.
- [25] Hill JC, Whitehurst DG, Lewis M et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. Lancet 2011;378:1560-71.

Peer review only

Supplementary Figure – Flow of participants through the study



210x297mm (300 x 300 DPI)

Supplementary table 1 - comparison of baseline characteristics between those included and excluded from primary care record analysis

		Included	Excluded	Difference ^a (95% CI)
n		1453	713	
Female	n (%)	824 (57)	414 (58)	-1.4 (-5.8, 3.1)
Age	Mean (SD)	52.0 (14.9)	49.0 (15.8)	2.6 (1.3, 4.0) ^d
HADS depression	Mean (SD)	6.4 (4.4)	6.2 (4.3)	0.2 (-0.1, 0.6)
HADS anxiety	Mean (SD)	7.9 (4.7)	7.6 (4.6)	0.3 (-0.1, 0.7)
SF36 physical function	Mean (SD)	36.1 (12.1)	37.2 (11.9)	-1.1 (-2.1, 0.03)
SF36 body pain	Mean (SD)	34.1 (8.5)	35.1 (8.8)	-1.1 (-1.8, -0.3) ^d
Pain duration > 1year	n (%)	803 (55)	399 (56)	-0.8 (-5.2, 3.7)
Severe pain interference ^b	n (%)	819 (56)	370 (52)	4.4 (-0.02, 8.9)
Currently employed	n (%)	750 (52)	386 (55)	-2.7 (-7.2, 1.8)
Time off work ^c	n (%)	341 (46)	175 (45)	0.2 (-5.9, 6.3)

CI, confidence interval; HADS, Hospital Anxiety and Depression Scale; SF-36, Short Form-36; SD, standard deviation

^a difference in means or proportions as appropriate; ^b quite a bit or extremely; ^c due to musculoskeletal problem in the last 6 months in those currently employed; ^d p<0.05

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

	Item No	Recommendation	Page
Title and abstract	1	(a) Indicate the study’s design with a commonly used term in the title or the abstract	1
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	2
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	4
Objectives	3	State specific objectives, including any prespecified hypotheses	4
Methods			
Study design	4	Present key elements of study design early in the paper	5
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	5
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	6,7
		(b) For matched studies, give matching criteria and number of exposed and unexposed	N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	6
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	6
Bias	9	Describe any efforts to address potential sources of bias	8,9
Study size	10	Explain how the study size was arrived at	7
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	6,7
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	8-10
		(b) Describe any methods used to examine subgroups and interactions	8,9
		(c) Explain how missing data were addressed	9
		(d) If applicable, explain how loss to follow-up was addressed	9
		(e) Describe any sensitivity analyses	9
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	10
		(b) Give reasons for non-participation at each stage	10, Suppl figure
		(c) Consider use of a flow diagram	Suppl figure
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Suppl table, Table 1
		(b) Indicate number of participants with missing data for each variable of interest	Table 3, 4

		(c) Summarise follow-up time (eg, average and total amount)	N/A
Outcome data	15*	Report numbers of outcome events or summary measures over time	Table 1, 2
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Tables 1, 2 & 4
		(b) Report category boundaries when continuous variables were categorized	6-7, Table 1
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not given
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	11
Discussion			
Key results	18	Summarise key results with reference to study objectives	19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	20
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	19-21
Generalisability	21	Discuss the generalisability (external validity) of the study results	20
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	22-23

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.