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DOI:
10.1016/S2665-9913(20)30099-0

Stratified care versus usual care for management of patients presenting with sciatica in primary care (SCOPiC): a randomised controlled trial

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Summary

Background Sciatica has a substantial impact on individuals and society. Stratified care has been shown to lead to better outcomes among patients with non-specific low back pain, but it has not been tested for sciatica. We aimed to investigate the clinical and cost-effectiveness of stratified care versus non-stratified usual care for patients presenting with sciatica in primary care.

Methods We did a two-parallel arm, pragmatic, randomised controlled trial across three centres in the UK (North Staffordshire, North Shropshire/Wales, and Cheshire). Eligible patients were aged 18 years or older, had a clinical diagnosis of sciatica, access to a mobile phone or landline number, were not pregnant, were not currently receiving treatment for the same problem, and had no previous spinal surgery. Patients were recruited from general practices and randomly assigned (1:1) by a remote web-based service to stratified care or usual care, stratified by centre and stratification group allocation. In the stratified care arm, a combination of prognostic and clinical criteria associated with referral to spinal specialist services were used to allocate patients to one of three groups for matched care pathways. Group 1 was offered brief advice and support in up to two physiotherapy sessions; group 2 was offered up to six physiotherapy sessions; and group 3 was fast-tracked to MRI and spinal specialist assessment within 4 weeks of randomisation. The primary outcome was self-reported time to first resolution of sciatica symptoms, defined as "completely recovered" or "much better" on a 6-point ordinal scale, collected via text messages or telephone calls. Analyses were by intention to treat. Health-care costs and cost-effectiveness were also assessed. This trial is registered on the ISRCTN registry, ISRCTN75449581.

Findings Between May 28, 2015, and July 18, 2017, 476 patients from 42 general practices around three UK centres were randomly assigned to stratified care or usual care (238 in each arm). For the primary outcome, the overall response rate was 89% (9467 of 10 601 text messages sent; 4688 [88%] of 5310 in the stratified care arm and 4779 [90%] of 5291 in the usual care arm). Median time to symptom resolution was 10 weeks (95% CI 6·4–13·6) in the stratified care arm and 12 weeks (9·4–14·6) in the usual care arm, with the survival analysis showing no significant difference between the arms (hazard ratio 1·14 [95% CI 0·89–1·46]). Stratified care was not cost-effective compared to usual care.

Interpretation The stratified care model for patients with sciatica consulting in primary care was not better than usual care for either clinical or health economic outcomes. These results do not support a transition to this stratified care model for patients with sciatica.

Funding: National Institute for Health Research.

Lancet Rheumatol 2020; 2: e401–11

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Introduction

The term sciatica describes symptoms of pain radiating from the low back to the legs, and it can be associated with sensory and motor deficits.[1,2] Occasionally, patients only have leg pain with no associated back pain. A prolapsed disc causing compression of lumbar spinal nerve roots is the most common cause of sciatica.[1,2] Sciatica has a substantial impact on patients and constitutes a considerable health-care, social, and economic burden.[3–5]

As in many countries, most patients with sciatica in the UK are managed in primary care. For most patients, especially those with a short symptom duration, usual care comprises mostly a stepped-care approach, starting with conservative interventions such as advice, medications, and physiotherapy, with those patients who show no improvement eventually being offered imaging, specialist assessment, and consideration of suitability for invasive treatments (eg, injections or surgery).[6,7] A longer symptom duration of sciatica is related to worse outcomes following both conservative and surgical treatment.[8] In the absence of a systematic way to identify patients who might need more support in their care, including a referral to specialists for consideration of more invasive treatments, there is considerable variation in practice. The current,

Research in context

Evidence before this study

We searched PubMed up to Dec 31, 2013, with the search terms "stratified care", "sciatica", and "radiculopathy". The search was restricted to English language publications. We found no previous trials of stratified care for patients with sciatica before undertaking our study. Therefore, no systematic review was possible. The evidence considered came from previous research on prognostic stratified care for patients with non-specific lower back pain (STarT Back and IMPaCT Back studies) and a cohort of patients with sciatica (ATLAS study) in the primary care setting, from which we examined the factors predicting referral of patients to specialist spinal services. These previous studies shaped the development of the stratification algorithm (previously published) that was tested in this trial.

Added value of this study

Before this trial, a UK Spinal Taskforce in 2013 highlighted the need for better information about the clinical and cost-effectiveness of early referral of patients with severe symptoms of sciatica for consideration of secondary care treatments such as surgery or spinal injections. The findings of this trial provide the first evidence about the clinical and cost-effectiveness of stratified care, including a fast-track pathway, for patients consulting in primary care with sciatica.

Implications of all the available evidence

In a primary care setting, where most patients with sciatica are assessed and managed, our findings do not support a transition from the mainly stepped care model to this stratified care model. However, testing ways to deliver care systematically to patients with sciatica could help to reduce practice variation. Taking into account that the key prognostic factors relevant in non-specific low back pain are not consistent prognostic factors in sciatica, further research is needed to explore different stratified care models for this population.

mainly stepped care, approach means that most patients have to show no improvement with previous interventions before being considered for further treatments, resulting in delays in referral to spinal specialists.

A model of stratified care for patients consulting with non-specific low back pain, which uses a stratification tool to identify their risk of disability related to persistent back pain in order to match patients to appropriate treatments, has previously been shown to be both clinically and cost-effective in the UK National Health Service (NHS).[9,10] There is insufficient evidence as to whether a similar approach specifically for patients presenting with sciatica in primary care could be beneficial.

A key challenge in the development of predictive and stratified care models for patients with sciatica is the scarce and inconsistent evidence for prognostic factors independently associated with outcome.[11–14] To date, it has not been possible to predict which patients might benefit from surgery.[15] An alternative stratification method is to test whether predicting and instigating early referral to spinal specialists improves outcomes compared to clinical care based on clinical judgement alone. We developed an adapted stratified care algorithm specifically for patients with sciatica presenting in primary care.[16] Briefly, the algorithm combines information about the risk (low, medium, or high) of persistent disability (using the STarT Back tool;[17] appendix p 9) with clinical criteria (current leg pain, pain below knee, interference with work or home activities, and objective sensory deficits) associated with referral to spinal specialist services, to allocate patients into one of three groups that are each matched to a care pathway. Patients at low risk of poor outcome, irrespective of clinical characteristics, are allocated to group 1 and are offered up to two sessions with a physiotherapist for brief support with self-management; patients at medium risk of poor outcome who have all four clinical characteristics, and patients at high risk of poor outcome with any three of the clinical characteristics, are allocated to group 3 with a matched care pathway of fast-track to MRI and referral to a spinal specialist; the remainder of patients are allocated to group 2 and offered up to six sessions of physiotherapy. The sensitivity, specificity, and positive predictive value of the algorithm for patient allocation to group 3 have been previously reported; sensitivity was 51%, specificity 73%, and the positive predictive value was 22% (C-statistic 0·70).[16] Details of the matched care pathways for each sciatica group have been previously reported in our published protocol.[18] The SCOPiC trial investigated whether this stratified care model led to faster resolution of sciatica symptoms compared with non-stratified usual care, and whether this approach was cost-effective. The linked qualitative interviews with patients and clinicians, exploring their views and experiences of the fast-track care pathway tested in the trial, will be reported separately.

See Online for appendix

Methods

Study design and participants

SCOPiC was a two-parallel-arm, pragmatic, randomised controlled trial with 1:1 allocation. An internal pilot phase assessed participant recruitment and follow-up rates over the first 8 months of recruitment, trial processes, and adherence to trial protocols. Progression criteria from the internal pilot phase to the main trial included achieving a recruitment rate of more than 70% of those eligible, and observing less than 25% loss to follow-up on the primary outcome. The internal pilot did not involve formal interim analysis of between-arm effects on the primary outcome or any other outcomes. Patients were recruited from general practices, in areas surrounding three centres in the UK (North Staffordshire, North Shropshire/Wales, and Cheshire). Five community NHS physiotherapy services were involved in the trial across the three centres, and

patients in the fast-track pathway were seen by NHS spinal specialists. Ethical approval was received from the National Research Ethics Service West Midlands – Solihull, UK, and the trial was done and analysed according to the protocol.[18]

Potential participants were identified by electronic pop-up computer prompts in general practice computer systems triggered by appropriate diagnostic or symptom codes,[19] or by weekly reviews of practice consultation records. Potentially eligible participants were sent information about the SCOPiC research clinic and the trial, and were invited to telephone an administrator to make an appointment at the SCOPiC research clinic to see a physiotherapist. Full eligibility screening and baseline assessments, including identification of each patient's sciatica group according to the stratification algorithm, were done at the research clinic by study physiotherapists.

Eligible patients were aged 18 years or older, with a clinical diagnosis of sciatica of any severity and duration following clinical assessment by a physiotherapist in the research clinics, had access to a mobile phone or landline, were not receiving treatment nor had received treatment in the last 3 months for the same problem, were not pregnant, and had no previous lumbar spine surgery. Patients with clinical suspicion (by their general practitioner [GP] or the assessing physiotherapist) of serious spinal pathology (eg, cauda equina syndrome, fracture, spondyloarthropathy, malignancy, infection, or foot drop) or serious physical or mental co-morbidities (as judged by their GP or the assessing physiotherapist) were excluded. The sciatica case definition for this trial was based on the assessing physiotherapist being at least 70% confident in their clinical diagnosis,[20,21] with at least one of the following being present: leg pain approximating a dermatomal distribution; leg pain worse than or as bad as back pain; leg pain worse with coughing, sneezing, or straining; subjective sensory changes approximating a dermatomal distribution; objective neurological deficits indicative of nerve root compression; positive neural tension test;[22,23] and (specifically for spinal claudication or spinal stenosis) leg pain worse with weight-bearing activities and better with sitting. Assessing physiotherapists recorded a specific clinical diagnosis of sciatica due to disc prolapse or stenosis.

Randomisation and masking

At the research clinic, eligible patients who gave written informed consent were randomly assigned by a computer-generated code, to either stratified care or usual care. Randomisation was done with a web-based service from Keele Clinical Trials Unit, and was stratified by centre and sciatica group allocation (sciatica groups 1, 2, and 3), by use of random permuted blocks of varying size (2, 4, and 6). Patients were told that the trial was comparing two approaches for the treatment of sciatica, one based on matching patients to treatment by use of a simple tool that helps to decide on the treatment pathway, and one based on treatment needed as discussed and agreed between the patient and physiotherapist. Different physiotherapists delivered treatment to participants in each trial arm to avoid contamination bias; physiotherapists were not masked to treatment allocation. Statisticians and outcome assessors were masked to treatment allocation.

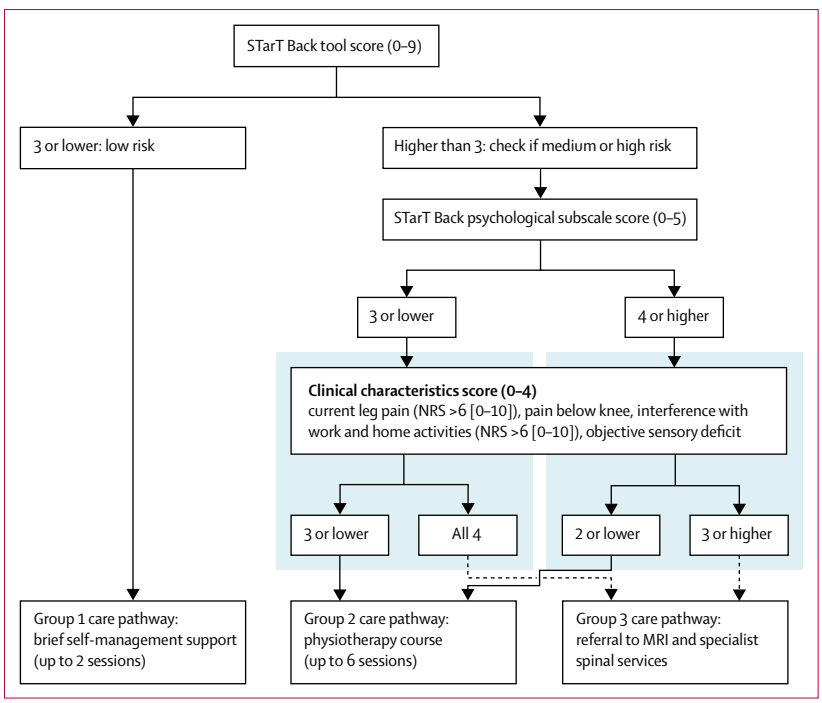

Figure 1: **Stratification algorithm for allocating patients to sciatica groups and matched care pathways**
NRS=numerical rating scale.

Procedures

In the stratified care arm, the stratification algorithm (figure 1) was used to allocate patients to one of three groups. Patients in group 1 were expected to do well and were therefore offered brief advice and support in up to two physiotherapy sessions. Group 2 was offered up to six physiotherapy sessions, and group 3 was fast-tracked to MRI and spinal specialist assessment within 4 weeks of randomisation.[18] Physiotherapists treating patients in groups 1 and 2 were responsible for providing good clinical governance and could overrule the stratification algorithm recommendation for matched care pathways if they thought it clinically appropriate. In addition to having a consultation at their general practice, all participants in the usual care arm had a consultation with a physiotherapist at the SCOPiC research clinic, their care was planned without the use of any stratification tools, and referrals for further physiotherapy or to other services were made at the discretion of the assessing physiotherapist and in consultation with the patient.[18]

Outcomes

Informed by the involvement of patients before the trial, the primary outcome was time to first resolution of sciatica symptoms, defined as "completely recovered" or "much

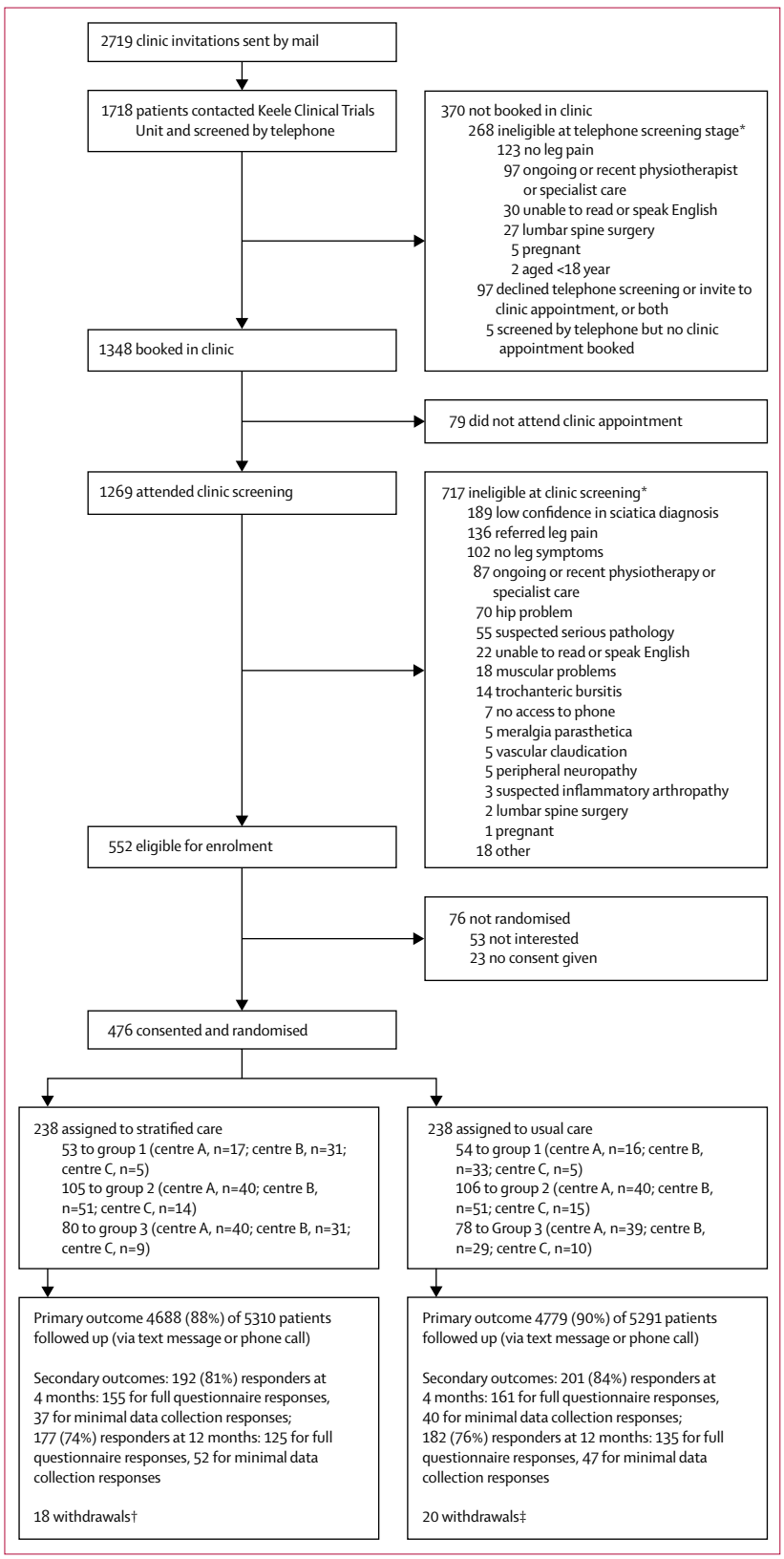

Figure 2: **Trial profile**
*More than one reason for ineligibility was possible. †Reasons (if known) for withdrawal as follows: not interested in further participation (n=5); seeing private therapist (n=2); poor health or no better (n=2); randomised in error (n=1); request by clinician (n=1); reason not known (n=7). One patient did not provide any data; nine had resolution of symptoms (five had stable symptom resolution) by the time of withdrawal. ‡Reasons (if known) for withdrawal as follows: not interested in further participation (n=4), poor health or no better (n=3), seeing private therapist (n=2), expected more treatment (n=2), family commitments (n=2), and reason not known (n=7). One patient did not provide any data; ten had resolution of symptoms (seven had stable symptom resolution) by the time of withdrawal.

better", measured on a 6-point ordinal scale and collected via text messages (or brief telephone calls). The scale's anchor was patients' baseline symptoms when they attended the SCOPiC research clinic. The text message read: "Compared to how you were at the SCOPiC clinic X weeks/months ago, how are your back and leg symptoms today?" Primary outcome data collection occurred weekly for the first 4 months for all participants, and then every 4 weeks between 4 and 12 months' follow-up, or until "stable resolution" of symptoms (defined as 2 consecutive months' responses of "completely recovered" or "much better").

Secondary clinical outcomes were collected at 4 and 12 months by use of self-completed postal questionnaires. These included: global perceived change (GPC; 6-point ordinal scale as per primary outcome data collection), physical function,[24] overall impact of sciatica symptoms,[25] back and leg pain intensity,[26] sleep disturbance,[27] fear of movement,[28] anxiety and depression,[29] risk of persistent back-pain related disability,[17] health-related quality of life (EuroQoL EQ-5D-5L),[30] general health,[31] neuropathic pain symptoms,[32] days lost from work and productivity loss due to sciatica, and satisfaction with care (appendix p 1). Furthermore, data were collected on health-care resource use and costs related to the delivery of the stratified care intervention and usual non-stratified care, over 12 months. Information was collected about serious adverse events and adverse events. Process outcomes included data on numbers of patients referred to physiotherapy and specialist spinal services, and were collected via patient questionnaires and hospital record reviews from participating NHS services. Where possible, we captured timing of referral and treatment.

We aimed to recruit 470 participants (see the statistical analysis plan in the appendix p 17 for further details) in order to detect a hazard ratio (HR) between 1·4 and 1·5 for time to resolution of symptoms (primary outcome) with 80–90% power, assuming an event (resolution) rate of 60% or greater over 12 months, 20% dropout, and intra-class correlation for clustering by physiotherapist at the level of 0·01 and allowing for a coefficient of variation in physiotherapist cluster size of 0·65.[33]

Statistical analysis

All analyses were by intention to treat, and were done and reported following the Consolidated Standards of Reporting Trials guidelines.[34]

	Stratified care (n=237*)	Usual care (n=238)
Age, years	50·7 (14·5)	53·3 (13·5)
Sex		
Female	131 (55%)	130 (55%)
Male	106 (45%)	108 (45%)
Motor deficit	60 (25%)	63 (26%)
Reflex deficit	80 (34%)	79 (33%)
Sensory deficit	115 (49%)	123 (52%)
Participants with at least one deficit	169 (71%)	167 (70%)
Leg pain approximating dermatomal distribution	216 (91%)	220 (92%)
Leg pain worse than or as bad as back pain	173 (73%)	173 (73%)
Leg pain worse with coughing, sneezing, or straining	84 (35%)	75 (32%)
Pain on straight leg raise (positive result; stratified care; n=237, usual care; n=237)	199 (84%)	197 (83%)
Clinically suspected nerve root (stratified care; n=234, usual care; n=235)		
L3	3 (1%)	3 (1%)
L4	13 (6%)	19 (8%)
L5	61 (26%)	74 (31%)
S1	141 (60%)	111 (47%)
More than one nerve root	5 (2%)	5 (2%)
Bilateral symptoms	5 (2%)	5 (2%)
IMD (stratified care; n=213, usual care; n=212)	14 228 (7387–21 790)	15 614 (8288–21 840)
Employed (in paid job; stratified care; n=236, usual care; n=236)	171 (72%)	160 (68%)
Time off work due to sciatica, in the last 12 months (yes), (stratified care; n=171, usual care; n=163)	84 (49%)	96 (59%)
Usual back pain intensity (NRS 0–10; stratified care; n=237, usual care; n=237)	5·9 (2·7)	5·8 (2·9)
Usual leg pain intensity (NRS 0–10; stratified care; n=237, usual care; n=237)	6·8 (2·2)	6·9 (2·2)
Symptom duration		
<2 weeks	15 (6%)	33 (14%)
2–6 weeks	99 (42%)	98 (41%)
6–12 weeks	58 (24%)	46 (19%)
3–6 months	31 (13%)	29 (12%)
6–12 months	10 (4%)	10 (4%)
>12 months	24 (10%)	22 (9%)
Physical function (RMDQ 0–23)	11·1 (5·2)	11·3 (5·4)
SBI (0–24)	14·6 (5·0)	14·5 (5·0)
S-LANSS score (stratified care; n=218, usual care; n=227)		
<12	124 (57%)	134 (59%)
≥12	94 (43%)	93 (41%)
Fear of movement (TSK 17–64)	40·4 (6·1)	40·8 (6·2)
HADS-Anxiety case		
Possible	64 (27%)	51 (21%)
Probable	55 (23%)	67 (28%)

(Table 1 continues in next column)

	Stratified care (n=237*)	Usual care (n=238)
(Continued from previous column)		
HADS-Depression case		
Possible	40 (17%)	48 (20%)
Probable	41 (17%)	39 (16%)
Sleep problem (yes)	149 (63%)	164 (69%)
General health		
Excellent	11 (5%)	13 (5%)
Very good	52 (22%)	49 (21%)
Good	107 (45%)	103 (43%)
Fair	50 (21%)	60 (25%)
Poor	17 (7%)	13 (5%)

Data are n (%), mean (SD), or median (IQR). IMD=Index of Multiple Deprivation (1–32 844, with higher scores indicating lower levels of deprivation). NRS=Numerical Rating Scale (0–10, with higher scores indicating worse symptoms). RMDQ=Roland-Morris Disability Questionnaire (0–23, with higher scores indicating higher levels of disability). SBI=Sciatica Bothersomeness Index (0–24 composite score with higher scores indicating worse symptoms). S-LANSS=Self-report Leeds Assessment of Neuropathic Symptoms and Signs (possible range from 0 to 24, with a score of 12 or more indicating possible neuropathic pain). TSK=Tampa Scale of Kinesiophobia (17–64, with higher scores indicating higher fear of movement). HADS=Hospital Anxiety Depression Scale (0–21, with higher scores indicating higher levels of anxiety or depressive symptoms, with a cutoff point of ≥11 considered indicative of 'probable case' of depression or anxiety). *In the stratified care arm, data are presented for 237 participants and not 238, as one person was randomly assigned in error and did not provide any data after randomisation.

Table 1: **Baseline characteristics of participants**

The primary, time-to-event analysis compared time to self-reported resolution of symptoms between the stratified care and usual care arms over 12 months' follow-up. The Kaplan-Meier survival analysis estimated the time from randomisation until reporting of first resolution of sciatica symptoms, and provided the relative median symptom resolution times of the two trial arms. Cox regression analysis estimated the HR for the rate of symptom resolution, adjusted for centre, sciatica group (stratifying variables), and pain duration (fixed effects), and accounting for clustering by physiotherapist (frailty or random effect). The secondary outcomes analysis (at 4 and 12 months) used longitudinal mixed-effect regression models as appropriate to the outcome data being analysed, adjusting for the same variables as per the primary analysis. Time-by-intervention arm interactions and time-by-baseline covariates were included to account for potential attrition bias. A descriptive summary of mean scores and frequency counts or percentages (as appropriate to the data) is presented for the two trial arms. For the between-arm comparisons, mean differences (numerical outcomes) and odds ratios (categorical outcomes) are presented along with 95% CIs and p values.

Prespecified sensitivity analyses (per protocol, based on alternative definitions of symptom resolution, alternative assumptions about missing data and interval-censoring, and complete case analyses—ie, those participants responding to all texts or phone calls) were done to assess the robustness of the primary analysis.

	Stratified care	Usual care	Between-arm effect (95% CI)	p value
Physical function (RMDQ, 0–23)				
4 months (stratified care; n=192, usual care; n=201)	6·5 (6·3)	6·2 (6·0)	MD 0·43 (–0·69 to 1·54)	p=0·45
12 months (stratified care; n=177, usual care; n=182)	5·0 (6·2)	5·5 (6·0)	MD –0·53 (–1·84 to 0·78)	p=0·43
Global perceived change (GPC)				
4 months (stratified care; n=188, usual care; n=194)				
Completely recovered	28 (15%)	26 (13%)	..	..
Much Better	50 (27%)	59 (30%)	..	..
Better	48 (26%)	59 (30%)	OR 0·88 (0·51 to 1·53)	p=0·66
No change	39 (21%)	32 (16%)	..	..
Worse	23 (12%)	18 (9%)	..	..
12 months (stratified care; n=174, usual care; n=176)				
Completely recovered	34 (20%)	30 (17%)	..	..
Much Better	63 (36%)	58 (33%)	..	..
Better	34 (20%)	42 (24%)	OR 1·43 (0·80 to 2·53)	p=0·22
No change	30 (17%)	34 (19%)	..	..
Worse	13 (7%)	12 (7%)	..	..
Usual back pain (NRS 0–10)				
4 months (stratified care; n=154, usual care; n=158)	3·8 (2·8)	3·4 (2·6)	MD 0·32 (–0·30 to 0·94)	p=0·31
12 months (stratified care; n=123, usual care; n=130)	3·2 (2·8)	2·7 (2·5)	MD 0·26 (–0·48 to 1·01)	p=0·49
Usual leg pain (NRS 0–10)				
4 months (stratified care; n=191, usual care; n=197)	3·3 (2·9)	3·1 (2·8)	MD 0·25 (–0·36 to 0·86)	p=0·42
12 months (stratified care; n=176, usual care; n=178)	2·9 (2·9)	2·8 (2·8)	MD 0·11 (–0·56 to 0·77)	p=0·75
SBI (0–24)				
4 months (stratified care; n=150, usual care; n=155)	7·9 (6·0)	7·5 (5·3)	MD 0·26 (–1·03 to 1·55)	p=0·69
12 months (stratified care; n=122, usual care; n=126)	6·7 (5·7)	6·5 (6·1)	MD –0·42 (–1·94 to 1·11)	p=0·59
S-LANSS (≥12)				
4 months (stratified care; n=136, usual care; n=138)	35 (26%)	33 (24%)	OR 1·17 (0·49 to 2·79)	p=0·72
12 months (stratified care; n=98, usual care; n=105)	22 (22%)	22 (21%)	OR 1·08 (0·39 to 2·98)	p=0·88
Fear of movement (TSK, 17–64)				
4 months (stratified care; n=145, usual care; n=154)	36·9 (8·4)	36·2 (7·4)	MD 0·53 (–0·87 to 1·92)	p=0·46
12 months (stratified care; n=117, usual care; n=122)	35·2 (8·5)	35·3 (7·8)	MD –0·37 (–1·88 to 1·13)	p=0·63
HADS-Anxiety case				
4 months (stratified care; n=150, usual care; n=157)				
Normal (0–7)	104 (69%)	103 (66%)	..	..
Possible (8–10)	26 (17%)	37 (24%)	OR 1·36 (0·59 to 3·13)	p=0·48
Probable (≥11)	20 (13%)	17 (11%)	..	..
12 months (stratified care; n=119, usual care; n=133)				
Normal (0–7)	75 (63%)	97 (73%)	..	..
Possible (8–10)	21 (18%)	16 (12%)	OR 2·30 (0·94 to 5·65)	p=0·070
Probable (≥11)	23 (19%)	20 (15%)	..	..

(Table 2 continues on next page)

Prespecified subgroup analyses included sciatica group (1, 2, and 3) and clinical diagnosis (disc-related sciatica or stenosis). Median time to resolution was calculated per intervention arm per specified subgroup. The adjusted Cox proportional hazards frailty model was repeated including additional interaction terms for intervention arm by subgroups within the models.

The base-case economic analysis comprised a within-trial cost-utility analysis, adopting an NHS perspective, done according to the intention-to-treat principle. Health-care resource data were obtained from self-reported questionnaires at 4 and 12 months, and valued with unit costs from standard sources.[35–37] Quality-adjusted life-years (QALYs) were calculated over a period of 12 months for each study participant by use of the area under the curve approach, controlling for imbalances in baseline utility scores with a multiple linear regression approach. Total costs and QALYs for all participants were estimated to calculate differences between stratified care and usual care. The cost per additional QALY gained was the key economic outcome of interest. To minimise bias, multiple imputation for missing costs and EQ-5D scores was done by the predictive mean matching method to account for the non-normality of the distribution of costs and EQ-5D values. Uncertainty around the incremental costs and QALYs (ie, the difference between stratified care and usual care) was investigated by use of the bootstrapping technique and results were presented on a cost-effectiveness plane. Cost-effectiveness acceptability curves were also used to reflect the probability of stratified care being cost-effective at different cost-per-QALY thresholds. The following sensitivity analyses were done: a health-care and societal perspective; use of additional information including sciatica-related injections, MRIs, and spinal surgeries from hospital records for participating services; a complete-case analysis to assess the impact of missing costs and outcomes data; and pre-specified analyses to explore the cost-effectiveness of the two interventions by sciatica group (stratified care or usual care by sciatica groups 1, 2, and 3).

Full details of the statistical analyses are included in the statistical analysis plan (appendix p 13–28). Analyses were done with SPSS, version 24, and Stata, version 15. External trial steering and data monitoring committees oversaw the trial.

The trial was prospectively registered with the ISRCTN Registry on Nov 20, 2014 (ISRCTN75449581).

Patient and public involvement

Patient and public involvement (PPI) was supported by the PPI infrastructure within Keele University, Keele, UK. Members with experience of the condition were involved in the development of the full application and commented on the plain English summary. All members said they recognised the value of the trial and highlighted that prompt pain relief is key, given the severity of the pain, which informed the choice of time to symptom resolution

as the primary outcome of the trial. PPI members reviewed the study documents. Two PPI members sat on the trial steering committee. A PPI group contributed to the nested qualitative interviews (reported separately) by advising on topic guides and contributing to the analysis of the qualitative data. A final PPI meeting was held to discuss the overall trial results and agree the key messages for patients and the public.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between May 28, 2015, and July 18, 2017, 476 participants were randomly assigned from 42 general practices. Figure 2 shows the flow of participants through the trial. At the point of randomisation, in the stratified care arm, the algorithm for matching patients to one of the three care pathways was followed in all but four cases (four patients in group 1 had recovered by the time of their assessment in the SCOPiC research clinic and were not referred on for the two physiotherapy sessions defined in the protocol within the care pathway for group 1). At the point of randomisation, in the usual care arm, 200 patients were referred for further physiotherapy treatment, 28 were deemed not to need further active treatment and were discharged back to their GP, and ten were referred for a spinal specialist consultation.

Patients in the two arms had similar key baseline characteristics (table 1). For the primary outcome, the overall response rate was 89% (9467 of 10 601 text messages sent; 4688 [88%] of 5310 in the stratified care arm and 4779 [90%] of 5291 in the usual care arm). The overall follow-up rate of the 4 month questionnaire, including minimal data collection, was 83% (81% in the stratified care arm and 84% in the usual care arm), and that of the 12 month questionnaire was 75% (74% in the stratified care arm and 76% in the usual care arm). Non-responders to the 4 and 12 month questionnaires were, on average, younger, lived in more deprived neighbourhoods (lower average index of multiple deprivation rank), and had slightly worse baseline health status than those who completed the questionnaires (appendix pp 1–2).

The internal pilot phase progression criteria were met, including recruitment and follow-up targets. No changes were made to the trial protocol.

Figure 3 summarises time to event data for the primary outcome. Median time to symptom resolution was 10 weeks (95% CI 6·4–13·6) in the stratified care arm and 12 weeks (9·4–14·6) in the usual care arm. This difference was not significant (HR 1·14; 95% CI 0·89–1·46). Details of the numbers of patients reporting improvements at each time-point are provided in the appendix (pp 2–3). The intra-class correlation for clustering by physiotherapist was 0·026 for the cumulated occurrence, or not, of an event by week 48. Sensitivity analyses showed no significant differences between the trial arms (appendix pp 3–4). Prespecified subgroup analyses showed similar (non-significant) outcomes between trial arms, except for the group of patients clinically diagnosed with spinal stenosis, for whom stratified care seemed to lead to faster symptom

	Stratified care	Usual care	Between-arm effect (95% CI)	p value
(Continued from previous page)				
HADS-Depression case				
4 months (stratified care; n=150, usual care; n=158)				
Normal (0–7)	117 (78%)	121 (77%)	OR 0·99 (0·41 to 2·42)	p=0·99
Possible (8–10)	18 (12%)	19 (12%)	··	··
Probable (≥11)	15 (10%)	18 (11%)	··	··
12 months (stratified care; n=119, usual care; n=133)				
Normal (0–7)	89 (75%)	103 (77%)	OR 1·24 (0·48 to 3·22)	p=0·66
Possible (8–10)	18 (15%)	15 (11%)	··	··
Probable (≥11)	12 (10%)	15 (11%)	··	··
Sleep problem (yes)				
4 months (stratified care; n=154, usual care; n=159)	54 (35%)	61 (38%)	OR 1·59 (0·66 to 3·82)	p=0·30
12 months (stratified care; n=124, usual care; n=132)	42 (34%)	41 (31%)	OR 2·21 (0·85 to 5·72)	p=0·10
General health				
4 months (stratified care; n=153, usual care; n=158)				
Excellent	5 (3%)	10 (6%)	··	··
Very good	47 (31%)	35 (22%)	··	··
Good	60 (39%)	69 (44%)	OR 1·21 (0·65 to 2·24)	p=0·56
Fair	32 (21%)	35 (22%)		··
Poor	9 (6%)	9 (6%)		··
12 months (stratified care; n=120, usual care; n=133)				
Excellent	9 (8%)	12 (9%)	··	··
Very good	43 (36%)	42 (32%)	··	··
Good	39 (33%)	47 (35%)	OR 1·49 (0·76 to 2·94)	p=0·25
Fair	27 (23%)	24 (18%)	··	··
Poor	2 (2%)	8 (6%)	··	··
Time off work (yes)				
4 months (stratified care; n=107, usual care; n=96)	45 (42%)	47 (49%)	OR 1·11 (0·47 to 2·61)	p=0·82
12 months (stratified care; n=75, usual care; n=81)	20 (27%)	15 (19%)	OR 2·52 (0·85 to 7·49)	p=0·095

Data are n (%) or mean (SD). MD=mean difference (stratified care minus usual care) by longitudinal linear mixed model adjusted for centre, group, duration of baseline symptoms (fixed effects) and clustering by physiotherapist and participant (random effects). OR=odds ratio (stratified care relative to usual care) by longitudinal logistic (ordinal for three or more categories, binary for two categories) mixed model adjusted for centre, group, duration of baseline symptoms (fixed effects) and clustering by physiotherapist and participant (random effects). RMDQ=Roland-Morris Disability Questionnaire (0–23, with higher scores indicating higher levels of disability). GPC=Global Perceived Change (rescaled as 1–5; 1=worse, 5=completely recovered); NRS=Numerical Rating Scale (0–10, with higher scores indicating worse symptoms). SBI=Sciatica Bothersomeness Index (0–24 composite score with higher scores indicating worse symptoms). S-LANSS=Self-report Leeds Assessment of Neuropathic Symptoms and Signs (possible range from 0 to 24, with a score of 12 or more indicating possible neuropathic pain). TSK=Tampa Scale of Kinesiophobia (17–64, with higher scores indicating higher fear of movement). HADS=Hospital Anxiety Depression Scale (0–21, with higher scores indicating higher levels of anxiety or depressive symptoms, with a cutoff point of ≥11 considered indicative of "probable case" of depression or anxiety).

Table 2: **Secondary outcomes at 4 months and 12 months**

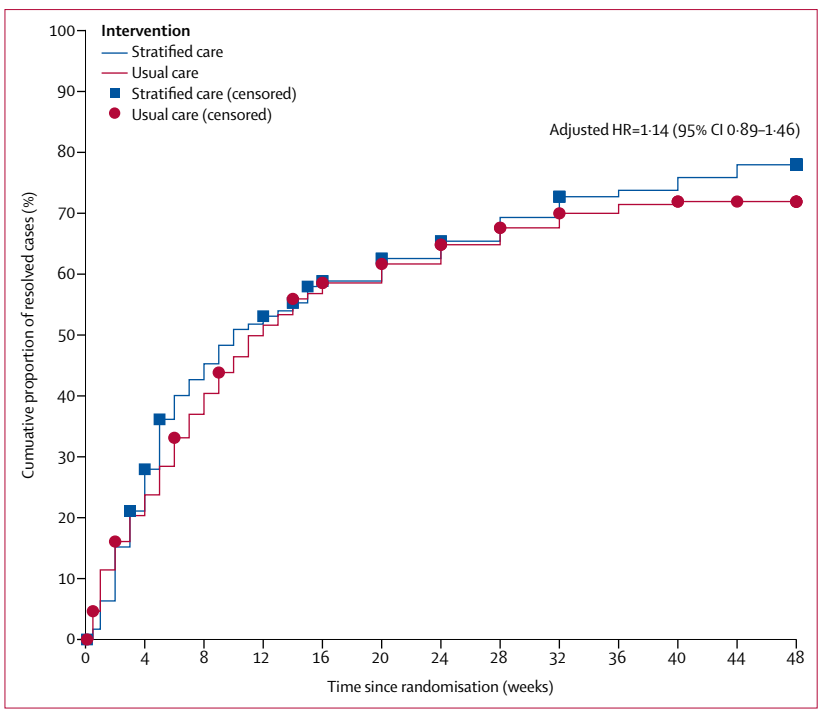

Figure 3: **Kaplan-Meier time-to-event analysis of the primary outcome (time to first resolution of sciatica symptoms)**

Cumulative proportion of resolved cases by week 48: 0·754 (all), 0·780 (stratified care), and 0·729 (usual care). HR=hazard ratio.*Estimation is limited to the largest event-free time if it is censored.

	Stratified care (n=238)	Usual care (n=238)	Mean difference (95% CI)	ICER
Mean costs, £	663·58 (737·14)	617·37 (935·50)	46·21 (–110·60 to 187·06)	Dominated
Mean QALYs	0·6599 (0·1731)	0·6713 (0·1685)	–0·011* (–0·035 to 0·013)	..

Data are mean (SD), unless otherwise indicated. ICER=incremental cost-effectiveness ratio. QALY=quality-adjusted life-year. *Adjusted for baseline utility.

Table 3: **Cost-utility analysis for stratified care versus usual care**

resolution (median 6 weeks faster resolution; HR 1·92 [95% CI 1·01–3·65]; appendix p 11).

Table 2 summarises secondary outcomes. No significant between-arm differences in secondary outcomes were observed. On average, participants in both arms improved over time on most outcomes. Approximately 25% of patients did not report symptom resolution during follow-up (defined as "completely recovered" or "much better"; figure 3). Of those responding to the 12 month questionnaire, 89 patients (43 in the stratified care arm and 46 in the usual care arm) reported being no better or being worse. The mean number of days lost from work due to sciatica over the 12 month follow-up was similar in both arms (5·48 days [SD 18·14] in the stratified care arm and 5·67 days [17·08] in the usual care arm). No related or unrelated adverse events or serious adverse events were reported in either trial arm. Most participants were satisfied with the care they received and the results of their care (appendix pp 4–5).

The overall median number of physiotherapy treatment sessions was similar for participants in both arms (2 [IQR 1–4] for the stratified care arm and 2 [0–3] for the usual care arm). Time to first physiotherapy appointment (for those who were referred to physiotherapy) was a median of 9 days (IQR 6–15) for patients in the stratified care arm versus 21·5 days (11–46) for those in the usual care arm. Treatments in the stratified care arm were delivered over a shorter timeframe (median 38 days [IQR 12·5–70] *vs* 66 days [29–97]) than in the usual care arm. Data on appointment numbers and timings at the specialist spinal clinics and treatment and referral decisions made are summarised in the appendix (p 5). Self-reported data and hospital records showed that 22 patients in the stratified care arm and 13 in the usual care arm received spinal injections; patients in the stratified care arm received the injections more quickly than those in the usual care arm (60 days [IQR 41–93] *vs* 161 days [113–253]), and five patients in the stratified care arm and eight in the usual care arm had spinal surgery, in similar timeframes.

Details of intervention costs, health-care resource use and costs, time off work, and quality of life (EQ-5D scores and QALY estimates) are provided in table 3 and in the appendix (pp 5–8) for both arms. Overall, minimal differences were observed in primary care, secondary care, and work outcomes between patients in the two trial arms, with the exception of slightly higher numbers of spinal injections in the stratified care arm versus the usual care arm, but fewer surgeries. As expected, stratified care was also associated with higher treatment costs driven by costs resulting from the fast-track pathway involving an MRI and visit to a spinal interface service. In the cost-utility analysis, stratified care was slightly less effective (QALYs –0·011: 95% CI –0·035 to 0·013) and more costly (£46·21; 95% CI –110·60 to 187·06) than usual care, and was therefore dominated. The net monetary benefit was –£275 if society's willingness to pay for a QALY is valued at £20 000.

The dominance of usual care is confirmed by the low probability of this model of stratified care being cost-effective at a willingness-to-pay threshold of £20 000 (appendix p 11). Sensitivity analyses showed that stratified care was not a cost-effective option from a health-care and societal perspective when the extra information about spinal surgeries and injections from hospital records was included in the analysis (appendix p 7). The subgroup analyses showed considerable uncertainty around the main estimates of the incremental costs and QALYs because of the small sample size in each sciatica group (1, 2, and 3), but overall stratified care remained a non-cost-effective option in all three groups compared with the usual care arm (appendix pp 8, 12).

Discussion

To our knowledge, this is the first trial to test a stratified care model in the primary care setting specifically for

patients with a clinical diagnosis of sciatica. We did not find convincing evidence that the stratified care model tested in this trial (combining prognostic information with clinical criteria) led to faster resolution of sciatica symptoms or benefits for other patient outcomes, compared to usual care. In the stratified care arm, the median time to first resolution of sciatica symptoms was slightly shorter (by 2 weeks), but this difference was not significant. By 12 weeks, approximately 50% of participants in both arms had reported first resolution of symptoms. By the end of the follow-up period at 12 months, 74% of patients in the stratified care arm and 71% in the usual care arm had reported resolution of symptoms. From a health economics perspective, we found no evidence that the model of stratified care tested in this trial was a cost-effective use of health-care resources when compared with usual NHS care. The usual care arm marginally dominated stratified care. Similar findings were observed in scenarios incorporating tests and treatment data from hospital records, and the three sciatica groups (1, 2, and 3).

Secondary outcomes analyses showed that, on average, participants in both trial arms reported similar, good improvements. Subgroup analyses were exploratory as the trial was not powered for these analyses, and as such these results should be treated with caution. The significant result observed with stratified care for patients clinically diagnosed with spinal stenosis is based on a small number of patients and could simply be a chance finding. However, further investigation of this subgroup could be warranted.

The results of this trial, testing a sciatica-specific stratified care model combining prognostic factors and clinical indicators of referral to spinal specialists, are different to those showing the effectiveness of a prognostic stratified care model for patients with non-specific low back pain.[9,10] At 12 months, the percentage change in disability in both arms of the SCOPiC trial, 54·9% for the stratified care arm and 51·3% for the usual care arm (based on mean RMDQ values at baseline and 12 months of follow-up), was considerably higher than that achieved in the STarT Back trial of stratified care for non-specific low back pain[9] (43·9% for the stratified care arm and 34% for the control arm).

Potential explanations for the results of the SCOPiC trial include the performance of the stratification algorithm in predicting referral to specialists, the natural and clinical course of sciatica symptoms in primary care, and the effectiveness of the usual care intervention. The algorithm's predictive performance in relation to referral to spinal specialists is acknowledged to be modest (C-statistic 0·70),[16] with a sensitivity of 51%, specificity of 73%, and positive predictive value of 22%, and a number of patients fast-tracked to MRI and specialist assessment might not have needed this care pathway. Additionally, our qualitative interview data, which will be published elsewhere, highlighted that for patients with a short duration of symptoms, clinicians were reluctant to consider invasive treatments such as injections and surgery before conservative treatment options were tried first, and before sufficient time for natural improvement had passed. As mentioned previously, no factors have been consistently shown to be associated with outcome in sciatica,[11–14] and thus would be useful to guide clinical decision making about early referral to spinal specialists. The stratified care model tested in this trial was designed to help with identification of patients who were likely to be referred to specialists at some point and instigating this referral early in the patient's presentation, in addition to matching the remainder of patients to conservative packages of care early on. However, the good improvement achieved by most patients in both arms, including those in sciatica group 3 who had the highest baseline levels of pain and disability (with approximately a fifth in both arms reporting recovery within 4 weeks from randomisation), is indicative of an overall favourable natural and clinical course despite the initial high pain and incapacity levels, and points to the fact that the current prognostic factors associated with outcome or with early referral to specialists are not adequately capturing the population most likely to benefit from such a treatment pathway.

In the usual care arm, all participants were seen by a physiotherapist (at the point of randomisation), and the majority were referred for physiotherapy treatment. We chose this model for recruiting patients into the trial, as other trials aiming to recruit patients with sciatica in general practices alone were not successful and were discontinued.[38] The consequence of this recruitment model was that a larger proportion of participants received more care than they would have if the care been solely directed by their GP. It is possible that the usual care intervention in this trial might have been more effective than the care usually received in the general practice setting in the UK.

Strengths of the trial include the target sample size being reached, the high follow-up rate for the primary outcome and overall good adherence to matched care pathways in the stratified care arm, and the face validity of the stratified care model tested, which was developed and agreed by all stakeholders involved in the management of patients with sciatica, and was developed with previous data from a similar primary care population.[16]

Limitations of our trial include the lack of external validation of the stratification algorithm before using it in this trial, and the fact that the trial design we used does not allow differentiation between the effect of the stratification algorithm (the subgrouping) from that of the matched care pathways. Additionally, the trial was not powered to detect differences at the level of each of the three sciatica groups, and therefore the conclusions apply to the overall stratified care approach for patients with sciatica consulting in primary care.

In conclusion, the results of this trial do not support a transition to this model of stratified care for patients presenting with sciatica in primary care. Future research

needs to identify consistent factors that predict outcome or treatment response in patients with sciatica, to inform new models of stratified care for patients with sciatica. Until such a time that prognostic models offer a clear advantage to clinical decision making in this population, testing ways to systematically deliver care for patients with sciatica could help to reduce unhelpful practice variation.

Contributors

KK, ML, and NEF had full access to the data and take responsibility for data integrity and accuracy of data analysis. NEF, KK, KMD, DAvdW, JCH, MA, CDM, and EMH conceived the trial. NEF, KK, ML, KMD, DAvdW, MA, JCH, SJ, CDM, and EMH obtained funding. NEF was the chief investigator. All authors participated in the design and conduct of the trial. KK produced the first draft of the manuscript. ML, RO, JK, and SJ led the statistical analysis with input from KK and NEF. MR and GH led the administrative, technical, and material support. All authors contributed to the drafting and approval of the final manuscript.

Declaration of interests

KK reports grants from the National Institute for Health Research and the Higher Education Funding Council for England. ML, KMD, MA, CDM, EMH, DAvdW, and NEF report grants from the National Institute of Health Research (NIHR). JCH reports grants from the NIHR, honoraria from lectures relating to the STarT Back trial findings. SJ reports grants from the NIHR, personal fees from independent advisor work at Pfizer chronic advisory board meeting (November, 2018) outside the submitted work. All other authors declare no competing interests.

Data sharing

Metadata, including the study protocol, statistical analysis plan, data dictionaries, and key study documents (patient information leaflet, blank or coded case report forms, and consent form), will be deposited on a publicly accessible repository. De-identified individual participant data that underlie the results from this trial will be securely stored on servers approved by a government-backed cyber security scheme and made available to bona-fide researchers upon reasonable request via our controlled access procedures. Unless there are exceptional circumstances, data will be available upon publication of main trial findings and with no end date. Data requests and enquiries should be directed to primarycare.datasharing@keele.ac.uk. We encourage collaboration with those who collected the data, to recognise and credit their contributions. The data generated from this trial will remain the responsibility of the sponsor. Release of data will be subject to a data use agreement between the sponsor and the third party requesting the data. De-identified individual patient data will be encrypted upon transfer.

Acknowledgments

This study was funded by the National Institute for Health Research (NIHR) Health Technology Assessment Programme (NIHR HTA project number 12/201/09). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the HTA programme, NIHR, NHS, or the Department of Health and Social Care. NEF was supported through an NIHR Research Professorship (NIHR-RP-011–015), KK was supported through a HEFCE Senior Clinical Lecturer award. EMH and NEF are NIHR Senior Investigators. CMD was funded by an NIHR Research Professorship in General Practice (NIHR-RP-2014–04–026), the NIHR School for Primary Care Research and NIHR Collaborations for Leadership in Applied Health Research and Care West Midlands. We thank all the participants and general practices that participated in the SCOPiC trial, the Midlands Partnership NHS Foundation Trust, the Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Foundation Trust, and Shropcom and the Mid-Cheshire NHS Foundation Trust for hosting the trial, all the NHS managers who facilitated the conduct of the trial, all the physiotherapists (community physiotherapy and interface settings) that participated in the recruitment and treatment of patients in the trial, the NIHR West Midlands Clinical Research Network, the Clinical Research Network Physiotherapy research facilitators (Lucy Huckfield, Yvonne Rimmer, and Katrina Humphries), members of the PPIE group from Keele for their contribution, and Keele Clinical Trials Unit (CTU). The trial team thanks and acknowledges the members of our Trial Steering Committee (Suzanne McDonough (chair), Phil Hannaford, Jeremy Fairbank, Catrin Tudur-Smith, Stephen Tatton, and Robert Taylor) and the Data Monitoring Committee (Ricky Mullis (chair), Nicola Walsh, Karla Hemming, and Terence O'Neill) for their valuable advice and support during the trial.

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