

Effect of Stratified Care for Low Back Pain in Family Practice (IMPACT Back): A Prospective Population-Based Sequential Comparison

Nadine E. Foster, DPhil¹

Ricky Mullis, PhD²

Jonathan C. Hill, PhD¹

Martyn Lewis, PhD¹

David G. T. Whitehurst, PhD^{3,4}

Carol Doyle, MSc¹

Kika Konstantinou, PhD¹

Chris Main, PhD¹

Simon Somerville, MSc¹

Gail Sowden, MSc¹

Simon Watball, HND¹

Julie Young, HND¹

Elaine M. Hay, MD¹

on behalf of the IMPACT Back Study team

¹Arthritis Research UK Primary Care Centre, Keele University, Keele, Staffordshire, United Kingdom

²The Primary Care Unit, Department of Public Health & Primary Care, University of Cambridge, United Kingdom

³Faculty of Health Sciences, Simon Fraser University, Burnaby, British Columbia, Canada

⁴Centre for Clinical Epidemiology and Evaluation, Vancouver Coastal Health Research Institute, Vancouver, Canada

ABSTRACT

PURPOSE We aimed to determine the effects of implementing risk-stratified care for low back pain in family practice on physician's clinical behavior, patient outcomes, and costs.

METHODS The IMPACT Back Study (Implementation to improve Patient Care through Targeted treatment) prospectively compared separate patient cohorts in a preintervention phase (6 months of usual care) and a postintervention phase (12 months of stratified care) in family practice, involving 64 family physicians and linked physical therapy services. A total of 1,647 adults with low back pain were invited to participate. Stratified care entailed use of a risk stratification tool to classify patients into groups at low, medium, or high risk for persistent disability and provision of risk-matched treatment. The primary outcome was 6-month change in disability as assessed with the Roland-Morris Disability Questionnaire. Process outcomes captured physician behavior change in risk-appropriate referral to physical therapy, diagnostic tests, medication prescriptions, and sickness certifications. A cost-utility analysis estimated incremental quality-adjusted life-years and back-related health care costs. Analysis was by intention to treat.

RESULTS The 922 patients studied (368 in the preintervention phase and 554 in the postintervention phase) had comparable baseline characteristics. At 6 months follow-up, stratified care had a small but significant benefit relative to usual care as seen from a mean difference in Roland-Morris Disability Questionnaire scores of 0.7 (95% CI, 0.1-1.4), with a large, clinically important difference in the high risk group of 2.3 (95% CI, 0.8-3.9). Mean time off work was 50% shorter (4 vs 8 days, $P = .03$) and the proportion of patients given sickness certifications was 30% lower (9% vs 15%, $P = .03$) in the postintervention cohort. Health care cost savings were also observed.

CONCLUSIONS Stratified care for back pain implemented in family practice leads to significant improvements in patient disability outcomes and a halving in time off work, without increasing health care costs. Wider implementation is recommended.

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INTRODUCTION

It has been stated that "most cases of back pain resolve regardless of the course of therapy, and some do not get better no matter what is done. Therein lies the problem for practitioners, patients, and policy makers."¹ Health care systems universally face the challenge of providing effective primary care for low back pain within constrained resources, in the face of increased demands for treatment and investigations.^{2,3} Back pain is now the 6th highest contributor to the global burden of disease.⁴ In the United Kingdom, 6% to 9% of adults consult a family physician for back pain each year,⁵ accounting for 14% of consultations.⁶ More than 60% still report pain and disability a year later,^{7,8} and 2% to 7% will develop severe persistent symptoms⁹ leading to high levels of reconsultation, work loss, and sickness certification.¹⁰ Recent guidelines recommend



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CORRESPONDING AUTHOR

Nadine Foster, DPhil
NIHR Professor of Musculoskeletal Health in Primary Care
Arthritis Research UK Primary Care Centre
Primary Care Sciences
Keele University
Staffordshire ST5 5BG, United Kingdom
n.foster@keele.ac.uk

evidence-based treatments, but the optimal approaches to target resources and improve the efficiency and effectiveness of primary care remain elusive.¹¹

In response to internationally agreed-on research priorities,¹² the recent Subgroups for Targeted Treatment (STarT) Back trial studied and demonstrated the clinical and cost-effectiveness of stratified care for nonspecific low back pain within physical therapy services in primary care.^{13,14} The trial compared stratified care—prognostic risk stratification into low, medium, and high risk groups combined with risk-matched treatment—with current best physical therapy practice and showed improved clinical targeting; low-risk patients fared well with self-management, while medium- and high-risk patients were more often appropriately referred for physical therapy. To operationalize the trial and to ensure high levels of protocol compliance necessary to achieve high internal validity, patients consulting their family physician with nonspecific low back pain were referred to community-based, physical therapy–led clinics, which hosted the research. This approach contrasts with usual practice internationally, whereby first-contact care is most commonly provided by family physicians, and only a small proportion of patients (approximately 20% in the United Kingdom) are referred to physical therapy.¹⁵ We therefore undertook the IMplementation to improve Patient Care through Targeted treatment (IMPACT Back) study to address the unanswered questions of whether stratified care implemented within a primary care family physician setting is clinically effective, leads to more targeted use of health care resources by changing physician referral behavior, and reduces health care costs.

METHODS

Design and Setting

IMPACT Back was a prospective, primary care–based, quality improvement study in England with a before-and-after design. Full methods are reported in detail elsewhere.¹⁶ Sixty-four family physicians from 5 practices in a single health care region in Cheshire, England, participated. Each practice identified consecutive adult patients consulting their physician with low back pain during a usual care phase (phase 1: 6-month recruitment in 2008) and a stratified care phase (phase 3: 12-month recruitment in 2008-2009). Phase 2 was dedicated to the adoption of stratified care among participating practices and linked community-based physical therapists using a quality improvement package of training and support. Practices represented a range of characteristics including different settings (urban, semiurban, rural), practice sizes (ranging from 7-19 physicians and 9,754-23,649 patients in their populations), models of access

to physical therapy, and research experience (yes vs no). Practices were initially approached by members of the Primary Care Research Network in the West Midlands in the United Kingdom and recruited after an initial meeting with the research team at which the study was discussed. Five of 7 approached practices participated.

Patient Sample

Eligible adults (aged ≥ 18 years) consulting with nonspecific low back pain of any episode duration, with or without associated leg pain, were identified using a standardized set of diagnostic Read codes.^{16,17} Read codes are the standard clinical terminology system used in general practice in the United Kingdom, identifying patients' clinical symptoms and diagnosis. An independent steering committee oversaw the study. Ethical approval was granted by the Cheshire Local National Health Service Research Ethics Committee (protocol 07/H1017/143).

Phase 1: Usual Care

For 6 months at each family practice (phase 1), we installed computer templates in Egton Medical Information (EMIS) systems that generated a message during the consultation when certain Read codes were entered. This message facilitated patient inclusion and exclusion, and prompted physicians to obtain initial consent for patients to receive study information. Contact details of consenting, eligible patients were obtained by weekly downloads. These patients were mailed study packets with an invitation letter, information leaflet, baseline questionnaire, and consent form (for follow-up and back-related medical record review). During this phase, family physician management involved assessment, advice, medication, sickness certification, and referral for investigations or further treatment as appropriate (eg, to community physical therapy or secondary care specialists), based on clinical judgment in negotiation with patients. Community-based physical therapists managed patients using clinical judgment to determine the number and content of treatment sessions. Importantly, we did not make any attempt to change usual care of low back pain patients in this phase, and clinicians were naive to the stratified care model to be implemented in the next phase of the study.

Phase 2: Implementation

During a 3-month period (phase 2), we introduced stratified care using a quality improvement program.^{16,18} This evidence-based program for effecting clinician behavior change^{19,20} aimed to implement stratified care into the consultation by providing educational sessions, regular audit, peer feedback, and clinical mentoring opportunities. Details of the stratification tool and

matched treatments for each risk stratum have been published.^{18,21,22} Briefly, the tool consists of 9 self-report items capturing 8 prognostic factors: function (2 items), radiating leg pain, pain elsewhere, depression, anxiety, fear avoidance, catastrophizing, and bothersomeness. The score ranges from 0 to 9 and allocates patients into 3 risk groups: low, medium, or high risk of persistent disability. For patients in the low-risk group, family physicians gave written information on self-management and advice to keep active, prescribed pain medications where appropriate, and reassured patients about their good prognosis. For patients in the medium-risk or high-risk group, physicians were encouraged to refer patients to physical therapy and address their back-related concerns highlighted by the stratification tool.

We also trained 15 community-based physical therapists to stratify patients and provide risk-matched treatment.^{18,21,22} For patients categorized as low risk at the first physical therapy appointment, this approach involved a minimal package of assessment, education, and support for self-management, typically during a single session; for medium-risk patients, the physical therapy interventions focused on reducing pain and disability, increasing use of physical modalities (activity, exercise, and manual therapy), and encouraging patients in early return to work; for high-risk patients, psychologically informed physical therapy was provided.²² The informed physical therapy integrates simple cognitive-behavioral techniques with traditional physical therapy to reduce pain and disability, improve psychological functioning, and facilitate patients' confidence to self-manage future episodes. For all patients, physical therapists were encouraged to ask patients about their medication, counsel them about appropriate medication use, and liaise with family physicians with respect to those patients whose pain-relieving medication was insufficient to facilitate increases in physical activity.

Phase 3: Stratified Care

A new cohort of patients was recruited during a 12-month period (phase 3) to assess the impact of stratified care, using identical processes to those in phase 1. Recruitment over this period enabled evaluation of the pattern of physician engagement in stratified care over time, measured at 3-month intervals by the extent to which physicians exited from the computer template pop-ups before completing the template, during back pain consultations. The computer template (pop-up) in phase 3 included a screen prompting physicians to complete the stratification tool in real time (ie, during the consultation) and provided a risk group–matched treatment recommendation. The same clinicians treated patients in phases 1 and 3. Contamination bias across phases was reduced by using identical study informa-

tion packets and physician referral processes in both phases and ensuring that phase 1 participants reconsulting during phase 3 were not reinvited to participate.

Outcomes

To assess outcomes related to process of care, we captured physician clinical behavior pertaining to the targeting of health care resources by measuring numbers of referrals to physical therapy or other services, ordered diagnostic tests (radiographs, magnetic resonance imaging and computed tomography scans, blood tests), prescribed medications, consultations with the physician, and sickness certifications. These data were collected by research nurses from medical records for patients who gave consent. A key process outcome was risk-appropriate use of physical therapy (ie, nonreferral of patients at low risk and referral of patients at medium or high risk). Detailed data on physical therapy treatments were captured using case report forms for a sample of 40 patients each in phases 1 and 3 (80 patients in total).

To assess patient outcomes, we mailed patients self-report questionnaires at baseline (shortly after physician consultation) and at 2- and 6-month follow-ups. The primary clinical outcome was change in back-related disability at 6 months assessed with the Roland-Morris Disability Questionnaire (RMDQ)²³ on a scale of 0 to 24, where higher scores indicate greater disability. Descriptions of the secondary outcome measures are reported in detail elsewhere¹⁶ but included back pain intensity, depression and anxiety, catastrophizing, fear avoidance beliefs, pain self-efficacy, health-related quality of life, global rating of change since baseline, risk group ascertained with the stratification tool, time off work, adverse events, and patient satisfaction. Research nurses overseeing minimum data collection¹⁶ could not be masked to study phase.

We assessed additional back pain–related use of health care resources with questions on the self-report questionnaire at 6 months, to be used in our economic evaluation. These data included inpatient stays, outpatient visits, other health care appointments including those in private practice, prescribed medication, and over-the-counter medications and treatments.

Statistical Analysis

Our primary analyses compared phase 1 (usual care) with phase 3 (stratified care) for the key process of care outcome (proportion of risk-appropriate referrals to physical therapy), the primary clinical outcome (back-related disability measured by the RMDQ), and health care and societal cost-utility analyses. In secondary analyses, we tested for differences between study phases at the risk group level, which required a larger sample size than the primary analysis. Accordingly, the

secondary analysis was used for the power calculation to test superiority of stratified care over usual care for patients at medium and high risk, and noninferiority for patients at low risk. Allowing for a 20% loss to follow-up, we aimed to recruit 1,000 participants to provide 80% power to detect a small overall treatment effect size of 0.2, equivalent to a mean difference in RMDQ scores between phases of about 1.

Primary analysis was by intention to treat using imputed data sets (generated through multiple imputation by use of simulation based on a multivariate normal model). We obtained estimates of treatment effect—mean difference for numerical outcomes, odds ratios for categorical outcomes, and incidence rate ratios for lost work days—with 95% confidence intervals by regression models adjusted for baseline score, age, sex, baseline RMDQ score, back pain duration, and physician practice. A 30% reduction in RMDQ score from baseline has been reported to be a minimal clinically important difference in this score for an individual patient.²⁴ We therefore compared the proportion of patients achieving this difference in phases 1 and 3. Secondary analysis consisted of a per-protocol analysis comparing the subset of phase 3 patients who received risk-matched recommended treatment vs all phase 1 patients.

The cost-utility analysis focused on estimation of mean incremental quality-adjusted life-years (QALYs) and back-related health care costs (including National Health Service and private care) across phases 1 and 3. QALYs were generated from responses on the EQ-5D questionnaire, using United Kingdom–derived preference weights.²⁵ Health care costs were estimated from self-reported resource use data at 6 months; the costs applied to units of resource use are reported in Supplemental Table 1. A sensitivity analysis explored productivity losses within phases 1 and 3. Costs were assigned to periods of back-related work absence using respondent-specific wage rate estimates identified from national data for yearly earnings and UK Standard Occupational Classification codes.²⁶ In the economic analyses, no discounting was applied to costs or health benefits.

Further data collection and analyses specified in our protocol¹⁶ are reported in separate articles, for example, in-depth interviews eliciting physicians' and physical therapists' experiences of stratified care.

RESULTS

Patient Characteristics

A total of 922 patients were recruited: 368 in phase 1 and 554 in phase 3. The 725 patients invited who did not respond to our baseline questionnaire were on average younger (44 vs 54 years) and more likely to be male (50% vs 45%). Characteristics of the participating

patients in each phase are shown in Table 1. In general, there was little difference in baseline demographic and clinical characteristics. Risk group proportions at base-

Table 1. Baseline Characteristics of Potentially Eligible and Participating Patients

Characteristic	Phase 1	Phase 3
Potentially eligible patients		
Number invited (potentially eligible)	630	1,017
Age, mean (SD), y	47.9 (16.8)	49.2 (15.8)
Sex, female, No. (%)	340 (54)	570 (56)
Excluded, No. (%) ^a	28 (4)	47 (5)
Nonrespondents, No. (%)	234 (37)	416 (41)
Respondents, No. (%)	368 (58)	554 (55)
Consented to medical record review, No. (%)	307 (83)	421 (76)
Followed up at 2 mo, No. (%) ^b	254 (69)	332 (60)
Followed up at 6 mo, No. (%) ^c	233 (63)	314 (57)
Participating patients		
Age, mean (SD), y	53.0 (15.0)	54.1 (14.8)
Sex, female, No. (%)	202 (55)	330 (60)
Routine/manual laborer, No. (%) ^d	102 (35)	157 (37)
Currently in paid employment, No. (%)	227 (62)	323 (59)
Time off work for back pain, No. (%) ^e	109 (49)	133 (42)
Disability: RMDQ score, mean (SD) ^f	8.7 (5.9)	8.4 (5.7)
Pain intensity: NRS rating, mean (SD) ^g	5.3 (2.4)	5.0 (2.6)
Duration of back pain episode, No. (%)		
<1 month	75 (20)	94 (17)
1-3 months	62 (17)	102 (18)
3-6 months	75 (20)	111 (20)
6 months to 3 years	82 (22)	130 (24)
>3 years	74 (20)	117 (21)
Leg pain, No. (%)	279 (76)	408 (74)
Risk group, No. (%)		
Low	136 (37)	214 (39)
Medium	151 (41)	232 (42)
High	81 (22)	108 (20)

NRS = numerical rating scale; RMDQ = Roland-Morris Disability Questionnaire.

^a Exclusions: 8 patients in phase 1 and 23 patients in phase 3 had either died or moved primary care practice; 1 and 0 were unable to respond to questions; 11 and 19 did not want to participate; 6 and 4 did not have back pain; 1 and 0 had comorbid problems that were a priority; 1 and 1 were unable to take part.

^b Losses to follow-up at 2 months: 102 patients in phase 1 and 217 patients in phase 3 did not respond to mailing; 9 and 0 had either died or moved primary care practice since baseline; 2 and 3 did not want to continue to take part; 0 and 1 did not have back pain; 1 and 1 had comorbid problems that were a priority. All baseline participants were retained for the purposes of intention-to-treat analysis (by imputation).

^c Losses to follow-up at 6 months: 118 patients in phase 1 and 235 patients in phase 3 did not respond to mailing; 5 and 3 had either died or moved primary care practice since 2-month follow-up; 0 and 1 had comorbid problems that were a priority; 0 and 1 did not have back pain. All baseline participants were retained for the purposes of intention-to-treat analysis (by imputation).

^d Based on major groups 5 to 9 of the UK Standard Occupation Classification (SOC, 2000) for current or most recent paid job.

^e Respondents who were currently in paid employment at baseline and had time off in the 12 months before baseline.

^f On a scale of 0 to 24: 0 = no disability, 24 = maximum disability.

^g On a scale of 0 to 10: 0 = no pain, 10 = pain as bad as could be.

line were the same across both phases, with 38% at low risk, 42% at medium risk, and 20% overall at high risk for persistent disabling symptoms.

Process of Care Outcomes

As shown in Table 2, implementation of stratified care led to significantly more risk-appropriate referrals to physical therapy for medium- and high-risk patients (40% referred in phase 1 vs 72% referred in phase 3) but little difference for low-risk patients (65% vs 68% not referred). In phase 3, physicians followed the stratification tool's recommendation for risk-matched treatment in 393 patients (71%). The mean numbers of physical therapy treatment sessions provided in both phases were similar (3.8 vs 4.2), but physician consultations for back pain were more common in phase 3. Stratified care led to a significant more than 30% reduction in sickness certifications, as well as prescribing changes that included a decrease in use of nonopioids and a concurrent increase in use of mild opioids.

Patient Clinical Outcomes

The change in disability at 6 months was significantly better with stratified care than with usual care, with a mean difference between phases in RMDQ change

of 0.7 (95% CI, 0.1-1.4) (Table 3). Analyses of secondary outcomes showed significant benefits of stratified care in terms of fear avoidance beliefs, risk status, and patient satisfaction. Also, stratified care was associated with an overall 50% reduction in time off work. No adverse events were reported.

Evaluation Within Risk Groups

The benefit of stratified care on process outcomes was greatest for patients at high risk (evident in physician consultations and prescriptions) and medium risk (evident in prescriptions and sickness certification) (Table 4). Patients at high risk for poor outcome who were managed in phase 3 fared better in terms of disability, pain, and depression scores, with less work absence than those from phase 1. Patients at medium risk had significantly better outcomes with respect to fear avoidance beliefs and less time off work due to back pain in phase 3 compared to phase 1.

Secondary Analyses

Results at the 2-month follow-up are available from the authors; outcomes were similar for phase 1 and phase 3. The per-protocol analyses (Supplemental Tables 2-4), which included all phase 1 patients and only those phase

3 patients for whom the physician followed stratified care, showed greater improvements in favor of stratified care compared with the intention-to-treat analysis.

Economic Analyses

Disaggregated mean health care costs are reported in Table 5, with total health care costs reported in Table 6. Disaggregated mean resource use is reported in Supplemental Table 5. Overall, stratified care was associated with a mean cost saving of £34 per patient and an incremental QALY estimate of 0.003, with similar results observed in a complete-case analysis (cost saving = £66, incremental QALY = 0.008). Supplemental Figure 1 graphically illustrates the uncertainty around the incremental cost and QALY point estimates. Regarding the indirect costs associated with back pain—related work absence, stratified care was associated with a mean savings of £400 per employed patient over 6 months (Table 5).

Table 2. Process of Care Outcomes at 6-Month Follow-up

Outcome	Phase 1 (n = 368) No. (%)	Phase 3 (n = 554) No. (%)	Odds Ratio (95% CI)	P Value ^a
Risk-appropriate referral to physical therapy				
Not referred within the low-risk group	89 (65)	123 (68)	1.12 (0.74-1.68)	.64
Referred within the medium-/high-risk groups	93 (40)	270 (72)	2.36 (1.80-3.10)	<.001
Reconsulted family physician	88 (29)	159 (38)	1.51 (1.10-2.07)	.01
Prescribed medications^b				
Nonsteroidal anti-inflammatory drugs	136 (44)	159 (38)	0.76 (0.57-1.03)	.08
Antidepressants	31 (10)	42 (10)	0.99 (0.61-1.61)	.96
Nonopioids	66 (22)	53 (13)	0.53 (0.35-0.78)	.001
Opioids	88 (29)	201 (48)	2.27 (1.66-3.11)	<.001
Strong ^c	73 (24)	114 (27)	1.19 (0.85-1.67)	.31
Weak only	15 (5)	87 (21)	5.07 (2.87-8.97)	<.001
Neuromodulators/antiepileptics	18 (6)	20 (5)	0.80 (0.42-1.54)	.51
Issued a sickness certificate	45 (15)	40 (9)	0.61 (0.39-0.96)	.03
Had diagnostic tests ordered				
Blood test	110 (36)	154 (37)	1.03 (0.76-1.40)	.84
MRI scan/radiograph	47 (15)	55 (13)	0.83 (0.55-1.27)	.39

MRI = magnetic resonance imaging.

^a Derived by χ^2 test.

^b Ascertained from British National Formulary codes: nonsteroidal drugs (10.1.1), antidepressants (4.3.1), nonopioids (4.7.1), opioids (4.7.2), and antiepileptics (4.8.1).

^c Buprenorphine, butrans, co-codamol, codeine phosphate, DF Forte, Dtrans, fentanyl, kapake, matrifen, morphine, nabumetone, oxycodone, oxycontin, OxyNorm, Palladone, pethidine, tramadol, trazodone, Zydol.

Table 3. Patient Outcomes at 6-Month Follow-up

Outcome	Phase 1 (n = 368)	Phase 3 (n = 554)	Effect Estimate ^a (95% CI)	P Value ^a
Function and pain				
Disability: change in RMDQ score	2.2 (6.0)	2.7 (5.5)	0.71 (0.06 to 1.36) ^b	.03
Achieved MCID ^c , No. (%)	154 (42)	261 (47)	1.24 (0.92 to 1.67) ^d	.15
Pain intensity: change in NRS rating	1.7 (2.8)	1.9 (3.2)	0.29 (−0.05 to 0.63) ^b	.09
Physical function: change in SF-12 PCS score	−3.7 (11.5)	−3.9 (16.3)	−0.78 (−2.47 to 0.92) ^b	.35
Psychosocial outcomes				
Catastrophizing: change in PCS-CAT score	1.7 (8.3)	1.8 (10.3)	0.28 (−1.13 to 1.68) ^b	.67
Fear avoidance: change in TSK score	2.5 (8.3)	3.6 (11.2)	1.58 (0.53 to 2.62) ^b	.006
Anxiety: change in HADS subscale score	1.0 (4.4)	1.2 (4.7)	0.34 (−0.29 to 0.97) ^b	.27
Depression: change in HADS subscale score	1.0 (4.0)	1.4 (3.7)	0.46 (−0.07 to 0.98) ^b	.08
Mental health: change in SF12 MCS score	−1.9 (14.3)	−2.1 (13.7)	−0.56 (−2.77 to 1.64) ^b	.58
Pain self-efficacy: change in PSEQ score	−7.6 (12.8)	−7.2 (15.5)	−0.45 (−2.16 to 1.26) ^b	.60
Global change from baseline, No. (%)				
Completely recovered	38 (10)	63 (11)	1.22 (0.93 to 1.59) ^d	.16
Much better	102 (28)	178 (32)		
Better	88 (24)	129 (23)		
No change	95 (26)	127 (23)		
Worse/much worse	45 (12)	57 (10)		
Risk group, No. (%)				
Low	240 (65)	404 (73)	1.49 (1.05 to 2.12) ^d	.03
Medium	96 (26)	122 (22)		
High	32 (9)	28 (5)		
Work loss^e				
Absenteeism: days off work since baseline	7.9 (23.5)	4.3 (14.5)	0.47 (0.24 to 0.92) ^f	.03
Presenteeism: reduced productivity at work	2.2 (2.5)	2.0 (2.5)	0.17 (−0.42 to 0.75) ^b	.57
Satisfaction with care received, No. (%)^g				
Satisfied	161 (71)	215 (70)	1.15 (0.84 to 1.59) ^d	.39
Neutral	23 (10)	41 (13)		
Not satisfied	44 (19)	52 (17)		
Satisfaction with results of care, No. (%)^g				
Very satisfied/satisfied	133 (59)	209 (70)	1.50 (1.04 to 2.16) ^d	.03
Neutral	39 (17)	45 (15)		
Not satisfied	52 (23)	46 (15)		

CSQ-CAT = Coping Strategies Questionnaire – CATastrophizing subscale; HADS = Hospital Anxiety and Depression Scale; MCID = minimal clinically important difference; MCS = Mental Component Subscale; PCS = Physical Component Subscale; PSEQ = Pain Self-Efficacy Questionnaire; RMDQ = Roland and Morris Disability Questionnaire; SF-12 = Short Form 12; TSK = Tampa Scale of Kinesiophobia.

Note: Values are mean (SD) unless otherwise noted.

^a Effect estimate and 95% confidence interval derived by regression analyses adjusted for age, sex, general practice, baseline RMDQ, duration of pain, and corresponding baseline value.

^b Mean difference derived by linear regression.

^c Based on an MCID (≥30% reduction in RMDQ score from baseline and rating of “completely recovered” or “much better” or “better” according to the global change question).

^d Odds ratio derived by binary/ordinal logistic regression.

^e Based on 290 of 547 respondents who reported being currently employed at 6-month follow-up.

^f Incidence rate ratio derived by robust Poisson regression.

^g Based on 536 respondents for the care received question and 524 for the results of care question at the 6-month follow-up.

DISCUSSION

Compared with usual care, stratified care for patients with low back pain implemented in everyday family practice was associated with modest improvements in patients' outcomes overall, more targeted use of health care resources, and reduced sick certification without increased health care costs. Patient benefits included improvements in physical function, fear avoidance beliefs, satisfaction, and time off work. Significant changes to physician clinical behavior included increased numbers of risk-appropriate referrals to physical therapy, reduced prescribing of nonsteroidal medications, and many fewer sickness certifications. Benefits from stratified care also included a concurrent small overall reduction in health care resource use and large societal cost savings due to fewer periods of pain-related work absence.

Our study was powered to compare outcomes within patient risk groups (low, medium, and high risk). Stratified care did not adversely affect pain or disability outcomes for patients at low risk of poor outcome. Physicians prescribed fewer nonsteroidal anti-inflammatories and more weak opioid medications, and patients reported greater satisfaction with the results of care. Patients at medium risk received more physical therapy and more prescriptions for weak opioids, but fewer prescriptions for neuro-modulator medications and far fewer sickness certificates. We did not include opioid prescription in the treatment protocols or clinician training packages; therefore, this increase in weak opioid prescription was unintended. Prescription of

Table 4. Process of Care and Clinical Outcomes at 6-Month Follow-up by Risk Group

Outcome	Low Risk			Medium Risk			High Risk		
	Phase 1 (n = 136)	Phase 3 (n = 214)	P Value ^a	Phase 1 (n = 151)	Phase 3 (n = 232)	P Value ^a	Phase 1 (n = 81)	Phase 3 (n = 108)	P Value ^a
Process of care outcomes									
Reconsulted physician, No. (%)	19 (18)	33 (22)	.43	39 (31)	74 (41)	.056	30 (42)	52 (58)	.03
Prescribed medications, No. (%)									
Nonsteroidal anti-inflammatory drugs	46 (43)	43 (28)	.01	61 (48)	71 (39)	.15	29 (40)	45 (51)	.19
Antidepressants	2 (2)	8 (5)	.16	19 (15)	18 (10)	.20	10 (14)	16 (18)	.48
Nonopioids	11 (10)	11 (7)	.39	30 (23)	30 (17)	.14	25 (35)	12 (13)	.001
Opioids	19 (18)	47 (31)	.02	44 (34)	95 (53)	.001	25 (35)	59 (66)	<.001
Strong opioids	12 (11)	25 (16)	.24	37 (29)	49 (27)	.75	24 (33)	40 (45)	.13
Weak opioids	7 (7)	22 (14)	.046	7 (5)	46 (26)	<.001	1 (1)	19 (21)	<.001
Neuromodulators/antiepileptics	0 (0)	1 (1)	1.00	10 (8)	4 (2)	.02	8 (11)	15 (17)	.30
Issued sickness certification, No. (%)	10 (9)	11 (7)	.54	21 (16)	16 (9)	.046	14 (20)	13 (15)	.41
Blood test ordered, No. (%)	33 (31)	50 (33)	.73	46 (36)	65 (36)	.98	31 (43)	39 (44)	.92
MRI scan/radiograph ordered, No. (%)	12 (11)	10 (7)	.19	20 (16)	29 (16)	.91	15 (21)	16 (18)	.65
Clinical outcomes									
Disability: change in RMDQ score	0.9 (5.8)	0.9 (4.5)	.87	3.4 (6.3)	3.5 (6.0)	.21	2.3 (5.8)	4.8 (6.8)	.004
Achieved MCID, ^b No. (%)	67 (49)	103 (48)	.68	66 (44)	113 (49)	.17	22 (27)	45 (42)	.06
Pain intensity: change in NRS rating	1.0 (2.9)	0.8 (3.0)	.83	2.3 (3.0)	2.4 (3.1)	.52	1.9 (2.6)	2.9 (3.3)	.02
Physical function: change in SF-12 PCS score	-2.2 (15.2)	-2.6 (16.5)	.98	-5.7 (13.9)	-4.0 (11.9)	.79	-2.3 (13.1)	-6.1 (14.8)	.051
Catastrophizing: change in PCS-CAT score	0.5 (7.8)	0.5 (6.4)	.86	1.2 (7.3)	1.1 (10.0)	.83	4.9 (8.6)	6.0 (11.7)	.36
Fear avoidance: change in TSK score	2.8 (9.2)	3.1 (8.4)	.42	1.7 (7.6)	3.3 (7.5)	.02	3.3 (7.1)	5.3 (12.3)	.09
Anxiety: change in HADS subscale score	0.7 (4.1)	0.6 (4.2)	.82	0.8 (3.7)	1.0 (4.0)	.09	2.1 (5.5)	2.7 (4.3)	.22
Depression: change in HADS subscale score	0.4 (4.1)	0.6 (3.8)	.90	1.4 (3.3)	1.4 (3.3)	.45	1.2 (4.3)	2.7 (3.6)	.007
Mental health: change in SF-12 MCS score	-1.1 (13.4)	-0.2 (14.4)	.61	-1.2 (13.8)	-2.0 (12.8)	.23	-4.8 (17.4)	-6.4 (11.7)	.63
Pain self-efficacy: change in PSEQ score	-4.9 (13.7)	-3.1 (13.4)	.31	-9.6 (16.8)	-8.4 (15.2)	.72	-8.4 (12.5)	-12.6 (17.0)	.07
Global change since baseline: much improved, No. (%)	67 (49)	116 (54)	.48	53 (35)	88 (38)	.11	19 (24)	41 (38)	.09
Risk group: low risk, No. (%)	117 (86)	197 (92)	.50	97 (64)	169 (73)	.30	35 (43)	57 (53)	.02
Absenteeism since baseline ^c	0.5 (2.3)	0.9 (3.4)	.50	11.3 (26.3)	5.3 (18.7)	.005	15.5 (35.5)	9.4 (16.8)	.41
Presenteeism ^c	1.5 (2.0)	1.2 (1.5)	.32	2.3 (2.3)	2.3 (2.8)	.87	3.7 (3.1)	3.2 (2.8)	.62
Satisfied with care received ^d	59 (75)	81 (76)	.87	77 (75)	99 (70)	.39	25 (54)	35 (59)	.61
Satisfied with results of care ^d	48 (62)	81 (76)	.03	63 (64)	93 (68)	.50	22 (47)	35 (61)	.14

Notes: Values are mean (SD) unless otherwise noted. See Table 3 for abbreviations.

^a P values were derived by χ^2 test for the process outcomes, and by regression analyses for the clinical outcomes (adjusted for age, sex, family physician practice, baseline RMDQ score, duration of pain, and corresponding baseline value—as detailed in Table 3).

^b Based on an MCID ($\geq 30\%$ reduction in RMDQ score from baseline) and rating of “completely recovered” or “much better” or “better” according to the global change question.

^c Based on 290 of 547 respondents who reported being currently employed at the 6-month follow-up.

^d Based on 536 respondents for the care received question and 524 for the results of care question at the 6-month follow-up.

Table 5. Costs of Back Pain-Related Health Care and Work Absence Per Patient

Health Care Resource	Cost, Mean (SD), £	
	Phase 1 (n = 233)	Phase 3 (n = 314)
Primary care contacts		
Family physician: surgery	36.82 (53.5)	32.38 (50.1)
Family physician: home visit	0.45 (6.9)	2.04 (20.5)
Practice nurse: surgery	1.51 (6.2)	0.80 (3.8)
Practice nurse: home visit	0.09 (1.3)	0.06 (1.1)
Physiotherapy service		
NHS	33.15 (60.8)	45.09 (77.2)
Private health care	13.82 (63.7)	11.90 (40.8)
Hospital-based care		
NHS consultant	33.64 (84.5)	29.95 (80.7)
NHS admissions	9.79 (91.6)	12.84 (116.9)
NHS radiograph	4.39 (12.9)	3.97 (11.0)
NHS CT scan	0.43 (6.6)	1.32 (11.2)
NHS MRI scan	16.90 (55.0)	17.38 (53.9)
NHS blood tests	0.30 (2.2)	0.06 (1.0)
NHS epidural injections	3.51 (26.6)	2.09 (19.9)
Private consultant	15.54 (71.5)	9.25 (55.2)
Private admissions	4.97 (75.8)	3.68 (65.3)
Private diagnostic tests	3.07 (23.3)	3.80 (25.4)
Private epidural injections	0.88 (13.4)	0.02 (0.1)
Other health care professionals		
NHS acupuncture	2.44 (17.5)	1.83 (20.6)
NHS osteopathy	0.16 (2.5)	3.19 (20.8)
NHS "other"	8.52 (46.7)	4.96 (33.9)
Private acupuncture	11.90 (67.1)	3.34 (23.3)
Private osteopathy	11.08 (37.0)	9.02 (38.7)
Private "other"	15.41 (63.0)	4.85 (24.7)
Out-of-pocket treatments ^a	15.69 (53.0)	17.50 (83.7)
Prescribed medication ^a	17.32 (80.1)	6.56 (19.5)
Work absence costs: time off work due to low back pain ^b	758.75 (2481.3)	358.95 (1160.4)

CT = computed tomography; MRI = magnetic resonance imaging; NHS = National Health Service.

Notes: Analyses were among patients providing responses to the resource use questions at 6 months. Corresponding resource use data are reported in Supplemental Table 5.

^a Aggregate estimate that combines analgesics (nonopioid and weak opioid), nonsteroidal anti-inflammatory drugs, gels, creams, sprays, aids, and appliances.

^b The estimation of indirect costs focused on respondents in paid employment at 6-month follow-up: 132 of 229 (58%) in phase 1 and 158 of 310 (51%) in phase 3.

mild opioids is in line with back pain guidelines, however.¹¹ Patients at medium risk also reported improved fear avoidance beliefs and significantly less time off work (>50% reduction). Patients at high risk, managed using stratified care, received more health care overall (physician consultations, referrals to physical therapy, and prescriptions for mild opioids); however, this greater use in turn led to significant improvements in disability and pain, depression, and time off work.

Improvements in the management of low back pain are needed,²⁷ yet changing behavior among family physicians is an identified challenge as clinicians struggle to have the time, skills, or inclination to translate evidence into practice to improve patient care.²⁸ Physicians followed the screening tool's recommendation for matched treatment in 71% of cases, which remained stable over a 12-month period. Stratified care's greatest impact on physician behavior was to reduce sickness certification (from 15% to 9%). Because of the high annual consultation rate for back pain among working-age adults (6%),⁵ this finding alone could result in substantial societal cost savings if family physicians routinely adopted stratified care. For example, an average saving of £400 per person consulting with back pain in the UK labor force of 29.17 million²⁹ equates to an overall saving of more than £700 million (>\$1.1 billion US).

IMPACT Back is the first study to test the implementation of stratified care for low back pain within a primary care physician setting. The results extend the findings of the STarT Back trial.^{13,14} The mean difference in patient disability in IMPACT Back was less than that in STarT Back, due in part to the higher proportion of low-risk patients in physician practice (38% vs 26%) and the variability in physician engagement with stratified care. Our per-protocol analysis demonstrated, however, that when patients were managed according to stratified care, absolute improvements in outcomes more closely repli-

Table 6. Total Back Pain-Related Health Care Costs in Different Analyses

Population	Estimated Cost, Mean (SD), £		Mean Difference (95% CI), £	P Value
	Phase 1	Phase 3		
Intention-to-treat (N = 922)	276.48 (585.3)	242.94 (500.5)	-33.54 (-98.6 to 31.5)	.31
Complete resource use data (N = 547)	261.79 (362.0)	227.90 (309.8)	-33.89 (-91.8 to 24.0)	.25
Complete resource use and EQ-5D data (N = 447)	287.29 (380.1)	221.25 (312.5)	-66.04 (-132.2 to 0.2)	.05

Note: The mean difference was calculated as the phase 3 estimate minus the phase 1 estimate. Confidence intervals were generated using conventional parametric methods.

cated the STarT Back trial.¹³ Previous implementation studies of back pain care have had mixed success but tend to conclude that multifaceted and active implementation strategies are of benefit.^{19,30} Results from our qualitative interviews with primary care physicians and physical therapists provide further information.^{31,32} Our quality improvement program, while aimed at primary care clinicians and teams, could be described as an integrated care organizational approach because it comprised various changes including revised professional roles, use of computer prompts and decision aids, and continued education. It remains to be seen whether physician-led stratified care will be encouraged in the same way it is for physical therapy services. For example, financial incentive initiatives, such as the UK Commissioning for Quality and Innovation payments,³³ are rewarding physical therapy services to implement stratified care for back pain patients.

Although IMPaCT Back was not a randomized controlled trial, it has produced a reliable estimate of the effect of implementing stratified care for low back pain in physician practice. We opted for a pre-post design and not a cluster-randomized design because of contamination issues as 4 of the 5 participating general practices referred patients to physical therapists within the same health care region's physical therapy service. One limitation was our reliance on physicians to identify potentially eligible patients, which raises the possibility of selection bias; however, baseline data for both phases demonstrate such contamination did not occur and that our population was similar to that in previous UK primary care back pain studies.^{13,17,21} A second limitation was the differences in data sources used to determine patients' risk group in phase 1 (baseline questionnaires) and phase 3 (computer template completed in the physician consultation). There were limitations in selecting a 2-month follow-up time point, because most medium- and high-risk patients had not finished their physical therapy treatment at this point, as waiting times to first physical therapy appointments in both study phases averaged 4 to 6 weeks, similar to national averages.³⁴ Finally, given the multiple objectives of this study, the problem of multiple testing and overall inflated type I error needs to be considered, although it is unlikely that we would obtain so many significant results if stratified care had no effect on outcomes.

In conclusion, our study shows that stratified care, in which prognostic screening is combined with matched treatment, is effective when implemented among physicians in primary care. It is associated with improved patient outcomes and reductions in work absence, without an increase in health care resource use. These results address guideline recommendations for further research on stratified care¹¹ and have implications for

future family physician practice. Stratified care is associated with benefits for patients and more targeted use of health care resource without increasing health care costs and should be implemented more widely.

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Key words: low back pain; stratified care; subgroups; family practice; primary care; quality improvement; screening; practice-based research

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