Targeted treatment in primary care for low back pain: the treatment system and clinical training programmes used in the IMPaCT Back study (ISRCTN 55174281)

Gail Sowden^{a,b,*}, Jonathan C Hill^a, Kika Konstantinou^{a,c}, Meenee Khanna^{a,d}, Chris J Main^a, Paula Salmon^e, Simon Somerville^{a,f,g}, Simon Wathall^a and Nadine E Foster^a on behalf of the IMPaCT Back study team

^aArthritis Research UK Primary Care Centre, Primary Care Sciences, Keele University, Keele, Staffordshire, ST5 5BG, UK, ^bInterdisciplinary Musculoskeletal Pain Assessment and Community Treatment Service and ^cStaffordshire Integrated Spinal Service, Haywood Hospital, High Lane, Burslem, Stoke-On-Trent, ST6 7AG, UK, ^dEarnswood Medical Centre, Eagle Bridge Health & Well Being Centre, Dunwoody Way, Crewe, CW1 3AW, UK, ^ePhysiotherapy Department, Leighton Hospital, Middlewich Road, Crewe, Cheshire, CW1 4QJ, UK, ^fThe John Kelso Practice, Ball Haye Road, Leek, Staffordshire, ST13 6QR, UK and ^gThe Haywood Hospital Rheumatology Centre, High Lane, Burslem, Stoke-on-Trent, Staffordshire, ST6 7AG, UK. *Correspondence to Gail Sowden, Arthritis Research UK Primary Care Centre, Primary Care Sciences, Keele University, Staffordshire, ST5 5BG, UK; E-mail: g.sowden@cphc.keele.ac.uk

Received 11 April 2011; Accepted 19 May 2011.

Background. The IMPaCT Back study (IMplementation to improve Patient Care through Targeted treatment for Back pain) is a quality improvement study which aims to investigate the effects of introducing and supporting a subgrouping for targeted treatment system for patients with low back pain (LBP) in primary care. This paper details the subgrouping for targeted treatment system and the clinical training and mentoring programmes aimed at equipping clinicians to deliver it.

The subgrouping and targeted treatment system. This system differs from 'one-size fits all' usual practice as it suggests that first contact health care practitioners should systematically allocate LBP patients to one of the three subgroups according to key modifiable prognostic indicators for chronicity. Patients in each subgroup (those at low, medium or high risk of chronicity) are then managed according to a targeted treatment system of increasing complexity.

The subgrouping tools. Subgrouping tools help guide clinical decision-making about treatment and onward referral. Two subgrouping tools have been used in the IMPaCT Back study, a 9-item version used by participating physiotherapists and a 6-item version used by GPs.

The targeted treatments. The targeted treatments include a minimal intervention delivered by GPs (for those patients at low risk of poor outcome) or referral to primary care physiotherapists who can apply physiotherapy approaches to addressing pain and disability (for those at medium risk) and additional cognitive-behavioural approaches to help address psychological and social obstacles to recovery (for those at high risk).

The training packages. Building on previous interventions for other pilot studies and randomized trials, we have developed and delivered clinical training and support programmes for GPs and physiotherapists.

Discussion. This paper describes in detail the IMPaCT Back study's subgrouping for targeted treatment system and the training and mentoring packages aimed at equipping clinicians to deliver it, within the IMPaCT Back study.

Study registration. ISRCTN55174281.

Keywords. Implementation, low back pain, primary care, subgrouping, targeted treatment.

[©] The Authors 2011. Published by Oxford University Press.

This is an Open Access article distributed under the terms of the Creative Commons Attribution Non-Commercial License (http:// creativecommons.org/licenses/by-nc/2.5), which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

Background

Current research evidence has emphasized the high prevalence and costs of low back pain (LBP)¹⁻⁴ and demonstrated that despite available clinical guidelines, the outcomes of primary care management for LBP patients are suboptimal.⁵ This has spurred interest in the early identification of LBP patients at risk of chronicity and the provision of early secondary prevention.⁶ We have developed and validated simple to use, brief clinical tools to subgroup LBP patients according to their risk of chronicity (low, medium and high),⁷ developed targeted treatments for patients in each subgroup^{8,9} and developed training programmes to support primary care health professionals to deliver these. A randomized controlled trial (RCT) (the STarT Back trial: ISRCTN 37113406) has investigated the clinical and cost-effectiveness of this subgrouping for targeted treatment system versus best current care provided by physiotherapists.^{8,10} The IMPaCT Back study (IMplementation study to improve Patient Care through Targeted treatment for Back pain) is a quality improvement study designed to introduce and support this subgrouping for targeted treatment system in primary care and to study the effects on patients, practitioners and health care resource use. The design of the IMPaCT Back study is described elsewhere.¹¹ In brief, the study is investigating whether the subgrouping for targeted treatment system is used and is helpful in everyday primary care, with LBP patients (n =1000), GPs and physiotherapists. Clearly, the subgrouping for targeted treatment system is an example of a complex intervention^{12,13} and therefore, full detail of the intervention and how health professionals are supported to deliver it, is needed. This paper details the subgrouping for targeted treatment system (the subgrouping tools and the targeted treatments) and the clinical training and mentoring programmes used to facilitate its delivery.

Developing the targeted treatments and clinical training and support programmes

Three targeted treatment pathways delivered by physiotherapists have been developed and tested as part of a previous clinical trial^{8–10} to match LBP patients classified at low, medium and high risk of chronicity with an appropriate treatment. In order to equip physiotherapists to deliver targeted treatment pathways, we developed a stepped training and mentoring package.^{8,9} In developing the targeted treatment pathways and the training and mentoring programmes, we considered current LBP management guidelines and current evidence and consensus regarding physiotherapy interventions.^{14–23} We drew on previous experiences of physiotherapy-led psychosocial interventions in a previous trial,²⁴ and a review of relevant RCTs and observational studies.²⁵ We also considered the content of existing leading pain management programmes and held workshops with internationally recognized experts.

In the IMPaCT Back study,¹¹ we further developed the training and support programmes, firstly in light of feedback from the physiotherapists who participated in the previous trial,⁹ secondly from an updated review of other studies and guidelines²⁶ and thirdly in order to adapt it for use with GPs. Fourthly, we used data from the initial observational phase of the IM-PaCT Back study of current clinical practice and practitioners' attitudes, beliefs and behaviour regarding LBP, to further guide the development of the targeted treatments and training packages. Fifthly and lastly, we reviewed previous implementation research²⁷⁻³² and specifically studies which aimed to change the behaviour of health care practitioners in managing LBP³²⁻³⁸ in order to build on interventions which appeared promising. For example, interactive workshops that include patient examples, practice time, role play, simulation and review can result in moderately large changes in practice, while didactic educational sessions alone are unlikely to change practice.^{27,29}

The following first details the subgrouping for targeted treatment system implemented in the IMPaCT Back study and then describes the GP and physiotherapy training and mentoring programmes.

The subgrouping tools

The STarT Back tool⁷ is specifically designed for primary care settings and is a subgrouping tool that allocates patients into low-, medium- or high-risk subgroups in order to guide decision making about treatment and referral. This validated tool fits on one side of an A4 page and contains items relating to physical (four items: two items on back related disability; one on leg pain and one on co-morbid pain) and psychological predictors (five items: one item each on catastrophising; anxiety; depression; bothersomeness and pain related fear). If patients score 4 or more of five on the psychological prognostic indicators, they are allocated to the high-risk subgroup. If they score between 4 and 9 on the subgrouping tool but have 3 or fewer of the five psychological indicators, they are allocated to the medium-risk subgroup. If they score between 0 and 3 on the subgrouping tool, they are allocated to the low-risk subgroup.

Two versions of the subgrouping tool will be used within the IMPaCT Back study: the original 9-item STarT Back tool⁷ (see Appendix 1) and a modified 6-item version which subgroups patients into two subgroups in the GP consultation (see Appendix 2).

The 9-item subgrouping tool

In the IMPaCT Back study, we will introduce and support the use of the paper-based 9-item STarT Back tool that has been previously developed and validated.⁷ This will be completed by the patient at the patients' initial physiotherapy appointment, as this fits most closely with paper-based working practices within physiotherapy. The tool is quick for patients to complete and quick and easy for the physiotherapists to score and is used to indicate which targeted treatment the patient should receive.

The 6-item sub-grouping tool

Discussions with GPs in our clinical advisory group revealed the need for a GP subgrouping tool to subgroup patients into two groups only (low risk or not low risk of chronicity) and that the 9-item tool was felt to be too long to be used in normal GP consultations. We therefore carried out some further analyses to investigate whether we could reduce the number of items while retaining appropriate sensitivity and specificity of the subgrouping tool. Methods identical to the predictive validity testing conducted for the original 9-item tool⁷ were repeated using receiver operator characteristic curve analysis³⁹ and demonstrated that it was possible to remove three items of the original 9-item tool, yet retain the predictive validity of the 'at risk' patient subgroup (i.e. those classified as medium and high risk by the 9-item tool). The analysis demonstrated that six of the original 9items predicted persistent bothersome and disabling LBP at 6 months with a sensitivity of 89% and specificity of 84%, compared to the 9-item tool's predictive validity of 85% sensitivity and 81% specificity. Therefore, a 6-item subgrouping tool was developed for use by GPs, retaining the items for leg pain, disability $(\times 2)$, catastrophic thinking, depression and bothersomeness. It generates a score ranging from 0 to 6, with patients scoring ≤ 2 characterized as at low risk of chronicity and those scoring ≥ 3 characterized as not at low risk. Those not at low risk are recommended for onward physiotherapy referral.

Embedding the 6-item subgrouping tool into GP practices

In order to implement the subgrouping for targeted treatment system in general practice, the 6-item tool needs to be integrated into routine GP consultations, which are on average between 7 and 10 minutes in duration. The 6-item subgrouping tool was piloted in one practice, suggesting GPs found the tool easy to use, it added, on average, up to 2 minutes to the consultation. In the IMPaCT Back study, the tool is being offered to GPs in both a computer-based format embedded in the EMIS (Egton Medical Information

Systems).⁴⁰ GP computer system, the most commonly used clinical software in UK primary care and a paperbased format completed by the GP and patient in the consultation.

The electronic 6-item subgrouping tool. The majority of primary care consultations in the UK are recorded electronically using software designed for this purpose. It was felt that in order to support GPs in using the 6-item subgrouping tool and to maximize recruitment to the IMPaCT Back study, the tool should be offered to GPs as a computerized tool for completion during the GP consultation. The software allows the user to write protocols and templates for their own purposes and has successfully been used to embed screening tools for patients with musculoskeletal conditions in a previous study.⁴¹ We therefore wrote a similar protocol and developed an electronic template ('pop-up screen') that is activated whenever a Read Code indicating a non-specific LBP problem is entered onto the system. This pop-up screen will help remind the GP about the IMPaCT Back study and prompts completion of the subgrouping tool, automatically generating a recommendation about targeted treatment to support clinical decision making.

The paper 6-item subgrouping tool. A paper-based version of the 6-item subgrouping tool is also available for GPs who may find the clinical software intrusive when listening and talking to patients. Descriptions of the pop-up prompts and 6-item tool used are freely available at www.keele.ac.uk/startback. Again, it was important that the paper-based tool is in a format that is easy for the GP to use. Many GPs are already using a similar tool, the PHQ-9⁴², to diagnose and assess the severity of depression as part of the Quality and Outcomes Framework.⁴³ Therefore, we designed the paper-based version of the subgrouping tool to have a similar format and layout of questions in the hope that familiarity will encourage adoption and use of the new tool.

The targeted treatments

In the IMPaCT Back Study, the targeted treatments include a minimal intervention delivered by GPs (for those patients at low risk of chronicity) or onwards referral to primary care physiotherapists who have received specific training as part of the IMPaCT Back study (for those patients deemed to not be at low risk).

Within the physiotherapy consultation, the targeted treatments also include a minimal intervention delivered by physiotherapists (for those patients at low risk of chronicity at the time of physiotherapy consultation), the use of physiotherapy approaches to addressing pain and disability (for those at medium risk) and additional cognitive-behavioural approaches to help address psychological and social obstacles to recovery (for those at high risk). See Figure 1 for an illustration of the subgrouping and targeted treatment system.

The GP delivered targeted treatment for patients in the low-risk subgroup

Patients classified at low risk of chronicity at the time of GP consultation are to receive best primary care advice and management by their GP. All patients will have a brief clinical assessment to screen for red flags and GPs will encourage patients to ask questions relating to any specific concerns about their LBP. GPs will provide reassurance about good overall prognosis, the benign nature of the LBP and simple messages and advice about pain relief, appropriate physical activity levels, return to normal activity, including work, avoiding bed rest, appropriate use of pain relieving modalities and the role of further investigations. To reinforce these key messages the Arthritis Research UK advice sheet about back exercise⁴⁴ can be given to the patient. Onward referral to other services will not be recommended for this patient subgroup, although re-consultation with the GP is to be advised if symptoms persist.

Referral of patients not at low risk to study physiotherapists

GPs will refer patients classified as not at low risk by the 6-item subgrouping tool to an IMPaCT Back study physiotherapist where they should receive the appropriate targeted treatment. Patients will then be given the 9-item subgrouping tool by the physiotherapist at their first appointment.

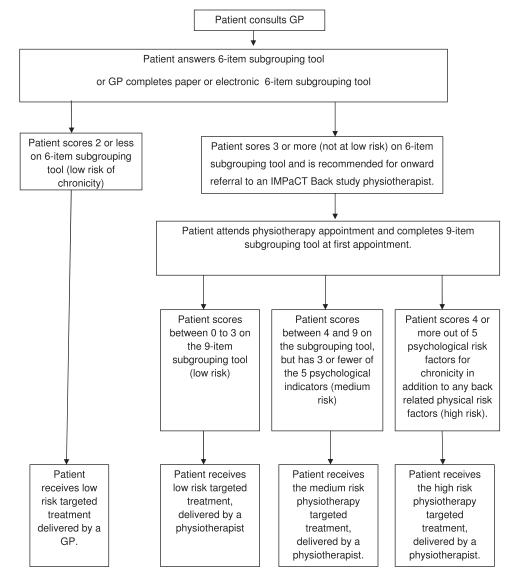


FIGURE 1 The Subgrouping and Targeted Treatment System

We anticipate that some of the patients who are classified as not at low risk at the time of the GP consultation and who are hence referred onwards for physiotherapy will have improved by the time they complete the 9-item subgrouping tool at their first physiotherapy appointment and will now be classified as at low risk. For these patients, the physiotherapists should deliver similar key messages to those used by the GPs, and treatment should be limited to only one or two physiotherapy sessions.

The targeted treatment for patients in the medium-risk subgroup

The medium-risk patients will receive a targeted treatment that focuses on the secondary prevention of future LBP-related disability and addresses current symptoms and back pain-related concerns. All participating physiotherapists have received 3-day training in the targeted treatment for the medium-risk subgroup (this training is described in detail later). Some psychological prognostic indicators will need to be addressed in this subgroup of patients, but as these patients score \leq 3 of five on the psychological items of the subgrouping tool, additional specific training for physiotherapists to do this was not considered necessary. Physiotherapists will carry out a comprehensive assessment (including a physical examination) and provide evidence-based management similar to that described above for GPs. In addition, they will negotiate an individualized treatment plan with the patient aiming to reduce symptoms, disability and promote self-management. They will use a range of interventions including advice, explanation, reassurance, education, manual therapy and exercises. Acupuncture treatment may be provided at the discretion of the physiotherapist and patient. Consistent with evidence-based guidelines,¹⁴⁻²⁶ bed rest, traction, massage and electrotherapy are not recommended. All treatments will be delivered in National Health Service physiotherapy outpatient settings with guidance that although the number of treatment sessions will vary according to patient need, most patients are likely to have up to six face to face physiotherapy sessions over a 3-month period. If there is no satisfactory improvement during treatment, then reassessment of the patient is advised. Where indicated, patients in the medium-risk subgroup should be referred onwards for consideration for investigations or secondary care interventions.

The targeted treatment for patients in the high-risk subgroup

Patients in the high-risk subgroup will have four or more of five psychological risk factors for chronicity in addition to any back-related physical risk factors. They will receive the treatment targeted at the highrisk subgroup, delivered by physiotherapists who have participated in an additional 6 days training in cognitive-behavioural approaches (this training is described in detail later) in addition to the 3 days training that all the study physiotherapists received. The objectives of the targeted treatment for patients in the highrisk subgroup are to reduce disability, reduce pain (where possible), improve psychological functioning and enable the patient to manage ongoing and/or future episodes of back pain.

The physiotherapists will provide evidence-based management similar to that described above, as appropriate, but in addition, they will target psychosocial obstacles to recovery by adopting a cognitivebehavioural approach. This approach is underpinned by a specific focus on communication skills, with careful attention to language and by collaborative goal setting.

These physiotherapists will carry out a comprehensive biopsychosocial assessment. This will include a physical examination, exploration of the impact that pain is having on the patient's physical and psychosocial functioning and the structured identification of potential obstacles to recovery using stem and leaf questions.45 Following initial exploration of the patient's beliefs and expectations regarding LBP and its management, if it is felt that their current understanding is not helpful in enabling them to improve their functioning, then specific effort will be focused on trying to ensure that the patient has a credible understanding of the nature of their pain (e.g. cause, mechanisms, prognosis), with clarification of the role of investigations, invasive interventions and treatments in LBP. Physiotherapists will do this in ways which align with the patient's personal experience, using guided discovery and patient-friendly language. Discussion about the development and maintenance of disability and the relationship between pain and activity will help build rapport and to validate and normalize the patient's experiences. Education and advice will help to address gaps in knowledge and correct possible misunderstandings, it is hoped that this will facilitate behavioural change, build the patient's confidence and contribute to a reduction in patient's distress.

Having discussed the influence of pain on current functioning, opportunities for patient's to respond differently to difficult internal experiences (thoughts, feelings and bodily sensations) and to maintain or alter activity in keeping with their goals will be explored. Patients will receive guidance on a variety of pain rehabilitation techniques including pacing in order to maintain or increase activity and graded activity principles and practice. Advice and support in returning to usual activities, sleep and work will be provided, when indicated, for example, support in developing and implementing a return to work plan.

There will be a specific focus on the prognostic indicators including the psychological ones (catastrophizing, low mood, anxiety and pain-related fear) with the adoption of simple cognitive behavioural techniques. For example, in order to improve low mood, attention may be paid to setting small achievable goals that are meaningful to the patient and in supporting them in establishing a structure and routine and in gaining rewarding and mastery experiences. Fear avoidance beliefs and behaviours may be addressed by relating feared activities to longer term goals, by exploring and building the importance of these goals, by providing information and reassurance and by facilitating patients to engage incrementally in previously feared activities.

Patients will be encouraged to put skills into practice between physiotherapy sessions and progress will be reviewed at each session and effort and achievement reinforced. Physiotherapists will also help patients to problem solve their individual difficulties. The role of active self-management of ongoing or future episodes will be emphasized.

As in the medium-risk subgroup, the number of treatment sessions will be based on individual need but most are likely to have up to six individual face-to-face physiotherapy sessions over a 3-month period. As this is a treatment pathway, where indicated, patients in the high-risk subgroup should be referred onwards for consideration for investigations or secondary care interventions, including interdisciplinary pain management.

Training and support programmes—GPs

An interactive practice-based training and support package

In order to familiarize and support GPs in the subgrouping for targeted treatment system, a training and support package has been developed. Following a literature review of evidence-based guidelines for managing LBP in primary care, a clinical advisory group including practicing GPs agreed that the European Back Pain Guidelines¹⁴ provided the best framework for this training package. The training package focused on those areas that have previously been identified as problematic in the primary care management of LBP.⁵ The structure, content and methods of delivery of the training programmes for GPs and physiotherapists are summarized in Appendix 3.

Best Practice Updates and patient case-based discussion. Practice-based group educational sessions referred to as 'Best Practice Updates' were organized at each GP practice. They were delivered during one session led by members of the IMPaCT Back study team including a primary care Information Technology (IT) specialist, a GP researcher with Special Interest (GPwSI) in musculoskeletal medicine, a senior musculoskeletal physiotherapist and a Consultant Rheumatologist. The time and duration of the Best Practice Updates was agreed with participating practices to fit in with practice constraints and to use protected continuing professional development time wherever possible.

At these Best Practice Updates, the content, delivery and timeline of the study and the new subgrouping and targeted treatment system was discussed. The electronic and paper versions of the subgrouping tool were introduced and 'screen shots' demonstrating the use of the EMIS-based electronic subgrouping tool presented, supplemented by a brief reference manual. A presentation and discussion about the implementation of evidence-based care for LBP in routine primary care focussed on the areas that GPs commonly find challenging including diagnostic labelling, use of imaging, red flag assessment, sickness certification and return to work, activity promotion and reassurance. Data from the first observational phase of the study which monitored usual practice was fed back to GPs to facilitate discussion. Part of the Best Practice Update session focussed on the operational issues, for example identifying key personnel who might assist in the implementation of the IT and paper subgrouping systems and agreeing systems for reviewing referral rates to physiotherapy services and providing adequate support to those services if referral rates rise. Reflective discussion among the IMPaCT Back team members and feedback from the participating practices was used to shape the educational package as the study progressed.

In addition to the Best Practice Update sessions, it is envisaged that further practice-based group discussion sessions will be arranged that focus on patient case-based examples, to review how the subgrouping for targeted treatment system is working within the practice and related physiotherapy service. These meetings will aim to highlight the potential benefits of the subgrouping and targeted treatment system in practice and the importance of good communication and a consistent approach between the GPs and associated physiotherapy service.

Support for GPs. Meetings between the General Practice Research staff in the IMPaCT Back study team and the link GPs at each practice will be set up to discuss experiences of the subgrouping for targeted treatment system and the processes involved in the study. Link GPs will be encouraged to disseminate information/reminders regarding the IMPaCT Back study to their colleagues in order to facilitate engagement with the new care system and patient recruitment.

Additional one-to-one or small group educational meetings will also be offered to each GP practice in order to review the use of the subgrouping tool, the aims of the study, the targeted treatments or any other study-related issue. These can occur at regular intervals throughout the study, as required.

Training and support programmes physiotherapists

Organizational support

Support for the IMPaCT Back study has been provided by key leads within the Primary Care Trust, including the physiotherapy service managers. Local physiotherapy opinion leaders are championing the subgrouping for targeted treatment system with their colleagues and developing and supporting the implementation of the patient care pathways and the associated systems and paperwork to enable the successful delivery of this new way of assessing and managing patients. The involvement of the physiotherapy service will be supported through additional funding in acknowledgement of the time that physiotherapists spend away from clinical practice while they attend training and mentoring sessions. We have negotiated that the training and mentoring programmes will be explicitly linked into individual physiotherapists' Continuing Professional Development plans with support from physiotherapy service managers. We have also facilitated agreements that physiotherapists will have slightly longer assessment (up to 1 hour) and treatment sessions (up to 45 minutes) for those patients who are identified as at high risk of chronicity. Physiotherapy sites have been given a study poster to display in order to raise general awareness about the initiative among patients. We have also agreed onward care pathways for those patients felt by physiotherapists to require the input of mental health services, more specialist pain management services or secondary care services including orthopaedics.

Interactive physiotherapy training and support package We developed a stepped training and support package for participating physiotherapists, detailed below.

Physiotherapists' training package for patients in the low- and medium-risk subgroups. Approximately, 30 primary care physiotherapists attended a 3-day training course and are receiving a subsequent clinical mentoring programme. The training package was developed and delivered by a senior physiotherapist (Spinal Extended Scope Practitioner) with input from a musculoskeletal GPwSI, a consultant spinal orthopaedic surgeon, a consultant rheumatologist and a disability advisor. The training incorporated pre-training reading materials and used a combination of lectures, interactive group discussions, paper patients (based on real LBP patients) and observations of real patients as they are assessed and treated. The training was supplemented by a comprehensive manual, providing clear guidelines and treatment algorithms for the evidence-based assessment and treatment of patients with LBP, either with or without leg pain.

The focus of the training was on equipping the physiotherapists to assess and target back pain, leg pain, co-morbid pain and disability by adopting evidencebased practice. The training included evidence-based assessment of LBP, including the use and interpretation of the subgrouping tool to guide treatment. It also included detailed information about the role of diagnostic investigations, medication, epidural injections and surgery in back pain and radiculopathy. Current guidelines for managing LBP in primary care were discussed, including appropriate reassurance and explanation of back pain symptoms, advice about analgesia, the maintenance of, or return to, usual activities (including work) and patients who present a clinical or management concern (e.g. those with signs of potential serious pathology or red flags or significant radicular symptoms). The training included current best physiotherapy practice for the management of disability, back pain and referred leg pain, including the role of exercise and manual therapy as well as strategies for equipping patients with the skills to manage future recurrences. Goal setting, pacing and graded exercise were covered briefly. Consideration was given to the configuration and availability of local services such as interface clinics and secondary care spinal services and how to refer study patients to these services. A disability advisor outlined the role of Job Centre Plus in return to work facilitation so that physiotherapists may appropriately signpost patients to them.

Physiotherapists' training package for patients in the high-risk subgroup. Of the 30 primary care physiotherapists participating in the 3-day training detailed above, 9 went on to participate in a further 6 days of training, making a total of 9-day training. The additional 6 days were delivered primarily by a consultant physiotherapist and a clinical psychologist, both with expertise in pain rehabilitation. The purpose of the 6day training was to develop the physiotherapist's skills in applying a cognitive-behavioural approach to patients with LBP in order to reduce their pain and disability, improve their psychological functioning and enable them to manage ongoing and/or future episodes of LBP. Specific attention was paid to the assessment and management of physical and psychosocial prognostic indicators. This was essentially a further refinement of approaches developed in previous trials.8,24

The training first explored some of the most influential psychological predictors of chronicity (fear, anxiety, low mood and catastrophizing) to explain how they can contribute to the development and maintenance of pain and disability, this was illustrated with models such as the fear avoidance model.⁴⁶

Secondly, the training built on the physiotherapists existing expertise in exploring the impact of an individuals' pain on activity, work, sleep, relationships and mood, as well as how to facilitate discussions with patients about the relation between physical and psychosocial factors. Considerable time was allocated to communication skills training, collaborative goal setting and on helping the physiotherapists to identify potentially modifiable obstacles to patients achieving these goals, using stem and leaf questions.⁴⁵ The physiotherapist practised their clinical reasoning in differentiating pain-related distress from non-pain-related distress and modifiable from non-modifiable obstacles to recovery and in integrating complex information in order to identify appropriate targets for treatment and plan treatment sessions accordingly.

The third part of the training focused on reducing disability as well as pain and distress (where possible). Different ways of overcoming potentially modifiable biopsychosocial obstacles was explored. For example, gaps in patient's knowledge (relating to pain and activity) might be met, expectations managed or unhelpful beliefs gently challenged, by the provision of individualized information, reassurance and advice. The importance of checking the effect that any information or advice, for example, giving patient's an explanation for their pain, had on the patient, particularly on their behaviour was emphasized. The physiotherapists explored different ways of helping patients to modify activities (i.e. to start, do more or less, alter the quality or persist in an activity), depending on what would be most likely to enable the patient to achieve their goals. Specific time was therefore allocated to skills training in simple pain rehabilitation techniques, such as motivational interviewing, problem solving, pacing, graded activity and return to work facilitation (e.g. liaising with the workplace). Training also aimed to assist the physiotherapists in working with patients to try to improve their sleep, mood and social functioning.

The final stages of the clinical training explored how to deal with the most distressed or complex patients and how to recognize when levels of distress or complexity were beyond that which a primary care physiotherapist can reasonably manage and when to refer to other services either directly or via the GP. Physiotherapists were encouraged to familiarize themselves with other relevant services such as chronic pain services and how to appropriately refer or signpost patients to them.

In an attempt to embed the approach into clinical practice, the physiotherapists were given a tool to help monitor patient's progress. The importance of reinforcing progress, modifying treatment and enabling patients to actively self-manage ongoing or future setbacks or recurrences were emphasized.

This further 6 days of training was delivered using a variety of methods including interactive presentations, group discussion, role play, paper patients (based on real LBP patients), paper-based exercises, audio and video training materials and the use of simulated patients (actors working to specific scripts in the role of patients). The training was supplemented by pre-training reading and written training materials, and we aimed to make the training as interactive, experiential, skills based and patient focussed as possible. The training was delivered in blocks with time in between to practice and consolidate skills. Participating physiotherapists were given written and audio materials to use with patients in treatment sessions, worksheets for patient's to complete between sessions and aide memoirs to reinforce key messages. Some of these methods are discussed further elsewhere.⁹ A summary of the key content covered in the GP Best Practice Updates and in the two physiotherapy training packages can be found in Appendix 3.

Physiotherapy support. Previous experience in supporting physiotherapists to change their practice with LBP patients^{8,24} has highlighted the need for clinical mentoring of physiotherapists after the initial training programmes are complete. Ongoing mentoring is likely to be the most effective way of consolidating and further developing the physiotherapists' knowledge, skills and confidence in delivering this subgrouping and targeted treatment system. Hence, a programme of individual feedback and regular group mentoring and outreach visits has been developed and is being delivered. The IMPaCT Back study team are providing 2 hours per month of group clinical mentoring for 6 months following the training programme. Physiotherapists participating in the 3-day training programme are mentored as a group by the senior physiotherapist (Spinal Extended Scope Practitioner) responsible for their training and those participating in the additional 6 days of training are mentored as a separate group by the consultant physiotherapist and clinical psychologist. These mentoring sessions provide the opportunity for physiotherapists to discuss recent patient cases and increase their confidence in the use of the assessment and management techniques introduced in the training programme. A variety of methods are used iteratively to maximize the effectiveness of mentoring, including observation and feedback with LBP patients, demonstration and practice. In addition, the clinical mentors are available by e-mail and telephone to support physiotherapists in implementing the subgrouping for targeted treatment system. Senior physiotherapists from within the participating physiotherapy service, identified as opinion leaders, will then take responsibility for ongoing mentoring between 6 and 12 months, in order to facilitate sustainability of the subgrouping for targeted treatment system in the longer term.

Referral rates to physiotherapy and patient waiting times are being monitored monthly in order to identify and react promptly to any increase in demand for the service as a result of the new system. An outreach visit to each physiotherapist in their usual clinical setting will incorporate observation of each physiotherapist delivering a patient assessment or treatment session and feedback on this. In addition, individual feedback will be provided following observation and video recording of each of the physiotherapists participating in the additional 6 days of training. This involves two video recordings of them conducting an assessment of a simulated patient (actor), once at the end of training and once after 6 months practice and clinical mentoring.

Conclusions

The IMPaCT Back study is investigating the effects of introducing and supporting a new care system, subgrouping for targeted treatment, for LBP patients in primary care. This paper has detailed the subgrouping for targeted treatment care system and the training packages for health care professionals involved. If the IMPaCT Back study shows that subgrouping for targeted treatment is used by health professionals and is helpful for improving patients' outcomes, further dissemination of this system and the training programmes to support it will be required.

Acknowledgements

We would like to thank all members of the wider IMPaCT Back study team including: Ricky Mullis, Carol Doyle, Julie Young, Martyn Lewis, David Whitehurst, Adele Higginbottom, Stephanie Tooth, Pauline Ong, Jackie Gray, Rhian Hughes and Elaine Hay. We thank the participating GP practices, physiotherapy services and patients. The IMPaCT Back study is funded with a Project Grant awarded by the Health Foundation Engaging with Quality in Primary Care initiative (grant code: 346/4540) and support from the UKCRN. N.E.F. thanks the National Institute of Health Research, UK for an NIHR Primary Care Career Scientist award and J.C.H. thanks the Arthritis Research UK for funding his post as a lecturer in physiotherapy.

Authors' contributions: S.S., S.W., M.K. and N.E.F. developed and delivered the training programmes for participating GPs. G.S., K.K., C.J.M. and J.C.H. led the training programmes and G.S., C.J.M., K.K. and P.S. led the mentoring programmes for participating physiotherapists. J.C.H. led the development of the subgrouping tools and S.S. and S.W. adapted it for use with GP EMIS systems. N.E.F. is the principal investigator for the IMPaCT Back study. G.S. wrote the first draft of this manuscript and all authors have contributed to revisions, have read and approved the final manuscript.

Declaration

Funding: The IMPaCT Back study is funded with a Project Grant awarded by the Health Foundation Engaging with Quality in Primary Care initiative (grant code: 346/4540) and support from the UKCRN. N.E.F. thanks the National Institute of Health Research, UK for an NIHR Primary Care Career Scientist award and J.C.H. thanks the Arthritis Research UK for funding his post as a lecturer in physiotherapy. Keele University is supporting the nested qualitative investigation. N.E.F. thanks the National Institute of Health Research, UK for an NIHR Primary Care Career Scientist award. (346/4540).

Ethical approval: the Cheshire Local NHS Research Ethics Committee (Study number: 07/H1017/143). Conflict of interest: none.

References

- ¹ Dunn KM, Croft PR. Classification of low back pain in primary care: using "bothersomeness" to identify the most severe patients. *Spine* 2005; **130**: 1887–92.
- ² Maniadakis N, Gray A. The economic burden of back pain in the UK. *Pain* 2000; **84:** 95–103.
- ³ Croft PR, Macfarlane GJ, Papageorgiou AC, Thomas E, Silman AJ. The outcome of low back pain in general practice: a prospective study. *BMJ* 1998; **316**: 1356–59.
- ⁴ Hestbaek L, Leboeuf YC, Manniche C. Low back pain: what is the long-term course? A review of studies of general patient populations. *Eur Spine J* 2003; 28: 149–65.
- ⁵ Somerville S, Hay E, Lewis M *et al.* Content and outcome of usual primary care for back pain: a systematic review. *Br J Gen Pract* 2008; **58**: 790–97.
- ⁶ Koes BW, van Tulder MW, Thomas S. Diagnosis and treatment of low back pain. *BMJ* 2006; **332:** 1430–34.
- ⁷ Hill JC, Dunn KM, Lewis M *et al.* A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008; **59:** 632–41.
- ⁸ Hay EM, Dunn KM, Hill JC *et al.* A randomised clinical trial of subgrouping and targeted treatment for low back pain compared with best current care. The STarT Back Trial Study Protocol. *BMC Musculoskelet Disord* 2008; **9:** 58.
- ⁹ Main CJ, Sowden G, Hill JC, Hay EM. Integrating physical and psychological approaches to treatment in low back pain: The development and content of the STarT Back trial's "high risk" intervention (StarTBack; ISRCTN 37113406) Physiotherapy. 2011 (in press).
- ¹⁰ Hill JC, Dunn KM, Lewis M *et al.* A randomised trial of targeted primary care for low back pain compared with current best practice: the STarT Back trial [ISRCTN37113406]. *The Lancet* 2011 (in press).
- ¹¹ Foster NE, Mullis R, Young J et al. IMPaCT Back study protocol. Implementation of subgrouping for targeted treatment systems for low back pain patients in primary care: a prospective population-based sequential comparison. BMC Musculoskelet Disord 2010; **11**: 186.
- ¹² Medical Research Council. A Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health. London, UK: MRC, 2000.

- ¹³ Campbell NC, Murray E, Darbyshire J *et al.* Designing and evaluating complex interventions to improve health care. *BMJ* 2007; **334:** 455–9.
- ¹⁴ van Tulder M, Becker A, Bekkering T *et al.* Chapter 3. European guidelines for the management of acute nonspecific low back pain in primary care. *Eur Spine J* 2006; **15 (suppl 2):** S169–91.
- ¹⁵ European Commission (EC), Cost Action B13 Management Committee. European Guidelines for the Management of Acute Low Back Pain. http://www.backpaineurope.org (accessed on 13 June 2011).
- ¹⁶ European Commission (EC), Cost Action B13 Management Committee. European Guidelines for the Management of Chronic Low Back Pain. http://www.backpaineurope.org (accessed on 13 June 2011).
- ¹⁷ Moffett JK, Mannion AF. What is the value of physical therapies for back pain? *Best Pract Res Clin Rheumatol* 2005; **19**: 623–38.
- ¹⁸ Childs JD, Fritz JM, Flynn TW *et al.* A clinical prediction rule to identify patients with low back pain most likely to benefit from spinal manipulation: a validation study. *Ann Intern Med* 2004; **141:** 920–28.
- ¹⁹ Brennan G, Fritz J, Hunter S *et al.* Identifying subgroups of patients with acute/subacute non-specific low back pain: results of a randomized clinical trial. *Spine* 2006; **31:** 623–31.
- ²⁰ Long A, Donelson R, Fung T. Does it matter which exercise?: A randomized control trial of exercise for low back pain. *Spine* 2002; **29:** 2593–602.
- ²¹ Hayden JA, van Tulder MW, Malmivaara AV, Koes BW. Metaanalysis: exercise therapy for nonspecific low back pain. *Ann Intern Med* 2005; **142**: 765–75.
- ²² Hayden JA, van Tulder MW, Tomlinson G. Systematic review: strategies for using exercise therapy to improve outcomes in chronic low back pain. *Ann Intern Med* 2005; **142:** 776–85.
- ²³ Kool JP, Oesch PR, Bachmann S et al. Increasing days at work using function-centered rehabilitation in nonacute nonspecific low back pain: a randomized controlled trial. Arch Phys Med Rehabil 2005; 86: 857–64.
- ²⁴ Hay EM, Mullis R, Lewis M *et al.* Comparison of physical treatments versus a brief pain-management programme for back pain in primary care: a randomised clinical trial in physiotherapy practice. *Lancet* 2005; **365:** 2024–30.
- ²⁵ van der Windt D, Hay E, Jellema P, Main CJ. Psychosocial interventions for low back pain in primary care: lessons learned from recent trials. *Spine* 2008; **33**: 81–9.
- ²⁶ Savigny P, Kuntze S, Watson P et al. Low Back Pain: Early Management of Persistent Non-Specific Low Back Pain. London, UK: National Collaborating Centre for Primary Care and Royal College of General Practitioners, 2009.
- ²⁷ Grimshaw JM, Eccles MP. Is evidence-based implementation of evidence-based care possible? *Med J Aust* 2004; **180**: S50–1.
- ²⁸ Haines A, Kuruvilla S, Borchert M. Bridging the implementation gap between knowledge and action for health. *Bull World Health Organ* 2004; **82**: 724–32.
- ²⁹ O'Brien MA, Freemantle N, Oxman AD et al. Continuing education meetings and workshops: effects on professional practice and health care outcomes. *Cochrane Database Systematic Reviews* 2001; issue 1. Art. No.: CD003030. doi: 10.1002/ 14651858.CD003030.
- ³⁰ Jamtvedt G, Young JM, Kristoffersen DT, O'Brien MA, Oxman AD. Audit and feedback: effects on professional practice

and health care outcomes. *Cochrane Database Systematic Reviews* 2006; issue 2. Art. No.: CD000259. doi: 10.1002/14651858.CD000259.pub2.

- ³¹ Doumit G, Gattellari M, Grimshaw J, O'Brien MA. Local opinion leaders: effects on professional practice and health care outcomes. *Cochrane Database Systematic Reviews* 2007; issue 1. Art. No.: CD000125. doi: 10.1002/14651858.CD000125.pub3.
- ³² Ammendolia C, Hogg-Johnson S, Pennick V, Glazier R, Bombardier C. Implementing evidence-based guidelines for radiography in acute low back pain: a pilot study in a chiropractic community. J Manipulative Physiol Ther 2004; 27: 170–9.
- ³³ Dey P, Simpson CW, Collins SI *et al.* Implementation of RCGP guidelines for acute low back pain: a cluster randomised controlled trial. Br J Gen Pract 2004; 54: 33–7.
- ³⁴ Bekkering GE, van Tulder MW, Hendricks EJM *et al.* Implementation of clinical guidelines on physical therapy for patients with low back pain: randomized trial comparing patient outcomes after a standard and active implementation strategy. *Phys Ther* 2005; **85:** 544–55.
- ³⁵ Engers AJ, Wensing M, van Tulder MW *et al.* Implementation of the Dutch low back pain guideline for general practitioners: a cluster randomised controlled trial. *Spine* 2005; **30:** 559–600.
- ³⁶ Schectman JM, Schroth WS, Verme D, Voss JD. Randomized controlled trial of education and feedback for implementation of guidelines for acute low back pain. *J Gen Intern Med* 2003; **18:** 773–80.
- ³⁷ Bishop PB, Wing PC. Knowledge transfer in family physicians managing patients with acute low back pain: a prospective randomised control trial. *Spine J* 2006; **6:** 282–8.
- ³⁸ Evans DW, Breen AC, Pincus T *et al.* The effectiveness of a posted information package on the beliefs and behavior of musculoskeletal practitioners: the UK Chiropractors, Osteopaths, and Musculoskeletal Physiotherapists Low Back Pain ManagemENT (COMPLeMENT) randomized trial. *Spine* 2010; **35:** 858–66.
- ³⁹ Hanley JA, McNeil BJ. The meaning and use of the area under a receiver operating characteristic (ROC) curve. *Radiology* 1982; 143: 29–36.
- ⁴⁰ Egton Medical Information Systems http://www.emis-online.com/ (accessed on 13 June 2011).
- ⁴¹ Mallen CD, Peat G, Thomas E *et al.* The assessment of the prognosis of musculoskeletal conditions in older adults presenting to general practice: a research protocol. *BMC Musculoskelet Disord* 2006; **7:** 84.
- ⁴² Kroenke K, Spitzer RL. The PHQ-9: A new depression and diagnostic severity measure. *Psychiatr Ann* 2002; 32: 509–521.
- ⁴³ DOH QOF Guidelines 2009. http://www.dh.gov.uk/en/Healthcare/ Primarycare/Primarycarecontracting/QOF/index.htm (accessed on 12 May 2009).
- ⁴⁴ Arthritis Research UK Patient Information 2007. http://www. arthritisresearchuk.org/pdf/6533_exercises.pdf. (accessed on 12 May 2009).
- ⁴⁵ Main CJ, Watson PJ. Appendix to chapter 8 initial assessment questionnaire. In: Gifford L (ed). *Topical Issues in Pain 3. Sympathetic nervous system and pain. Pain management. Clinical Effectiveness*, CNS Press, 2002: pp. 193–200.
- ⁴⁶ Lethem J, Slade PD, Troup JDG, Bentley G. Outline of fearavoidance model of exaggerated pain perceptions. *Behav Res Ther* 1983; **21**: 401–8.

Appendix 1:

Patient name: _

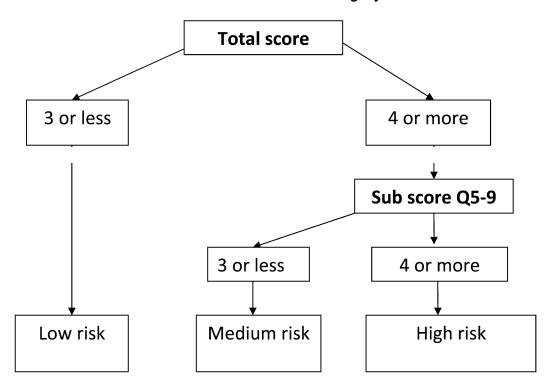
The 9-item STarT Back screening tool.

__ Date: _

Thinking about the last 2 weeks tick your response to the following questions:

			Disagree 0	Agree 1
1	My back pain has spread down my leg(s) at some tir	ne in the last 2 weeks	П	Π
2	I have had pain in the shoulder or neck at some time in the last 2 weeks			П
3	I have only walked short distances because of my back pain			
4	In the last 2 weeks, I have dressed more slowly than usual because of back pain			
5	It's not really safe for a person with a condition like mine to be physically active			
6	Worrying thoughts have been going through my mind a lot of the time			
7	I feel that my back pain is terrible and it's never going to get any better			
8	In general I have not enjoyed all the things I used to enjoy			
9.	Overall, how bothersome has your back pain been in	n the last 2 weeks?		
Not a		Moderately	Very much	Extremely
	otal score (all 9): Sub	Score (Q5-9):		

The 9-item STarT Back Tool Scoring System.



Appendix 2:

The 6-Item STarT Back Screening Tool.

Patient name: _____ Date: _____ Thinking about the last 2 weeks tick your response to the following questions:

		Disagree 0	Agree 1
1	My back pain has spread down my leg(s) at some time in the last 2 weeks		
2	I have only walked short distances because of my back pain		
3	In the last 2 weeks, I have dressed more slowly than usual because of back pain		
4	I feel that my back pain is terrible and it's never going to get any better		
5	In general I have not enjoyed all the things I used to enjoy		

· · · · ·

Not at all	Slightly	Moderately	Very much	Extremely
0	0	0	1	1

Recommend referral if score is ≥ 3 .

Appendix 3:

Key content covered in the training packages.

	Key content covered
GP best practice updates	The subgrouping and targeted treatment system and study design, protocols and relevant documentation Use and interpretation of the 6-item subgrouping tool to guide treatment and referral to physiotherapy Screening for red flags and diagnosis Reassurance about good overall prognosis, the benign nature of the LBP and addressing concerns Role of further investigations Simple messages and advice about pain medication Appropriate use of pain relieving modalities Advice about appropriate physical activity levels, return to normal activity, including work and avoiding bed rest
Low- and medium-risk training	Sickenss certification The subgrouping and targeted treatment system and study design, protocols and relevant documentation Use and interpretation of the subgrouping tool to guide treatment
	The role of diagnostic investigations, medication, epidural injections and surgery in back pain and radiculopathy Appropriate reassurance and explanation re: low back pain symptoms Appropriate advice about analgesia. Advice about the maintenance of, or return to, usual activities (including work) Onwards referral of patients who present a clinical or management concern (e.g. those with signs of potential serious pathology or red flags or significant radicular symptoms) Current guidelines for managing LBP in primary care, including current best physiotherapy practice for the management of disability, back pain and referred leg pain, including the role of exercise and manual therapy as well as strategies for equipping patients with the skills to manage future recurrences. Goal setting, pacing and graded exercise will be covered briefly The configuration and availability of local services such as interface clinics and secondary care spinal services and how to refer study patients to these services
High-risk training	 The role of Job Centre Plus in return to work facilitation. Specific biopsychosocial factors that contribute to the development and maintenance of chronic pain and disability The importance of key processes and how to utilise knowledge of them in treatment Identifying key psychosocial prognostic indicators using stem and leaf questions Exploring the impact of an individuals' pain on activity, work, sleep, relationships and mood Basic and advanced communications skills training including rapport building, listening, demonstrating empathy and motivational interviewing skills Facilitating discussions with patients about the relation between physical and psychosocial factors Applying the biopsychosocial and cognitive behavioural models to the management of pain and pain related disability and distress Making sense of the assessment information, clinical reasoning, identifying appropriate targets for treatment and treatment planning
	Explaining pain and providing reassurance Problem solving difficulties Managing patients' expectations Promoting an active rehabilitation self-management approach Challenge patients' unhelpful or inaccurate beliefs and expectations, for example through the provision of individualized information, reassurance and advice Pacing and graded activity in order to sustain or increase meaningful physical function Improving sleep, mood, social and work functioning Dealing with distressed or complex patients and when to refer onwards or seek additional input Goal setting Monitoring and reinforcing progress and modifying treatment Supporting patients in active self-management of future set-backs or recurrences How to appropriately refer or signpost patients to other services such as chronic pain services