

Design and Development of a Decision Support Package for Low Back Pain

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Objective. To develop a decision support package for people with low back pain (LBP) referred for physiotherapy.

Methods. We used a program of exploratory work, including literature reviews, a Delphi study, a nominal group with physiotherapists, focus groups with patients, and secondary analysis of existing interview data.

Results. We developed an information booklet describing the evidence-based treatment modalities available in a physiotherapy department. This includes data on likely benefits and risks and how the intervention is delivered. The booklet specifically addresses questions identified as important in our exploratory work. Space is provided for patients to note down the pros and cons of each treatment and what matters to them when choosing treatments. The patient is subsequently directed to a section that explores any gaps in knowledge, values, support, and choice before finally clarifying if a treatment decision is possible. At this stage they are encouraged to note down any questions or concerns they have to be discussed at the first physiotherapy consultation. This overall package includes patient material in the form of a booklet posted prior to their consultation, plus the enhanced consultation with the specially trained physiotherapist. Patients then receive their chosen treatment. In addition we developed a training package for physiotherapists that explains the content of the booklet and supports them in using informed, shared decision making in their consultation.

Conclusion. This package has the potential to improve effectiveness of treatments and patient satisfaction for LBP by facilitating patient choice and therefore matching patients more effectively to different treatments.

INTRODUCTION

Nonspecific low back pain (NSLBP) will probably affect all of us at some point in our lives. The National Institute for Health and Care Excellence (NICE) defines it as “tension, soreness and/or stiffness in the lower back region for which it is not possible to identify a specific cause of the pain” (1). NSLBP is a common, costly, and disabling con-

dition, making it difficult to manage from both an occupational health and a primary care perspective (1–5). In the UK it is the largest single cause of absence from work, where the cost associated with loss of production was estimated at £3.8 billion in 1993 and health care costs at £1,632 million in 1998 (2,3,6). In the Global Burden of Disease 2010 study, musculoskeletal disorders were a leading cause of years lived with disability, with low back

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Significance & Innovations

- We have developed an evidence-based decision support package (information booklet plus a training package for physiotherapists) that gives people with back pain information and support in deciding between evidence-based treatments.
- This approach has considerable potential to improve outcomes from low back pain by matching people to the treatment that they and their health professional have chosen as most likely to be suitable for them.

and neck pain specifically highlighted as they had been in 1990 (7).

The existing treatment options available to patients with NSLBP typically have small to moderate average treatment effects and similar costs, making it difficult to choose one treatment over another. In 2009, NICE published guidelines on the management of NSLBP present for greater than 6 weeks but less than 1 year. It recommends offering patients a choice of a course of manual therapy, acupuncture, or supervised group exercise (1). The guidance states that health professionals should take into account the patient's expectations and preferences as part of patient-centered care (1,8). Patients should be supported to allow engagement with their health professionals while discussing their treatment options (1,9,10).

Research suggests that patients seeking care for NSLBP in physiotherapy departments want more information about the available treatment options to aid their decision making (11–17). There is evidence that patient expectations are not being met, hindering the decision-making process (10,18–20). In an ideal scenario, health care professionals should adopt an informed shared decision-making approach. This means a greater involvement by the patient in choosing the treatment he or she would most prefer, after a discussion with their health professional, during which they have received factual information about different available options (9,21,22).

Patient Decision Aids (PDAs) have been used to emphasize the importance of choice and preference, provide details of the benefits and risks of particular choices and, in some cases, provide a patient's perspective (21,23–26). The main purpose of PDAs is to support patients in discussing treatment options during consultation with health professionals. These aids have been developed for conditions such as breast and prostate cancer, hypertension, and hormonal replacement therapy to help with either treatment or screening decisions. Randomized controlled trials (RCTs) investigating the effectiveness of the PDAs for these conditions have shown positive effects on patient satisfaction with the decision-making process, enhanced knowledge acquisition, and less decisional conflict or anxiety when making a decision on treatment preference (24,25,27,28).

We are testing whether a decision support package (DSP) to help patients attending a physiotherapy department make choices about management improves outcome

for people with LBP (29). We describe here the design and development of our DSP, including the development of patient material and training for physiotherapists.

PATIENTS AND METHODS

Ethical approval for this study was granted by Warwickshire Research Ethics Committee. To develop our DSP, we undertook a program of exploratory work. The development process was modeled on the International Patient Decision Aid Standards Collaboration (IPDAS) framework and its related checklist (30,31). These cover best practice in the development of DSPs under 3 broad headings: appropriateness of content, how robust and transparent is the development process, and effectiveness in achieving a good quality decision. Our development work aimed to answer the questions below.

Question A: what components make a DSP effective for benign disorders with multiple moderately effective treatment options? We undertook a systematic review of research papers reporting evaluation of decision aids for treatment of benign disorders, with multiple moderately effective treatment options, where the decision aid had been shown through an RCT to be effective. Our inclusion criteria were patients experiencing mild, nonprogressive sickness, any condition that had multiple and moderate effective treatment options, and RCTs carried out in any setting. We excluded trials of cancer treatment. We searched Medline, CENTRAL (Cochrane Central Register of Controlled Trials), CINAHL, Embase, and PsycINFO (2006–2010). Data were extracted on the components of these decision aids.

Question B: what are the recommended and effective treatments for inclusion in the DSP? To identify the treatments for which there was evidence of cost effectiveness, we updated the NICE guidelines on treatment for NSLBP (1). The guideline development group reviewed the RCT evidence for back pain treatments up to July 2008. We updated the searches in June 2010 to identify any new trials published in the intervening period. To be included, studies needed to be RCTs involving adults age ≥ 18 years with NSLBP of any duration, where the total sample size was >349 . We selected this sample size as our cutoff point because this is the minimum size required for an RCT to detect a statistically significant effect with sufficient power of at least 80% at the usual significance level of 5% (2-sided) and 1:1 treatment allocation, if the standardized effect size is 0.3. Standardized effects of ≤ 0.3 have been seen in large high-quality LBP trials (32).

Question C: from the perspective of “expert patients,” what do patients living with NSLBP consider important when deciding between treatment options? In a Delphi study (33) we set out to identify from patients, with experience of and expertise in back pain, what the key features of a DSP should be, considering both general decision support and in relation to each of the treatments from which a patient might choose. The first stage in the Delphi

Round 1 Delphi Questions
In this round we asked the responders to answer the questions based on the scenario that they had consulted a physiotherapist who had provided them with four treatment options: a course of acupuncture, a course of supervised group exercise, a course of manual therapy, or a group cognitive-behavioral program.
1. From what you know about back pain, what are the most important factors you would take into account when making treatment choices about your back pain?
2. What general information would you want to know about the above four treatments?
3. What specific information would you want to know about:
a) acupuncture?
b) group exercise? (supervised exercise program in a group of up to 10 people)
c) manual therapy? (this might be the sort of treatment you would receive from a osteopath or a chiropractor)
d) group cognitive-behavioral approach? (a group therapy targeting human behaviors and beliefs)
4. How would you like the above information to be presented? (e.g., as written material, web-based material, interactive material)
5. When should this information be presented to patients?

Figure 1. Details of questions asked in Delphi round 1.

process was to identify participants who were “experts” in the experience of back pain. We identified and approached BackCare (<http://www.backcare.org.uk/>), the National Association for Patient Participation (<http://www.napp.org.uk/>), the Expert Patients Programme Community Interest Company, and the Expert Patient Programmes (EPP; <http://www.expertpatients.co.uk/>). Through these organizations we were able to promote the Delphi study and recruit participants. Our participants were mainly volunteers in these organizations, EPP tutors, or patients who had lived with back pain.

The Delphi group technique was adopted from Gallagher et al (34). This process involves the generation of ideas by the group, followed by discussion and ranking, the advantage being all participants have an equal opportunity to contribute to the discussion as a formal systematic approach is adopted. Twenty-three experts were recruited and sent round 1 of the questionnaire. Subsequent rounds were only sent to the responders. There were 3 rounds; the questions in round 1 were informed by literature searches and the expertise of the grant collaborators and were all open-ended, providing responders with the opportunity to answer using free text (Figure 1).

Question D: when deciding between treatments, what are the information and support needs of people living with NSLBP attending a physiotherapist? To ensure our DSP met the needs of all patients, not only those with expertise, we undertook a review of qualitative studies involving people with back pain, secondary analysis of an existing set of data, and a focus group. Our analysis involved constant comparison with the results of questions

A and C above to identify new issues. We only report the issues not identified through questions A and C above.

Systematic literature review. We reviewed qualitative studies on treatment choice. Our inclusion criteria were adults age ≥ 18 years with NSLBP of any duration and studies carried out in any setting with a qualitative component allowing details of why different therapies were chosen to be identified. We searched Medline (1980–2010), EMBASE (1980–2010), PsycINFO (1980–2010), AMED (1985–2010), and CINAHL (1980–2010). Two independent reviewers extracted data on participants’ accounts of why these patients chose different therapies.

Secondary analyses. We conducted secondary analyses of interview data collected in a pragmatic multicenter RCT of a cognitive-behavioral approach for NSLBP in primary care, i.e., the Treatment Strategies for Rheumatoid Arthritis (BeST) trial, to identify factors that influence patients’ treatment decisions. The data were collected from patients who had at least moderately troublesome subacute or chronic NSLBP of a minimum of 6 weeks’ duration (35). Transcripts were analyzed by 2 members of the research team.

Focus group study. We conducted a focus group study to help us understand what patients think is most important when making treatment choices for NSLBP. Two focus groups were conducted at the physiotherapy department at Coventry and Warwickshire Hospital; 100 patients seeking care from the physiotherapy department for back pain were sent an invitation pack. Fourteen participants responded with an interest in taking part. Of these, 5 participants attended, leading to 2 focus groups, one group with 2 participants and the other with 3 participants.

The discussion was focused on how patients make decisions about back pain treatments, i.e., the factors they would look for when choosing between treatments, what information would they like to help them choose between treatments, and what they think of the existing materials offered to them about back pain.

Question E: are there existing decision support materials available that patients find helpful? To help address this question, we included questions in our focus group (detailed in question D) about patients’ views on the existing materials offered to them about back pain.

Question F: from the perspective of physiotherapists, what do patients living with NSLBP consider important when deciding between treatment options? The aim of the nominal group (NG) was to determine, from the physiotherapist’s perspective, what information patients seeking care for NSLBP need in order to make informed decisions about their back pain treatment and how it should be delivered (36). We conducted the NG in the physiotherapy department at Warwick Hospital. Physiotherapists were invited to participate in a 2-hour NG technique, and 12 physiotherapists were recruited. The questions discussed were 1) what should the content of the DSP be to enable patients to make decisions about their back pain management? and 2) how should this DSP be delivered?

The NG process ensures each person within the group

has an opportunity to contribute ideas. Initially, the physiotherapists individually thought about their answers to these questions. The facilitators then collated ideas by systematically asking each participant to provide feedback for 1 answer; this process continued until all answers had been reported and documented. Thereafter, answers were discussed and clarification was sought as necessary. The next phase involved ranking. The group collectively decided on the top 10 answers. During this stage there was some grouping of ideas to form higher-order categories. Each physiotherapist was then asked to rank the 10 selected ideas in order of importance, giving 1 point to the least important and 10 points to the most important. The facilitators totaled the points for each of the 10 items and presented these to the group for discussion. Thereafter, participants were asked to rate the items, giving them a rank of 100 to the most important and between 0–100 for the remaining items.

RESULTS

What components make a DSP effective for benign disorders with multiple moderately effective treatment options? We found 14 RCTs meeting our inclusion criteria (Figure 2). The included studies were based on a number of different conditions, including fibromyalgia, chronic pain, cardiac problems, depression, diabetes mellitus, and labor-related issues, all of which had multiple treatment options. Most of the decision aids were in written format,

but other methods included audio guides, computerized programming, and videos. Most decision aids included information on pathogenesis/illness, common symptoms, diagnosis of condition, prognosis of condition, causes of condition, benefits, potential harms, treatment options, weighing advantages and disadvantages, and examples of other decision-making processes. Each of these components was included in our DSP.

What are the recommended and cost-effective treatments for inclusion in the DSP? The 2009 NICE NSLBP guidelines advise offering patients with NSLBP lasting from 6 weeks to 1 year a course of manual therapy, exercise therapy, or acupuncture (1). In our literature update we only found 1 new trial, the Back Skills Training Programme (35). This was a pragmatic multicenter RCT of a cognitive–behavioral approach for NSLBP in primary care. The results from this trial indicated a positive effect in both the short term and long term. All 4 of these interventions are in the range usually considered cost effective by the NHS: a cost per quality-adjusted life year of £20,000 (approximately \$30,000). If the data from the BeST trial had been available to the guideline development group, we considered it likely that a cognitive–behavioral therapy approach would have been recommended. Based on this we offered our participants a cognitive–behavioral approach to back pain management as one of the treatment options.

Based on these results, we included manual therapy,

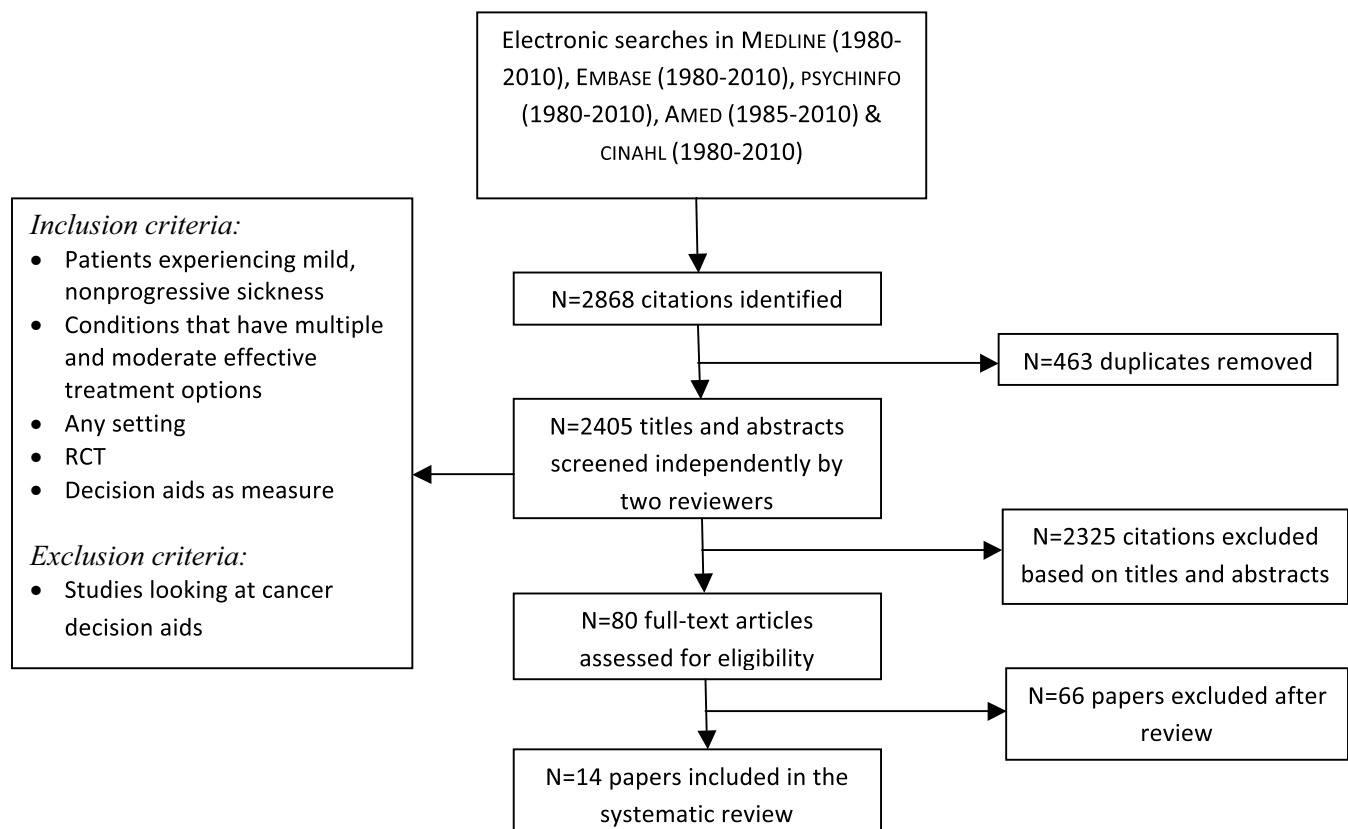


Figure 2. Flow chart of decision aids search strategy. RCT = randomized controlled trial.

Table 1. Summary of results from Delphi exercise

Core content	Specific details
General treatment information	What are the reasons for being recommended these treatments? What is the success rate? What is the evidence for these treatments? What does the treatment involve? How does the treatment work? What are the treatment benefits?
Practitioner Location and availability	What qualifications/skills does the practitioner have? How many and how long are the treatment sessions? How accessible is the treatment facility? What is the availability of the treatment (waiting list)? Where is the treatment being delivered?
Information for each treatment option	How does the treatment work? What does the treatment involve? What are the treatment benefits? How long is the treatment effect (long and short term)? What are the side effects? What is the duration of treatment? How many sessions are there? What is the after treatment follow-up plan? Is there a risk of further harm/damage?
Manual therapy	Do I have to take my clothes off? Will it cause me any discomfort or pain? Will I need to do any exercises at home? What should I wear?
Structured group exercise	What type of exercises will we do? Will the exercise be personalized or general? What should I wear? What is the number of staff to patient ratio? What will be the level of difficulty? How many participants will there be in the group? What age range is this type of treatment for? Will I need to attend all sessions? Will I need to do the exercises at home? Will there be worksheets to monitor my progress? Will the groups be mixed sex? Will the group be supervised?
Cognitive-behavioral therapy	Can I stand during sessions to alleviate my pain? Will the room facilities include comfortable chairs? Will there be worksheets to monitor my progress? Will there be breaks? Will the information I provide in the group be kept confidential? Will I have to talk about my feelings? How many participants will there be in the group? Will the groups be mixed sex?
Acupuncture	Where do the needles go? How long are the needles? How long are the needles in for? Are the needles sterile? How many needles will be used in a session? Can I drive afterwards? Will I sit or stand? Will it cause me any discomfort or pain?

acupuncture, group/individual exercise, and a cognitive-behavioral program as our treatment options in our decision aid.

From the perspective of “expert patients,” what do patients living with NSLBP consider important when deciding between treatment options? Table 1 summarizes the results of the Delphi exercise summary. We collated the

answers into categories: those that were general for all the 4 treatment options and those that were specific for each treatment option. Using this information we developed round 2, in which each participant was asked to rate each factor on a scale of 1–10, where 1 = least important and 10 = most important. Total scores were calculated for each question and discussed by the research team. Following discussion on how to choose the most important factors to

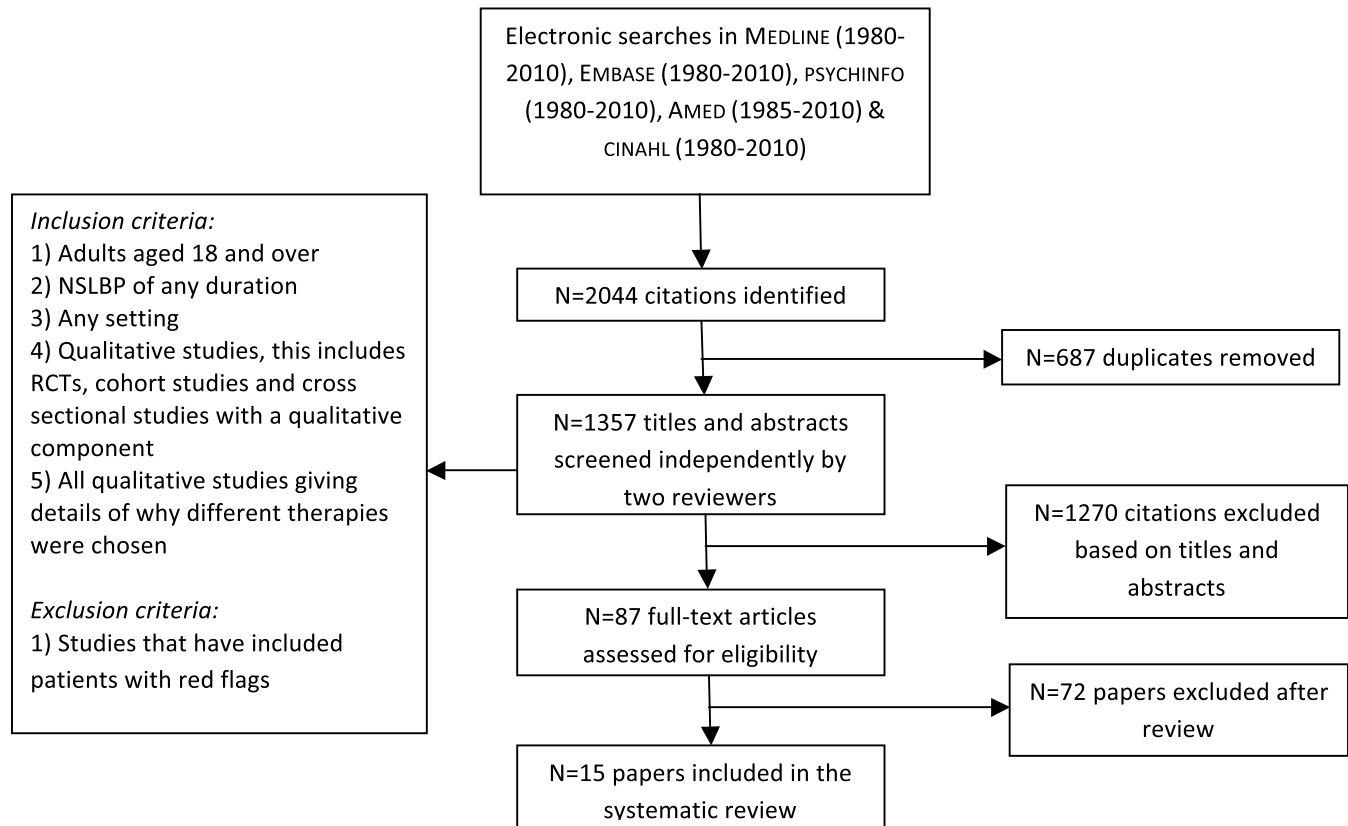


Figure 3. Flow chart of qualitative studies selection. NSLBP = nonspecific lower back pain; RCTs = randomized controlled trials.

help inform development of the decision aid, the mean score for each question was calculated and used as the cutoff mark. Responses with a total sum greater than the average were considered to be the most important factors when choosing between different treatments. Those questions that had obvious top choices were not included in round 3. We used round 3 to help clarify any unclear answers by asking participants to rank answers.

When deciding between treatments, what are the information and support needs of people living with NSLBP attending a physiotherapist? To address this question we drew upon the results from our literature review, secondary analysis, and focus groups.

Literature review. From our literature review we identified 15 studies (Figure 3). From extracting qualitative accounts of why patients chose certain treatments it was possible to group reasons into the following categories: 1) advice from family and friends, 2) previous experience and personal experience, 3) severity of pain determines use of medication, 4) learning about treatments from physiotherapist and general practitioner (GP), 5) forced into treatments (particularly medication) by health care professionals, 6) desperation to find relief, 7) cost implications, 8) trial and error, 9) time factors, and 10) lack of information.

Secondary analysis. Our secondary analysis of the BeST transcripts indicated most people's reason for treatment choice was based on recommendation by health profes-

sionals, family, and/or friends. The factors that frequently influenced treatment choice included length of waiting list, side effects, costs, and previous experience with these treatments. Patients reported that they were mainly only given leaflets on back management and exercise and that they would have liked more information from their GP or other health professional with specialist knowledge about back pain. Some participants expressed they would have liked to receive results from tests quickly in order to help determine the cause of back pain and how best to manage and treat it.

Focus group study. In summary, patients reported they made decisions about back pain treatments primarily from visiting their GP during an acute episode and, in some cases, participants reported they would relinquish treatment decision making to the GP as the expert. When patients have the opportunity to choose between treatments, the factors they would be most interested in are treatments recommended by their GP that have a good success rate, those that are likely to offer pain relief, treatment sessions that fit in with their lifestyle and are not too time consuming or invasive, treatments that will allow early tests or diagnoses to be undertaken by someone that specializes in back pain, and, finally, those treatments that do not have fatigue as a side effect. Information that might help patients choose between treatments included having the opportunity to discuss choices with their GP (including treatment success rates, benefits, and effects), having material provided in an easy-to-read format, having more informa-

Table 2. Summary of results from nominal group exercise*

What should be the content of the DSP in order to help patients make decisions about their back pain management?	How should this DSP be delivered?
Provide a definition of LBP, anatomy, risk factors associated with LBP Normalize LBP and chances of lifestyle changes due to LBP Explain what each treatment option will involve	Choice of all formats: audio/visual CDs, interactive DVD, leaflet and handouts, online/web site access Not “too wordy” Discussion between members of staff (physiotherapists) and patients regarding the treatment options Visual and/or audio CDs
Emphasize the commitment required from each patient to the treatment Explain the ability to function/carry out certain tasks with LBP State the time scales of each treatment and the effectiveness of each treatment, and estimated time scales until benefits are experienced	Via internet or online access Handouts with CDs and/or online access
Explain the long-term prognosis with chances of recurrence Explain the shared process of decision making, based on patient–physiotherapist interaction/communication Provide information on reasons why different tests are undertaken	Interactive DVD Combination of leaflets and online access for staged shared decision making Should include FAQs section and lastly
Provide details of cognitive and holistic approaches to LBP management	Should include “notes” section

* DSP = decision support package; LBP = low back pain; FAQs = frequently asked questions.

tion in GP surgeries, including details of other treatment providers, and being given a firm diagnosis or being referred to the professional who can make the diagnosis.

Are there existing decision support materials available that patients find helpful? From our focus group we found the existing material available to back pain patients was deemed to be limited. Most patients felt they did not get enough information from their GP and were often referred to physiotherapy and given the Back Book (37), which in itself was thought to be limited in information. They felt having access to internet sites from the NHS and other registered charities on different treatments would be valuable. Table 2 below shows the top 10 answers for the 2 questions asked during the NG meeting.

DSP. Based on the data from all of the exploratory work described above we developed a patient DSP. The package is in the form of a patient booklet that summarizes NSLBP and associated causes and symptoms. It details the 4 different treatment interventions available and answers the common questions associated with each option. We included a worksheet for the patient to determine if they have had enough information provided to them, any concerns they may have, and a list of all the references used to develop the DSP. We chose to provide this as a booklet rather than an interactive online resource because both patients and physiotherapists felt it would be more accessible in this form.

A draft of the DSP was sent to experts in back pain and patients to ensure the format and the content were acceptable. The document was reviewed by the lead physiotherapist and study collaborators.

Physiotherapist training. The physiotherapy training was developed using a patient-centered model of care (38).

The aims of the 2-hour program were to give the physiotherapists an overview of the Improving Patient Choice in Treating Low Back Pain (IMPACT) study, their role, and to become familiar with the DSP and how to efficiently use the tool within the consultation. The specific learning objectives were for the physiotherapists to develop an understanding of and explore how to incorporate the DSP within their patient-centered consultations, facilitate patient involvement, and provide appropriate information by recognizing and responding to patient concerns. The training involved direct teaching methods and interactive group work using case studies.

To map communication skills to the DSP, we used principles from the Calgary-Cambridge Guidelines (39), a validated, evidence-based model for communication skills training in medicine. This included specific tasks of the consultation, i.e., commencing the consultation, gathering information, explanation and planning, and closing the consultation, as well as functional aspects of the consultation, which included building a relationship and providing structure (39). Each section was tailored to NSLBP consultations. The DSP was particularly relevant to the explanation and planning stage, learning how to use the DSP to facilitate shared decision making using open questions to gather more information if needed, informing the patient based on the responses, and facilitating their involvement. The training also addressed the use of nonverbal communication skills, which have been associated with better patient outcomes (40).

DISCUSSION

In this study, we have described the development of a DSP package for NSLBP. Currently, this package is being tested in a pilot cluster RCT in Coventry. The RCT results will be available after 2013.

The development of an evidence-based and patient-centered decision aid is time consuming and resource intensive. Decision aids, if developed well, can be a useful resource for patients in making decisions (41–44). Since 1999 there has been a rapid increase in the number of patient decision aids available; however, the quality and process by which they were developed is not always clear. Therefore, the IPDAS collaboration has developed a set of guidelines against which to assess quality of decision aids (31). It is important that decision aids are not viewed as stand-alone, but rather as a package to aid the decision-making process with the health care professional (45). Our package offers the patients an opportunity to review information on available treatments for back pain before they see their physiotherapists. The booklet has been designed to try and answer the questions that emerged from our exploratory work as important to patients when deciding to have a treatment or, more specifically, choosing between the different evidence-based treatments for back pain.

In developing this package the research team has pooled data from multiple sources, including the existing literature and views of both patients and physiotherapists. We have sought to interpret the outputs from different theoretical standpoints to ensure high-quality analyses. This decision aid was developed using the theoretical principles outlined in the IPDAS framework (30,31); this will therefore allow us to make comparisons with other packages developed using the same principles. The guidelines recommend assessing patients' and clinicians' views, determining the format of the decision aid, and synthesizing the evidence before producing a draft version for circulation to patients and clinicians for acceptability. Our extensive exploratory work provides a detailed insight from the patient and clinician perspective going beyond simple surveys and vignettes. Our DSP also complies with the components of the Ottawa Decision Support Framework (46) in that the patient booklet includes a section to help the patient with the decision-making process, and within this there is an area for patients to write down concerns they would like to discuss with the physiotherapist at their appointment.

Caution must be taken in interpreting the results from the focus groups due to poor uptake. Only 5 patients were included over 2 focus groups, one with 2 participants and the other with 3.

We are now piloting the DSP in a cluster RCT with satisfaction with treatment at 3 months using a 5-point Likert scale (very satisfied to very dissatisfied) as our primary outcome. If the results of the RCT are significant, and those receiving the intervention show greater satisfaction with treatment, or the intervention appears to be cost effective, this may be a good indication for a larger RCT in order to look at the implication on clinical outcomes. This larger trial will allow exploration of clinical effectiveness and acceptability of this package in the NHS.

AUTHOR CONTRIBUTIONS

All authors were involved in drafting the article or revising it critically for important intellectual content, and all authors ap-

proved the final version to be submitted for publication. Dr. Patel had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study conception and design. Patel, Ngunjiri, Sandhu, Griffiths, Thistlethwaite, Brown, Friede, Lord, Tysall, Woolvine, Underwood.

Acquisition of data. Patel, Ngunjiri, Woolvine, Underwood.

Analysis and interpretation of data. Patel, Ngunjiri, Sandhu, Griffiths, Thistlethwaite, Lord, Underwood.

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