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Integrating physical and psychological approaches to treatment in low back pain: the development and content of the STarT Back trial's 'high-risk' intervention (StarT Back; ISRCTN 37113406)

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Abstract

A new randomised controlled trial of intervention in low back pain has been described recently. In this trial, a screening and targeted approach was found to be more effective and cost-effective than current best practice. Nested within the intervention arm were three different interventions targeting patients identified as 'low', 'medium' or 'high' risk dependent on the presence of (mainly) psychosocial risk factors. In this paper, the development and content of the STarT Back trial's 'high-risk' intervention is described. It offers a systematic approach, termed 'psychologically informed practice', to the integration of physical and psychological approaches to treatment for the management of people with low back pain by physiotherapists. The term 'disability' is used to refer to self-reported pain-associated functional limitations, and 'psychological' is used to refer to the beliefs/expectations, emotional responses and behavioural responses associated with low back pain.

Keywords: Psychosocial intervention; STarT Back; Low back pain; Psychologically informed practice

Introduction

The recent National Institute for Health and Clinical Excellence guidelines for low back pain recommend a combined physical and psychological treatment programme for patients with low back pain presenting with a high level of disability or distress [1], although there are no specific guidelines on how to do this. Previous research in this field has demonstrated that although cognitive-behavioural approaches appear to be acceptable to patients, and are able to achieve comparable clinical outcomes to other active interventions [2], evidence for their superiority over other treatments is far from robust. A recent Cochrane review of clinical trial evidence concluded that the benefits from the use of early psychosocial interventions for patients with musculoskeletal pain were limited [3]. In low back pain, a number of plausible reasons have been suggested to explain these findings, including: the selection of heterogeneous patient populations in clinical trials; insufficient targeting of interventions on modifiable risk factors; insufficient competencies of care providers; insufficient intensity or duration of the intervention; inadequate adherence to treatment protocols; and inadequate assessment of outcome [4]. Alternatively, it may be that psychosocial interventions are ineffective. However, a recent trial in chronic low back pain demonstrated the superiority of a group cognitive-behavioural therapy intervention package compared with usual care in terms of more effectiveness (Roland and Morris Disability Questionnaire) at 1 year, and cost-effectiveness, mainly as a consequence of the group treatment format [5]. Further research is clearly needed.

In response to the limitations described by van der Windt *et al.* [4], the present authors developed a novel way of stratifying patients with low back pain according to prognostic risk factors, and targeting treatment accordingly [6]. This new approach to stratifying for targeted treatment (the Keele STarT Back approach) is currently being evaluated in clinical studies [7,8]. The aim of this paper is to describe the rationale, development process, key learning objectives, structure and methods of delivery of the training package for physiotherapists delivering treatment to those patients classified as 'high risk' for poor outcome in the future.

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Rationale for the high-risk treatment and training package

The Keele STarT Back Screening Tool produces two scores: an overall score and a distress subscale score [9]. The distress subscale score is used to identify the high-risk group. Responses to the following five items are added to score this subscale: fear, anxiety, catastrophising, depression and bothersomeness. Subscale scores therefore range from 0 to 5, with patients that score 4 or 5 being classified as high risk. The overall score is used to separate the low-risk patients from the medium-risk group. Scores range from 0 to 9 and are produced by adding the responses to all the tool items; patients who achieve a score of 0 to 3 are classified as low risk and those with scores of 4 to 9 are classified as medium risk. The nine-item scale is shown in Appendix A.

The high-risk training and treatment package was developed in the context of increasing adoption of the biopsychosocial model of pain and disability [10], and recognition of the strength of psychological and social influences on clinical outcome. The authors aimed to adopt a multifaceted approach, with a shift in treatment focus from pain reduction to pain rehabilitation (in a broad sense), and a cognitive-behavioural approach in which attention is directed at both psychosocial and biomedical aspects of pain and function [11]. A further shift from pain rehabilitation to secondary prevention, with a broadening of focus to include the identification and targeting of potentially modifiable risk factors, offered exciting new challenges and opportunities to develop a newer, more patient-centred approach to health care. This new type of combined treatment which integrates a cognitive-behavioural approach with traditional physiotherapeutic intervention is perhaps best described as 'psychologically informed practice' [12]; a 'middle way' between biomechanically focused physiotherapy and 'full-blown' cognitive-behavioural therapy. It should be emphasised, however, that this style of management with its focus on psychosocial factors assumes knowledge of the biomedical basis of the symptoms, and experience in treating those aspects of pain. The training was offered to experienced musculoskeletal physiotherapists (i.e. Agenda for Change Band 7 or above). However, providing physiotherapists are experienced in the management of musculoskeletal conditions, there is no reason why this training could not be delivered to physiotherapists at a lower banding. No specialised knowledge or expertise in psychology is required.

The STarT Back approach

Although several back pain classification tools have already been developed to aid clinical decision making [13–16], they do not consider the entire spectrum of patients with non-specific low back pain on the basis of potentially modifiable targets for intervention, and have not been customised for use in primary care settings.

Therefore, the authors developed and validated a new screening tool designed for primary care; the STarT Back Screening Tool [9,17,18]. This was designed to identify a patient's risk status (low, medium or high) of poor outcome using established physical and psychosocial prognostic factors. Allocation to the high-risk subgroup is mainly driven by the tool's psychological variables, highlighting the importance of psychological factors as prognostic indicators of clinical outcome. However, although the high-risk group was identified using psychological indicators, these subjects also score the highest on physical risk indicators, illustrating the clinical complexity of this group. Details of the tool, translations into different languages and scoring systems are available at www.keele.ac.uk/startback.

Development of the training package for clinicians delivering the high-risk intervention

The content of the high-risk intervention was guided by the risk profile of patients in the high-risk subgroup, so that the new intervention could be designed to target their clinical characteristics specifically. Hence, the eight specific risk factors measured by the screening tool (disability, comorbid pain, referred pain, anxiety, mood, fear, catastrophising/negative future expectations and overall bothersomeness) were the framework for the intervention, and the training package focused on ways of providing physiotherapists with the appropriate skills to manage patients who presented with some or all of these risk factors.

In order to develop the content of the training package, a training development group (TDG) was established with two specific objectives: to review and critically appraise the training provided in previous trials and programmes, and to act as an advisory group for development of the new psychologically informed high-risk intervention and training package. The TDG reviewed the literature and identified experts and opinion leaders with particular expertise in the delivery of similar programmes in the musculoskeletal field. Identified experts were then invited by the TDG to attend a series of think tank workshops to facilitate the TDG in designing the new intervention and training package. Professors Linton (Orebro, Sweden), Sullivan (Montreal, Canada), Morley (Leeds, UK) and Watson (Leicester, UK) agreed to participate in the workshops. The overall objectives of the think tank workshops are shown in Box 1.

Following detailed workshop discussions and review of recent high-profile training programmes [2,19–22], a number of key recommendations were made for the development of the intervention and training package, as shown in Box 2.

Over the next 6 months, following specific feedback from the TDG, a draft training package for the high-risk subgroup was developed. This training was piloted with four physiotherapists over a 6-day programme. This followed the 3-day training programme on management of the low- and medium-risk subgroups, to ensure that the high-risk

Box 1: Objectives of the think tank workshops.

- To become familiar with the STarT Back approach, with a particular focus on the 'high-risk' group.
- To compare and contrast similar cognitive-behavioural programmes for low back pain, both nationally and internationally, in terms of their selection, design, format, intervention content, outcomes and training.
- To review current approaches and methodologies for training relevant to secondary prevention in primary care physiotherapy, ensuring that the training content has been delivered as intended.
- To design a pilot study to investigate and evaluate the present training to ensure quality assurance, fidelity, research governance and feasibility.

Box 2: Development of the training: principal recommendations from the think tank workshops.
The training should:

- develop physiotherapists' ability and confidence in dealing with high distress, negotiating patient uncertainty and addressing concerns appropriately, starting with the patients' own beliefs and preferences [23];
- equip therapists to relate individual patient problems to the broad objectives of reducing identified predictors for chronicity, including physical and psychological factors;
- shift towards a skills-based approach with less emphasis specifically on the theoretical content;
- include sufficient time for the establishment of new skills re-inforced by a system of clinical mentoring; and
- distinguish between generic skills (e.g. effective reassurance) for all subgroups and specific skills (e.g. addressing low mood) for the high-risk subgroup [24].

therapists understood the whole treatment context. Following the pilot training course, some of the topics were revised, enhancing in particular the focus on skills development, such as specific targeted communication skills. Real 'high-risk' anonymised case studies identified as part of the pilot training were used to illustrate the range of clinical presentations which might be anticipated, and to re-inforce the need for a combined physical and psychological approach. The 'experiential learning' was developed further with the introduction of simulated patients and monthly group clinical mentoring sessions, which comprised case discussions and the revision of particular topics as requested by the course participants. A monitoring tool was also developed using

Box 3: Key learning objectives.

- Understand the effects of pain on beliefs/expectations, emotions and pain behaviour, and how these contribute to the overall experience of pain.
- Appreciate the range of individual differences in how patients with pain present during consultations.
- Be able to conduct a biopsychosocial assessment and identify potential targets for intervention and potential psychosocial obstacles to progress.
- Recognise and successfully manage the angry and distressed patient.
- Employ clear clinical reasoning to make sense of the assessment findings and use them to develop an appropriate intervention strategy.
- Blend biomedical, cognitive and behavioural techniques into the overall management of pain, pain-associated disability and its emotional impact.
- Embed advice within a patient-centred approach to maximise the development of the patient's skills in self-management.
- Adopt a flexible approach and modify treatment as appropriate in response to patient progress.

the eight constructs in the Keele STarT Back Screening Tool (see www.keele.ac.uk/startback). This enabled clinicians to evaluate their progress in shifting patients' risk factors (see Appendix A).

Key learning objectives of the STarT Back high-risk training course

The overall aims of the course are to give participants knowledge of the relevant evidence base, an adequate understanding of key processes involved in the transition from acute to chronic pain, the opportunity to develop the relevant clinical skills to tackle obstacles to recovery through psychologically informed re-activation, and to establish their confidence to utilise these skills effectively. The key learning objectives are shown in Box 3.

Structure and methods of delivery of the STarT Back high-risk training course

The structure of the final high-risk training course comprises a 6-day programme, consisting of blocks of 2 days with time in between to put skills into practice, with additional mentoring sessions. The methods of delivery include a mixture of didactic teaching, small group discussion, role play and elicitation of psychosocial risk factors with simulated patients, supplemented by comprehensive written material

Box 4: Core topics covered during the training programme.

- Use of communication skills to put patients at ease and facilitate self-disclosure.
- Investigation in the individual patient of the specific relationships between beliefs/expectations, distress and pain behaviour as a precursor to identifying targets for intervention and obstacles to recovery.
- Building on the physiotherapists' existing expertise in exploring the relationship between physical and psychosocial factors.
- Explaining the difference between acute and chronic and recurrent pain, and offering a credible explanation of the nature of pain, pain mechanisms and the development of chronic pain and disability.
- Challenging unhelpful or mistaken beliefs to order to identify agreed achievable behavioural targets.
- Use of techniques such as goal setting, pacing and graded activity to establish successful behavioural change.
- Reshaping patients' expectations using a patient-centred approach to build confidence and enhance self-efficacy.
- Application of simple pain management techniques to problems of sleep, mood, social and work functioning.
- Anticipating and dealing with recurrences and flare-ups.
- Understanding when further specialist help is required and knowing where and how to access services.

and handouts. Prior to attending the course, trainees are given key references designed to provide: a general orientation to the biopsychosocial framework; recent research knowledge about the nature of pain, central pain mechanisms and the development of disability; and an overview of psychological factors and their role in the transition between acute and chronic pain. This material is discussed and referred to during the training. The core topics covered during the training are shown in Box 4.

The course is followed by 12 months of formal, monthly clinical mentoring in a group, in addition to direct access (by phone or e-mail) to the trainers to enable discussion of problematic cases.

In keeping with modern educational theory, and its recommendation of triangulation, a range of teaching and learning methods were used and are described below.

Formal trainer-led teaching

Teaching on core topics is presented in interactive presentations of 30 to 45 minutes, with handouts, opportunity for discussion and clarification. Bullet-pointed text material is supplemented wherever possible with illustrative material and patient audio/video clips, and sessions are interspersed with more interactive and experiential training.

Group discussions

In these sessions, the trainees are invited to use 'paper patients' (with anonymised real patient biographies in addition to some constructed biographies) as a basis for developing their knowledge and practice in a range of skills using a systematic approach. Various ways of addressing specific issues are compared and contrasted. Key topics addressed in these discussion sessions include: identifying the nature and possible psychological factors contained within the patient histories; understanding the psychological influences on patient presentation; identifying potential targets for intervention; and identifying potential psychological obstacles to re-activation. Trainees are then encouraged through practice in pairs (role play) to develop tailored, patient-focused intervention strategies which are discussed amongst the trainees and with the trainers. The trainees then attempt to use these strategies with their patients in between the blocks of training, and their progress is reviewed at the subsequent training session. Back-up written and audio materials to use with patients in treatment sessions are also provided.

Experiential learning

Three types of experiential learning are invoked: (1) role play; (2) conducting an interview with a simulated patient; and (3) practice with patients in between training and mentoring sessions, and discussion of this in the next session.

Role play

Role plays are conducted in a variety of different formats ranging from role play in pairs and triads, to 'stop/start' role play techniques. Role play in triads involves the trainees being grouped into triads with each trainee being asked independently to identify the most awkward/difficult/uncomfortable question that they might be asked by patients or the most difficult situation. Trainee A's questions are given to Trainee B who plays the part of a patient and asks the questions to Trainee C who responds to them as a treating physiotherapist. The procedure is repeated for each of the three sets of questions in turn so that each trainee has the opportunity to see how their colleagues deal with their questions or situations. The trainers also played the parts of both patient and therapist so that the trainees had an opportunity to observe and discuss different ways in which therapists might interact with patients. The 'stop/start' method involves a trainee playing the role of the clinician in front of the group with the discourse between them and the 'patient' being stopped by the trainers at key points. The group then discuss the different ways that the clinician could proceed, and the clinician then role plays one or more of these. Other volunteers may take

over the role of the clinician. The sessions conclude by identifying the key lessons learned from the role plays in terms of managing difficult issues or situations.

Conducting an interview with a simulated patient

Case biographies are made available to professional actors who are accustomed to assisting medical training by playing the part of patients. The trainees are initially given no information about the 'patients' except that they have low back pain. They are asked individually, in the presence of both clinical trainers, to conduct a biopsychosocial assessment, paying particular attention to eliciting the psychosocial risk factors using good communication skills, with a view to development of a treatment plan. The interviews are video recorded and are evaluated in terms of the style and content of the interview. The trainees initially evaluate their own performance and are then offered feedback by the trainers and the simulated patient.

Formal clinical mentoring and access to trainers

Trainees are asked to keep a record of the patients they see and invited to discuss them during the clinical mentoring sessions (described below). They are encouraged specifically to attempt the identification and management of risk factors with their patients, and to discuss these within the group.

The physiotherapists and the two trainers (CJM and GS) meet for a 2-hour session on a monthly basis. The meetings comprise reviews of clinical cases, presented in turn by each of the physiotherapists, and further clarification and expansion of course content, focusing on particular topics suggested by the physiotherapists. The mentoring has two main functions: (1) to use the clinical material to illustrate general principles and the application of specific knowledge and skills to the assessment or management of individual patients; and (2) to offer reassurance, support and encouragement to the physiotherapists to build their confidence in managing the high-risk group of patients. A 'helpline' is provided to facilitate direct access to the trainers in the event of significant or urgent clinical decisions which arise between mentoring sessions.

Discussion

This paper has described the rationale underpinning the Keele STarT Back approach, and the development of the key learning objectives, structure and methods of delivery of the training programme for the physiotherapists who treat the complex (high-risk) patients in the STarT Back approach to managing low back pain in primary care [7].

The authors have attempted to extend the core expertise in biomedical management with a clear and explicit additional focus on psychosocial aspects of pain of the physiotherapists who underwent training. The approach, termed 'psychologically informed practice' [12], is best understood as a type of physiotherapy. Although it uses psychological principles, it should not be confused with the much more intense and systematised cognitive-behavioural therapy delivered by mental health practitioners. Nonetheless, by blending the specific training in the identification and management of psychosocial risk factors with an evidence-based pain management approach, the authors believe that they have delivered a more comprehensive and broadly based approach to training than has been developed previously in the context of individual patient management in primary care.

Training physiotherapists to undertake combined interventions to address physical and psychological obstacles to recovery has the potential to prevent the development of unnecessary incapacity in primary care. Some recent research has demonstrated the potential utility in skilling physiotherapists to expand their role and improve patient outcome [5,25]. This study has added to the research agenda in this field by developing and describing an approach whereby training physiotherapists to deliver targeted interventions goes hand in hand with the identification of risk through screening. The StarT Back approach offers a core level of training for those who will see low- and medium-risk patients, and additional skills for therapists who manage patients identified as high risk. In this way, the clinical outcome is likely to be optimised. A particularly systematic approach was adopted in developing the training package, basing it on previously gathered data, expert clinical opinion and academic advice, and explicit attempts were made to integrate the awareness and management of both biological and psychosocial factors, i.e. the appropriate use of both 'hands on' and 'hands off' approaches.

Physiotherapists who attended the training programme appeared to be willing to participate in an intensive training course, engage with the biopsychosocial framework, and to attempt to integrate it into their clinical practice. The recommendations of the TDG of a shift in approach to a much more practical, skills-oriented approach seemed to enhance the degree of engagement of the trainees, with the focus on communication skills and ways of explaining core topics in language which patients understood being particularly well received. Incorporating some of the newer teaching approaches, such as experiential learning, were initially viewed with some apprehension but appeared to be effective in developing skills and enhancing confidence. Feedback from the trainees particularly endorsed the specific additional value of the clinical mentoring.

Specific evaluation of the impact of training was beyond the remit of this study, but independent qualitative interviews conducted before and after training in the subsequent Impact Back Study, using the general StarT Back approach, suggest that the training has led to improvement in confidence in managing psychosocial factors, and change in clinical practice [26]. Further evaluation of the StarT Back approach is offered as part of the implementation study [27].

Further challenges

There are, of course, unanswered questions in terms of screening, efficacy of the training in the establishment of enhanced skills, establishing the extent to which trained

physiotherapists implement the training in clinical practice, and the feasibility of delivering this training in routine clinical practice. The clinical and cost-effectiveness of this new approach have been reported in the main trial outcome papers [7] and the aforementioned implementation study [27]. The evidence-based approach to training seems to be acceptable to physiotherapists, and appears to develop their skills and enhance their confidence in integrating physical and psychological approaches to treatment with a real prospect of improved patient outcome [26].

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Appendix A. The Keele 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 had pain in the **shoulder** or **neck** at some time in the last 2 weeks	☐	☐
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 is 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 is 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 the **last 2 weeks**?

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

Total score (all 9): _____ Subscore (Q5 to 9):_____

The STarT Back Tool Scoring System