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A cognitive-behavioural programme for the management of low back pain in primary care: a description and justification of the intervention used in the Back Skills Training Trial (BeST; ISRCTN 54717854)

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Abstract

A multicentre randomised controlled trial has been commissioned to evaluate cognitive-behavioural (CB) approaches in the management of subacute and chronic low back pain in primary care. This paper describes the development of the CB intervention based on best-available evidence. Several methods were used to design the intervention. Risk factors for the development of chronic low back pain were identified from the literature to provide targets for treatment, essential components of a CB intervention were considered using the CB treatment model, and the optimal delivery method was used to balance clinical effectiveness and cost-effectiveness within primary care.

Keywords: Intervention design; Low back pain; LBP; Cognitive behavioural; CBT; Early intervention; Risk factors

Introduction

The National Institute of Health Research, Health Technology Assessment programme, commissioned a multicentre randomised evaluation of cognitive-behavioural (CB) approaches in the management of subacute and chronic low back pain (LBP) in primary care. An intervention package was designed and implemented, and 701 participants with moderate to severe LBP lasting for longer than 6 weeks were randomised. The trial design is described in detail elsewhere [1]. In brief, participants were randomised to receive active management, which comprised a session of advice supported by the 'Back Book' [2], or the same intervention in addition to a 6-week CB group programme delivered by a health professional. The advisory session was consistent with current best practice guidelines for primary care [3,4]. The trial assessed the clinical effectiveness and cost-effectiveness of the intervention over 12 months using self-report questionnaires. The primary outcomes were disease-specific measures of pain and function, with secondary outcomes including back beliefs, generic health-related quality of life and resource use. The trial concluded that the Back Skills Training programme was effective in reducing the population burden of LBP, with approximately twice as many people benefiting from treatment compared with an optimised advice package [5]. The intervention was highly cost-effective. In accordance with the Medical Research Council's guidelines for the development and evaluation of randomised controlled trials for complex interventions [6], the purpose of this paper is to describe the theoretical basis and details of the intervention.

Background to problem

LBP is a common problem with a lifetime prevalence of 49% to 80% [7], with 2% to 7% of cases developing chronic persistent problems [8]. LBP has wide ranging effects including impact on work and social activities, relationships, and mental and general health [9,10]. The economic impact of LBP is estimated at £10 668 million each year in the UK (based on 1998 figures) including direct costs, benefit payments and loss of productivity [7]. The majority of these costs are generated by those with the most chronic symptoms [11].

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The population of back pain sufferers is highly diverse in its characteristics, and there have been a number of attempts to determine causality and identify syndromes. None have been entirely satisfactory. However, there is a growing body of epidemiological evidence that points to physical activity and a variety of psychological risk factors as being important to the genesis of chronic LBP. CB models may be useful in modifying these health behaviours and risk factors through targeted action on beliefs and positive coping strategies.

The CB model

The CB model states that the way in which a person thinks about their problem will produce emotions, including associated physical sensations, which then drive behaviour [12]. Often, the behaviour will inadvertently maintain the thoughts or beliefs, thus creating a maintenance or vicious cycle effect.

CB approaches encompass a range of interventions that aim to change behaviour directly using models of learning, and to change behaviour indirectly by changing beliefs. This model was initially used within health care in intensive multidisciplinary pain management programmes based within secondary care for individuals with the most severe and disabling pain problems [13].

Aspects of these programmes have been investigated in other LBP populations, although there has been a wide variation in the design and delivery of treatment packages. A recent systematic review of CB for chronic LBP (>12 weeks) suggested that there were short-term benefits in pain and disability associated with some forms of CB treatment, but longer-term outcomes had yet to be determined [14]. Since then, several more trials have been published. The greatest benefits were seen in trials using usual-care control groups [15–17], with the least significant benefits seen in trials comparing CB approaches with other interventions [18–22]. Trials of CB interventions in subacute LBP (6–12 weeks) have shown improvements in disability measures to varying degrees, suggesting that earlier intervention may be beneficial; however, these conclusions are limited to short-term successes [23–26]. Alternative explanations for the variation between trial results include contact time, professionals delivering the intervention, level of expertise, components included in the programmes, method of delivery and rigour of the adherence to the underlying principles of the CB interventions.

In designing this intervention, the following factors had to be taken into consideration:

- What does the research on risk factors for chronic LBP identify as potentially important health behaviours, beliefs and psychological constructs to incorporate into an intervention?
- What does the CB treatment model consider important in the design of a CB intervention?
- What is the optimal delivery method to balance clinical effectiveness and cost-effectiveness?

Identifying the targets for a CB intervention for LBP

There have been several systematic reviews of risk factors for LBP chronicity in recent years [27,28]. Psychological/behavioural and social factors have been found to be more important in the development of LBP-related disability than the physical risk factors associated with the initial onset of pain [29]. In summary, the key modifiable risk factors appear to be psychological and behavioural factors that have a mediating effect on activity levels. Psychological constructs including catastrophising, passive coping, fear avoidance and depression can lead to decreased activity levels, or to 'overactivity' for some LBP patients. These changes in activity levels are seen to be involved in the development of chronic LBP. Therefore, the targets of the CB intervention of the Back Skills Training (BeST) Trial were:

- to increase activity levels;
- to manage periods of overactivity;
- to specifically address catastrophising and fear avoidance;
- to improve coping skills.

The detailed evidence base is set out below.

Psychological and behavioural

There is consistent evidence that coping strategies, catastrophising and fear avoidance are key factors in the progression of acute LBP to chronic disability [29].

Distress has also been identified as an important risk factor [27]; however, it is difficult to define distress separately from the other psychological constructs and mood [30–32].

Many studies have pointed to the importance of coping strategies and beliefs held by patients [33,34]. A sense of personal control and self-efficacy are associated with active coping strategies (e.g. taking exercise). A lack of personal control and feelings of helplessness are associated with passive (maladaptive) coping strategies, such as rest [35–38].

The strong link between beliefs predicting behaviour has been shown in two studies [39,40]. A reduction in patients' belief that they were disabled and that increased pain signified harm and the need to restrict activity was strongly associated with a reduction in pain behaviours, physical disability and depression. These beliefs are commonly referred to as 'catastrophic beliefs' as they describe thoughts about the worst-case scenario. They lead to avoidance of the feared activity or pain, which has been labelled 'fear-avoidance' behaviour and has been consistently and strongly associated with the progression of acute LBP to disability [41–46]. In addition, catastrophising is associated with hypervigilance for symptoms, which increases pain perception [47,48]. Interventions that have used CB approaches to target catastrophising and fear-avoidance behaviours have shown significant benefits in reducing disability [49]. At the other end of the activity level spectrum, there is also a group who appear to increase their activity levels in response to pain [50]. This apparent overac-