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Group cognitive behavioural interventions for low back pain in primary care: Extended follow-up of the Back Skills Training Trial (ISRCTN54717854)


1. Introduction

Low back pain (LBP) is amongst the top 6 most costly health conditions, and one of the top 3 most disabling health conditions [9]. LBP ranges in presentation from acute pain (<6 weeks’ duration), subacute pain (>6 to <12 weeks’ duration), and chronic pain (>12 weeks’ duration) [26]. Chronic LBP is the most complex and costly presentation [20].

Most LBP is managed by primary care practitioners. Long-lasting effective treatments are elusive, particularly for subacute and chronic pain [20]. Most clinical guidelines recommend that primary care practitioners give advice to remain physically active, prescribe appropriate medication, and, when symptoms persist, provide referral for nonpharmacological therapies [1,20,31]. Advice to remain active is better than usual general (family) practice [24] but has a short-lived effect [28]. Exercise, acupuncture, manipulation, and postural approaches produce small to moderate short-term (<4 months) benefits, but long-term (>12 months) benefits are typically small or not statistically significant [19,21,22,33].

Cognitive behavioural interventions (CBIs) are recognized as potentially effective treatments for LBP in primary care, but there is uncertainty and a need for definitive evaluations with long-term follow-up [19,21,22,31,33]. CBIs encompass a growing number of variants, including Internet-based, one-to-one sessions delivered by a clinical psychologist, group CBI, condition specific, generic formats, behavioural activation, and mindfulness-based cognitive therapy [10,11]. Other factors which may influence the effectiveness of CBIs include the professional background and training of practitioners and the intensity and duration of the intervention. The evidence to support lower intensity CBIs (<100 h duration), which are most suited to primary care, is equivocal [31].

In a previously published randomized controlled trial, we evaluated a group-based CBI suitable for primary care. The intervention was designed to be delivered by a range of primary care practitioners (nurses, physical and occupational therapists, psychologists) and was of relatively low intensity and delivered in a group format. We designed a short training course for qualified health care professionals (nurses, physical and occupational therapists, psychologists) and was of relatively low intensity and delivered in a group format.

Keywords: Clinical trial Cognitive behaviour therapy Extended follow-up Low back pain

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practitioners with little or no experience in CBIs, and a structured 6-week intervention that adhered to the principles of cognitive behavioural therapy and encouraged consistency in delivery. This intervention, called Back Skills Training, demonstrated reduced disability, reduced pain, and improved health-related quality of life in troublesome subacute and chronic LBP, with effects sustained at 12 months [21,22]. We report here long-term follow-up (>12 months) of the Back Skills Training Trial.

2. Methods

2.1. Design

This study was a long-term follow-up of a randomised, controlled trial with investigator blinding. The original trial and intervention design and results are reported in detail elsewhere [17,21,22,35]. We present a summary here. The trial registration number is ISRCTN54717854. The Multi-centre Research Ethics number is MREC/03/7/04.

2.2. Setting

The study setting was general (family) practice.

2.3. Study participants

We recruited participants from 56 general practices in 7 localities across England and used a mix of record searches and attendances to identify potential participants. Inclusion criteria were that participants should be aged 18 or over and have at least moderately troublesome LBP of a minimum of 6 weeks’ duration. We excluded participants whose physician was concerned they may have a serious cause for their LBP (infection, fracture, malignancy); those with severe psychiatric or psychological disorders; and people who had participated previously in a CBI for LBP.

2.4. Randomisation

We used telephone registration and computer-generated block randomisation, stratified for centre and LBP severity (moderately vs very/extremely troublesome) and with random block length. Participants were randomised to the experimental intervention in a ratio of 2:1. Allocation was concealed. An independent unit set up and administered the randomisation.

2.5. Control intervention

All participants received a 10–15-min session of best practice advice to remain active, provided by a trained health professional and supplemented by The Back Book [4].

2.6. Cognitive behavioural intervention

We designed a bespoke CBI for primary care management of LBP, comprising an individual assessment (1 h duration) and 6 sessions of group therapy (1.5 h duration each). In summary, we drew together the essential elements of a cognitive behavioural approach and targeted health behaviours and beliefs that are broadly accepted as being on the causal pathway between LBP and disability [17]. We considered the optimal delivery method to balance clinical and cost-effectiveness in primary care, and selected a group therapy model. The cognitive behavioural model states that the way a person thinks about his or her problem will produce emotions, including associated physical sensations, which then drive behaviour [16]. Often the behaviour will inadvertently main-

2.7. Treatment fidelity

We followed existing guidelines on promoting treatment fidelity [2]. We developed a framework to assess treatment fidelity that included prespecification of the essential components of the intervention, including a range of therapist behaviours, skills, and actions. We adapted a preexisting assessment tool [3], which is used widely to assess cognitive behavioural therapist competence in generic settings. We audiotaped or observed a random selection of sessions and assessed therapist competence against the tool. Results of the treatment fidelity are reported elsewhere [22].

2.8. Other treatments

Where possible, we requested that general practitioners avoid referral to other treatments whilst participants were receiving the CBI.
2.9. Baseline measurements

Demographic and baseline data was collected from participants during the prerandomisation stages of the trial, including date of birth, sex, ethnic origin, employment status, frequency of back pain in the past 6 weeks, pain severity, Hospital Anxiety and Depression Score (HADS), fear-avoidance beliefs and pain self-efficacy, and the Short Form 12 version 2 (SF12) measure of health-related quality of life [27,32,36].

2.10. Outcome measurements

Data were collected via postal questionnaires. In the initial trial design, we collected follow-up at 3, 6, and 12 months after randomisation. The first participant was randomised on April 8, 2005. All participants were requested to provide a final extended follow-up on March 11, 2009. The extended follow-up questionnaire contained the 2 primary outcome measures; the Roland and Morris Disability Questionnaire (RMQ) [30], which measures back pain disability (scale 0–24; lower scores indicate less severe disability), and the Modified von Korff Scale (MVK) [34], which measures pain and disability separately (scale 0–100; lower scores indicate less pain and disability). Secondary outcome measures included self-rated benefit from treatment [7], some measures of health care resource use and the EuroQol-5 Dimensions (EQ-5D; scale –0.59 to 1; lower scores indicate worsening health related quality of life) [12]. Those who did not respond to the extended follow-up questionnaire were sent one reminder letter 2 weeks after the initial questionnaire had been sent out, and participants could opt to provide data over the telephone if they wished.

2.11. Ethics

The West Midlands Multi-centre Research Ethics Committee approved the trial protocol and longer-term follow-up (MREC/03/7/04). All participants gave written informed consent.

2.12. Sample size estimate

The original sample size aimed to detect a between-group standardised mean difference in the primary end points at 12 months of 0.42 (around 1.8 change points between groups on the Roland Morris questionnaire score). Power was 90% and significance 0.01. We assumed an intraclass correlation coefficient for therapist effects of 0.01 [33], and inflated the sample size with a design effect of 1.07. With a 2:1 (test:control) treatment allocation and allowing for a 25% loss to follow-up, we aimed to recruit 701 participants.

2.13. Statistical analysis

The analysis was intention to treat. We investigated differences in baseline characteristics of those participants providing extended follow-up (>12 months) and those who did not to assess selection bias. Subsequent analyses were restricted to those who provided extended follow-up data.
participants providing extended follow-up only. We examined the characteristics of the sample providing extended follow-up by treatment allocation. We estimated within-group changes over characteristics of the sample providing extended follow-up only. We examined the difference between response and nonresponse (P < .05).

Table 1
Characteristics of the sample who responded to an extended follow-up request (response, n = 395) and those who did not (nonresponse, n = 366).

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Subcharacteristic</th>
<th>Nonresponse</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>BPA (n = 119)</td>
<td>BPA + CBI (n = 187)</td>
</tr>
<tr>
<td>Age (y)</td>
<td>Mean ± SD</td>
<td>51.4 ± 16.4</td>
<td>50.9 ± 15.0</td>
</tr>
<tr>
<td></td>
<td>Sex</td>
<td>48 (40)</td>
<td>71 (60)</td>
</tr>
<tr>
<td></td>
<td>Ethnicity</td>
<td>102 (88)</td>
<td>156 (80)</td>
</tr>
<tr>
<td></td>
<td>Work status</td>
<td>8 (7)</td>
<td>12 (7)</td>
</tr>
<tr>
<td></td>
<td>Frequency LBP in last 6 weeks</td>
<td>87 (81)</td>
<td>128 (78)</td>
</tr>
<tr>
<td></td>
<td>Between every day and 1/2 of the days, n (%)</td>
<td>12 (11)</td>
<td>20 (12)</td>
</tr>
<tr>
<td></td>
<td>Between 1/4 and 1/2 of the days, n (%)</td>
<td>9 (8)</td>
<td>17 (10)</td>
</tr>
<tr>
<td></td>
<td>Pain severity</td>
<td>62 (52)</td>
<td>92 (49)</td>
</tr>
<tr>
<td></td>
<td>Moderate, n (%)</td>
<td>114 179 111 275</td>
<td>111 168 106 253</td>
</tr>
<tr>
<td></td>
<td>Severe, n (%)</td>
<td>119 185 112 279</td>
<td>118 187 114 281</td>
</tr>
<tr>
<td></td>
<td>SF-12</td>
<td>36.1 ± 10.3</td>
<td>36.8 ± 9.0</td>
</tr>
<tr>
<td></td>
<td>Physical</td>
<td>111 168</td>
<td>106 253</td>
</tr>
<tr>
<td></td>
<td>Mental</td>
<td>45.4 ± 11.2</td>
<td>42.8 ± 11.6</td>
</tr>
<tr>
<td></td>
<td>EQ-5D</td>
<td>0.54 ± 0.30</td>
<td>0.52 ± 0.30</td>
</tr>
<tr>
<td></td>
<td>Pain self-efficacy</td>
<td>39.1 ± 13.8</td>
<td>37.1 ± 13.9</td>
</tr>
<tr>
<td></td>
<td>Fear-avoidance beliefs</td>
<td>4.8 ± 6.1</td>
<td>13.8 ± 6.4</td>
</tr>
</tbody>
</table>

BPA, best practice advice; CBI, cognitive behavioural intervention; LBP, low back pain; HADS, Hospital Anxiety and Depression Score; MVK, Modified von Korff Scale; EQ-5D, EuroQol-5 Dimensions.

* Statistically significant difference between response and nonresponse (P < .05).

3. Results

3.1. Characteristics of the sample

Fifty-six percent (395 of 701) of the original cohort provided extended follow-up data with a mean duration of follow-up of 34 months (median 33.3 months, range 0–50 months, Fig. 1). Fig. 2 gives the study flow chart, and the characteristics of the extended follow-up sample are given in Table 1. In comparison to the participants in the original sample, the extended follow-up sample had slightly less disability and pain, was older, and had better quality of life and mental health at baseline. These differences were small.

Within the extended follow-up sample, characteristics of those randomised to the advice-only and CBI arms were well matched. The majority of participants in the extended follow-up experienced pain every day over the last 6 weeks (72%) and had chronic symptoms (393 of 395, 99.5%). The duration of extended follow-up was (mean ± SD) 34 ± 6.3 months in the CBI arm and 34 ± 6.2 months in the best practice advice arm (P = .257). The time from randomisation to the first CBI session was 45 ± 33 days.

3.2. Therapist competence and compliance

The CBI sessions were delivered by 19 therapists, the majority of whom had little or no prior experience of cognitive behavioural therapy. Thirty-five of 62 groups (57%) had at least one session
observed. The core elements of the CBI were delivered satisfactorily in the majority of observed sessions. For example, homework was set in 86% and reviewed in 63% of observed sessions, listening skills were appropriate in 100%, thoughts/beliefs were elicited in 100%, and the cognitive behavioural model was referred to in 77% of observed sessions. The core elements of the CBI were delivered satisfactorily in the majority of observed sessions. For ... made, and the raw score was used instead of change from baseline.

Table 2 gives the treatment effect estimates at each time point. At the extended follow-up time point, participants in the CBI arm had better recovery than the best practice advice arm in both the RMQ and MVK disability (mean difference between groups RMQ 4.4, 95% CI –0.07 to 8.87). There was no statistically significant between-group difference in the MVK pain scores (mean difference 4.6, 95% CI –1.00 to 10.28). There was a small difference in self-reported benefit in favour of the CBI group. There were statistically significant differences in the EQ-5D scores at various time points during the first 12 months, but there was no statistically significant difference between trial arms at the extended follow-up time point.

3.5. Resource use during the extended follow-up period

Table 3 summarises resource use data by treatment group. During the extended follow-up period, there was no statistically or clinically important difference in the health care resource use, nor in the number of work days lost or change in work pattern. There was a trend towards greater use of primary care consultation in the best practice advice arm.

4. Discussion

We have previously shown that group CBI in terms of LBP is an effective and cost-effective treatment for people with subacute and chronic LBP over 12 months [21,22]. We now report that the effects of CBI on disability are sustained beyond 12 months, and that CBI is more effective than best practice advice in reducing back pain–related disability over an average of 34 months, and up to 50 months. In the long term, improvement in LBP occurs with best practice advice, but this is at a slower rate, is of reduced magnitude, and has limited impact on disability.

Treatments that have a lasting impact on chronic LBP are elusive. Our sampling strategy was to target people with subacute and chronic LBP of at least moderate troublesomeness. The great majority of participants, both in the original trial and extended follow-up, had chronic symptoms. A question is whether the differences between treatment groups are attributable to the CBI, or nonspecific effects such as therapist or attention effects. By its nature, a pragmatic trial cannot directly answer this question. However, a number of factors suggest that the cognitive behavioural element drives the effect. The therapists were able to achieve a satisfactory level of skill...
We provided best practice advice to the control and treatment arms, in accordance with international guidance. This provided a good reference with many control interventions reported in other trials and is more effective than usual general practice care [24]. Overall, the best practice advice group had some benefit in terms of back pain disability, but this was roughly half that of the CBI group. The control group did experience an improvement in pain after 12 months, but changes in disability were very small. The late recovery of pain in the best practice advice arm may be the result of natural history, or possibly the pursuit of other treatments during this period. There was some suggestion that the best practice advice arm had consulted their general practitioner more frequently after the 12-month follow-up.

The strengths of randomised comparisons are well known. There are some limitations of this extended follow-up. First, not all people randomised provided extended follow-up. Despite this, we retained an adequate sample size to detect clinically important differences at 80% power and an alpha value of 0.05. This was because our original sample size for the 12 months' follow-up included inflation for therapist effects (which were negligible); we had better follow-up than we anticipated; and the study was powered at 90% and alpha was 1%. One reason why follow-up was lower in the extended time period was that people may have forgotten about their involvement in the study, given the long time period that had elapsed for some individuals. The ethical approval for the extended follow-up allowed only for a single contact and reminder. We followed just under 60% of the original sample, with those who responded to the long-term follow-up being older and having somewhat less disability, less pain, and better mental health at baseline than those who did not respond. There is potential to bias the generalisability of the findings. However, we assess this as small. Although mental and baseline disability status have been reported as being prognostic indicators in primary studies and reviews [29], the robustness of both reviews and the underpinning evidence means that it is difficult to draw definitive conclusions [18]. In the Back Skills Training Trial analysis and several other well-conducted large trials, there is no evidence of treatment interaction effects (ie, subgroup effects) related to disability, pain severity, depression, or other psychosocial variables [33,35]. Additionally, the randomised groups were well matched. Overall, we believe the treatment estimate to be robust and generalizable.

The value of an extended follow-up was not apparent until the analysis of the 12-month data. We had 2 options. We could either wait until all patients reached the maximum follow-up point that was achieved by the first entrants into the trial (ie, 50 months), or we could instigate a single follow-up point, recognising that participants would be contributing data for differing time periods. Our approach was to select a single chronological point for follow-up (this was determined by logistics and funding). Duration of follow-up was not a statistically significant factor (ie, predictor of treatment outcome), and the length and distribution of follow-up was identical between both groups. We are confident that estimates relating to the importance of time around the point of central tendency (34 months) will be robust, but we accept that there is increasing uncertainty towards the margins of the distribution (50 months).

These limitations withstanding, that this CBI remains an effective treatment over such a prolonged time period is encouraging. According to the interpretation of Cohen [6], the treatment effect size was moderate at most time points for the outcomes we collected, but the differences in the RMQ and MVK are important, particularly in the context of this being a pragmatic trial.

The effect sizes are consistent with several international guideline bodies that have recommended treatments on the basis of

![Fig. 3. Mean change from baseline over time for those who responded (n = 395) of extended follow-up only (RMQ and MVK). Error bars represent the standard error.](image-url)
similar or smaller effects [5,31]. The estimates of recovery in the best practice advice arm are consistent with an Australian inception cohort study of people with chronic back pain in primary care [7].

It was not our intention to report a full economic analysis, but rather to provide estimates of utility and resource use for others who may wish to undertake economic modelling, recognising that reporting of economic outcomes over prolonged time periods are scarce in the literature. Scores indicate a substantial gain in utility, initially observed over a 12-month period, are sustained and we provide further support for the adoption of CBI into clinical practice.

Few randomised studies of LBP interventions have reported follow-up over such a prolonged period. A recent systematic review of acupuncture for LBP reported only one study with 24 months’ follow-up; it concluded a small sustained treatment benefit [37]. The longest period of follow-up in randomised studies is a 5-year follow-up of a CBI in primary care, which also reported sustained benefit [23]. Two other studies have reported clinically and statistically significant sustained effects of chiropractic treatment in comparison to hospital outpatient care at 3 years [25], and structurally significant sustained effects of chiropractic manipulation, acupuncture, or other forms of treatment (notably those delivered on a one-to-one basis). We now demonstrate that the therapeutic effect is sustained over a prolonged time period, and we provide further support for the adoption of CBI into clinical practice.

We conclude that the positive effects of group CBI on LBP disability, initially observed over a 12-month period, are sustained to at least 3 years. CBI is more effective than best practice advice in reducing LBP-related disability.
Conflicts of interest statement

None of the authors have conflicts of interest to declare.

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Data Monitoring Committee: R. Hills, G. MacFarlane, P. Watson.

References


