A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain. The Back Skills Training (BeST) trial

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HTA

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Abstract

A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain. The Back Skills Training (BeST) trial

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Objectives: To estimate the clinical effectiveness of active management (AM) in general practice versus AM plus a group-based, professionally led cognitive behavioural approach (CBA) for subacute and chronic low back pain (LBP) and to measure the cost of each strategy over a period of 12 months and estimate cost-effectiveness.

Design: Pragmatic multicentred randomised controlled trial with investigator-blinded assessment of outcomes.

Setting: Fifty-six general practices from seven English regions.

Participants: People with subacute and chronic LBP who were experiencing symptoms that were at least moderately troublesome.

Interventions: Participants were randomised (in a ratio of 2:1) to receive either AM+CBA or AM alone.

Main outcome measures: Primary outcomes were the Roland Morris Disability Questionnaire (RMQ) and the Modified Von Korff Scale (MVK), which measure LBP and disability. Secondary outcomes included mental and physical health-related quality of life (Short Form 12-item health survey), health status, fear avoidance beliefs and pain self-efficacy. Cost–utility of CBA was considered from both the UK NHS perspective and a broader health-care perspective, including both NHS costs and costs of privately purchased goods and services related to LBP. Quality-adjusted life-years (QALYs) were calculated from the five-item EuroQoL.

Results: Between April 2005 and April 2007, 701 participants were randomised: 233 to AM and 468 to AM+CBA. Of these, 420 were female. The mean age of participants was 54 years and mean baseline RMQ was 8.7. Outcome data were obtained for 85% of participants at 12 months. Benefits were seen across a range of outcome measures in favour of CBA with no evidence of group or therapist effects. CBA resulted in at least twice as much improvement as AM. Mean additional improvement in the CBA arm was 1.1 [95% confidence interval (CI) 0.4 to 1.7], 1.4 (95% CI 0.7 to 2.1) and 1.3 (95% CI 0.6 to 2.1) change points in the RMQ at 3, 6 and 12 months respectively. Additional improvement in MVK pain was 6.8 (95% CI 3.5 to 10.2), 8.0 (95% CI 4.3 to 11.7) and 7.0 (95% CI 3.2 to 10.7) points, and in MVK disability was 4.3 (95% CI 0.4 to 8.2), 8.1 (95% CI 4.1 to 12.0) and 8.4 (95% CI 4.4 to 12.4) points at 3, 6 and 12 months respectively. At 12 months, 60% of the AM+CBA arm and 31% of the AM arm reported some or complete recovery. Mean cost of attending a CBA course was £187 per participant with an additional benefit in QALYs of 0.099 and an additional cost of £178.06. Incremental cost-effectiveness ratio was £1786.00. Probability of CBA being cost-effective reached 90% at about £3000 and remained at that level or above; at a cost-effectiveness threshold of £20,000, the CBA group had an almost 100% probability of being considered cost-effective. User perspectives on the acceptability of group treatments were sought through semi-structured interviews. Most were familiar with key messages of AM; most who had attended any group sessions had retained key messages from the sessions and two-thirds talked about a reduction in

fear avoidance and changes in their behaviour. Group sessions appeared to provide reassurance, lessen isolation and enable participants to learn strategies from each other.

Conclusions: Long-term effectiveness and cost-effectiveness of CBA in treating subacute and chronic LBP was shown, making this intervention attractive to patients, clinicians and purchasers. Short-term (3-month) clinical effects were similar to those found in high-quality studies of other therapies and benefits were maintained and increased over the long term (12 months). Cost per QALY was about half that of competing interventions for LBP and because the intervention can be delivered by existing NHS staff following brief training, the back skills training programme could be implemented within the NHS with relative ease.

Trial registration: Current Controlled Trials ISRCTN37807450.

Funding: The National Institute for Health Research Health Technology Assessment programme.

Contents

List of abbreviations

A&E	Accident and Emergency		ICER	incremental cost-effectiveness ratio
AM	active management		ICUR	incremental cost–utility ratio
AM+CBA	Active Management + Cognitive Behavioural Approach		ISAP	International Society of Pain
ANOVA	analysis of variance		ISRCTN	International Standard Randomised Controlled Trial Number
BABCP	British Association of Behavioural and Cognitive Psychotherapies		LBP	low back pain
BEAM	Back Pain Exercise and Manipulation		MCID	minimal clinically important difference
BeST	Back Skills Training		MRC	Medical Research Council
CB	cognitive behaviour		MRI	magnetic resonance imaging
CBA	cognitive behavioural approach		MVK	Modified Von Korff Scale
CI	confidence interval		NICE	National Institute for Health and Clinical Excellence
CT	computerised tomography			
DMEC	Data Monitoring and Ethics Committee		PCA	prescription cost analysis
			PCT	primary-care trust
EQ-5D	EuroQoL five dimensions		QALY(s)	quality-adjusted life-year(s)
FABQ	Fear Avoidance Beliefs Questionnaire		RMQ	Roland Morris Disability Questionnaire
GP	general practitioner		SD	standard deviation
GPRF	General Practice Research Framework		SF-12	Short Form 12-item health survey
ICC	intracluster correlation			

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices, in which case the abbreviation is defined in the figure legend or in the notes at the end of the table.

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Executive summary

Background

Low back pain (LBP) is a common and costly problem for which cognitive behavioural approaches may be effective.

Design

A randomised controlled trial was undertaken with a parallel economic and qualitative evaluation comparing active management (AM) with AM plus group treatment using a cognitive behavioural approach (CBA). We randomised individuals using a stratified unbalanced randomisation (2:1 in favour of the CBA arm).

Setting

Fifty-six general practices were recruited from seven English regions.

Control intervention

Primary-care nurses attended a 1-hour training session on the management of LBP, focusing on internationally accepted best practice recommendations for primary care to promote physical activity and analgesia, and to encourage a positive outlook. Nurses were asked to cascade this information within their general practices, and to see each trial participant for an individual advisory session promoting this approach. The advisory session was supplemented with a copy of the *The Back Book*, which was designed by experts in LBP, to reinforce the messages described above.

Intervention (cognitive behavioural approach) arm

Physiotherapists, nurses, psychologists and occupational therapists delivered a simple cognitive behavioural formulation that was tailored for LBP, and designed to target unhelpful beliefs about pain and activity, and promote engagement in leisure, physical and occupational activity.

Therapists attended a 2-day training course and were supported with remote mentorship. The intervention was structured and standardised using a treatment manual for both therapists and participants. Each participant attended for an individualised assessment that included goal setting. Thereafter, the CBA intervention was delivered in groups, with approximately eight people starting each cycle. The contents of the group sessions included goal setting, pacing, challenging beliefs, managing pain and improving communication with health professionals. We defined compliance as attending the assessment and at least three of the six group sessions.

Recruitment

We identified potential participants by searching electronic general practice records, and from direct referrals from general practitioners. Each potential participant went through a two-stage eligibility check to ensure they had at least moderately troublesome back pain present for at least 6 weeks and to exclude those with a serious disorder causing their LBP.

Follow-up

We collected follow-up data at 3, 6 and 12 months. The primary method of data capture was postal questionnaire. This was supplemented with telephone data collection for individuals who did not return a questionnaire but were happy to provide information.

Clinical outcomes and analysis

The primary outcomes were the Roland Morris Disability Questionnaire (RMQ) and the Modified Von Korff Scale (MVK), which measure LBP and disability. Secondary outcomes included mental and physical health-related quality of life (Short Form 12-item health survey; SF-12), health status, fear avoidance beliefs and pain self-efficacy. The planned sample size was 700. We analysed the

difference in change from baseline scores at each time point, and also analysed these over time to yield a single summary score. We used a linear regression model for the analysis, as the clustering effects (therapist and groups) were found to be non-significant. Models were adjusted for age, sex and baseline covariates. Subgroup analyses were prespecified for fear avoidance beliefs, and the severity and duration of LBP.

Economic analysis

We considered the cost–utility of the CBA programme from both the UK NHS perspective and a broader health-care perspective. We included all NHS costs needed to deliver the interventions and to provide health care associated with LBP over a 12-month time horizon. For the health-care perspective we included both NHS costs and costs of privately purchased goods and services related to LBP. Quality-adjusted life-years (QALYs) were calculated from the EuroQoL five dimensions. We collected cost data from participant questionnaires. Costs were in UK pounds (£) actualised to 2008 using the Retail Price Index. Discounting was not applied.

Results

Between April 2005 and April 2007 we randomised 701 participants who provided baseline data; 233 were randomised to best care (AM) and 468 to best care (AM)+CBA. Nearly 60% (420/701) were female, mean age of participants was 54 [standard deviation (SD) 14.9] years and mean baseline RMQ was 8.7 (SD 4.9). Outcome data were obtained for 85% of participants at 12 months.

Benefits were seen across the range of outcome measures in favour of CBA. There was no evidence of group or therapist effects. Both treatments showed improvements over baseline, but these were of a different magnitude and time course. Overall, CBA resulted in at least twice as much improvement as AM and, for the primary outcomes; improvements were sustained or increased over time. Mean additional improvement in the CBA arm was 1.1 [95% confidence interval (CI) 0.4 to 1.7], 1.4 (95% CI 0.7 to 2.1) and 1.3 (95% CI 0.6 to 2.1) change points in the RMQ at 3, 6 and 12 months respectively. Additional improvement in MVK (pain) was 6.8 (95% CI 3.5 to 10.2), 8.0 (95% CI 4.3 to 11.7) and 7.0 points (95% CI 3.2 to 10.7) at 3, 6 and 12 months. For

MVK (disability), additional improvements were 4.3 (95% CI 0.4 to 8.2), 8.1 (95% CI 4.1 to 12.0) and 8.4 points (95% CI 4.4 to 12.4) at 3, 6 and 12 months. All differences in the primary outcomes at 6 and 12 months were statistically significant. Differences in physical health-related quality of life and intermediary outcomes were substantial. At 12 months, the treatment effect size was 0.31, 0.41 and 0.45 for the RMQ, MVK and SF-12 physical health scales respectively. At the same time point, 60% of the CBA arm and 31% of the AM arm reported some or complete recovery.

Economics

The mean cost of attending a CBA course was £187 per participant, which accounted almost entirely for the average difference in NHS costs between the AM and AM+CBA arms (£224.65 versus £421.52). CBA resulted in an additional benefit in QALYs of 0.099 and an additional cost of £178.06. The incremental cost-effectiveness ratio was £1786.00. The probability of CBA being cost-effective reached 90% at about £3000 and remained at that level or higher above that threshold. At a cost-effectiveness threshold of £20,000 group CBA had an almost 100% probability of being considered cost-effective. The cost per QALY was similar in all sensitivity and prespecified subgroup analyses. From the participant perspective CBA resulted, on average, in an additional £130 of out-of-pocket expenses, increasing cost per QALY to £3093.

Qualitative study

We explored user perspectives on the acceptability of group treatments and sought insights into how the intervention might work. Semi-structured interviews were completed in a purposive sample of 34 trial participants (AM = 18, AM+CBA = 16). Almost everyone was familiar with the key messages of the AM approach, although they had not previously received a copy of *The Back Book*. Most of those who had attended any group sessions had retained key messages from the sessions and two-thirds talked about a reduction in fear avoidance and changes in their behaviour. Most also found the exercises helpful and had incorporated exercise into their daily lives. Different individuals reported different strategies included in the CBA package to be helpful. Several people mentioned the importance of the assessment session. Group sessions appear to provide reassurance, to lessen

isolation and to enable participants to learn strategies from each other.

Conclusions

This definitive large-scale randomised controlled trial has demonstrated the long-term effectiveness and cost-effectiveness of CBA in treating subacute and chronic LBP. The clinical effectiveness and cost-effectiveness outcomes are likely to make this intervention attractive to patients, clinicians and purchasers. Our short-term (3-month) clinical effects are similar to those found in high-quality studies of other therapies such as manipulation, acupuncture or exercise. Strikingly, and in contrast to many previous studies, the benefits we observed were maintained and increased over the long term (12 months). The intervention is extremely cost-effective from an NHS and a health-care perspective; cost per QALY is less than or about half that of competing interventions for LBP. Finally, because the intervention can be delivered by existing NHS staff following a brief, 2-day training session, the back skills training programme could be implemented into the NHS with relative ease.

Future research questions

Future research on implementation of the CBA programme will help to ensure that the benefits we found can be translated into a reduction in LBP and associated disability. Further work is needed to examine alternative strategies to delivery, particularly where these improve patient choice and ability to either attend the sessions or gain the cognitive skills and behavioural stimulus embedded in the approach. Some evidence that CBA may also be of help for other musculoskeletal disorders is given by the effects of the package on generalised physical health-related quality of life. Extended follow-up of the BeST cohort may provide additional useful information on the sustainability of clinical effectiveness and cost-effectiveness, and guide the development of brief interventions to help maintain effects over much longer time periods.

Trial registration

This trial is registered as ISRCTN37807450.

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Chapter 1

Introduction

Background

Low back pain (LBP) is a major public health problem in Western industrialised societies.[1] In the UK, the annual period prevalence is approximately 37%[2,3] and LBP is so common that it affects almost everyone at some time during his or her lifetime.[4] For the majority, LBP follows a recurrent, fluctuating time course, with about 70% of patients having at least one recurrence within 12 months.[5,6] Annually around one in three people have an acute bout of LBP, but symptoms resolve quickly and pose no ongoing problem.[7] A significant proportion of people self-manage LBP without consulting the NHS. Estimates suggest that between 7% and 20% of the adult population who experience LBP consult a general practitioner (GP)[8] and this results in 2.6 million additional consultations annually.[9] Of these people, 75% have symptoms 1 year later[10,11] and about 30% develop persistent disabling LBP.

The direct health-care costs associated with LBP in 1998 were £1628 million; the majority of this expenditure was on physiotherapy and general practice.[1] During the years 1994 and 1995, 116 million production days were lost in the UK as the result of LBP, costing an estimated £10,668 million in production and informal care costs.[1] The majority of these costs are generated by those with the most chronic symptoms, and as a consequence the prevention and amelioration of chronic disabling pain is now the focus of research and clinical activity in this field.[12]

This introduction provides a background to our sampling strategy, risk factors for developing chronic LBP and reasons why cognitive behavioural approaches (CBAs) may be helpful in LBP, an overview of current management of LBP, and the evidence to support CBA at the time the trial was designed.

Sampling approach and risk factors for the development of chronic low back pain

The population of people who suffer from low back pain is highly diverse. There have been a number of attempts to define different subgroups but none are satisfactory or in widespread use. We focused our trial on non-specific LBP, which is a term used to describe the majority of presentations, i.e. those in which no serious cause (infection, cancer or fracture) for LBP can be identified. The primary focus of our trial was the prevention or amelioration of disabling LBP in those with established (subacute or chronic) symptoms. We defined LBP according to Croft *et al*.[11] and used the International Society of Pain (ISAP) definitions of acute, subacute and chronic duration (*Table 1*). The ISAP provides a simple and widely used definition of back pain syndromes, although this does not include activity limitation.

Considerable advances have been made in identifying risk factors and understanding the processes involved in the development of chronic LBP.[14] Psychological, social and behavioural risk factors have been found consistently to be stronger predictors of chronic disability than the physical factors associated with the initial onset of pain.[15] This does not mean that physical symptoms are unimportant; for example, pain radiating down the leg is acknowledged to be a risk factor for developing chronic symptoms.[16,17] However, a recent prospective study found only a weak association between structural changes and pain and no association with disability or future health care.[18]

Psychological risk factors play an important role in the progression of LBP to chronic disabling LBP. A review of psychological risk factors found that coping strategies, beliefs, distress, depressive mood and somatisation were associated with the development of persisting pain and disability.[19,20] Of these, 'fear of movement' (which is a negative health belief about the relationship between pain and re-injury such that if I increase my back pain, I am causing further damage, so I should avoid movement), has been that most consistently and strongly associated with the progression to chronic disability.[21,22] Participation in physical recreational activity is associated with lower LBP and a reduced risk of progression to disability.[23] There is now a widely held belief that increasing physical activity and/or exercise participation is important

TABLE 1 *Case definitions used in the Back Skills Training (BeST) trial*

Low back pain – pain of musculoskeletal origin in the area bounded by the 12th rib and below by the gluteal folds (Croft *et al.* 1998)[11]
Acute pain – lasting 6 weeks or less
Subacute pain – lasting 6–12 weeks
Chronic pain – lasting more than 3 months (International Association for the Study of Pain, Merskey *et al.* 1979)[13]

in managing LBP.[24] Physical activity is usually characterised as a behavioural factor.

Social factors are also important. A systematic review of social risk factors identified low social support in the workplace, heavy manual work and low job satisfaction as strong risk factors for the occurrence of chronic back pain.[25] More recent studies have also found strong correlations between chronic back pain and low socioeconomic status, educational level, work satisfaction and female gender.[6,26,27]

Epidemiological evidence suggests that interventions that address this range of psychological, behavioural and social risk factors offer hope in reducing the burden of LBP. Recent clinical guidelines[6,26] stress the importance of assessing psychosocial factors and emotional distress, and suggest that such assessments might assist in targeting intervention more appropriately. Cognitive behavioural approaches encompass a range of interventions that aim to directly change behaviour using models of learning, and to indirectly change behaviour by changing beliefs and behavioural risk factors However, it is broadly acknowledged that there is insufficient evidence to determine the optimal methods of assessment and intervention and that large-scale evaluation is required.

Current management in the UK

The majority of LBP is managed in primary care, with a small number of people referred to secondary care, often only for a single consultation and with little consistency or rationale.[28] About 9% of the population with LBP attend for physiotherapy treatment, usually after primary-care consultation.[1] Chiropractic and osteopathy are used less often.[1]

Since 2000, there has been a major change in the approach to managing LBP in primary care known

as the active management (AM) strategy, which forms the core of all international guidelines.[29–31] The AM strategy discourages bed rest for LBP and instead advocates physical activity.[10] Appropriate medication is encouraged, although many classes of pain medication have been shown to have limited long-term benefits and are recommended most often for the management of acute LBP.[32,33] An information booklet called *The Back Book*[34] has facilitated implementation of the AM guidelines in the UK. *The Back Book* was designed to challenge negative beliefs and behaviours, rather than merely to impart factual information. A randomised controlled trial evaluating *The Back Book* showed a positive effect on patients' beliefs and clinical outcomes, maintained at 1 year, for those with both acute and recurrent back pain.[25,35]

A 2007 systematic review[36] evaluating the effectiveness of advice for the management of LBP compared advice offered to acute, subacute and chronic LBP patients. The review suggests that advice to stay active is sufficient for acute LBP patients and could be more widely implemented in practice. There is uncertainty about the management of both subacute and chronic LBP. No conclusions could be drawn from the evidence base about the optimal method of advice, and although there are suggestions in the literature that additional treatments may be beneficial, differences in case definitions of LBP and the treatments tested make it difficult to draw substantial conclusions about what type of advice is optimal for various presentations of LBP.

Unlike most guidance, and at the time of planning this trial, most UK guidelines tentatively recommended early referral to physical treatments, including acupuncture, spinal manipulation and exercise.[1] The evidence for these treatments has strengthened during the lifetime of the Back Skills Training (BeST) trial. More recent studies have raised some doubt about the effectiveness of traditional physiotherapy approaches to LBP; for example a comparison of routine physiotherapy with a single session of advice for LBP found no

difference in treatment outcomes.[37] An Australian study of participants with subacute LBP, found physiotherapist-directed exercise and advice were each slightly more effective than placebo, with greatest effectiveness when combined.[38] A Cochrane review concludes that exercise therapy appears to be slightly effective at decreasing pain and improving function in adults with chronic LBP.[39] A meta-analysis of the effectiveness of spinal manipulation therapy for LBP concluded that there is no evidence to suggest that manipulation is superior to other standard treatments for acute LBP.[40] However, a recent large UK trial comparing manipulation with exercise and a combination of manipulation and exercise found small medium-term benefits in each treatment arm, and greater benefits if treatments were combined.[24]

We selected the active management strategy and *The Back Book* as the intervention for the control arm of the trial, as these were recommended as best practice strategies within UK guidance at the time of starting and during the conduct of the trial.

Cognitive behavioural approaches in low back pain

The CBA includes a range of therapies deriving from cognitive and behavioural psychological models that aim to teach an individual to tackle their problems using specific psychological and practical skills.[41]

Cognitive behavioural approaches for managing LBP were first introduced in the UK as part of inpatient pain management programmes for those with very chronic/severe LBP. Intensive (> 100 hours of therapy) multidisciplinary bio-psychosocial rehabilitation programmes were found to improve pain and function for patients in the

secondary-care setting.[42] Systematic reviews suggest that the type of CB treatments for chronic LBP (> 12 weeks) that could be delivered in primary care appear to have short-term benefits but, possibly, no sustained long-term benefits.[43]

Although there has been no formal systematic review, trials of CBA in populations with acute and subacute LBP report a mixed picture, including some improvement in disability.[44–46]

Although some trials pointed to the potential for CBA in treatment of subacute and chronic LBP, there was a mixed picture of results. Few programmes found sustained benefits. Differences in results may be attributable to poor research design, but more likely they are the result of variable adherence to the principles of CBA and differences in how the programmes are delivered. These include the amount of contact time, level of expertise, components included in programmes and method of delivery. Indications are that the important attributes of effective interventions are ensuring that the health-care professionals who deliver the interventions are able to elicit psychosocial risk factors, implementing a CB framework that results in modification of beliefs as well as behaviours (as opposed to delivering skills alone), and delivering a treatment that is credible to patients.[47,48]

The aim of this study was therefore to develop and test a group-based CBA intervention that could be delivered within the UK NHS and that could be accessed from primary care. We carried out a definitive randomised controlled trial with a parallel economic and qualitative study that would provide a comprehensive evaluation of CBA as a treatment for subacute and chronic LBP, and provide the NHS with evidence to support decision-making in this area of clinical practice.

Chapter 2

Characteristics and description of the intervention

Introduction

A detailed description of the theoretical basis of the intervention, as well as dose and mode of delivery is an essential step in the reporting of randomised trials of complex interventions.[49] Our approach was to draw together the essential elements of a CBA, ensuring that the intervention was consistent with the principles of CB therapy, and that we targeted health behaviours and beliefs that are broadly accepted as being on the causal pathway between LBP and disability. The intervention was developed by systematically reviewing experimental and observational literature, and linking the results of these reviews into a CB framework. We also considered the optimal delivery method to balance clinical effectiveness and cost-effectiveness.

The CB model states that the way a person thinks about their problem will produce emotions, including associated physical sensations, which then drive behaviour.[50] Often, the behaviour will inadvertently maintain the thoughts or beliefs, so creating a maintenance or vicious cycle effect. The following sections provide a rationale for the risk factors selected as treatment targets for the CBA.

Identifying the targets for a cognitive behavioural intervention for low back pain

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 lead to decreased activity levels or, for some, overactivity. These changes in activity levels are implicated in the development of chronic disabling LBP through a pathway of deconditioning, and worsening pain. We specified the targets of the CB intervention:

- to increase activity levels
- to manage periods of overactivity

- to specifically address catastrophising and fear avoidance
- to improve coping skills.

There is consistent evidence across various reviews that coping skills, catastrophising and fear avoidance are key factors in the progression of acute LBP to chronic disability. Distress has also been identified as an important risk factor;[51] however, it is difficult to define distress separately from the other psychological constructs and mood.[6,18,52]

Many studies have pointed to the importance of coping strategies and beliefs held by patients.[19,53] 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 and catastrophising.[54–57]

The strong link between beliefs predicting behaviour has been shown in two studies.[3,58] 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' and lead to avoidance of the feared activity or pain. This behaviour has been labelled 'fear avoidance' and has been consistently and strongly associated with the progression of acute LBP to disability.[21,22,59–61] In addition, catastrophising is associated with hypervigilance for symptoms, which increases pain perception.[62,63] Interventions that have used CBA to target catastrophising and fear avoidance behaviours appear to reduce disability in the short term.[64]

At the other end of the activity level spectrum, there are people who increase their activity levels in response to pain.[65] This overactivity has been linked to mood and to unhelpful beliefs[66] and can lead to poor control over pain and subsequent activity.

Depression is associated with the risk of developing chronic LBP,[67] with a hypothesised pathway of apathy, demotivation and low mood resulting in decreased activity and poor outcome. Exercise is effective in the management of depression[68] and has the potential to reverse this cycle.[69]

Pain intensity has been positively and consistently associated with a poor outcome.[70] However, pain intensity is not independent of other psychological constructs such as catastrophising.[71] Education on pain mechanisms appears effective in changing beliefs and improving physical functioning.[72]

Low levels of physical activity have been shown to correlate with future episodes of persistent LBP.[23,73,74] In addition, a significant proportion of the LBP population will reduce their activity levels in response to developing LBP.[75] The resultant 'deconditioning or disuse syndrome' describes the physical decline in strength, mobility, endurance and coordination that is postulated to contribute to ongoing pain.[76]

Several systematic reviews have investigated the efficacy of exercises in the treatment of LBP and found modest improvements in pain and function.[77–78] Hayden *et al*.[79] went on to perform a meta-regression to identify features of the exercise programmes associated with successful outcomes. They concluded that the most effective exercises were conducted as part of an individualised supervised programme and included stretching and strengthening exercises. Although counterintuitive, particularly for those suffering LBP, exercise does not increase recurrence of pain.[80–82] There have been relatively few interventions that have focused on improving general or functional activities.[78]

The intervention did not intend to target social factors that are not modifiable within the context of a primary care-based intervention (e.g. educational level, work-related risk factors, job satisfaction). Models of pain based on disc degeneration, posture, injury, weight and leg-length discrepancy were excluded because there is little evidence to support a relationship between these factors and chronic LBP.[83,84]

Framework and structure of the cognitive behavioural intervention

The British Association of Behavioural and Cognitive Psychotherapies (BABCP) has developed definitions of CB therapy[41] and suggests that the following components are essential:

- The intervention should be delivered collaboratively, i.e. intervention draws on the expertise of therapist and client and direction of treatment is determined jointly.
- The intervention should use a goal-oriented approach, i.e. treatment is centred around achieving the client's goals.
- The intervention should use the CB model, i.e. intervention links thoughts, feelings and behaviours.
- The intervention should explore unhelpful beliefs through CB questioning techniques, e.g. the use of open questions to help the client consider alternative ways of thinking.
- The intervention should focus on the development of specific psychological and practical skills to enable the client to tackle problems independently, e.g. problem-solving and relaxation skills.
- The intervention should use homework to achieve skill development, e.g. practising skills discussed during treatment sessions.

We designed an intervention comprising an assessment followed by six group sessions based on these principles. The CB model we developed to underpin the interventions is shown in *Figure 1*. The figure depicts the concept that back pain leads to altered activity and associated physical changes, which in turn leads to maintenance or worsening of pain. These relationships are mediated by unhelpful thoughts and feelings. The shaded boxes indicate the key skills developed by the BeST intervention, and their hypothesised mode of action.

Group format

The intervention was designed for group delivery. A review of outcomes in individual versus group CB therapy found little difference in efficacy.[85] Group treatment has the potential to maximise cost-effectiveness[86] as well as providing additional non-specific effects. These benefits include participant modelling of helpful coping strategies, support and increased opportunity for developing problem-solving, a key skill in self-management.[87]

Assessment session

We chose an initial one-to-one assessment session of up to 90 minutes, which would allow the therapists to better understand an individual's problems and negotiate goals. This assessment also
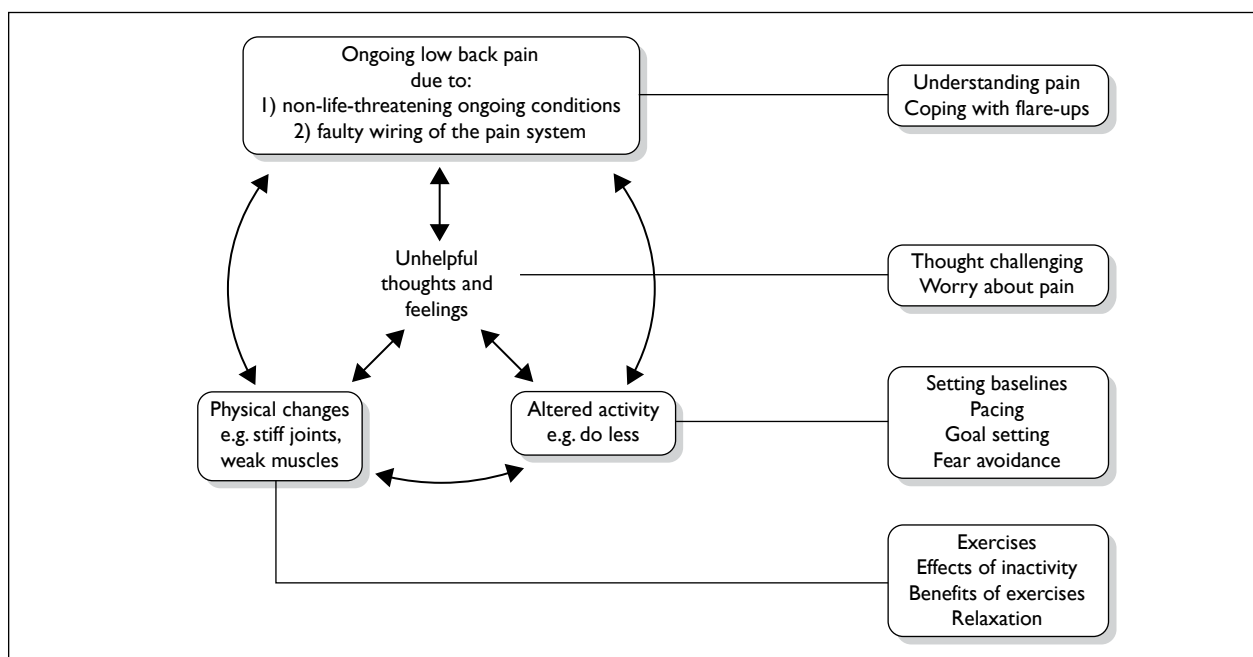
FIGURE 1 *Integrated model of LBP. Text in boxes indicates how sessions target components.*

included the negotiation of a simple home exercise programme as we considered promotion of physical activity central to the intervention (this could be as little as one activity). These exercises were checked and progressed on at least one occasion during the group sessions. Goal setting for the programme was an important product of the assessment. Goals were set collaboratively in the assessment session and reviewed as a group in the second session.

Group session length

Group sessions were of 90 minutes' duration, with a frequency of once per week for 6 weeks (i.e. a total of 10.5 hours including the assessment). The length of the sessions and overall programme was designed to facilitate attendance while ensuring sufficient time to develop skills. A small study on pain management programmes found no difference in outcomes between group or individual treatment and programmes that were 15, 30 or 60 hours in duration.[88] However, very brief interventions of less than 1 hour were found not to be effective.[89]

Group session content

The content of each session was prespecified and documented in the therapist's manual. Details of the session contents are given in *Table 2*. Therapists were requested not only to cover the content of the sessions but also to respond flexibly to participants' needs as necessary.

Group structure

Each session was structured in line with standard CB therapy approaches to include agenda setting, topics and homework review. The work of the previous session was reviewed briefly at the beginning of each session, and all sessions included a 10-minute break midway through to allow participants to move around and exercise (if they wished to). Each session started with agenda setting, which included asking participants what they wanted to cover in the sessions. Homework was reviewed at some point during each session to allow for group problem-solving.

Each session focused on one or more of the components of the CB model shown in *Figure 1*. We used simple CB maintenance models for fear avoidance and hypervigilance to provide a structure and rationale for the skills being taught in the sessions (*Figures 2* and *3*). These provide a conceptual framework for the relationship between thoughts, feelings and behaviours which could be communicated to participants, and form the foundation of discussions to enable problem-solving to break vicious cycles.

We prespecified a benchmark in attendance to define those who we believed had been compliant with the intervention, and those who had not. This threshold was attendance at the assessment session and at least three of the six group sessions. Although not evidence based, we hypothesised that this was the minimum number of sessions required

TABLE 2 *Details of CBA sessions*

	Session number					
	1	2	3	4	5	6
Assessment						
History taking, including current problems and eliciting beliefs on LBP and activity						
Collaborative goal setting with plan to start activity goal						
Exercises chosen collaboratively from options with level negotiated						
Exercises practised and progression discussed						
Understanding pain	✓					
Group activity to demonstrate hurt does not equal harm						
Current thinking on causes of long-term pain explained						
Discussion on group's experience of alternative treatments for LBP with reference to research evidence and need to self-manage						
Benefits of exercise	✓					
Discussion of physical impact of inactivity or altered activity and how changes impact on pain (disuse syndrome)						
Discussion on effects of activity/exercise						
Introduction to LBP model (*Figure 1*)						
Pain fluctuations		✓				
Overactivity/underactivity cycle explained						
Use of pacing						
Group problem-solving for overactivity, e.g. gardening						
Working out starting point for exercises or activities		✓				
How to use baseline setting						
How to set goals		✓				
SMART system used to break down an example goal						
Feedback from group on how progressing with goals from assessment						
Group problem-solving problems with goals						
Unhelpful thoughts and feelings			✓			
Styles of unhelpful thinking discussed, including catastrophising						
Link with unhelpful behaviours						
Identifying unhelpful thoughts						
Group problem-solving for challenging unhelpful thoughts						
Restarting activities or hobbies				✓		
Discussion on activities commonly avoided in LBP						
Fear avoidance cycle (*Figure 2*)						
Group problem-solving out of cycle						
Development of specific goals relating to restarting activities						
When pain worries us					✓	
Effect of attention to pain explored through group activity						
Hypervigilance cycle (*Figure 3*) used to link unhelpful thoughts and behaviours						
Group problem-solving out of cycle						
Discussion on the use of medication/distraction/alternating activities						
Coping with flare-ups						✓
Discussion on causes of flare-ups						
Plan of what to do in and out of flare-ups						
Revision of topics over previous sessions and questions						
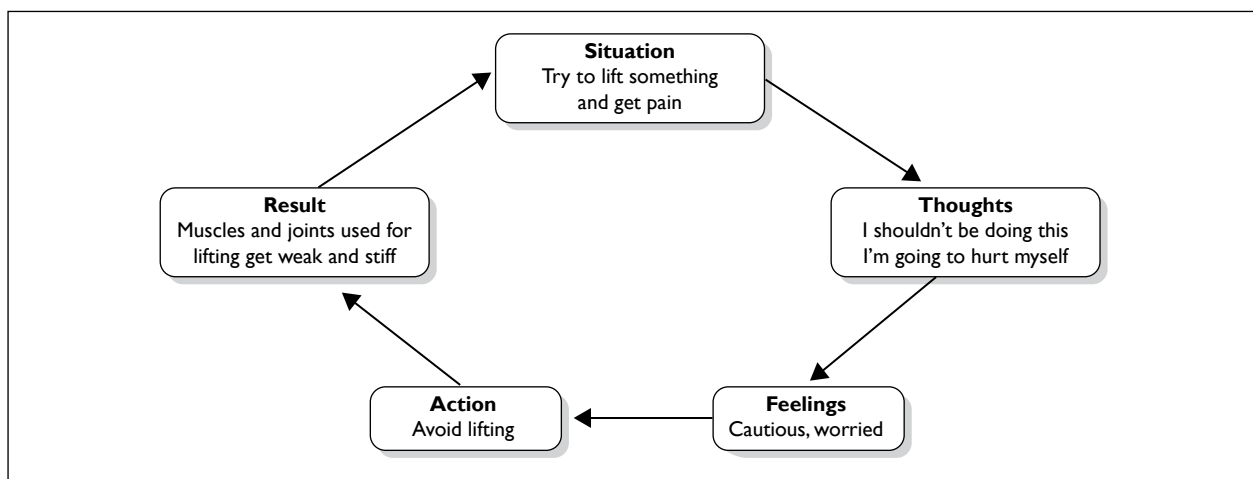
FIGURE 2 *Fear avoidance cycle used in BeST session 4.*
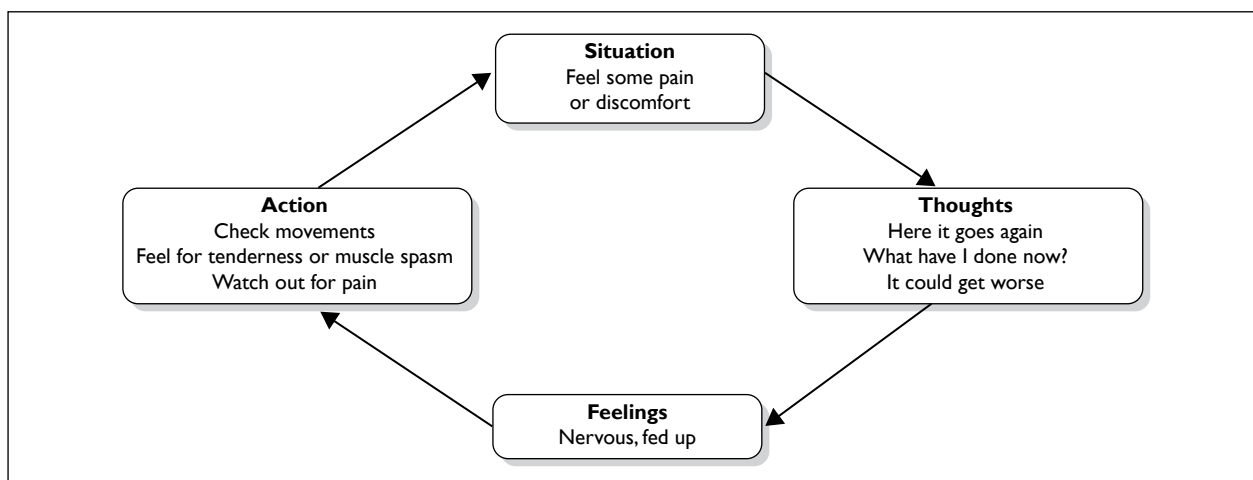
FIGURE 3 *Hypervigilance cycle used in BeST session 5.*

to cover the key components of CBA as defined by the BABCP.[41]

Group size, equipment and space required for running the groups

The only equipment needed was exercise mats, a flipchart easel, pad and pens. The optimal size for a therapy group has not been determined. A size of six to 10 is popular in practice as it is thought to encourage group discussion and problem-solving. Therefore we determined that the venue had to be sufficiently large to seat up to 10 participants in a circle with space to move around and place exercise mats on the floor during the break if participants wanted to do some exercises or have their exercises reviewed by the therapist running the group.

Before running the groups, each therapist was provided with all the necessary paperwork and materials.

Targeting of specific risk factors

Catastrophic thoughts were targeted in several ways: pain education, teaching participants how to identify these thoughts and challenging beliefs, specific education on fear avoidance and hypervigilance using vicious cycles, and through the therapist's use of questioning. The CB model identifies three levels of thinking.[50] The most 'superficial' of these is negative automatic thoughts and these will tend to directly relate to the present situation. For example, a participant faced with a lifting task might have the thought 'I'll hurt myself'. Other levels of thinking include

9

'assumptions' or 'rules' such as 'In order to be safe, I need to be careful at all times' and 'core beliefs' or 'schema' such as 'I am vulnerable'. These two deeper levels of thinking are usually related to more global domains about the person. They can be targeted directly within the context of CB psychotherapy. Within the trial, we trained health professionals to identify the negative automatic thoughts related to LBP. The questioning techniques that were adopted by the therapists in the trial were not designed to delve for deeper meanings such as the 'downward arrow technique',[90] but to help patients explore alternative ways of thinking around their LBP, known as 'guided discovery'.[91]

Depression and underactivity were targeted through education on the effects of inactivity and the benefits of exercise, and through providing participants with the skills needed to increase their activity levels: goal setting, baseline setting, pacing and techniques to manage increases in pain.

Overactivity was targeted through thought challenging and developing pacing skills.

Passive coping was addressed through developing problem-solving skills and alternative helpful pain management techniques, such as relaxation, using medication and planning for potential flare-ups.

Participant information folder

A high-quality participant information folder was designed for the intervention and provided to each participant at the first assessment appointment

(*Figure 4*). The folder contained an overview of the sessions, how and where the groups would be run, therapist contact details, what participants should expect and exercise sheets. During the assessment these exercise sheets were personalised and the goal sheets were filled in. To support participants in working towards their goals while waiting for the group sessions to start, there were information sheets on goals and how to set baselines (starting level for activity). In addition, there were information sheets on sleep, medication and communicating with health professionals.

At each group session participants were given sheets to add to their folders that summarised the content of the session and provided details of their 'homework' task. If a participant missed any sessions, either the inserts were provided at subsequent sessions or they were sent through the post if the participant was unable to attend any other sessions. As the folder was only provided at the therapist assessment, any participant who did not attend for this session received only the active management intervention.

Pilot study and refining of the intervention

Several pilot groups were run as part of the study pilot procedures. An independent researcher collected feedback comments, which were given anonymously to the intervention development team. Comments were very positive, although more supervision of exercises was requested. As a result the therapists were instructed to ensure that each
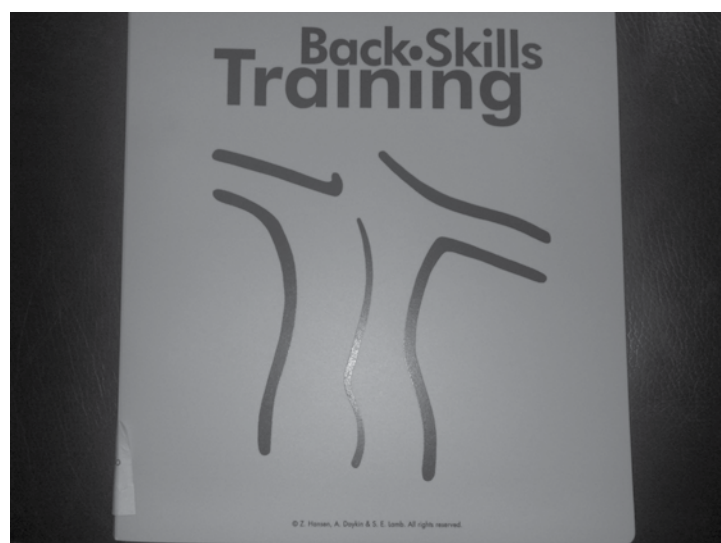
FIGURE 4 *Participant information folder.*

participant had at least one opportunity to have their exercises reviewed during the programme.

Therapist recruitment and training

A 2-day programme was developed to train registered health professionals (physiotherapists, psychologists, nurses or occupational therapists). The length of training reflects the typical length of informal training programmes for qualified staff currently available in the UK. We trained a spectrum of health professionals. This was a pragmatic decision – LBP is a common condition and there are unlikely to be sufficient numbers of psychologists to meet demand. It is recognised that generic pain management skills cross professional boundaries.[92] For example, when CBAs have been applied in diabetes self-management, the treatment effect sizes are found to be the same for psychological specialists and non-specialist clinicians.[93] Although there are high rates of distress and low mood among LBP sufferers in primary care, these symptoms are generally not severe. Therefore, a prolonged training programme in psychological management for the therapists in the trial was not felt necessary.

With this in mind the training was designed to ensure that individuals with different professional backgrounds would be equipped with the same basic knowledge and skills and that the intervention was effective regardless of which health-care professional delivered it. This included equipping psychologists with knowledge of LBP, physical activity and exercise prescription.

The training covered an understanding of LBP and the risk factors associated with chronicity, understanding the CB model, developing basic CB skills such as questioning techniques, developing group facilitation skills and learning the topics to be covered in each session, including pain management techniques. Training was delivered by a cotrained CBT therapist/physiotherapist and a clinical psychologist and was documented in an extensive training manual.[49]

Therapist support

In addition to the training already described, each therapist received a comprehensive treatment manual detailing the rationale and content of each session, including suggested dialogue. In response to feedback from the first training session a website

and DVD were developed. The website contained all support materials, including trial updates and a 'frequently asked questions' section; a screen print is shown in *Figure 5*. The website also had a forum for posting questions to be answered by the trial intervention team and by other therapists. This section was not used; therapists preferred to e-mail or phone the trial team directly.

The DVD was a recording of sessions 1 and 3 run for volunteers from the research department as group participants. Feedback from therapists indicated that they found the DVD very useful before running the programme for the first time.

Within psychological therapies it is usual practice to have regular supervision sessions with a senior therapist to discuss cases. This is not normal practice within most of the other professions allied to medicine. For the purposes of the trial we allowed for flexible supervision, which consisted of discussions either face-to-face on-site visits or via phone or e-mail, whichever was convenient and appropriate for the issues to be discussed. Supervision was provided during the course of the trial by the clinical research fellow, which was on average 1.5 hours per group run. This supervision usually centred on difficulties encountered in the groups, for example difficulties in setting goals with some individuals.

Satisfaction with training

All therapists were asked to provide anonymous feedback in a questionnaire sent out 2 weeks after training; 72% of therapists rated the training as 'very good' with the remaining 28% rating it as 'good'. Confidence to deliver the intervention was rated as 'fairly confident' or 'very confident' by at least 75% of all therapists for each of the skills taught. The exception was 'thought challenging'. A significant proportion of therapists rated themselves as 'a little confident' (45%) or 'not at all confident' (10%) in these techniques. As this skill was new to the majority of therapists this rating was to be expected.

Assessment of treatment fidelity

Quality of the intervention delivery was checked via three processes:

- a site visit was made to a group session for each therapist during their first programme of intervention

FIGURE 5 *Screen print of BeST Therapist webpage.*

TABLE 3 *Session content and therapist skills*

Item		Not achieved (% of total)	Partially achieved (% of total)	Satisfactorily achieved (% of total)
Content	Set agenda	5 (14)	8 (23)	22 (63)
	Homework reviewed	0 (0)	1 (3)	34 (97)
	Topics covered	0 (0)	3 (9)	32 (91)
	Break	0 (0)	0 (0)	35 (100)
	Homework set	0 (0)	5 (14)	30 (86)
	Feedback elicited	6 (17)	7 (20)	22 (63)
	Exercises checked in break	0 (0)	1 (3)	34 (97)
Style	Encouraged group participation	0 (0)	4 (11)	31 (89)
	Listened appropriately	0 (0)	0 (0)	35 (100)
	Empathy demonstrated	2 (6)	1 (3)	32 (91)
	Elicited beliefs/thoughts	2 (6)	11 (31)	22 (63)
	Questioning style demonstrated	2 (6)	8 (23)	25 (71)
	Referred to CB model	4 (11)	4 (11)	27 (77)
	Appropriate pacing of session	1 (3)	7 (20)	27 (77)
	Appeared professional	0 (0)	0 (0)	35 (100)
Environment	Comfortable	0 (0)	1 (3)	34 (97)
	Spacious	0 (0)	0 (0)	35 (100)

- subsequent groups had one session randomly selected for audio recording
- treatment records were screened for each participant.

The session content and skills demonstrated by the therapist were assessed via these processes using a checklist that included items shown in *Table 3*. The audio recordings were used as an observational tool as part of a process of evaluation to determine treatment fidelity, and were not used for further training and feedback.

Summary

A CB intervention was designed that targeted known modifiable risk factors for the development of chronic disabling LBP. The intervention adhered strongly to the principles of a CBA and was structured with sufficient flexibility to allow delivery in a variety of settings and by a range of different health professionals. The training and support package was practical to allow for roll out within the NHS if the intervention proved effective.

Chapter 3
Methods

Aims

There were two aims:

- To estimate the clinical effectiveness of AM in general practice versus AM in general practice plus a group-based, professionally-led CB package (AM+CBA) for subacute and chronic LBP in terms of:
    - reduction in disability associated with LBP
    - reduction of pain or improved tolerance of pain symptoms
    - reduction of further medical, rehabilitation or surgical treatment for LBP
    - improvements in quality of life.
- To measure the cost of each strategy, including treatment and subsequent health-care costs, over a period of 12 months and to estimate cost-effectiveness. The methods employed in the economic analysis are detailed in Chapter 6.

In addition, we planned to interview a selection of participants to gain insight into the experience of LBP and of the treatments delivered as part of the trial (for the methods used, see Chapter 5).

Research methods
Study design

The study comprised a pragmatic, multicentred randomised controlled trial, with investigator-blinded assessment of outcomes.

Setting

Fifty-six general practices were recruited from seven regional clusters across the UK.

Practices

The original plan had been to recruit clusters of general practices that had participated in the UK Back pain Exercise and Manipulation trial (UK BEAM) that had been run by the Medical Research Council (MRC) General Practice Research Framework (GPRF).[94] However, when conducting the pilot study, it became evident that there

were insufficient GPRF practices interested in participating in this new study within each area to ensure a flow of recruitment sufficient to sustain the group-based service delivery model. Therefore, alternative strategies were used. The majority of practices were recruited through collaboration with the primary-care trusts (PCTs), and had not been involved in the UK BEAM study. Fewer than 5% of practices were involved in the BEAM study. This strategy was implemented successfully, although it was labour intensive and caused a delay in starting recruitment. By June 2004, all PCTs in England had been contacted and where interest was expressed a series of visits was undertaken. Initially, seven PCTs were recruited. By the end of November 2004, two PCTs withdrew their consent to participate for logistical reasons, and by July 2005, five clusters (Coventry, Norwich, Langbaurgh, Heart of Birmingham and Solihull) had launched the BeST trial in their PCT. To speed up recruitment and meet target dates for the end of recruitment, two additional PCTs, South and North Warwickshire, were launched in January and March 2006 respectively.

Participants

Our aim was to recruit people with subacute and chronic LBP, who were experiencing symptoms that were at least moderately troublesome. Low back pain presents in a wide variety of ways, and typically patients present with a spectrum of severity and chronicity. The treatment for acute LBP (defined as a first episode that has occurred for less than 6 weeks) is agreed, and although not evidence based, it is generally recognised that psychological therapies are most likely to benefit those with subacute and chronic conditions.[95] We wished to exclude people who had transient, minimally troublesome symptoms.

Eligibility criteria

The eligibility criteria were as follows.

Inclusion criteria
For entry into the trial, the following inclusion criteria had to be fulfilled:

- participants had attended general practice reporting LBP of at least moderate troublesomeness for > 6 weeks
- participants had to be aged 18 years or older
- participants were able to give informed consent.

Exclusion criteria

Participants were not eligible for BeST if they:

- were aged < 18 years
- had been managed previously in a CB programme
- had factors associated with serious pathology [these included cauda equina symptoms, systemic illness (including cancer, human immunodeficiency virus infection, fever), widespread neurology, severe unremitting night-time pain, violent trauma (fall from height, road traffic accident) and substantial unexplained weight loss]
- had severe psychiatric or personality disorders sufficient to merit exclusion as determined by the GP.

Treatments

Active management (reference group)

Both the treatment and reference (control) groups received an intervention that was consistent with best practice in primary care (see Chapter 1, Current management in the UK). Nurses were trained in the approach using a 1-hour training session that included methods to cascade the information within their practice environments. The nurses provided the AM to all trial participants and, in addition, provided each with a copy of *The Back Book*.[35,96] The active management intervention lasted approximately 15 minutes.

Cognitive behavioural therapy (for the experimental arm only)

In addition to AM, participants randomised to CBA received up to six sessions of group therapy (for details, see Chapter 2).

Study procedures

From initial identification of participants to randomisation

Participants consulting their GP in the previous 6 months with LBP were identified from computerised searches of primary-care records or from general practice attendances.

A list of potential participants was screened by GPs, who identified those patients who should be excluded on the basis of serious illness or mental-health problems. The GPs were encouraged to make prospective referrals of any participants they considered suitable for the trial, although only a small number of participants were referred this way. In some practices, searches were repeated after 12 months to identify further participants.

Once potential participants had been identified, an invitation letter (including an information sheet) to participate in the trial, and an initial approach questionnaire (see Appendix 1) was sent out to determine interest and eligibility. The GP signed the approach letter. Potential participants were given approximately 2 weeks to send the initial approach questionnaire back. If there was no reply after 2 weeks a second letter was sent out. Those participants who expressed an interest in the trial and appeared to meet the initial inclusion criteria were contacted by a research nurse and the first of two assessment appointments with the research nurse was scheduled. The reasons for decline/withdrawal/exclusion were documented at all stages.

At the first nurse assessment, the trial was explained in more detail to the participant. In general these appointments were carried out face-to-face at the participant's own GP surgery, although sometimes the appointment was conducted over the telephone. Each of the nurses was provided with a laptop and the nurse determined whether the subject was eligible by completing the computerised first nurse assessment questionnaire (see Appendix 2). Those participants who were temporarily excluded (e.g. because they were awaiting or receiving treatment) were issued a temporary exclusion letter (see Appendix 3). The temporarily excluded participants were allowed to enter the trial once they had become eligible by contacting the nurse and arranging an appointment. For those participants interested in taking part in the trial who met all the study inclusion criteria, a second appointment was made (appointment two – nurse randomisation appointment). This appointment was arranged for within 1–2 weeks of the first nurse appointment to allow time for the participant to consider whether they would like to enter the trial. For those participants who did not attend either of the two

nurse appointments, a reminder telephone call was made and the opportunity was provided for another appointment to be made if the participant wished.

At the nurse randomisation appointment, the nurse randomisation assessment questionnaire (see Appendix 4) was completed. If the participants satisfied the eligibility criteria and provided informed consent then they were asked to (1) sign the informed consent form (see Appendix 5) and (2) complete the baseline questionnaire (see appendix 6). Every participant randomised then had an active management session supplemented by *The Back Book*[96] and it was stressed that they should read and follow the advice given.

The nurse then filled in the randomisation form (see Appendix 7). The information on this checklist was telephoned through to the randomisation office at the MRC Clinical Trials Unit in London (see Randomisation, below). The unit then provided the nurse with the additional treatment allocation for that participant. The nurse would then let the participant know to which treatment they had been randomised. If the randomisation appointment occurred at a time when the randomisation office was closed, the randomisation form was faxed and the treatment allocation was provided once the office reopened.

From randomisation to follow-up

For those participants randomised to AM+CBA, the nurse sent a notification letter to the therapist and provided the participant with a copy. The nurse also advised the participant that the therapist would contact them to arrange a time to start their treatment within the next 2 weeks and asked the participant to contact the therapist if this did not happen. The nurse e-mailed the therapist with confirmation of final numbers referred into the group to check that the number of referrals made matched the number of referrals received.

Follow-up

Follow-up was conducted at 3, 6 and 12 months after randomisation using self-administered questionnaires. The majority of questionnaires were completed in postal format (see Appendix 8). Response was tracked carefully by the trial

office, and a reminder questionnaire was sent after 2 weeks if a follow-up questionnaire had not been returned. If the questionnaire had still not been returned after a further 2 weeks, participants were telephoned to check that the questionnaires had been received and to arrange for another to be sent if needed. If the questionnaire remained unreturned after a further 2 weeks a telephone call was made to the participant to request a core set of data that was collected over the telephone at a time convenient to the participant. All people who provided core outcomes were willing to continue to participate in the trial. Core outcomes are detailed in Appendix 9.

The clinical record form was stamped with the date and initialled on receipt at the Warwick Trials Unit Office. It was then checked for correctness and completeness and coded for the data input clerk. Any queries were checked with the statistician. Missing data were clarified with participants where possible.

The baseline and follow-up data were single-entered into the database by the data input clerk. The accuracy of the data entry was checked by taking a 10% random sample (70 participants) and completing a 100% correctness check on all the variables on the database against the record forms (baseline, 3, 6 and 12 months). There is no firm guidance as to what constitutes an acceptable error rate. Shen[97] suggests a very conservative error rate of 0% for the primary outcome and 0.5% for the secondary outcomes. This was achieved in BeST.

The baseline and follow-up data were validated continuously through the trial and reported at intervals to the Data Monitoring Committee (see Data monitoring and ethics committee, p. 27). After the final validation checks, the database was 'frozen'. If changes were required thereafter, these were formally documented. The clinical outcome data were validated in SAS (SAS Institute, Cary, NC, USA). The health economic data were validated in SAS and then transferred to STATA (Statacorp, College Station, TX, USA) for analysis.

The validation checks carried out included:

- eligibility criteria
- consecutive date checks
- range checks
- missing data checks.

Outcome assessments

Demography and baseline assessments

Appendix 11 lists the demographic and clinical data that were collected at each of the three prerandomisation stages. The baseline assessments are listed in Appendix 6.

The data included date of birth, sex, LBP/ symptoms in the past 6 weeks, frequency of back pain in the past 6 weeks, troublesomeness in the past 6 weeks, ethnic origin, age when left full-time education and employment details.

Although we had proposed to collect the Acute Low Back Pain Screening Questionnaire (ALBPSQ)[98] as part of the baseline assessment, this was dropped in the set-up phase of the study to reduce respondent burden, and in recognition that many of the other measures were capturing duplicate information.

Clinical outcomes

We were guided in the selection of outcome measures by three principles. First, we wished to be consistent with the international recommendations for clinical trials of LBP interventions.[99,100] Second, we considered more recent methodological studies

of LBP outcome measures. Third, we did not want to overburden participants with too many outcomes.

The International Forum of LBP has recommended that trials should measure five domains: pain symptoms, function, generic health status, work disability and satisfaction of care.[99,100] *Table 4* details the measures used in this trial[101] and the time points of data capture.

A copy of all follow-up questionnaires is provided in Appendix 8.

Primary outcomes
We selected two primary outcome measures a priori because of concerns with the scaling of the Roland Morris Questionnaire.

Roland Morris Questionnaire
The Roland Morris Questionnaire (RMQ) is the most widely used measure of LBP disability in primary-care trials. Originally derived from the Sickness Impact Profile, it contains 24 items relating to a range of functions commonly affected by LBP.[102] It takes less than 5 minutes to complete. It has good reliability[101] but there are concerns that it does not conform to many of the assumptions that underpin its use in statistical analysis (scaling

TABLE 4 Outcome measures used in the Back Skills Training Trial

Domain	Measures	Time points
Primary measures		
Pain-associated disability	Roland Morris Questionnaire[102]	0, 3, 6, 12
Pain	Modified Von Korff Scale[103]	0, 3, 6, 12, Tel[a]
Disability		
Secondary measures		
Occupational and other limitations	Numbers of days off work, reduced activity and bed rest	0, 3, 6, 12, Tel[a]
Health-related quality of life	Short Form-12 version 2[104]	0, 3, 6, 12, Tel[a]
Back pain beliefs	[a]Fear avoidance scale (first five items only)[105]	0, 3, 6, 12
Self-efficacy	Pain self-efficacy questionnaire[106]	0, 3, 6, 12
Satisfaction with treatment	Single-item rating of satisfaction with treatment[99]	3, 6, 12
Global rating of change	Seven-point rating[99]	3, 6, 12
Economic analysis		
Resource use	Resource use questionnaire	3, 6, 12 Tel[a]
Health-related quality of life; time trade-off score	EuroQoL five dimensions (health utility)[107]	0, 3, 6, 12, Tel[a]
a Telephone core data.		

and normality of distribution). Data from the Oxfordshire Low Back Pain Trial suggested that it had a marked ceiling effect, failing to capture important clinical information on improvement in participants with subacute or chronic LBP attending NHS physiotherapy. It has been shown to be differentially sensitive at low, mid and high ranges, with (not unsurprisingly) better sensitivity in the middle range.[108,109] In the low to mid range, the RMQ is less sensitive to within-group changes than the Aberdeen Low Back Pain Score, but better at detecting between-group differences.[101]

Scoring

Completion of the RMQ scale comprises a mark next to each appropriate statement.

Interpretation

The total number of marked statements is added up to form a score (out of 24), and a low score is associated with less disability.

Modified Von Korff Scale

The Modified Von Korff Scale (MVK)[103] assesses two dimensions – pain and disability associated with back pain in the last 4 weeks. It is made up of six items, each of which is scored on a scale of 0 (no pain/disability) to 10 (worst pain/disability). The first three of these items relate to disability and ask about how back pain interferes with (1) daily activity, (2) recreation and (3) ability to work. The last questions relate to pain and assess the (1) worst pain, (2) average pain and (3) rating of back pain today. The questionnaire was administered at baseline, 3, 6 and 12 months.

Scoring

The scale has two dimensions:

$MVK_{disability}$: Disability score = [(sum points of the first three questions)/3] × 10

MVK_{pain}: Pain score = [(sum points of the last three questions)/3] × 10.

Interpretation

The higher the score, the more severe the disability or back pain.

Secondary outcomes

Occupational disability and limited activity days

Three separate questions were used to elicit the number of days in the period from 0 to 3 months, 3 to 6 months and 6 to 12 months that participants:

- had to cut down on normal activities (for more than half a day)
- had time off work because of low back or leg pain (sciatica).

These questions were recommended by the International Forum, and have been used widely (summarised in Deyo *et al.*[99]).

Participant satisfaction

Participant satisfaction was assessed using the single-item question recommended by the International Low Back Pain Forum:[99] 'Over the course of treatment for your LBP or leg pain, how satisfied were you with your overall medical care?' We modified this question slightly to reflect care over the duration of the study, and by changing the term 'medical care' to 'one related to health care'. The question that was asked was 'How satisfied are you with the treatment you received?' Responses were rated on a five-point Likert scale, ranging from 'very dissatisfied' to 'very satisfied'.

Psychological and behavioural measures

We included these measures because they measure constructs hypothesised to lie on the causal pathway of effect, and we hoped that they would provide some explanation as to why the treatment may or may not be effective.

Fear avoidance beliefs questionnaire

The Fear Avoidance Beliefs Questionnaire (FABQ) is a measure of the degree of fear of pain and disability, and the avoidance of physical activities that can result. Each item is scored from 0 (completely disagree) to 6 (completely agree). This scale has two dimensions (fear avoidance beliefs about work and fear avoidance beliefs about physical activity). We selected only the section of the measure concerned with physical activity as it has generic applicability.

Scoring The scores from each of these items are summed to provide a total score. Minimal scale score is 0 and maximum scale score is 24.

Interpretation The higher the scale scores the greater the degree of fear and avoidance beliefs shown by the participant.

Pain self-efficacy

This is a measure of the patient's confidence to carry out a range of activities despite the back pain. There are 10 items, ranging from 0 (not at all confident) to 6 (completely confident).

Scoring The scores are totalled with the total ranging from 0 to 60.

Interpretation A lower score indicates reduced self-efficacy of the participant.

Quality of life

Quality of life was measured using the Short Form-12 (SF-12) version 2. The SF-12 (a short version of the SF-36) is a measure of health-related quality of life and is widely used in back pain trials. The SF-12 has performed well in previous clinical trials of LBP using postal follow-up.[110]

Scoring

The SF-12 manual was used to score the SF-12. Results were expressed in terms of two meta-scores: physical and mental components.

Interpretation

The SF-12 is scored so that a high score indicates better physical functioning. The physical and mental scores have a range of 0–100 and were designed to have a mean score of 50 and a standard deviation (SD) of 10 in a representative sample of the US population (see *Table 5* for age-specific SF-12 scores). Scores > 50 therefore represent above-average health status. On the other hand, people with a score of 40 function at a level lower than 84% of the population (one SD) and people with a score < 30 function at a level lower than approximately 98% of the population (two SDs).

Health economics – EuroQoL five dimensions

The EuroQoL five dimensions (EQ-5D)[111] measure was collected at baseline, 3, 6 and 12 months' follow-up.

The instrument (see Appendix 8) contains a description of the health state in five dimensions or items: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. It measures health on five dimensions and a tariff is available

for deriving a single utility score. Completion takes less than 5 minutes.[107]

Scoring

The items are three levels of severity for each item: 1 (no problems), 2 (some problems) and 3 (unable to do/extreme problems). For each item, the respondents must indicate the level of severity that best describes their personal health state at the time of giving the answers. The subject's global health state is defined as the combination of the level of problems for each of the five dimensions. Health states defined by the EQ-5D can be converted to a single summary by applying scores from a standard set of weights (or preferences) derived from general population samples.[107]

Interpretation

The weightings represent the strength of societal preference for a described health state and are scored between 0 (death or worst imaginable health state) and 1 (full health or best imaginable health state). The quality adjustment is then multiplied by the expected life-years in the assessed health state to arrive at the total quality-adjusted life-years (QALYs) achieved. The total utility associated with a health-care intervention is then the sum of utility weights declared by respondents multiplied by the time spent in those states.

Resource use questionnaire

Resource use was monitored for the economic analysis and to gain insight into other treatments being used either as a consequence of or alongside the treatments being tested in the trial. A self-report questionnaire was administered to ascertain whether participants had additional hospital treatment for their LBP during the follow-up period, specifying whether this was NHS or private treatment; any GP consultations; and any manipulation, massage, etc. which they received during follow-up. Participants were also asked about the number and types of any medications and treatments, including pain-relieving medications. Participants were asked to distinguish

TABLE 5 *Short Form-12 mean scores (general US population)*

Age (years)	Physical component	Mental component
45–54	50	50
55–64	47	51
65–74	44	52
≥ 75	39	50

between prescription and out-of-pocket expenses. We used a structured closed questionnaire to ascertain these data, based on a questionnaire that had been used in previous LBP trials.[37] Participant self-reported information on service use had been shown to be accurate in terms of intensity of use of different services.[112]

Other treatments

There was a possibility that participants would seek other forms of treatment during the follow-up period. The resource use questionnaire allowed us to monitor changes in the amount or types of analgesia used, use of physical treatments (osteopathy, chiropractic or physiotherapy), alternative therapies, or referral to secondary-care services. Participants and GPs were encouraged to refrain from referral of participants to other treatments where possible during the first 3 months after randomisation and while participants were attending the CBA course.

Randomisation

The randomisation system

Initially a web-based randomisation system was planned. This system was very difficult to implement as it depended on the research nurses being able to access an NHS web link or secure internet link in the practices. The nurses were not always able to have access to practice computers and were often allocated rooms without internet access. Instead, an independently administered telephone randomisation service was used at the MRC Clinical Trials Unit in London. Random allocations were generated by an independent statistician in a ratio of 2:1 in favour of the intervention arm of the trial. Randomisation reports were sent to the trial office on a weekly basis.

Method of randomisation

We used stratified block randomisation. The randomisation was stratified by region (recognising the heterogeneity likely to exist between regions). It was important to balance the severity of back pain (moderately versus very/extremely troublesome) over the two treatment arms in case there was a difference in response based on severity. Block lengths were sufficiently large to ensure that predictions of treatment allocation could not be

made, and that the allocation ratio of 2:1 could be achieved.

In the initial application, randomisation was based on equal assignment (a ratio of 1:1) over the two therapy groups. It was recognised, during the trial set-up stages, that such an allocation would produce an insufficient yield of participants to run the groups for the AM+CBA arm. As a result, random allocation was conducted using a 2:1 (AM+CBA:AM) ratio. This had little impact on the power of the trial and considerably improved efficiency.

The details required by the randomisation officer are shown on the randomisation form (see Appendix 7).

Quality assurance

We implemented a quality assurance protocol to monitor and ensure that research nurses were adherent to the trial protocol. Each research nurse was visited on at least two occasions by a senior research nurse from the MRC GPRF, and observed taking consent and delivering the active intervention component of the intervention. Problems were minimal.

Compliance

We measured compliance with the intervention by the number of sessions attended. This information was ascertained from records collected by the therapist providing the treatment.

Formal approvals

The original ethics approval for the project was dated 26 March 2003 with a substantial amendment approving protocol amendments on 22 July 2004. Further amendments for the qualitative interview study and consent, change to patient information sheets and promotional posters were all approved on 5 March 2005. An amendment to the randomisation procedure was submitted on 24 May 2005 and approved via chairman's action on 14 July 2005. Further chairman's action approval was received on 7 September 2005 for a change in trial personnel. A substantial amendment was approved on 25 January 2006 for version control. Chairman's action was sought on 5 July regarding

follow-up procedures and approval was received on 1 September 2006.

Adverse events

Risks and benefits

The risks to participants in this trial were considered small. The potential benefits were minimisation of back pain symptoms and prevention of chronic problems.

Potential side effects and monitoring

It was anticipated that there were unlikely to be any serious side effects from the treatments. Possible potential side effects were worsening of symptoms if other more effective treatments were withheld. All adverse events were reported to the Data Monitoring and Ethics Committee (DMEC). Serious adverse events were defined as those that resulted in death or admission to hospital as a result of the intervention, or that caused unwarranted distress to a participant. All deaths and potential events were reported to the Chief Investigator, who determined whether the event might have been or was attributable to the intervention. Events were reported to the ethics committee and to the DMEC.

Sample size

The primary outcome measures were the RMQ and MVK assessed over 12 months.

Increasingly it has been recognised that advances in modern health care are most likely to yield moderate improvements, but in the context of highly prevalent conditions like LBP, these are considered worthwhile.[113]

Choice of treatment effect

Deciding the minimal clinically important difference (MCID) between groups was problematic, particularly for the RMQ. Previous trials (including the UK BEAM, Oxfordshire Low Back Pain Trial and York Back Pain and Exercise Trial) adopted a clinically significant difference between groups of 2.5 RMQ points, based on the views of an expert group of clinicians and researchers. This equates to a large standardised effect size of 0.65,[114] assuming an SD of 4.0. Differences of this magnitude had not been

observed in several large trials (effect sizes were 0.35 for BEAM and 0.36 for the York Low Back Pain Trial[115]). Careful back tracking through trials (reviewed by Bombardier *et al*.[100]) suggested that the MCID had been derived from a few studies of short-term benefits (< 8 weeks) of therapies in LBP. This is the stage at which one would expect to see the largest differences between groups because of the natural history of LBP. Powering a trial on the short-term clinical benefit was unlikely to be sufficient to monitor longer-term impacts of public-health significance. The majority of outcomes reported for CBA suggest moderate benefits at 1 year, with a between-group effect size of approximately 0.35 for the majority of outcomes reported in efficacy trials.[116] This equates to a between-group difference of approximately 1.4 change points on the RMQ disability score (i.e. new treatment approaches are approximately half as good again as the comparative treatment at reducing disability). We therefore considered that an effect size of 0.35 would be a suitable target for the CBA to be worthwhile.

The power of the trial

We selected a power of 90% recognising that economic analyses required greater power. Based on the experience of previous trials, the number of participants we intended to recruit was adequate for the purposes of the economic analysis.[117]

We selected a significance level of 0.01 because of the need for a definitive trial. The sample size was sufficient to detect worthwhile benefits in the range of secondary outcome measures at conventional levels of statistical significance.

Adjustment for cluster effects of group interventions

The unit of randomisation was the individual, but the sample size estimate was inflated to account for the occurrence of cluster effects relating to grouping of patients together in each CB programme, and the clustering of outcomes around individual therapists (therapist effects). Previous studies of LBP report the intracluster correlation coefficient (ICC) for therapist effects to be 0.01,[94] although comparative data on group effects were not available. The ICC of 0.01 was used as an estimate for the therapist and group effects. Based on collecting outcome data on an average of seven people per group we inflated our sample size by 1.07.

Loss to follow-up

We assumed a loss to follow-up of 25% at 12 months, as achieved in the BEAM trial.[94]

Sample size estimate

The sample size was estimated at the outset of the trial, and subsequently revised during trial set-up as we examined the practical aspects of setting the trial up. In the original sample size estimate [Health Technology Assessment (HTA) application], we used an effect size of 0.35 SD points, 90% power and $p < 0.01$ and inflation factor for clustering yielding an estimate of 262 in each group. We specified that we wished to detect a between-group difference of approximately 1.4 change points and a standardised effect size of 0.35. Assuming loss to follow-up of 25% and a balanced allocation between treatment and control (1:1), we aimed to recruit 350 in each group (700 in total).

As we progressed with the early phases of the trial, and with the experience gained in another trial we were conducting of group treatments, we opted to use an unbalanced randomisation (2:1 in favour of the intervention). The reason was pragmatic; we could not sustain a flow of participants to fill the groups in a reasonable time frame using balanced randomisation. A randomisation balance of 2:1 can be adopted with inconsequential loss of power, but further imbalances necessitate an increase in study size.[118,119] We estimated that a change to unbalanced randomisation without further inflation of the sample size would still allow us to detect clinically worthwhile benefits (effect size 0.42 and a between-group difference of 1.8 RMQ points.[118] We chose not to increase the sample size target, recognising that if loss to follow-up was 25% as predicted the study still had power to detect clinical worthwhile improvements. At the end of the trial, follow-up was better than anticipated, and we retained power to detect the original differences specified.

Using the proposed 700 participants and a 2:1 randomisation, we needed approximately 233 participants in the AM group and 467 participants in the AM+CBA arm.

Pilot study

We undertook a series of pilot studies to refine the study procedures and ensure that the intervention was acceptable and deliverable in the format intended.

The intervention was piloted at the Nuffield Orthopaedic Centre NHS Trust in Oxford in the first instance. Two CBA cycles were completed and participants provided feedback on the contents and revised contents of the intervention. We then piloted the intervention in primary care along with the study procedures.

We planned to carry out the pilot study in three general practices in the Coventry area and to recruit 30–40 participants. In fact it was carried out in only one of the practices for the following reasons:

- one practice dropped out when they learnt more about the trial
- we were forced to run the pilot over the July/ August period because of a 7-week delay in the Central Office for Research Ethics Committees confirming ethical approval because of an internal Central Office for Research Ethics Committees communication problem (as a consequence the research nurse who was secured to run the second practice was unavailable – she had to cover leave, went on holiday and was subsequently stranded abroad by hurricanes; however, this practice participated in the main trial).

We tested one of the two recruitment strategies – identification of participants through participant record searches but not prospective identification of participants via the GPs. In general the pilot study had been successful and useful in refining the study methods and in particular, methods related to the approach to participants.

Data management

All the databases were developed in Microsoft ACCESS 2002.

The prerandomisation and randomisation information was captured on laptops, whereas the baseline and follow-up data were collected using postal clinical research forms or by telephone and then entered into the database manually. Computerised validation checks were incorporated into the data sets to minimise data errors.

Database specifications were set up by the statistician and programmer for each variable collected at baseline and follow-up assessments.

Statistical analysis

Prerandomisation and randomisation

The trial has been reported in accordance with the CONSORT[120] guidelines that have now been extended to consider the reporting of complex interventions. All statistical tests were two-sided. The statistical analyses were carried out using SAS (version 9.13) and STATA (version 9). The health economic analyses were carried out using STATA. The demographic profile of the sample was summarised as the mean, SD, range and number of participants missing. The categorical data have been summarised using the number (and percentage) of participants within each category.

CONSORT flowchart
The CONSORT flowchart details the number (and percentage) of participants who were recruited into the trial from the second nurse's assessment time point. The flowchart depicts the passage of participants through the trial (prerandomisation, intervention allocation, follow-up and primary data analysis).

Recruitment of randomised participants
The number (and percentage) of participants at baseline and follow-up was detailed as follows:

- with data/clinical research forms present
- with core data present
- with no data present.

The follow-up (response) rates were derived from the total data present (i.e. sum of first two bullet points). The cumulative number of withdrawals over each time period was calculated and the frequency of loss to follow-up, blank questionnaire return and withdrawal (with reasons) was summarised.

The primary analysis method was 'intention-to-treat'. The participants were analysed according to the therapy to which they were randomised, irrespective of the treatment they actually received.

Intention-to-treat formed the basis for computing the proportion of participants at different stages of the trial from randomisation to 12-month follow-up. The main summary tables and analysis are based on the intention-to-treat population unless otherwise specified.

Per protocol analysis
Participants who did not adhere to the treatment at the prespecified level of three or more sessions or who were incorrectly randomised were removed to form a per protocol sample. These analyses were undertaken using the primary outcomes and informed the sensitivity analysis.

Clinical outcomes: baseline and follow-up

Two sets of analyses were carried out:

- *primary analysis* observed case analysis
- *sensitivity analysis* missing data imputed at case level and questionnaire level and per protocol analysis.

Change from baseline to each of the follow-up assessments
Outcomes were summarised as the change from baseline score. The absolute scores were not used because the distribution of the data was, for some outcome measures, substantially non-normal. This was expected, particularly for the RMQ. A range of transformation methods were investigated, but none was able to normalise the data.

We needed to identify a method of summarising the data that would allow us to implement parametric methods including random effects and hierarchical modelling. Non-parametric covariance analysis[121] is substantially limited in both scope and interpretation and was rejected because it does not allow consideration of clustering effects within the model. Similarly, more sophisticated statistical methods of modelling the probability density function[122] while allowing for non-normality are significantly limited in interpretation and do not allow for consideration of clustering effects.

The interpretation of change from baseline scores is listed in *Table 6*.

Change from baseline is interpreted as 'improvement'/'deterioration' in condition from the point the participant provides the first (baseline) clinical assessments and this was found to be normally distributed for all the outcomes. This provided the only robust method of transforming the absolute scores. Although commonly reported

in many trials, analyses based on change from baseline have to be interpreted with caution. Difficulties arise when there are differences in the central tendency and/or distribution of baseline scores between the randomised groups;[123] this is not the case for BeST.

We investigated the time frame of improvements. We focused our interest on the average improvement over all follow-up time points, and on the benefit sustained at 12 months, as both indicators are of public health interest.

Summary statistics (observed data) at each follow-up time point

The absolute continuous questionnaire scores were summarised using means, SDs, median, range and the number of participants with and without the questionnaire score.

The effect sizes were calculated as the mean difference of the absolute values of the treatment effects at the relevant follow-up point divided by the pooled SD of baseline means.

Statistical analysis – linear regression models (observed data) at each follow-up time

Linear regression models were fitted to the data using the change from baseline values as the response. Unadjusted and adjusted (for baseline, age and sex) estimates (and standard errors) were obtained for the treatment effect with a 95% confidence interval (CI). Values of p were obtained using the Wald method.

Statistical analysis – random effect models (observed data)
Incorporation of therapist/group session random effects

Random effect regression models were fitted to estimate any potential group or therapist effects. The intervention is delivered as an assessment plus six group sessions. The intention was that once a cohort of participants was scheduled to a group, they would attend all of the sessions with that cohort, as opposed to changing between cohorts. The clinical rationale is that people build up a relationship with other participants over time. An additional potential effect arises from therapists (MRC Population Health Science Research Network workshop: Clustering effects in individually randomised controlled trials and other studies, 2007). We used hierarchical random effect models implemented in SAS (PROC MIXED) to model these effects.

Other effects, such as regional clusters and general practices were not incorporated into the models in a formal manner. Randomisation was stratified by regional clusters, and hence we do not anticipate any imbalance.

Intracluster correlation coefficients

The ICCs were used to quantify the clustering effects arising from therapist and group effects in the primary outcomes. The smaller the ICC, the less the clustering effect.

TABLE 6 *Interpretation of the absolute and change scores*

Questionnaire/ score	Interpretation of absolute score	Change from baseline (baseline – follow-up)
RMQ	Lower score implies less disability; higher score implies more disability	–ve implies deterioration; +ve implies improvement
MVK (disability)	Lower score implies less disability; higher score implies more disability	–ve implies deterioration; +ve implies improvement
MVK (pain)	Lower score implies less pain; higher score implies more pain	–ve implies deterioration; +ve implies improvement
FABQ	Lower score implies less fear/avoidance; higher score implies more fear/avoidance	–ve implies deterioration; +ve implies improvement
Pain self-efficacy	Lower score implies less confidence; higher score implies greater confidence	–ve implies became more confident; +ve implies became less confident
SF-12 (physical and mental)	Lower score implies poor functioning; higher score implies better functioning	–ve implies functioning has improved; +ve implies functioning has deteriorated

FABQ, Fear Avoidance Beliefs Questionnaire; MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form-12; –ve, negative; +ve, positive.

Random effect models

Two models were fitted separately with group and therapist session as a random effect. These models were adjusted for sex, age and baseline outcome.

Longitudinal models (observed data)

Longitudinal regression techniques enable us to generate a single estimate of treatment over the 12-month period (analogous to using area under the curve analysis to derive a single estimate for the entire time period). The original protocol stated that we would use area under the curve analysis, so this is a deviation in computing method but not in original intention.

Four longitudinal models were fitted with varying covariance–variance structure (compound symmetry, unstructured, heterogeneous, autoregressive heterogeneous). The model with the smallest Akaike's Information Criterion was selected.

Longitudinal models were fitted with fixed effects (age, sex and baseline) and a random effect (group/therapist).

Numbers needed to treat

We estimated the number needed to treat (with a 95% CI) for the primary outcomes at 12 months and the global indicator of change.

This calculation required us to specify the minimally important change for an individual. Although there is no strong consensus, we used the thresholds suggested by previous studies.[124,125]

These were a 30% change from baseline, i.e. [(baseline – follow-up at 12 months)/baseline] × 100. Here scores changing by ≤ 30% are considered as deterioration or stability in disability and those > 30% are improvement. However, owing to rounding errors generated in the method of calculation, the method is imprecise. We also calculated numbers needed to treat based on the global indicator of change distinguishing between those people who reported any improvement versus none or deterioration, and those people who reported stability of symptoms or improvement versus deterioration.

Employment (hours)/days off sick/ number of days off sick

Change in work status in the last 3 months was summarised using numbers and % of participants with change in their work status. Hours of

employment and days off sick were statistically tested using chi-squared test statistics. Number of days off work (as sick) was analysed using the Wilcoxon signed rank test.

Harm (safety) data

The number (and percentage) of participants who have a serious adverse event/death/complaint is reported.

Treatment satisfaction and global indicator of change

We used a seven-point scale to measure satisfaction and global change.[99] The number of participants (and percentage) within each of the 'satisfaction'/'global change' categories is given for each treatment arm over the course of the study. A chi-squared test for trend was used to assess the difference in treatment effect at each of the three time points.

Subgroup analysis

The potential biases inherent in undertaking multiple subgroup analyses are well recognised.[126] However, the BeST trial offers a unique opportunity to generate hypotheses about the profile of participants most likely to benefit from group-based CBA. The most scientifically robust method of subgroup analysis is a test of interaction between treatment and outcome that has been appropriately powered. This can substantially increase sample size requirement. A rough rule is that detection of interactions approximately twice the size of the main effect requires no increase in the sample size, provided that the subgroups are of equal size, the subgroup comparisons are limited and prespecified, and the results are considered hypothesis-generating as opposed to confirmatory.[126] We report three prespecified analyses alongside the main trial results:

- participants with subacute versus chronic LBP at study entry (duration was entered as a continuous variable, and then in a separate analysis as a binary variable using a cut point of 3 years' duration)
- participants with moderately versus very/ extremely troublesome back pain at study entry
- participants with higher versus lower fear avoidance at study entry (≤ 14 or > 14 on the Fear Avoidance Scale).

These comparisons assume detection of large effects and that subgroups are of roughly equal size.

Monitoring and time line

Trial Steering Committee

A Trial Steering Committee was responsible for monitoring and supervising the progress of BeST towards its interim and overall objectives.

Data Monitoring and Ethics Committee

The DMEC was independent of the trial and monitored the ethical, safety and data integrity aspects of the trial. The DMEC determined what analyses were required at each of the meetings and these were supplied by the trial statistician.

Chapter 4
Results

Participant approach and characteristics of the randomised sample

A total of 9771 people were identified from primary contacts or from primary-care record searches and were sent an initial approach screening questionnaire. Of these people, 3604 returned the screening questionnaire and 3496 provided data that could be used to assess potential eligibility.

Of these, 1465 appeared eligible. The most common reasons for ineligibility were that people no longer had back pain ($n = 481$), their back pain was not of sufficient frequency ($n = 611$) or troublesomeness ($n = 479$), or they were pregnant ($n = 20$). Some participants had several reasons for ineligibility.

All 1465 apparently eligible people were invited to attend the first nurse assessment check: 971 attended the first nurse assessment, and of these 833 were eligible for the second nurse assessment; 754 people attended the second nurse assessment and 705 were randomised. Baseline data were not received for four of these and they have been excluded from our analyses.

There were no important differences between those participants who were determined eligible and randomised, and those who were determined eligible and were not randomised. All randomised participants met the eligibility criteria.

The characteristics of the randomised sample are shown in *Table 7*. In summary, the majority of the randomised sample (70%) experienced back pain every day. The most common presentation was pain in the back or buttocks, and stiffness and restricted range of motion. Just over half of the randomised sample reported their back pain to be moderately troublesome (55%), the remainder reporting very or extremely troublesome pain. The average age of the sample was 54 years, and nearly 60% of participants were women. Most had left full-time education before the age of 15, and approximately half of the sample reported that they were currently working. If participants were working then they were generally in full-time work (working between 25 and 40 hours a week), were in professional or skilled manual work and were being paid. The majority of those not working were retired.

Description of sample by cluster

The study recruited from 56 general practices from seven regions across England: Norwich (27.8% of the sample), Coventry and Solihull (26.8%), South Warwickshire (18.6%), Birmingham (12.6%), Langbaurgh (7.5%) and North Warwickshire (6.7%). The characteristics of each regional sample were generally consistent (*Table 8*). The only exception was ethnicity. Although overall the sample was representative of the UK population ethnic mix, the regional samples were different in their ethnic make-up. The Birmingham cluster provided the majority of Asian participants. Birmingham also had the greatest proportion of people who were not working.

Success of randomisation

The severity of back pain was used as a stratification variable along with the regional centre and, as shown in *Table 9*, the randomisation resulted in a satisfactory balance in the stratification variables over the treatment groups.

Flow and characteristics of randomised participants

Figure 6 presents the flow diagram for the study. The number of participants randomised and in whom a baseline assessment was received by the trial office was 701 (233 on the AM and 468 on AM+CBA). An additional four people provided consent and were randomised but no baseline questionnaire was received for them. Hence they have been excluded from the analysis (*Figure 6*).

In summary, 78% of the participants provided data at 3 months, 83% at 6 months and 85% at

TABLE 7 *Demographic information for those participants who attended the second nurse assessment by randomisation status*

Details		Attended second nurse assessment	Eligible and randomised
No. of participants	Total	754	705
	(with data)	722	701
Age (years)	Mean (SD)	54 (15)	54 (15)
	Range	18–85	18–85
	Missing	6	2
Gender	Male	289 (40%)	279 (39%)
	Female	427 (59%)	420 (60%)
	Missing[a]	6 (1%)	2 (0%)
Ethnic origin	White	632 (88%)	618 (88%)
	Mixed	8 (1%)	7 (1%)
	Asian	29 (4%)	29 (4%)
	Black	13 (2%)	11 (2%)
	Chinese	2 (0%)	2 (0%)
	Missing[a]	38 (5%)	34 (5%)
Frequency of back pain	Every day	487 (68%)	477 (68%)
	Every day to ¾ days	104 (14%)	102 (15%)
	¾ to ½ a day	56 (8%)	56 (8%)
	Missing[a]	70 (10%)	66 (9%)
Troublesome back	Not at all	0	0
	Slightly	7 (1%)	0
	Moderately	392 (54%)	382 (55%)
	Very/extremely	323 (45%)	319 (45%)
Left full-time education (years)	16 or less	400 (55%)	387 (55%)
	17–19	169 (23%)	165 (23%)
	20 or over	113 (16%)	113 (16%)
	Still in further education	3 (0%)	3 (0%)
	Missing[a]	28 (4%)	37 (5%)
Currently working	Yes	303 (42%)	299 (42%)
	No	302 (42%)	289 (41%)
	Missing[a]	117 (16%)	117 (16%)

a Percentage missing is based on the number of participants at each assessment.

12 months. Approximately 1% of the clinical research forms were returned blank over the course of the trial. A greater amount of the data was collected by telephone follow-up at 12 months (14%) compared with 3 months (4%) and 6 months (8%). There was no difference in the amount of telephone follow-up between the two arms of the trial at any of the follow-up time points ($p = 0.13$). There was no significant difference in the amount of non-response between treatments over time ($p = 0.24$; *Table 10*).

Just over 5% (38/701) of participants withdrew over the course of the trial. There was no association between withdrawal and treatment allocation at any of the time points ($p = 0.66$). The usual reason for withdrawal was that participants did not want to complete questionnaires – 15 participants (2%).

TABLE 8 Demographic details of randomised participants by regional cluster

		Birmingham	Coventry	Solihull	Langbaurgh	Norwich	North Warwickshire	South Warwickshire
N		88	126	63	53	191	47	131
Age (years)	Mean (SD)	52.3 (16.55)	50.4 (14.47)	58.3 (14.39)	53.7 (12.04)	55.9 (13.99)	51.9 (13.62)	52.7 (15.29)
	Missing	1	0	0	0	1	0	0
Gender	Male	34 (38.2%)	51 (40.5%)	23 (36.5%)	25 (47.2%)	76 (39.6%)	20 (42.6%)	50 (38.2%)
	Female	55 (61.8%)	75 (59.5%)	40 (63.5%)	28 (52.8%)	115 (59.9%)	27 (57.5%)	80 (61.1%)
	Missing	0	0	0	0	1 (0.5%)	0	1 (0.8%)
Ethnic origin	White	60 (67.4%)	117 (92.9%)	61 (96.8%)	32 (60.4%)	185 (96.4%)	45 (95.8%)	118 (90.1%)
	Mixed	2 (2.3%)	0	0	0	1 (0.5%)	0	4 (3.1%)
	Asian	19 (21.4%)	5 (4.0%)	1 (1.6%)	0	0	0	4 (3.1%)
	Black	7 (7.9%)	1 (0.8%)	0	0	1 (0.5%)	0	2 (1.5%)
	Chinese	0	0	1 (1.6%)	0	1 (0.5%)	0	0
	Missing	1 (1.1%)	3 (2.4%)	0	21 (39.6%)	4 (2.1%)	2 (4.3%)	3 (2.3%)
Troublesomeness	Moderately	41 (46.1%)	74 (59.7%)	34 (53.8%)	29 (54.7%)	101 (52.6%)	29 (61.7%)	74 (56.5%)
	Very/extremely	48 (53.9%)	52 (41.3%)	29 (46.0%)	24 (45.3%)	91 (47.4%)	18 (38.3%)	57 (43.5%)
	Missing	–	–	–	–	–	–	–
Left full-time education (years)	16 or less	37 (41.5%)	79 (62.7%)	38 (60.3%)	17 (32.1%)	121 (63.0%)	31 (66.0%)	64 (48.9%)
	17–19	21 (23.6%)	31 (24.6%)	17 (27.0%)	8 (15.1%)	47 (24.5%)	13 (27.7%)	28 (21.4%)
	20 or over	30 (33.7%)	12 (9.5%)	7 (11.1%)	7 (13.2%)	19 (9.9%)	3 (6.4%)	35 (26.7)
	Still in full-time education	0	1 (0.8%)	0	0	1 (0.5%)	0	1 (0.8%)
	Missing	1 (1.1%)	3 (2.4%)	1 (1.6%)	21 (39.6%)	4 (2.1%)	0	3 (3.1%)
Currently working	Yes	37 (41.6%)	53 (42.1%)	25 (39.7%)	19 (35.9%)	62 (32.3%)	24 (51.1%)	69 (52.7%)
	No	47 (52.8%)	60 (47.6%)	11 (17.5%)	13 (24.5%)	89 (46.4%)	21 (44.7%)	58 (44.3%)
	Missing	5 (5.6%)	13 (10.3%)	27 (42.9%)	21 (39.6%)	41 (21.4%)	2 (4.3%)	4 (3.1%)

TABLE 9 *Number (and percentage) of participants randomised by treatment and regional cluster/severity of back pain*

Cluster	Severity of pain	Treatment AM (%)	AM+CBA (%)	Total
Birmingham	Moderate	14 (6)	27 (6)	41 (6)
	Severe	16 (7)	32 (7)	48 (7)
Coventry	Moderate	23 (10)	51 (11)	74 (11)
	Severe	20 (9)	32 (7)	52 (7)
Solihull	Moderate	13 (6)	21 (5)	34 (5)
	Severe	7 (3)	22 (5)	29 (4)
Langbaurgh	Moderate	11 (5)	18 (4)	29 (4)
	Severe	4 (2)	20 (4)	24 (3)
Norwich	Moderate	34 (15)	67 (14)	101 (14)
	Severe	31 (13)	60 (13)	91 (13)
North Warwickshire	Moderate	10 (4)	19 (4)	29 (4)
	Severe	6 (3)	12 (3)	18 (3)
South Warwickshire	Moderate	25 (11)	49 (11)	74 (11)
	Severe	19 (8)	38 (8)	57 (8)
Total		233	468	701

Missing data and characteristics of the randomised sample

There was no statistically significant difference in the return rates between the two arms of the trial at any of the follow-up time points ($p = 0.67$). There was no evidence of a systematic difference in the baseline characteristics of participants who provided follow-up data and those who did not (see Appendix 12). The most common pattern of missing data was for data to be missing at the first follow-up point, and then complete for the remainder (*Table 11*). We obtained some follow-up data on over 90% of participants. Reasons for withdrawal are given in *Table 12*.

The demographic characteristics of all randomised participants (by treatment group) are shown in *Table 13*. Demographic and baseline characteristics were well balanced across the treatment arms.

Treatments received

Intervention arm (AM+CBA)

One participant was randomised to AM but received CBA in addition to AM.

Details of therapists for cognitive behavioural approach

We used a variety of methods to recruit the therapists and although we targeted all allied health and nursing professionals, it was mainly physiotherapists who responded. We recruited and trained 19 therapists: 14 physiotherapists, two occupational therapists, one nurse, one clinical psychologist and one health psychologist. In total 77.3% ($n = 378$) of participants attended groups facilitated by physiotherapists, 6% ($n = 30$) saw occupational therapists, 9% ($n = 45$) saw psychologists and 3% ($n = 15$) saw nurses.

Details of the therapists are shown in *Table 14*. The therapists had a range of experience with years since professional qualification ranging from 2 to 32 years with a mean of 13.6 years (SD 9.6). Some therapists had experience of running similar groups in the past.

Attendance for assessment and sessions in the trial

Attendance for the assessment and group sessions is summarised in *Table 15*. Nearly two-thirds (63%) of the participants randomised to receive CBA attended the assessment session and at least three of the six group sessions, and were therefore considered to have received the basic elements of
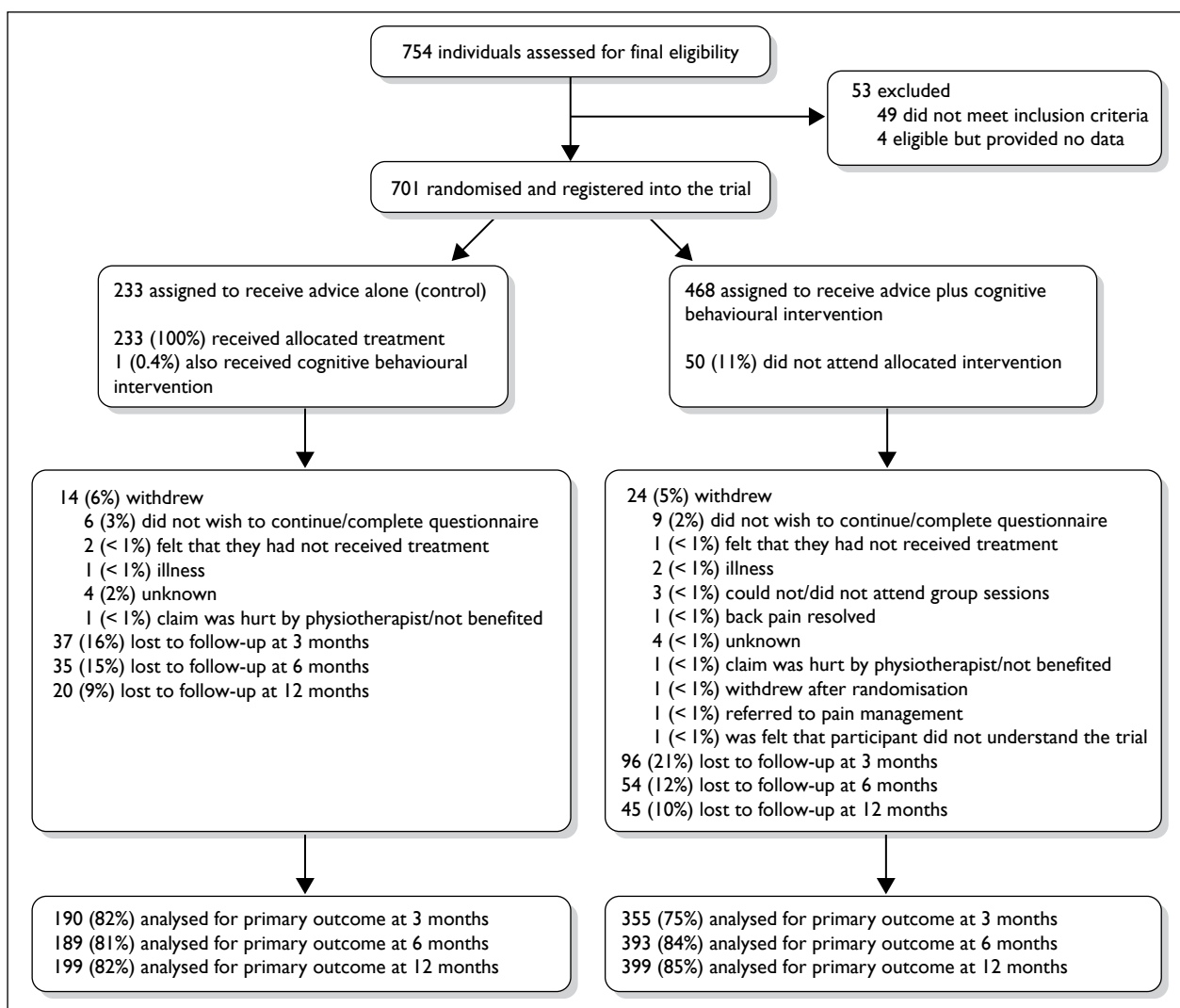
FIGURE 6 *Flow chart of the trial.*

the treatment. Just over 10% of people randomised to CBA did not attend any of the programme. Attendance at all six sessions was achieved by 25% of the sample. There was no evidence to suggest that therapist characteristics were associated with attendance – neither the professional background (*Table 16*), previous experience with CBA nor years since qualification were associated with attendance rates (*Table 15*).

There were few differences between the groups of participants who were adherent and those who were not. On average, participants who adhered were 4.5 years older than those who did not (95% CI 1.8 to 7.5), and had slightly lower pain scores at baseline [MVK (pain) mean difference 4.5, 95% CI 0.94 to 8.19]. There were no differences in RMQ, MVK (disability), sex, troublesomeness of pain or fear avoidance beliefs at baseline.

There were 174 (37%) participants who did not comply (i.e. had not received three or more group-based sessions of the therapy) with the AM+CBA therapy.

Therapists were asked to document the reasons for non-attendance if possible. A reason was documented in 80 cases (*Table 17*).

In addition four participants were excluded from the groups by the therapists (*Table 18*).

Time from randomisation to starting treatment
Table 19 provides summary statistics for the time scale of treatment delivery. The target time for attendance at the therapist assessment was set at 45 days after randomisation. Of those participants who attended the assessment, 271 out of 418 (65%)

TABLE 10 *Flow of all randomised participants*

		AM (%)	AM+CBA (%)	Total (%)	*p*-value[a]
Number of participants (with postal questionnaires)	Baseline	233	468	701	0.67
	Month 3	179 (77)	335 (72)	514 (73)	
	Month 6	177 (76)	352 (75)	529 (76)	
	Month 12	161 (69)	339 (72)	500 (71)	
Number of participants (with core data)	Baseline	0	0	0	0.13
	Month 3	11 (5)	20 (4)	31 (4)	
	Month 6	12 (5)	41 (9)	53 (8)	
	Month 12	38 (16)	60 (13)	98 (14)	
Total number of participants (with any data)	Baseline	233 (100)	468 (100)	701 (100)	
	Month 3	190 (82)	355 (76)	545 (78)	
	Month 6	189 (81)	393 (84)	582 (83)	
	Month 12	199 (85)	399 (85)	598 (85)	
Cumulative withdrawals	Month 3	6 (3)	17 (4)	23 (3)	0.66
	Month 6	9 (4)	21 (5)	30 (4)	
	Month 12	14 (6)	24 (5)	38 (5)	
Lost to follow-up (discrete)	Month 3	34 (15)	83 (18)	117 (17)	0.24
	Month 6	30 (13)	44 (9)	74 (11)	
	Month 12	19 (8)	42 (9)	61 (9)	
Returned blank	Month 3	1 (0.4)	6 (1)	7 (1)	
	Month 6	3 (1)	5 (1)	8 (1)	
	Month 12	1 (0.4)	3 (0.6)	4 (0.6)	
Other reasons for no data	Month 3	2 (1)	7 (2)	9 (1)	
	Month 6	2 (1)	5 (1)	7 (1)	
	Month 12	0	0	0	

a   *p*-values are from the chi-squared test assessing an association of time and treatment for each of the grouped participants.

received their assessment within the target time and 313 (75%) had completed the group treatment by the 3-month follow-up time point (*Table 19*).

Meeting the target time proved more difficult to achieve for some of the groups. This was mainly because of delays at one site: 16% of participants at this site were assessed before 45 days compared with an average of 80% across the other sites (*Figure 7*). There did not appear to be pressures on venue or staff time at this site but there were consistent delays in assessing participants and starting groups. A minority of other groups were delayed by last minute changes in therapist availability.

Thirteen participants attended a group at a later date than the first one they were randomised to due to changes in their personal circumstances after randomisation. No participants switched to a different group once sessions had commenced. There was no change-over in therapist during any of the 6-week group sessions. The attendance rate for those who started the group in less than 45 days was the same as for those who waited longer than 45 days (71% and 70% respectively).

Number and size of groups
Group size was difficult to standardise because of variations in recruitment rate. In total, 62 groups were run with a mean size of eight (SD 1.62, range 4–12). A breakdown of the group sizes and attendance rates is given in *Table 20*. Group size was not associated with attendance rate (*p* = 0.17).

Group intervention venue and time
During the trial, a variety of premises were used and a range of times were offered to cater for the needs of the participants. The venue setting did not impact on attendance compliance, with 63%

TABLE 11 Tracking of participants longitudinally who returned clinical research forms/core outcomes

3 months	6 months	12 months	Total (%)
Present	Present	Present	492 (70.2)
Present	Present	Absent	18 (2.6)
Present	Absent	Absent	21 (3.0)
Present	Absent	Present	14 (2.0)
Absent	Present	Present	58 (8.3)
Absent	Absent	Present	34 (4.9)
Absent	Present	Absent	14 (2.0)
Absent	Absent	Absent	50 (7.1)

TABLE 12 Reasons for withdrawals in each arm

	AM (%)	AM+CBA (%)	Total (%)
Did not wish to continue/complete questionnaires	6 (3)	9 (2)	15 (2)
Felt they did not receive treatment	2 (1)	1 (0.2)	3 (0.4)
Illness	1 (0.4)	2 (0.4)	3 (0.4)
Could not/did not attend groups	0	3 (0.6)	3 (0.6)
Back pain resolved	0	1 (0.2)	1 (0.1)
Unknown	4 (2)	4 (1)	8 (1)
Withdrew after randomisation	0	1 (0.2)	1 (0.1)
Claims was hurt by physiotherapist/not benefiting	1 (0.4)	1 (0.2)	2 (0.3)
Referred to pain management	0	1 (0.2)	1 (0.1)
Was felt participant did not understand the trial	0	1 (0.2)	1 (0.1)
Deaths	0	1 (0.2)	1 (0.2)
Withdrawals (total)	14 (6)	25 (5)	39 (6)

TABLE 13 Demographic characteristics for all randomised participants by treatment

Details		AM	AM+CBA
	N	233	466
Age (years)	Mean (SD)	54 (15)	53 (15)
	Range	19–85	18–85
	Missing	–	2
Gender	Male	90 (39%)	189 (40%)
	Female	142 (61%)	278 (59%)
	Missing	1 (0%)	1 (0%)
Ethnic origin	White	206 (88%)	412 (88%)
	Mixed	3 (1%)	4 (1%)
	Asian	8 (3%)	21 (5%)
	Black	4 (2%)	7 (2%)
	Chinese	1 (0%)	1 (0%)
	Other	11 (5%)	23 (5%)
Frequency of back pain	Every day	162 (70%)	315 (67%)
	Every day to ¾ days	31 (13%)	71 (15%)
	¾ to ½ a day	16 (7%)	40 (9%)
	Missing	24 (10%)	42 (9%)

TABLE 13 *Demographic characteristics for all randomised participants by treatment (continued)*

Details		AM	AM+CBA
Back pain troublesomeness	Moderately	130 (56%)	252 (54%)
	Very/extremely	103 (44%)	216 (46%)
	Missing	0	0
Left full-time education (years)	16 or less	121 (52%)	266 (57%)
	17–19	61 (26%)	104 (22%)
	20 or over	40 (17%)	73 (16%)
	Still in full-time education	2 (1%)	1 (0%)
	Missing	9 (4%)	24 (5%)
Duration of back pain (pain first ever started, years ago)	N	226	446
	Mean	13 (13)	13 (13)
	Median	9	10
	Range	0.25–53.0	0.12–84.0
	Missing	7	22
Back pain	Comes and goes over time	53 (23%)	108 (23%)
	Fairly constant	122 (52%)	250 (53%)
	Getting worse	55 (24%)	104 (22%)
	Getting better	1 (0%)	4 (1%)
	Missing	2 (1%)	2 (0%)
Received treatment for back pain in last 6 months	Yes	80 (34%)	197 (42%)
	No	151 (65%)	269 (58%)
	Missing	2 (1%)	2 (0%)
Received benefit payments (of any type)	Yes	97 (42%)	180 (39%)
	No	135 (58%)	281 (60%)
	Missing	1 (0%)	7 (2%)
Currently working	Yes, full time	71 (31%)	156 (33%)
	Yes, part time	39 (17%)	82 (18%)
	No	122 (52%)	228 (49%)
	Missing	1 (0%)	2 (0%)

attendance for both PCT premises and private community premises. The day and time of the group did impact on compliance. Groups run on a Friday had an attendance of 70% compared with around 61% on other days. Groups running around lunchtime and after work saw the best compliance, with 68% and 65% respectively. Evening groups were surprisingly poorly attended (51%) despite being requested by participants.

Thirty-five group sessions (56% of all groups run) were assessed for quality assurance either with an assessor in the session or via audio recordings. The results are shown in *Table 21*.

As many of the therapists were new to the CB skills of questioning, agenda setting, eliciting beliefs and feedback we expected these items to be more difficult to achieve, and this was reflected in the quality assurance scores. The remaining skills were evidenced in most groups.

Description of treatment effectiveness
Data summaries by treatment group are given in *Table 22* for the primary outcomes and in *Tables 23* and *24* for the secondary outcomes.

Therapist and group effects

The ICCs were very small and there was no evidence of significant clustering effects related either to group sessions or to therapist (*Table 25*), the implication being that group session and therapist effects were negligible. Estimates of the

TABLE 14 *Characteristics of therapists who delivered the BeST intervention (based on data for 2006)*

Therapist number	Profession	Years qualified	Grade	Gender	Experience of running similar groups	Number of groups run in trial	Total participants seen in trial (% of total number in CBA arm)
1	Physiotherapist	9	Senior I	Female	Yes	12	91 (19)
2	Physiotherapist	10	ESP	Male	Yes	5	30 (6)
3	Physiotherapist	10	Senior I	Male	No	1	7 (2)
4	Physiotherapist	8	Clinical specialist	Female	Yes	1	5 (1)
5	Physiotherapist	14	Senior I	Male	No	4	32 (7)
6	Physiotherapist	9	Senior I	Female	No	5	43 (9)
7	Physiotherapist	31	Senior I	Female	Yes	6	52 (11)
8	Occupational therapist	4	Senior II	Female	No	3	22 (5)
9	Physiotherapist	23	ESP	Female	No	1	8 (2)
10	Clinical psychologist	2	Band 7	Female	No	2	16 (3)
11	Physiotherapist	12	Clinical specialist	Female	Yes	3	18 (4)
12	Physiotherapist	21	Clinical specialist	Female	Yes	3	24 (5)
13	Health psychologist	3	Band 6	Female	No	4	29 (6)
14	Occupational therapist	32	Senior I	Female	No	1	8 (2)
15	Physiotherapist	2	Senior II	Male	No	1	5 (1)
16	Physiotherapist	7	Senior I	Female	No	2	13 (3)
17	Nurse	24	Band 7	Female	No	2	15 (3)
18	Physiotherapist	25	Senior I	Female	No	3	26 (6)
19	Physiotherapist	12	Senior II	Female	No	3	24 (5)

Grade provides the level at which the therapist is working within the NHS, with increasing levels of responsibility and expertise the titles of the grades are Junior, Senior II/Band 6, Senior I, Clinical specialist/extended scope practitioner (ESP)/Band 7.

TABLE 15 *Number (and percentage) of participants attending the assessment and group sessions*

	No. (%) of participants
Did not attend for assessment	50 (11)
Attended assessment	418 (89)
Attended assessment plus ≥1 session	358 (77)
Attended assessment plus ≥2 sessions	325 (69)
Attended assessment plus ≥3 sessions	294 (63)
Attended assessment plus ≥4 sessions	275 (59)
Attended assessment plus ≥5 sessions	225 (48)
Attended assessment plus ≥6 sessions	121 (26)
The number of sessions attended does not imply consecutive sessions.	

TABLE 16 *Number (and percentage) of patients seen by each therapist profession with attendance rates*

Profession	Attended <3 group sessions (%)	Attended ≥3 group sessions (%)	Total (%)
Physiotherapists	136 (36)	242 (64)	378 (100)
Occupational therapists	11 (37)	19 (63)	30 (100)
Nurses	7 (47)	8 (53)	15 (100)
Psychologists	20 (44)	25 (56)	45 (100)

TABLE 17 *Reasons provided by participants for not attending*

	No. of participants (%)
Unknown	95 (54)
Unwell	18 (10)
Changes to work	16 (9)
Family issues	15 (9)
Decided format of group 'not for them'	10 (6)
Difficulty attending – other	10 (6)
Decided no benefit to intervention	4 (2)
Moved	3 (2)

TABLE 18 *Reasons provided by the therapists for excluding the four participants from the group*

Therapist	Reason
8	Patient has other musculoskeletal disorders and also very resistant to change. Participant and therapist agreed that the group was not for him
6	Wife aggressive to therapist and wanted to attend sessions. Participant had learning difficulties
7	Excluded after randomisation by GP
5	Excluded as participant was receiving private physiotherapy

TABLE 19 *Time from randomisation to assessment, the first group session and attendance at last CB group*

	No. of days from randomisation to assessment	**No. of days from assessment to session one**	**No. of days from randomisation to session one**	**No. of days from randomisation to last CB session attended**
Mean	25.7	17.7	43.1	82.1
Median	21.0	14.0	38.0	77.0
SD	22.3	13.7	26.0	26.4
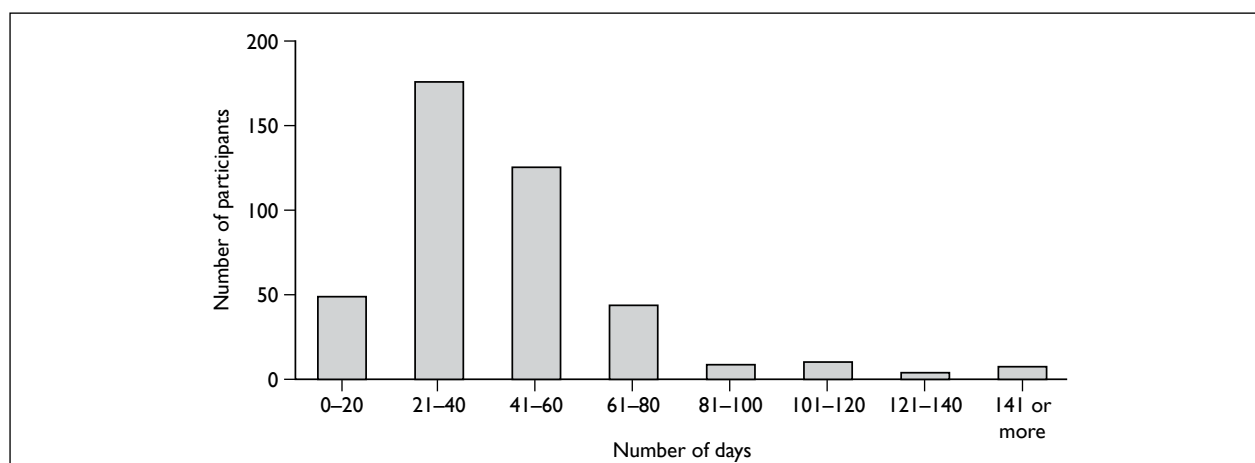
FIGURE 7 *Number of days from randomisation to receiving assessment.*

TABLE 20 *Group size with number of patients and attendance rates at group sessions*

Group size	**No. of groups run at this size**	**Total participants**	**Attended ≥3 group sessions (%)**
4	2	8	6 (75)
5	3	15	10 (67)
6	11	66	44 (67)
7	14	98	60 (61)
8	14	112	70 (64)
9	10	90	52 (58)
10	6	60	40 (68)
11	1	11	5 (46)
12	1	12	7 (64)

TABLE 21 *Quality assurance tool with percentage achieved during visits or via recordings*

Item		Not achieved (% of total)	Partially achieved (% of total)	Satisfactorily achieved (% of total)
Content	Set agenda	5 (14)	8 (23)	22 (63)
	Homework reviewed	0 (0)	1 (3)	34 (97)
	Topics covered	0 (0)	3 (9)	32 (91)
	Break	0 (0)	0 (0)	35 (100)
	Homework set	0 (0)	5 (14)	30 (86)
	Feedback elicited	6 (17)	7 (20)	22 (63)
	Exercises checked in break	0 (0)	1 (3)	34 (97)
Style	Encouraged group participation	0 (0)	4 (11)	31 (89)
	Listened appropriately	0 (0)	0 (0)	35 (100)
	Empathy demonstrated	2 (6)	1 (3)	32 (91)
	Elicited beliefs/thoughts	2 (6)	11 (31)	22 (63)
	Questioning style demonstrated	2 (6)	8 (23)	25 (71)
	Referred to CB model	4 (11)	4 (11)	27 (77)
	Appropriate pacing of session	1 (3)	7 (20)	27 (77)
	Appeared professional	0 (0)	0 (0)	35 (100)
Environment	Comfortable	0 (0)	1 (3)	34 (97)
	Spacious	0 (0)	0 (0)	35 (100)

TABLE 22 *Summary statistics for the primary clinical outcome measures at each follow-up time point by treatment (unadjusted)*

		RMQ		MVK (disability)		MVK (pain)	
		AM	AM+CBA	AM	AM+CBA	AM	AM+CBA
Baseline	*N*	232	468	228	455	230	463
	Mean	8.5	8.8	46.2	48.5	59.4	59.3
	SD	4.72	4.99	23.79	23.85	19.51	19.24
	Median	7.5	8.0	46.7	50.0	60.0	56.7
	Range	0–22	0–23	0–100	0–100	10–100	6.67–100
Month 3	*N*	179	335	187	345	189	354
	Mean	7.3	6.5	38.8	35.3	52.9	46.76
	SD	5.28	5.27	24.68	24.33	22.74	23.13
	Median	6.0	5.0	36.7	30.0	53.3	46.7
	Range	0–24	0–24	0–100	0–96.67	0–100	0–100
Month 6	*N*	177	352	183	381	187	387
	Mean	7.4	6.1	41.8	33.9	53.0	44.5
	SD	5.34	5.44	24.72	25.94	23.29	25.16
	Median	6.0	4.0	43.3	30.0	53.3	43.3
	Range	0–23	0–24	0–100	0–100	0–100	0–100
Month 12	*N*	159	339	189	374	195	392
	Mean	6.9	6.1	40.0	33.3	51.0	44.5
	SD	5.12	5.62	25.22	26.22	23.93	26.04
	Median	6.0	4.0	40.0	26.7	50.0	46.7
	Range	0–22	0–24	0–100	0–100	3.33–100	0–100

MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire.

TABLE 23 *Summary statistics for the health-related quality of life outcome measures at each follow-up time point and treatment*

		SF-12 (physical)		SF-12 (mental)	
		AM	AM+CBA	AM	AM+CBA
Baseline	*N*	217	421	217	421
	Mean	46.1	44.5	37.5	37.1
	SD	11.03	11.51	10.08	9.31
	Median	46.4	43.9	37.4	37.3
	Range	17–73	11–69	12–61	7–62
Month 3	*N*	176	332	176	332
	Mean	46.4	47.0	39.1	40.7
	SD	11.25	11.44	10.38	11.05
	Median	47.6	48.9	39.8	42.4
	Range	12–68	11–71	11–62	7–61
Month 6	*N*	177	362	177	362
	Mean	46.1	47.6	39.2	41.0
	SD	10.61	11.45	10.33	11.26
	Median	47.0	49.6	39.7	41.7
	Range	17–66	11–71	10–69	7–68
Month 12	*N*	187	375	187	375
	Mean	47.0	46.4	38.6	41.9
	SD	11.35	11.51	11.31	11.77
	Median	47.9	48.3	39.3	43.5
	Range	12–68	13–71	13–63	7–70

SF-12, Short Form 12-item health survey.

treatment effects were not altered by the inclusion of therapist or group effects and hence results are based on the linear models adjusted for age, sex and the baseline value of the variable being tested. Within the adjusted models, only age and baseline measures were statistically significant. This was consistent across all the outcomes and time points.

Adjusted effects are given in *Table 26*. Both tables provide the estimate of difference in change between the intervention groups with a 95% CI.

Primary outcomes
Back pain related disability – Roland Morris Disability Questionnaire
Figure 8 shows the change from baseline in the RMQ for each of the follow-up time points by treatment arm. Improvements in LBP-related disability occurred in the CBA and AM arms of the trial, but were of different magnitude and time course. Improvements in the AM arm were on average 1.1 RMQ points, with change occurring between baseline and 3 months and no further

change thereafter. The change in the CBA arm was almost double that of the AM arm by 3 months, and the treatment difference continued to widen at 6 and 12 months.

The difference between the treatment arms was estimated to be, on average, 1.1 RMQ points at 3 months, rising to 1.4 and 1.3 RMQ points at 6 and 12 months respectively. These differences between treatments were all statistically significant.

Back disability – Modified Von Korff Scale (disability)
Figure 9 shows the change in MVK (disability) by treatment arm. Both treatment arms showed improvements over baseline, but these were of different magnitude and time course. The AM group improved between 0 and 3 months, and declined thereafter. The CBA group showed a greater improvement. At 6 and 12 months the difference between CBA and AM was more than twofold.

TABLE 24 *Summary statistics for the secondary clinical outcome measures at each follow-up time point and treatment*

		FABQ		Pain self-efficacy	
		AM	AM+CBA	AM	AM+CBA
Baseline	N	219	443	223	453
	Mean	14.2	13.6	41.2	39.6
	SD	6.22	6.34	12.54	13.39
	Median	15.0	14.0	43.0	41.0
	Range	0–24	0–24	5–60	2–60
Month 3	N	173	319	173	325
	Mean	13.3	10.3	40.6	43.0
	SD	6.07	6.37	13.51	13.31
	Median	14.0	11.0	43.0	46.0
	Range	0–24	0–24	3–60	2–60
Month 6	N	168	336	170	333
	Mean	13.8	10.4	40.4	43.3
	SD	6.09	6.54	13.38	13.54
	Median	14.0	10.5	42.0	46.0
	Range	0–24	0–24	2–60	3–60
Month 12	N	152	320	155	317
	Mean	13.1	9.9	41.3	43.2
	SD	6.18	6.26	13.28	14.08
	Median	14.0	10.0	43.0	47.0
	Range	0–24	0–24	2–60	4–60

FABQ, Fear Avoidance Beliefs Questionnaire.

TABLE 25 *Intracluster correlation coefficient for RMQ score and MVK questionnaire (using change from baseline)*

		RMQ		MVK (disability)		MVK (pain)	
Cluster	Month	ICC	95% CI	ICC	95% CI	ICC	95% CI
Group session	3	−0.01	−0.02 to 0.001	−0.02	−0.04 to −0.02	0.01	−0.02 to 0.03
	6	0.09	−0.02 to 0.19	−0.04	−0.06 to −0.01	−0.02	−0.03 to −0.02
	12	−0.002	−0.02 to 0.02	−0.02	−0.02 to −0.02	0.02	−0.02 to 0.06
Therapist	3	0.01	−0.04 to 0.05	−0.02	−0.04 to 0.01	0.01	−0.03 to 0.05
	6	0.03	−0.02 to 0.09	−0.004	−0.04 to 0.03	−0.001	−0.03 to 0.03
	12	−0.0001	−0.04 to 0.04	−0.002	−0.04 to 0.03	−0.003	−0.03 to 0.03

ICC, intracluster correlation coefficient; MVK, Modified Von Korff scale; RMQ, Roland Morris Disability Questionnaire.

The difference between CBA and AM was estimated to be on average 4.3% at 3 months, 8.1% at 6 months and 8.4% at 12 months. The differences between treatments were statistically significant at all time points.

Back disability – Modified Von Korff Scale (pain)

Figure 10 shows the change in the MVK (pain) by treatment arm. Both treatment arms showed improvements over baseline, but these were of different magnitude and time course. Pain levels

TABLE 26 *Clinical outcome measures (using change from baseline) – adjusted (for age, sex and baseline) linear regression models analysis*

| | Period | N (%) | Mean difference between treatments | | |
			Mean	95% CI	*p*-value
RMQ	3	513 (73.2)	−1.1	−1.74 to −0.37	0.003
	6	528 (75.3)	−1.4	−2.14 to −0.72	<0.0001
	12	498 (71.0)	−1.3	−2.05 to −0.55	0.0008
	Longitudinal	1539 (73.2)	−1.2	−1.93 to 0.39	0.0001
MVK (disability)	3	519 (74.0)	−4.3	−8.20 to −0.42	0.03
	6	551 (78.6)	−8.1	−12.03 to −4.09	<0.0001
	12	552 (78.7)	−8.4	−12.39 to −4.35	<0.0001
	Longitudinal	1622 (77.1)	−6.5	−10.54 to −2.48	<0.0001
MVK (pain)	3	538 (76.7)	−6.8	−10.18 to −3.46	<0.0001
	6	569 (81.2)	−8.0	−11.73 to −4.30	<0.0001
	12	583 (83.2)	−7.0	−10.66 to −3.24	0.0003
	Longitudinal	1690 (80.4)	−6.7	−10.44 to −2.98	<0.0001
SF-12 (physical)	3	470 (67.0)	2.2	0.72 to 3.68	0.004
	6	497 (70.9)	1.8	0.34 to 3.25	0.016
	12	521 (74.3)	4.1	2.56 to 5.57	<0.0001
	Longitudinal	1488 (70.8)	4.1	2.08 to 6.04	<0.0001
SF-12 (mental)	3	470 (67.0)	1.3	−0.37 to 2.96	0.129
	6	497 (70.9)	2.5	0.78 to 4.26	0.005
	12	521 (74.3)	0.1	−1.62 to 1.80	0.91
	Longitudinal	1488 (70.8)	0.1	−2.16 to 2.34	0.91
FABQ (physical activity)	3	471 (67.2)	−2.6	−3.64 to −1.63	<0.0001
	6	480 (68.5)	−3.1	−4.15 to −2.05	<0.0001
	12	447 (63.7)	−3.0	−4.08 to −1.88	<0.0001
	Longitudinal	1398 (66.5)	−2.8	−3.98 to −1.73	<0.0001
Pain self-efficacy	3	483 (68.9)	3.2	1.34 to 4.93	0.0007
	6	490 (69.9)	4.1	2.30 to 5.98	<0.0001
	12	456 (65.0)	3.8	1.93 to 5.67	<0.0001
	Longitudinal	1429 (68.0)	3.9	1.94 to 5.85	<0.0001

FABQ, Fear Avoidance Beliefs Questionnaire; MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12-item health survey.

in the AM group improved gradually over the 12-month period. Improvements in pain were more than double in the CBA arm at 3 months, and pain continued to improve (although at a slower rate) between 3, 6 and 12 months. The effect on pain peaked at 12 months. These differences between treatments were statistically significant at all time points.

The difference between CBA and AM was estimated to be on average 6.8% at 3 months, 8% at 6 months and 7% at 12 months.

On average, a participant improved twice as much on the AM+CBA arm as on AM alone.

Secondary and intermediary outcomes
Short Form-12 physical subscale
Figure 11 shows the change in the SF-12 physical subscale by treatment arm. Both treatment arms showed improvements over baseline in the first 6 months of follow-up, but these were of different magnitude and time course. Improvements in the AM arm were very small, and by 12 months there was no difference in comparison with baseline.

FIGURE 8 *Roland Morris Questionnaire (RMQ) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*

FIGURE 9 *Modified Von Korff (MVK) (disability) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*
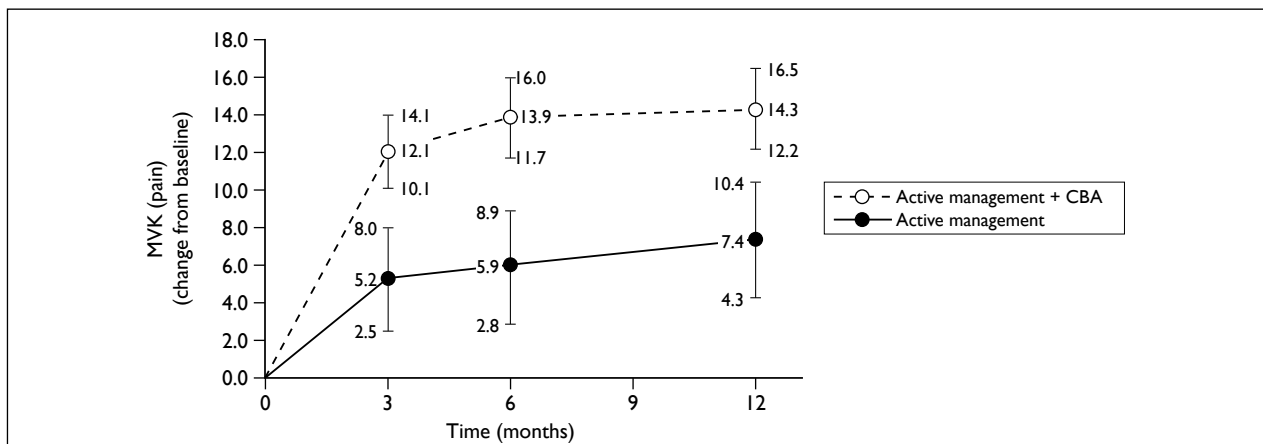
FIGURE 10 *Modified Von Korff (MVK) (pain) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*

Improvements in the CBA arm were larger, with the greatest improvement at 12 months.

The difference between CBA and AM was estimated to be on average 2.2 at 3 months, 1.8 at 6 months and 4.1 at 12 months. The differences between treatments were statistically significant at all time points.

Short Form-12 mental subscale
Figure 12 shows the change in SF-12 mental subscale by treatment arm. In the AM arm, there was no change in mental-health score across the 12 months. In the CBA arm, there were statistically significant improvements in mental health at 6 months, with the maximum improvement at 6 months. By 12 months, mental-health scores fell, and there was no statistically significant difference between the CBA and AM arms.

The difference between CBA and AM was estimated to be on average 1.3 at 3 months, 2.5 at 6 months, and 0.1 at 12 months.

Fear Avoidance Beliefs Questionnaire
Figure 13 shows changes in fear avoidance beliefs by treatment arm. In the AM arm, there was no evidence of change in fear avoidance beliefs across the 12 months. In the CBA arm, there were substantial improvements in fear avoidance at 3, 6 and 12 months. Improvement occurred between 0 and 3 months and was sustained to 12 months.

The difference between CBA and AM was estimated to be on average 2.6 at 3 months, 3.1 at 6 months and 3.0 at 12 months. The differences between treatments were statistically significant at all time points.
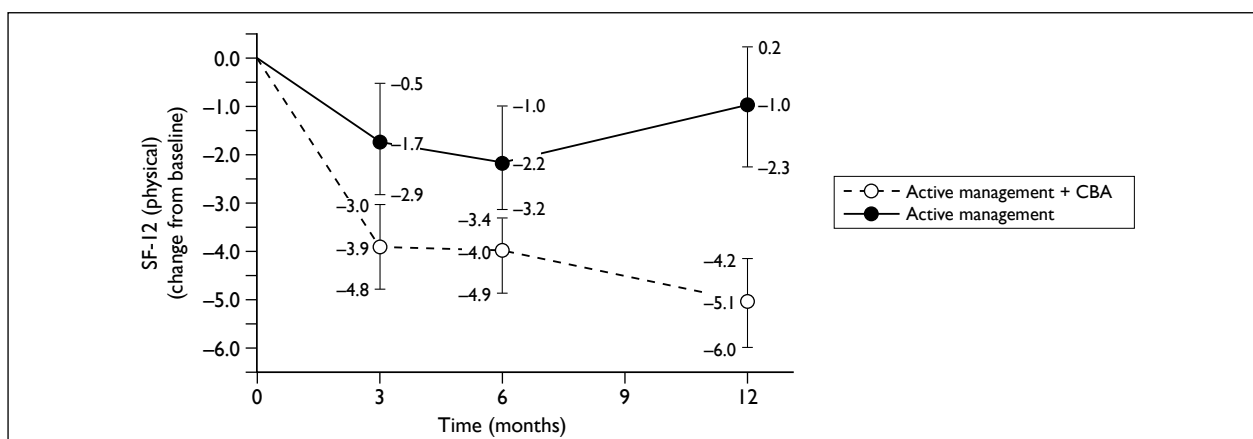
FIGURE 11 *Short Form 12-item health survey (physical) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*
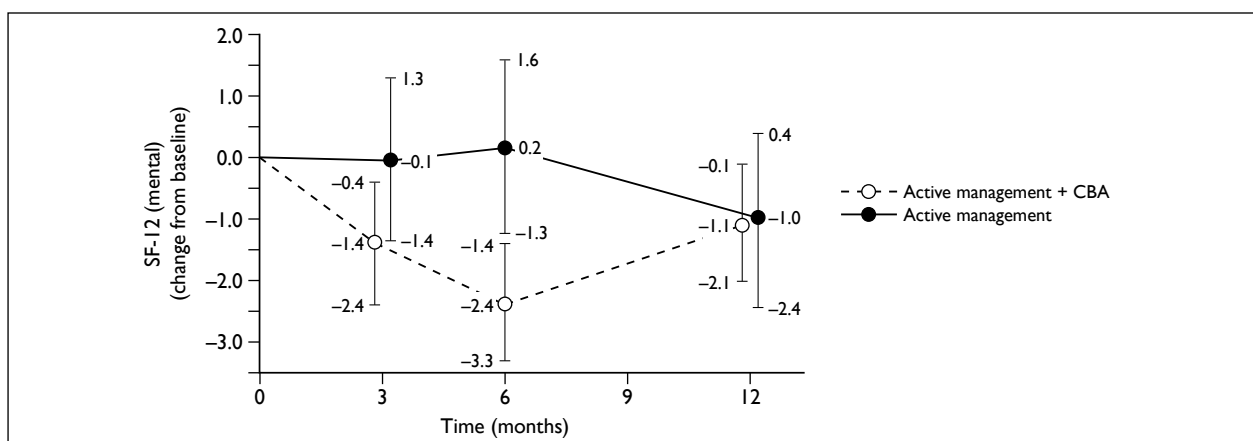
FIGURE 12 *Short Form 12-item health survey (mental) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*

Pain self-efficacy

Figure 14 shows pain self-efficacy by treatment arm. There was no discernible change in pain self-efficacy in the AM arm. Self-efficacy improved in the CBA arm, with maximal improvements at 6 months, and sustained improvement at 12 months.

The difference between CBA and AM was estimated to be on average 3.2 at 3 months, 4.1 at 6 months and 3.8 at 12 months. The differences between treatment arms were statistically significant at all time points.

Changes in employment and hours worked

The number and proportion of participants who were receiving any entitlements/benefits were very small for both therapy groups. There was a small difference in the numbers of people changing their

hours of work between the groups (in favour of the CBA) but these differences were not statistically significant. A slightly higher proportion of people randomised to CBA reported having sick days at 3 and 6 months, but this difference was small and not statistically significant. Overall there were no differences in the numbers of days off sick. Data on sickness, benefit claim and employment are given in Appendix 13.

Global indicators of change, benefit and satisfaction with treatment

Self-rated global assessments of change in back pain and satisfaction with treatment favoured CBA over AM (data shown in *Table 27*). Differences were statistically significant for all comparisons regardless of the time point of follow-up.

By 12 months, 60% of participants in the CBA arm rated that they had improvements, whereas
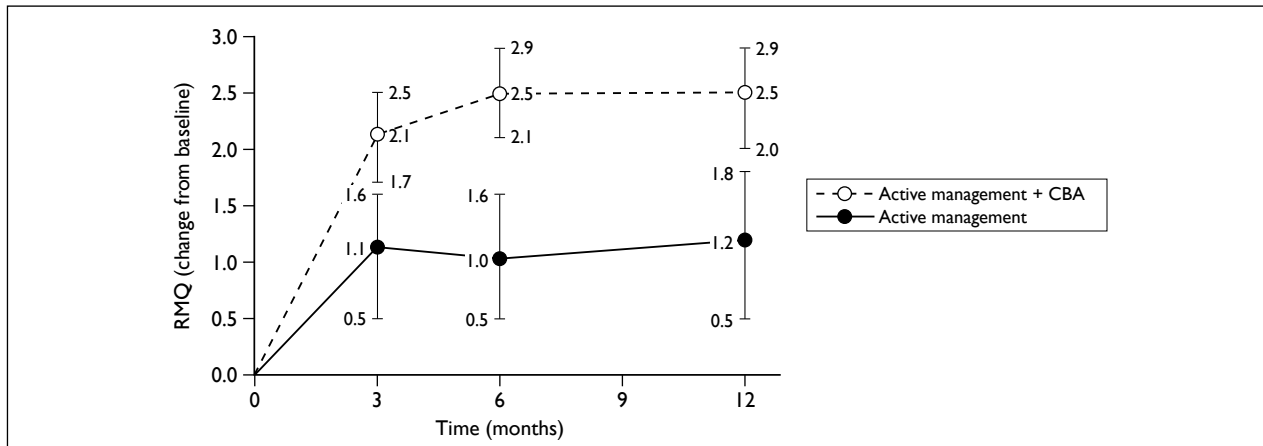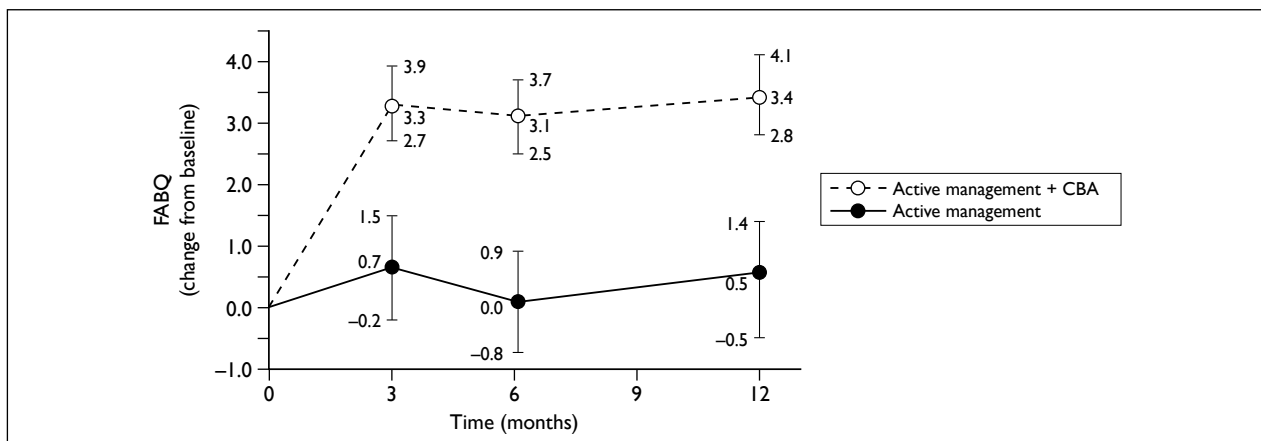

FIGURE 13 *Fear Avoidance Beliefs Questionnaire (FABQ) (physical activity) scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*
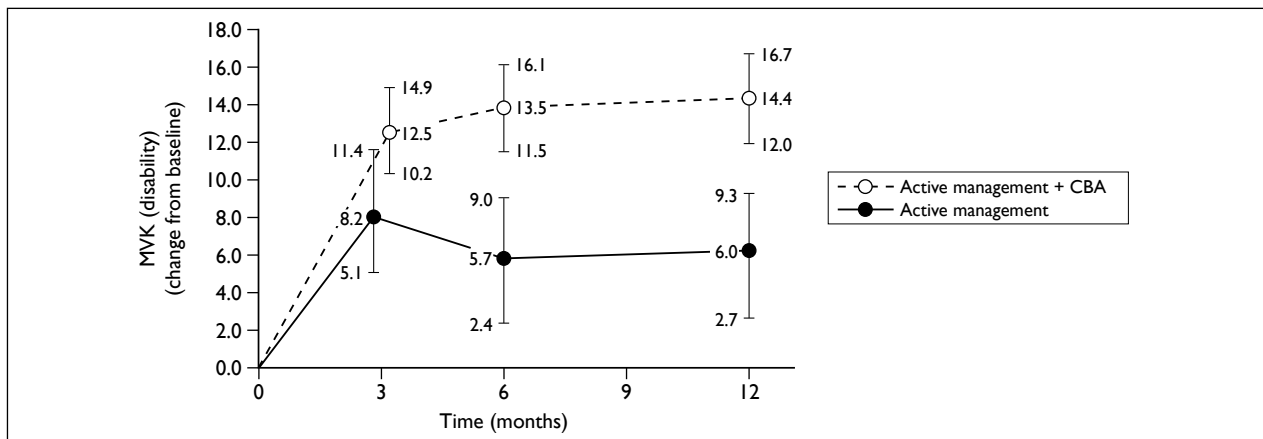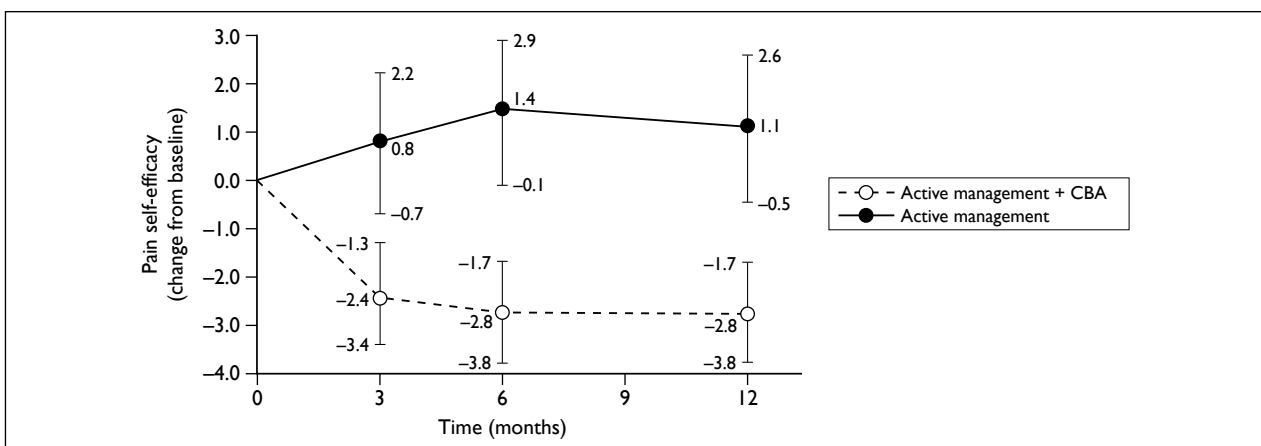

FIGURE 14 *Pain Self-efficacy scores (change from baseline). Least square estimates of the mean (95% CI) from the linear regression models (observed data).*

*TABLE 27 Change in back pain and treatment satisfaction (n, %)*

Month		AM	AM+CBA	p-value
Change in back pain				
3	Completely recovered	1 (0.5)	3 (1)	<0.0001
	Much improved	8 (4)	95 (27)	
	Slightly improved	45 (24)	98 (28)	
	No change	93 (50)	124 (35)	
	Slightly worsened	29 (16)	20 (6)	
	Much worsened	8 (4)	12 (3)	
	Vastly worsened	3 (2)	2 (1)	
6	Completely recovered	2 (1)	31 (12)	<0.0001
	Much improved	19 (10)	105 (41)	
	Slightly improved	35 (19)	82 (32)	
	No change	81 (44)	133 (11)	
	Slightly worsened	27 (15)	14 (1)	
	Much worsened	18 (10)	20 (2)	
	Vastly worsened	4 (2)	1 (1)	
12	Completely recovered	6 (3)	44 (11)	<0.0001
	Much improved	24 (12)	106 (27)	
	Slightly improved	32 (16)	85 (22)	
	No change	89 (45)	122 (31)	
	Slightly worsened	24 (12)	20 (5)	
	Much worsened	17 (9)	9 (2)	
	Vastly worsened	5 (3)	9 (2)	
Satisfaction				
3	Very dissatisfied	19 (11)	20 (6)	<0.0001
	Somewhat dissatisfied	23 (13)	11 (3)	
	Neither satisfied nor dissatisfied	75 (44)	46 (14)	
	Somewhat satisfied	38 (22)	117 (35)	
	Very satisfied	17 (10)	137 (41)	
6	Very dissatisfied	20 (12)	28 (8)	<0.0001
	Somewhat dissatisfied	20 (12)	23 (9)	
	Neither satisfied nor dissatisfied	84 (52)	71 (20)	
	Somewhat satisfied	24 (15)	111 (31)	
	Very satisfied	15 (9)	110 (31)	
12	Very dissatisfied	14 (9)	19 (6)	<0.0001
	Somewhat dissatisfied	22 (15)	21 (6)	
	Neither satisfied nor dissatisfied	72 (48)	76 (23)	
	Somewhat satisfied	30 (20)	104 (32)	
	Very satisfied	13 (9)	108 (33)	

p-value used chi-squared test from trend.

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31% in the AM arm reported improvement. Less than 25% of people randomised to AM reported a decline at 12 months, in comparison with 9% in the CBA arm. Similar trends were noted in the benefit question. Levels of satisfaction were greater in the CBA arm in comparison with AM.

Numbers needed to treat
Using a threshold of change of 30% to determine an MCID approximately seven participants would be needed on the AM+CBA arm to see one participant improve. The same estimate was gained using the MVK scales.

The numbers needed to treat using the global indicator of change scale was 7 (improvement versus stability or decline) or 3 (improvement and stability versus decline).

Estimates of the standardised difference (effect size)
The effect sizes for each of the outcomes are derived from the adjusted treatment estimates (*Table 28*).

Adverse events

Only one adverse event occurred during the study, and this involved a participant receiving AM. An adverse event notification (Appendix 10) was submitted to West Midlands MREC on 3 August 2006. This patient was admitted to hospital on 11 July 2006 with acute spinal cord compression, which was subsequently decompressed operatively. Following discharge, the participant developed a pulmonary embolus as a complication, which

TABLE 28 *Effect sizes of the clinical outcome measures at 12 months based on unadjusted differences estimated in regression modelling*

	Effect size
RMQ (absolute)	0.31
MVK (disability)	0.41
MVK (pain)	0.37
Pain self-efficacy	0.35
FABQ	0.47
SF-12 (physical)	0.45
SF-12 (mental)	0.07

FABQ, Fear Avoidance Beliefs Questionnaire; MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12-item health survey.

required readmission. Final discharge was on 27 July 2006. As part of the 'control intervention', the patient received *The Back Book* and a single session of advice. There is no indication that advice to stay active increases the risk of spinal cord compression, which affects a small proportion of back pain patients. *The Back Book* gives details of warning signs and advises immediate consultation with a doctor. The patient followed this advice and therefore the emergency was dealt with appropriately without delay.

Subgroup analysis

We undertook three prespecified subgroup analyses and one additional subgroup analysis based on the RMQ baseline score. For each of the three subgroups, no statistical interactions were found between the subgroups and the treatment assigned.

Fear avoidance beliefs at baseline

Results are given in *Table 29*. Fear avoidance at baseline was not associated with the size of treatment effect measured using the RMQ or the MVK (pain) either at 12 months or when considered over the entire follow-up period. However, there was a statistically significant interaction between baseline fear avoidance and outcomes measured using the MVK for disability. The treatment effect was substantially larger in the cohort who had baseline fear avoidance scores < 14 (i.e. were not fear avoidance at baseline). However, these observations were not consistent across all primary outcomes.

Pain severity (troublesomeness) at baseline

Results are given in *Table 30*. Estimates of the treatment effect were larger in people with moderately troublesome LBP as opposed to severe LBP. Active management had little or no effect in those with moderately troublesome back pain, which accounted for this. The interaction term was not statistically significant ($p = 0.07$). When the effect over the whole year was considered there was no indication of a difference between the two groups.

Duration of back pain

Results are given in *Table 31*. Estimates of the treatment effect were larger in people with

TABLE 29 *Subgroup analysis – linear regression and longitudinal models assessing the RMQ, MVK (disability) and MVK (pain) changes from baseline to 12 months and overall change from baseline respectively, for those with fear avoidance of < 14 and ≥ 14 at baseline*

			Mean	SE	N	Treatment estimate (95% CI)	p-value (interaction)
Roland Morris Disability Questionnaire							
12 months							
Fear avoidance × treatment	< 14	AM	1.1	0.49	72		0.56
	< 14	AM+CBA	2.5	0.33	156	1.3 (0.19 to 2.51)	
	≥ 14	AM	0.9	0.47	77		
	≥ 14	AM+CBA	2.7	0.32	165	1.8 (0.71 to 2.95)	
Longitudinal							
Fear avoidance × treatment	< 14	AM	0.8	0.39	223		0.74
	< 14	AM+CBA	2.3	0.27	463	1.5 (0.58 to 2.46)	
	≥ 14	AM	1.1	0.33	261		
	≥ 14	AM+CBA	2.4	0.25	511	1.3 (0.47 to 2.15)	
Modified Von Korff (disability)							
12 months							
Fear avoidance × treatment	< 14	AM	1.6	2.97	77	14.8 (7.76 to 21.88)	0.07
	< 14	AM+CBA	16.4	2.03	165		
	≥ 14	AM	8.2	2.62	99	6.0 (−0.36 to 12.38)	
	≥ 14	AM+CBA	14.2	1.93	182		
Longitudinal							
Fear avoidance × treatment	< 14	AM	3.1	2.34	228	11.7 (6.09 to 17.23)	0.03
	< 14	AM+CBA	14.7	1.61	480		
	≥ 14	AM	8.5	2.04	292	4.8 (−0.19 to 9.77)	
	≥ 14	AM+CBA	13.3	1.52	540		
Modified Von Korff (pain)							
12 months							
Fear avoidance × treatment	< 14	AM	9.4	2.52	80	6.6 (0.66 to 12.58)	0.92
	< 14	AM+CBA	16.0	1.69	179		
	≥ 14	AM	6.5	2.23	103	7.1 (1.62 to 12.48)	
	≥ 14	AM+CBA	13.5	1.64	189		
Longitudinal							
Fear avoidance × treatment	< 14	AM	7.3	1.96	235	6.9 (2.03 to 11.33)	0.91
	< 14	AM+CBA	14.0	1.34	504		
	≥ 14	AM	5.6	1.71	299	7.1 (2.90 to 11.22)	
	≥ 14	AM+CBA	12.7	1.26	562		
SE, standard error.							

moderately troublesome low back pain as opposed to severe low back pain. Active management having little or no effect in those with moderately troublesome back pain accounted for this. The interaction term was not found to be statistically significant ($p = 0.07$). When the effect over the whole year was considered there was no indication of a difference between the two groups.

TABLE 30 *Subgroup analysis – linear regression and longitudinal models assessing the RMQ, MVK (disability) and MVK (pain) change from baseline to 12 months and overall change from baseline respectively, for those with pain severity as moderate and very/extremely troublesome*

			Mean	SE	N	Treatment estimate (95% CI)	*p*-value (interaction)
Roland Morris Disability Questionnaire							
12 months							
Pain severity × Treatment	Moderate	AM	0.3	0.42	96	2.1 (1.07 to 3.07)	0.07
	Moderate	AM+CBA	2.4	0.30	185		
	Severe/very severe	AM	2.1	0.52	63	−0.6 (−1.82 to 0.58)	
	Severe/very severe	AM+CBA	2.7	0.33	154		
Longitudinal							
Pain severity × treatment	Moderate	AM	0.4	0.34	297	1.7 (0.90 to 2.51)	0.12
	Moderate	AM+CBA	2.1	0.24	557		
	Severe/very severe	AM	1.9	0.38	216	0.7 (−0.19 to 1.61)	
	Severe/very severe	AM+CBA	2.6	0.26	469		
Modified Von Korff (disability)							
12 months							
Pain severity × treatment	Moderate	AM	2.6	2.50	107	11.6 (5.53 to 17.73)	0.33
	Moderate	AM+CBA	14.3	1.85	197		
	Severe/very severe	AM	8.7	2.91	79	7.1 (0.11 to 13.97)	
	Severe/very severe	AM+CBA	15.8	1.99	169		
Longitudinal							
Pain severity × treatment	Moderate	AM	3.5	1.99	308	8.6 (3.78 to 13.42)	0.49
	Moderate	AM+CBA	12.1	1.46	574		
	Severe/very severe	AM	9.6	2.23	242	6.1 (0.76 to 11.42)	
	Severe/very severe	AM+CBA	15.7	1.56	498		
Modified Von Korff (pain)							
12 months							
Pain severity × treatment	Moderate	AM	3.9	2.14	110	9.0 (3.83 to 14.17)	0.27
	Moderate	AM+CBA	12.9	1.55	209		
	Severe/very severe	AM	11.2	2.45	84	4.6 (−1.16 to 10.44)	
	Severe/very severe	AM+CBA	15.9	1.67	180		
Longitudinal							
Pain severity × treatment	Moderate	AM	3.9	1.66	316	7.0 (3.02 to 11.02)	0.87
	Moderate	AM+CBA	10.9	1.20	602		
	Severe/very severe	AM	8.8	1.85	250	6.5 (2.10 to 10.92)	
	Severe/very severe	AM+CBA	15.3	1.29	522		
SE, standard error.							

TABLE 31 *Subgroup analysis – linear regression and longitudinal models assessing the RMQ, MVK (disability) and MVK (pain) change from baseline to 12 months and overall change from baseline respectively, for those with duration of back pain as recorded at baseline of ≤ 3 years and > 3 years*

			Mean	SE	N	Treatment estimate (95% CI)	p-value (interaction)
Roland Morris Disability Questionnaire							
12 months							
Duration (years) × treatment	≤ 3	AM	1.8	0.62	40	1.5 (−0.08 to 3.02)	0.96
	≤ 3	AM+CBA	3.2	0.45	83		
	> 3	AM	0.8	0.39	115	1.5 (0.59 to 2.43)	
	> 3	AM+CBA	2.3	0.27	240		
Longitudinal							
Duration (years) × treatment	≤ 3	AM	1.3	0.50	131	1.5 (0.33 to 2.73)	0.60
	≤ 3	AM+CBA	2.9	0.36	262		
	> 3	AM	0.9	0.30	369	1.2 (0.43 to 1.89)	
	> 3	AM+CBA	2.1	0.22	713		
Modified Von Korff (disability)							
12 months							
Duration (years) × treatment	≤ 3	AM	8.2	3.61	51	13.9 (5.17 to 22.57)	0.33
	≤ 3	AM+CBA	22.1	2.60	98		
	> 3	AM	4.1	2.25	131	8.7 (3.29 to 14.15)	
	> 3	AM+CBA	12.8	1.62	251		
Longitudinal							
Duration (years) × treatment	≤ 3	AM	9.1	2.82	153	10.1 (5.23 to 14.99)	0.49
	≤ 3	AM+CBA	19.2	2.06	285		
	> 3	AM	5.1	1.76	386	7.3 (3.04 to 11.54)	
	> 3	AM+CBA	12.4	1.29	735		
Modified Von Korff (pain)							
12 months							
Duration (years) × treatment	≤ 3	AM	7.9	3.17	51	10.9 (3.30 to 18.50)	0.26
	≤ 3	AM+CBA	18.8	2.22	104		
	> 3	AM	7.2	1.93	138	5.8 (1.12 to 10.44)	
	> 3	AM+CBA	13.0	1.39	267		
Longitudinal							
Duration (years) × treatment	≤ 3	AM	7.6	2.38	153	8.2 (2.50 to 13.94)	0.65
	≤ 3	AM+CBA	15.8	1.70	303		
	> 3	AM	5.8	1.47	399	6.7 (3.10 to 10.20)	
	> 3	AM+CBA	12.5	1.07	769		
SE, standard error.							

TABLE 32 *Subgroup analysis – linear regression and longitudinal models assessing the RMQ, MVK (disability) and MVK (pain) change from baseline to 12 months and overall change from baseline respectively, for those with RMQ < 4 and ≥ 4 at baseline*

			Mean	SE	N	Treatment estimate (95% CI)	*p*-value (interaction)
Roland Morris Disability Questionnaire							
12 months							
Baseline RMQ × treatment	< 4	AM	−0.2	0.75	29		0.20
	< 4	AM+CBA	0.2	0.53	57	0.4 (−1.37 to 2.23)	
	≥ 4	AM	1.3	0.35	130		
	≥ 4	AM+CBA	3.0	0.24	282	1.7 (0.88 to 2.56)	
Longitudinal							
Baseline RMQ × treatment	< 4	AM	−0.3	0.61	88		0.08
	< 4	AM+CBA	−0.2	0.43	138	0.1 (−1.37 to 1.57)	
	≥ 4	AM	1.3	0.27	425		
	≥ 4	AM+CBA	2.8	0.19	858	1.5 (0.86 to 2.16)	
Modified Von Korff (disability)							
12 months							
Baseline RMQ × treatment	< 4	AM	0.9	4.58	32	9.4 (−1.64 to 20.40)	0.94
	< 4	AM+CBA	10.3	3.26	63		
	≥ 4	AM	6.1	2.09	154	9.8 (4.80 to 14.84)	
	≥ 4	AM+CBA	15.9	1.49	303		
Longitudinal							
Baseline RMQ × treatment	< 4	AM	3.1	3.79	88	6.2 (2.81 to 15.15)	0.72
	< 4	AM+CBA	9.3	2.57	185		
	≥ 4	AM	6.8	1.62	462	7.9 (4.02 to 11.86)	
	≥ 4	AM+CBA	14.7	1.18	887		
Modified Von Korff (pain)							
12 months							
Baseline RMQ × treatment	< 4	AM	8.7	3.92	33	2.8 (−6.61 to 12.18)	0.31
	< 4	AM+CBA	11.5	2.73	68		
	≥ 4	AM	6.8	1.78	161	8.1 (3.85 to 12.39)	
	≥ 4	AM+CBA	14.9	1.26	321		
Longitudinal							
Baseline RMQ × treatment	< 4	AM	7.7	3.13	92	2.0 (−5.46 to 9.40)	0.16
	< 4	AM+CBA	9.7	2.15	191		
	≥ 4	AM	5.8	1.35	474	7.9 (4.60 to 11.10)	
	≥ 4	AM+CBA	13.6	0.97	933		
SE, standard error.							

Roland Morris score

Results are given in *Table 32*. The trend was toward large treatment effects in those participants with an RMQ greater than 4 at baseline. However, the interaction tests were not statistically significant. There was no evidence of a difference in models where the outcome was the MVK.

Sensitivity analysis

Per protocol analysis

There was no difference in the results when they were analysed using only those individuals who had attended at least the assessment and three sessions of CBA.

Multiple imputation of missing data

There was no difference in the results between the observed cases analysis and an analysis based on multiple imputations. The findings appear insensitive to the method of dealing with missing data.

Chapter 5
Qualitative study

BeST interview study

Introduction

The aims of the interview study were to explore user perspectives on the acceptability of both interventions tested and to gain insight into how the interventions might work. Previous studies have indicated the importance of understanding the patient's perspective within research on LBP.[127–130]

Method

We performed 34 semi-structured interviews, 4–5 months after randomisation, and after participants had received their intervention. Eighteen participants were from the AM arm and 16 were from the AM+CBA arm of the main BeST trial.

Sample

The interviewees were sampled purposively from two clusters local to the trial coordinating centre for pragmatic reasons of time and cost [Coventry and Solihull (one cluster) and South Warwickshire]. Sampling aimed for equal numbers of interviewees from the intervention and control arm of the study and a range of two key participant characteristics which relate to the nature of the intervention: disability as measured by the RMQ and fear avoidance as measured by the FABQ. Sampling categories for disability and fear avoidance were developed as follows. The RMQ has a 24-point scale and the median of the first 100 baseline scores was 9. Two categories were used for sampling: high (9–24) and low (0–8). As the CBA is aimed at reducing fear avoidance we also selected

the interviewees across three bands of the FABQ to ensure diversity; 0–9 for 'non-avoiders', 18–24 for 'avoiders' and a mid-range group of 10–17.

We aimed for equal numbers of interviewees in each of the cells of *Table 33*. However, the category representing high RMQ and low FABQ scores had few potential candidates.

Where there was a choice of potential interviewees we aimed to select individuals to reflect key demographic characteristics of the sample included in the clinical trial. We modelled this on the characteristics of the first 100 participants, and considered self-rated pain severity (as given by participants at the randomisation appointment) and gender representation in particular.

Interviewee recruitment

Participants were eligible to be contacted for interview if they had agreed to this on their initial consent form. A total of 40 of the 701 BeST trial participants were invited for interview by a phone call from a researcher (V.N.) who outlined that the face-to-face interview would last approximately 45 minutes and be held at a venue of their choice (*Figure 15*). Potential participants were informed that the interviews would be about their experience of back pain and their views of the interventions tested in the trial, and were briefed that the interviews would be recorded if they were in agreement. Four interviews were undertaken as a pilot and are not included in the final analysis. Two potential participants declined to be interviewed: one because of an operation; the other did not give a reason.

TABLE 33 *Number of interviewees in each sample category*

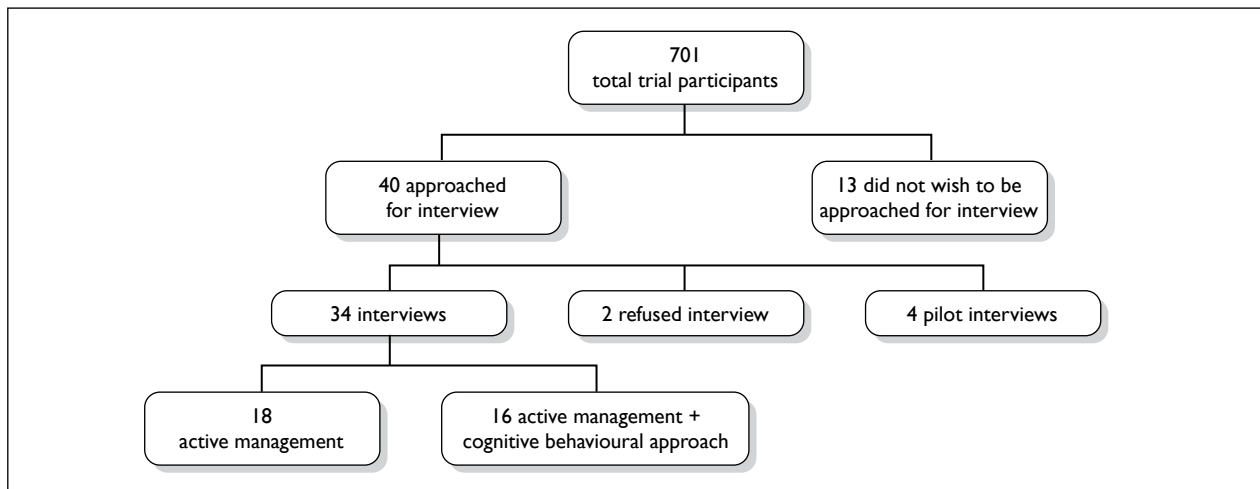|	Avoiders (FABQ=18–24)	Mixed (FABQ=10–17)	Non-avoiders (FABQ=0–9)
High disability (RMQ=9–24)	6	7	3
Low disability (RMQ=0–8)	5	7	6

FIGURE 15 *CONSORT diagram of interviews.*

Participant characteristics

Table 34 gives the demographic characteristics of the interviewees. The range of RMQ and FABQ pain severity scores was similar to the clinical trial sample, as was the proportion of males and females and people from ethnic minorities. There was a wide age range among the interviewees. In comparison with the trial, a greater proportion of interviewees left school at 16 years or less, suggesting that we were successful in accessing those of lower educational attainment.

Description of intervention

Attendance

Of the 16 AM+CBA interviewees, nine attended assessment plus at least three group sessions, a slightly lower proportion than that in the whole trial. *Table 35* lists the attendance of all interviewees for each group session.

Participants were considered to have received the intervention if they attended three or more group sessions. Four of the 16 interviewees randomised to the CBA did not attend any of the group sessions: two because of illness, one because of family commitments and one because after the initial assessment the interviewee decided the group would not be useful. Three interviewees attended the first one or two sessions only: two because of work commitments and one because of family commitments. Of these, one felt the group was not useful to him and two said the sessions were useful. The remaining nine attended three or more sessions but only one attended all six sessions. Absences were for a variety of reasons, such as a change in the time of the group and holidays.

The interview

A semi-structured interview schedule was designed and developed by undertaking four pilot interviews, which were not subsequently used in the analysis. In the final interview schedule, interviewees were asked about their lives in general and their back pain, as this formed the context for understanding their lived experience before and after the intervention.

The following questions regarding the interventions were asked of all interviewees:

- Which treatment did you have on this trial? Could you tell me what you thought of that?
- Were you given any written material to do with your back?

Questions asked only of the AM+CBA interviewees were:

- What do you think about physical activity for your back?
- How do you decide when to go back to work/ normal activities?
- How do you feel about the whole process of back skills training?
- How did you feel about the logbooks and goal setting?
- How did you feel about being in a group?
- Any other comments about the sessions?

Additional questions were included in the interview schedule and are provided in Appendix 14. However, these were not part of the commissioned project and hence are not reported here.

TABLE 34 *Characteristics of interviewees*

	All BeST trial participants (%)	AM (%)	AM+CBA (%)	All interview participants (%)	Interview AM (%)	Interview AM+CBA (%)
N	701	233	468	34	18	16
Age range (years)	18–85	19–85	18–85	19–76	19–76	28–69
Roland Morris Disability Questionnaire baseline scores						
Mean	8.7	8.5	8.8	8.7	8.4	9.1
Range	0–23	0–22	0–23	2–19	3–18	2–19
Missing	1	1	0	0	0	0
Fear Avoidance Beliefs Questionnaire baseline scores						
Mean	13.8	14.2	13.6	14.2	14.9	13.3
Range	0–24	0–24	0–24	0–24	6–24	0–24
Missing	39	14	25	1	0	1
Gender						
Male	284 (41)	90 (39)	189 (40)	16 (47)	8 (44)	8 (50)
Female	415 (59)	142 (60)	278 (60)	18 (53)	10 (57)	8 (50)
Missing	2 (0)	1 (0)	1 (0)	0 (0)	0 (0)	0 (0)
Severity of back pain						
Very/extremely	319 (46)	103 (44)	216 (46)	15 (44)	7 (39)	8 (50)
Moderate	382 (54)	130 (56)	252 (54)	19 (56)	11 (61)	8 (50)
Missing	2 (0)	0 (0)	2 (0)	0 (0)	0 (0)	0 (0)
Ethnicity						
White	618 (88)	206 (88)	412 (88)	31 (91)	17 (94)	14 (88)
Mixed	7 (1)	3 (1)	4 (1)	1 (3)	0 (0)	1 (6)
Asian	29 (4)	8 (3)	21 (4)	2 (6)	1 (6)	1 (6)
Black	11 (2)	4 (2)	7 (2)	0 (0)	0 (0)	0 (0)
Chinese	2 (0)	1 (0)	1 (0)	0 (0)	0 (0)	0 (0)
Missing	34 (5)	11 (5)	23 (5)	0 (0)	0 (0)	0 (0)
Age left education (years)						
Still in education	3 (0)	2 (1)	1 (0)	1 (3)	1 (6)	0 (0)
16 or less	387 (55)	121 (52)	266 (57)	19 (56)	7 (39)	12 (75)
17–19	165 (24)	61 (26)	104 (22)	9 (26)	6 (33)	3 (19)
20 or over	113 (16)	40 (17)	73 (16)	5 (15)	4 (22)	1 (6)
Missing	33 (5)	9 (4)	24 (5)	0 (0)	0 (0)	0 (0)

Prompts were used to expand on questions to elicit personal experience and opinions surrounding their LBP and the interventions. For example, if a person mentioned that a component of the intervention was not useful they were asked why, what should be changed and whether it would be useful to others. At the end of the interview, participants were asked if there was anything in the interview they wished to have removed from the audio recording, and were reminded that the interview was confidential to the research team and would be made anonymous when transcribed.

One participant had not finished the group sessions by the time of the interview, so was contacted later for a short telephone interview to ask about the last group session. One participant asked to see a copy of the transcript which was sent with a prepaid envelope for any comments (this was duly returned with minor typographical changes

TABLE 35 *Attendance at group sessions*

Interviewee identifier	Group[a]	Session						No. of sessions attended	Total no. in group
		1	2	3	4	5	6		
19	A	*	x	x	x	x	x	1	7
20	A	*	*	x	x	x	x	2	7
21	A	*	*	*	*	*	*	6	7
22	B	*	*	x	*	*	*	5	5
23	C	*	*	*	*	x	x	4	6
24	C	x	*	*	x	*	x	3	6
25	D	*	*	x	*	*	*	5	7
26	E	x	*	*	x	*	*	4	6
28	B	*	*	x	x	*	*	4	5
31	F	x	*	*	x	*	*	4	7
32	G	*	x	x	*	*	*	4	7
34	G	*	*	x	x	x	x	2	7
Total		9/12	10/12	5/12	5/12	8/12	7/12		

*, attended; x, did not attend.
a   Notation indicates which group participants attended.

only) and another asked for a copy of any excerpt which may be used in the final report, which was sent and elicited no response.

Data coding and analysis

All interviews were carried out by one researcher (V.N.). At the time of interview the interviewer was not aware of the detailed content of the course sessions, to reduce any tendency to ask leading questions. During analysis V.N. was briefed fully on the content to enable her to understand which part of the intervention interviewees were talking about.

Audio recordings of interviews were transcribed and checked by the interviewer. All transcripts were entered into NVivo, a computer software tool for managing qualitative data (NVivo, QSR, Portsmouth, UK). Thematic codes were developed based on the interview schedule, the components of the intervention and issues arising in the interviews. The research team agreed codes and their definition. All data were double coded and coding was compared. Where there were inconsistencies in coding these were discussed and agreed. The data were extracted from all interviews for each coded theme relevant to the experience of AM or AM+CBA. The number of participants mentioning a theme was counted, the content of the coded data was summarised and illustrative quotes were identified for presentation in the results.

Results

The results describe the interviewees' experiences of back pain, being on the trial and their account of the interventions they received. The first section summarises the accounts of receiving AM only. We then draw on the accounts of those receiving AM+CBA and summarise their account of the AM component, the individual assessment and the group sessions. The results include numbers of interviewees who talked about themes. Each interviewee may have talked about one or more of these themes.

Active management

This section summarises the accounts of the 18 interviewees who received AM only.

Nearly all the interviewees were familiar with the messages given in *The Back Book*, although none reported receiving the book previously. The advice to stay active, take regular analgesia and undertake exercise was familiar to all interviewees except one and had been gained from a variety of sources. The one interviewee who was unfamiliar with the content of *The Back Book* before the trial found the advice valuable.

> …it [*The Back Book*] did involve a certain amount of details…They were easily adaptable to yourself. It wasn't something where it was a

leaflet given to you that just has a list of things that you could do and that was it…it was done in a way that you could all sort of take bits from it that you needed. [Interviewee 5]

Seven interviewees felt that it was a 'good booklet':

> Yes, it's quite a neat little document to have for a point of reference and it was quite clearly laid out and yes, I think someone coming in initially having a problem with their back would probably benefit from that, because it may give some further insight into managing back pain, but for me I had seen…I'd been given literature like that before. [Interviewee 16]

Of these, three added they had found the information reassuring:

> …I think the one thing that was reassuring was that I couldn't make it any worse by carrying on doing things. [Interviewee 3]

Two of the seven also suggested that it may be useful for others in early episodes of back pain:

> …if it was the first time I done it, it would have been a great book but I've seen a lot of it before. [Interviewee 18]

Two-thirds of the interviewees reported that the advice in *The Back Book* was common sense, nothing new or similar to other advice they had received in the past:

> I thought it was common sense things really, I really did and I thought 'well it's not telling you anything that isn't real common sense'. [Interviewee 14]

> Well, I've been…it's exactly…I've been told and I've had things like that for years, so I do know…yes, I read it and it was in a way nothing new for me. [Interviewee 17]

> Well, I read it but it was all what I'd sort of read before as well when I've been to clinics and surgeries and things like that. [Interviewee 6]

However, six interviewees could not remember receiving *The Back Book* in the trial at all, even when prompted. One of these participants also said that he had 'lost interest' [Interviewee 9] after not being chosen for the group intervention and felt

that this was part of the reason that he could not remember the book.

The Back Book and AM session was considered too general or unhelpful by two interviewees who wanted specific treatments.

> Like it doesn't tell you what you've actually gotta do with your back. [Interviewee 8]

> I was hoping that I was going to get some… maybe go on an exercise course or something like that you know? You know, I mean it's interesting just talking but it doesn't really do anything does it? [Interviewee 10]

Active management and cognitive behavioural approach group intervention

This section summarises the accounts of the 16 interviewees who were in the AM+CBA arm of the trial. Of these, 12 attended at least one group session.

Two or more of the key messages of the CBA group intervention were picked up by 11 of the 12 interviewees attending at least one group session. Six of these had picked up three or more of the key messages.

Details of the interviewees' accounts are reported in the following sections covering the AM session, the initial assessment and the CBA group sessions.

Active management experience for the participants receiving CBA

All 16 AM+CBA interviewees received the AM session after randomisation. However, these interviewees' descriptions of the AM part of the intervention were more general and sometimes vague, compared with the AM interviewees. The parts of the intervention that followed this session were remembered more clearly. When asked about the AM component of the intervention, all 16 interviewees gave a response but often needed prompting. Some gave more than one comment in different themes and the themes were similar to those reported by participants randomised to AM.

Eight interviewees felt that *The Back Book* gave 'common sense' information or that they already knew the information from other sources. One of these interviewees compared *The Back Book* to the BeST intervention folder given at assessment:

It was interesting but it was straightforward about what it was. I think it was a good opener to whether you went on the programme…you know, if you were lucky enough to be chosen or whether you just had the booklet and it did explain backs and that but I preferred the folder. Yeah, the folder sticks in your mind more than the little book. [Interviewee 24]

Four interviewees could not remember anything about the AM session's content and four mixed up the BeST intervention folder given at assessment with *The Back Book*.

One participant thought *The Back Book* was unhelpful:

I did feel that…they didn't quite understand what it was like to have back pain…I just wondered if any of them had actually suffered any back pain and if they really understood exactly what it was like to have this…just this awful feeling really of never ever going to be any better. [Interviewee 32]

Initial assessment

All 16 interviewees attended the initial assessment before commencing the six group sessions. Their accounts of each of the assessment components are described below: exercises, goal setting, the BeST intervention folder and the relationship with the therapist.

Exercises

This section draws together interviewee accounts of exercise both at the initial assessment and throughout the group sessions, as the interviewees did not distinguish clearly between exercises at initial assessment and exercise discussed during group sessions.

Exercises were talked about and considered of benefit by nine interviewees:

Overall I feel they've been helpful,…really helpful…I was a bit worried until…about my knee, but now I know it's my back I can concentrate on that more. I've…because I cut all the exercises out that I…but I've started them up again and touch wood they're working. [Interviewee 22]

Exercises had been incorporated into their lives to good effect by seven of the nine interviewees:

I had the booklet (folder) with all the exercises, which is very good I have to say. They are good strengthening exercises, good flexible exercises, which in the training that I do…I do quite a lot of flexing and quite a lot of exercise anyway and I incorporate the booklet (folder) into that as well now, so from my point of view that's been a benefit. [Interviewee 19]

Exercises had increased the ability to cope for two of the nine interviewees:

…since going on the course, try and exercise; try and move it, try and free it up, whereas previously I'd have followed the…you know, lay down, rested it and I sort of picked up on that and it did make a difference the other day for sure. I went from absolute agony to…I actually phoned in work to say I wasn't coming in and then an hour and a half later I phoned in and said 'Yes, ok I'll come in I'm ok I'm better.' Not 'fixed' but better able to cope. [Interviewee 20]

…but I feel more confident that I'll be able to…if I do get it bad, get over it with the exercises and the same with the positive side as well, you know and sometimes it hurts, but you've got to go through it… [Interviewee 21]

The flexibility of how the exercises were taught was specifically mentioned and appreciated by four interviewees from the whole sample of 16:

I didn't really have any expectations. I thought it might have been harder in the exercises and I'm sort of thinking 'oh God, are they going to get me down on my hands and knees trying to do all the…' but it was very easy [therapist's name] was very good how she explained things and she saw to at least one of (us) each week to make sure that we were doing the exercises. If we had a problem with any of them she would help us through it… [Interviewee 24]

One participant had not done the exercises they had been shown, but said they might in the future:

…I'm not a natural exerciser so it's very hard to go from doing absolutely nothing to doing something you know on a regular basis…now I didn't do them but I know I could…I can if I wanted to, highly unlikely but if I wanted to I could do it but I would have said it was worth while. [Interviewee 25]

Two interviewees felt that they would have liked the opportunity to exercise and be shown how to do the exercise in the 'correct way':

> they were (not) going to actually…physically going to show you the exercises that you need to do…I think is sort of a real key to you know keeping flexibility right, making sure you are doing the exercise right. Because some people can do an exercise completely wrong and they're not stretching the muscle they're supposed to be stretching. [Interviewee 19]

> It would better that…if the exercises could actually be conducted in the sessions…It's not that we weren't allowed to do it, I should say. It's just that we weren't given the opportunity to do the exercise. [Interviewee 31]

One interviewee said that the exercises were ineffective for them. This interviewee was unable to attend any of the groups:

> …she gave me a set of exercises to do but they didn't seem to help you know, stretches and exercises but that didn't seem to help. [Interviewee 33]

One interviewee was already doing a lot of exercise:

> I'm already exercising more than most people exercise. [Interviewee 23]

Goal setting
Of the 16 interviewees, 13 talked about setting goals collaboratively with the therapist at the initial assessment.

Goal setting was popular with six interviewees:

> What mine (goal) was, was to walk to the shop and back and I did it within the first couple of weeks because the car was off the road so I had to do it and I was so pleased when I'd done it that I actually made it there and back. [Interviewee 24]

> Well I have joined the gym so that was one of my goals to go back and do that, but then I've got to work on that. [Interviewee 32]

Goal setting was already being used by a further two interviewees:

> Many things I learned on the course I already worked out myself over time…I've achieved the

goal that I actually set on the course with the swimming. [Interviewee 23]

Goal setting was not used by three interviewees:

> I'm not bothered about goal setting. [Interviewee 22]

> I felt I wasn't particularly bad enough to have to set goals, because it isn't restricting me in the way it was probably affecting other people. [Interviewee 26]

> I mean I'd like to go on it every day and do 'x' amount of time on it, but at the moment like I say, I actually haven't but that was one of my goals. [Interviewee 30]

Two interviewees felt that goal setting would be good for others:

> For some people I'm sure it's good, but for me personally…I was happier just doing it my way in the end. [Interviewee 20]

BeST intervention folder
Seven interviewees mentioned the folder.

Five interviewees found the folder good, of whom three specifically mentioned exercises and one used it for reference:

> It showed you exercises, it explained back pain, that going round in a circle. It gave me goals, what to deal with um...and once you'd done with one goal…you know, 'do you want to lead on to another goal?' With the exercises you started at one level and if you wanted to carry on different levels but each week we were given two pages about what we talked about that day which was very good. [Interviewee 24]

> Yes I did actually think it was quite useful but yes it has been quite good and I have referred to it strangely enough. [Interviewee 25]

No one used the logbooks.

Relationship with therapist
The relationship with the therapist at the initial assessment was described as positive or helpful by four interviewees:

> She was very good, everything was explained. She asked…she waited for us to answer and if we had any questions she'd listen to us and

she'd…you didn't feel as though you were being rushed. [Interviewee 24]

I felt quite uplifted when I came out actually, that somebody perhaps wanted to help me. I don't know. Whether just that feeling of, 'someone's listening'. [Interviewee 32]

Group sessions
Out of the 16 interviewees who attended for the initial assessment only 12 attended one or more group sessions. Their accounts of the group sessions are presented under the following themes: change in fear avoidance, value of interaction, pacing, pain education, relaxation and reinforcement. The final section reports the negative comments about the group sessions.

Change in fear avoidance
The most marked change in attitudes, beliefs and behaviours attributed to the group sessions was a decrease in fear avoidance, described by 10 interviewees:

I always assumed that if I was in pain that I was going to damage it (the back)…I'll take paracetamol or the Ibuleve gel around the area and since going on the course, try and exercise; try and move it, try and free it up, whereas previously I'd have followed the…you know, lay down, rested it and I sort of picked up on that and it did make a difference the other day for sure. [Interviewee 20]

I would take it easy and I will try and restrict the amount of heavy lifting I done I wouldn't lift it…I were conscious of not damaging it… because I was frightened to do these because what's the point of exercising and then doing your back in like? I'm not so worried about it now. [Interviewee 21]

You're afraid that if you push yourself too far that maybe you're doing more damage to your back…but as I say, that was good in the fact that what it showed me is that I can push myself that little bit further with the pain, and it's not actually doing any damage. [Interviewee 31]

The only things that have changed from the trial is that I will attempt more things…even though it hurts. [Interviewee 23]

I'd probably say it's (back pain) on a similar scale of what it was, but not…it's not emphasised by worry or fear. It's not being fed.

I'm not sitting there thinking about my back constantly basically, thinking 'Oh well I can't do that. Can I lift that?' I'd just go and lift it and lift it carefully. [Interviewee 26]

One interviewee talked of still being fear avoidant:

I like to do it if I can but I'm wary of it that is the main thing. I'm frightened of it…it sounds silly but I'd like to put it in a washing machine, wash it and put it back new which will never happen but yeah I'm frightened to do anything new with it in case it does it, I'll do it bit by bit…I prefer to do it bit by bit than to see how far I can go…years ago I'd have gone and done a whole lot but now you won't because you're frightened of your back. [Interviewee 24]

An understanding of cycles of pain and the link with fear avoidance was expressed by five interviewees:

I did tend to protect my back, I did tend to… but obviously if you're not going to use your back then you're going to lose your back, you know and you get into the circles and the whole thing made a lot of sense really. [Interviewee 21]

I guess that is a good thing to do, you know, to use the exercises because it is an absolute vicious circle. You don't exercise because your back hurts which in turn weakens your muscle which in turn makes your back bad and you're on the treadmill really so it's difficult. [Interviewee 25]

What I've tended to do as a result of the sessions is even though my back is aching I've pushed myself and not given in. I've gone on and done something and like…you know… I've gone down and taken her (niece) to the swimming baths. [Interviewee 31]

Value of interaction in the group sessions
The opportunity to share views and experiences with the group was valued by nine interviewees:

The difficulties they were having were all quite common with the difficulties I was having and from that, I found it quite comforting. [Interviewee 31]

Sometimes you can pick up more from the people because they've done things or

they get round things in a different way. [Interviewee 31]

That was…yes, just listening to what people did, what treatments they'd had yes, but other treatments that everybody had tried and what effectiveness that had had. [Interviewee 20]

I found it very good because we were…because when you are by yourself you're the only one with this problem and nobody else knows what you're going through. Because you're living with a family group and they might have a back ache but they don't have the back like we do… it was reassuring that you are not by yourself. [Interviewee 24]

One participant didn't feel comfortable in a group and attended only one session:

I wasn't comfortable with…(the group)…it's just because you feel a bit silly you know?… It's not the normal approach that you do. It's normally like us one to one or whatever and you feel like you can say what you want to say, or you don't want to sound stupid by saying something really simple that's not connected with the questions they're asking. [Interviewee 19]

Three interviewees gave accounts of why their group dynamics may not have worked as well as they might have. These were due to poor attendance or individuals not participating or monopolising the group.

Comparison was made between the interviewee and other group members by six participants, of whom four described their back pain as less severe than others:

Mine wasn't so bad compared to like some of them. [Interviewee 28]

I'm not a particularly bad case. When I was sat with the three guys from the group I knew…I was sitting there thinking 'Well, I'm not this… quite this bad.'…I thought 'Well, I'm not in his category', which obviously made me feel a lot better. [Interviewee 26]

I realise how lucky I was, because some people have suffered an awful long time. [Interviewee 19]

Pacing

The technique of pacing of activities was mentioned by three interviewees:

(If I) build up reasonably slow, then there's no reason why I can't have a go at anything, which is what I'm in the process of hopefully doing now. [Interviewee 21]

Difficulty in applying pacing in their lives was described by two interviewees:

I know I shouldn't (over) do it but you don't know how many good days you're going to get so… [Interviewee 22]

Although they said on the research you need to get a happy medium when you've got a bad back problem…they wanted you to get... so that you could do as much on a bad day as you could on a good day, that is impossible… because as I say sometimes you're totally incapable even to get out of bed sometimes so you can't do say a walk to the end of the road and back which they wanted you to do and I found that sort of, good idea but impossible to do. [Interviewee 24]

Pain education
Understanding the psychological component of pain was useful for three interviewees:

The psychological effects…because that's actually quite important because it does have a big effect on people. I'm sure it…well, certainly on me…I mean mostly in the evenings when I'm watching television I'm uncomfortable for most of the evening to be honest and I just keep shifting my position…Well, mainly what they were telling us at this back clinic. You distract yourself. That's really the only way. I get up, I walk round, I probably get myself a drink, watch television and get absorbed in something perhaps for an hour and I'm not thinking about it. During the daytime I just am busy and that takes my mind off it. [Interviewee 32]

However one participant did not find the pain advice useful:

That's something to do with mental high pain and I was like well yes if you want to know more…deeper into backs it's great but that was irrelevant for what…for me if you like… it weren't getting to the point you know? [Interviewee 34]

Relaxation techniques

Relaxation was described as useful by two interviewees of whom one had used it previously:

> I think it was good, I did pick up things and I mean we talked about relaxation and that was quite good and [therapist] went over some relaxation techniques, I found those useful. [Interviewee 25]

Reinforcement

The group sessions reinforced activities and beliefs they had already learnt about. These included exercise, goal setting, relaxation and pacing. One participant felt that the group had confirmed that there was nothing new that they had not already tried.

Dissatisfaction with the treatment

Four people made negative comments about the groups. The negative comments are described fully below.

One interviewee attended one group session only and stopped because of work commitments and because he had expected medical tests or a definitive diagnosis. He also stated a preference for a one-to-one treatment rather than a group and said:

> Going on the actual course…although I missed quite a lot because the first week I went I felt it was a little bit patronising I have to say, a little bit like going back to school and that sort of thing. [Interviewee 19]

Another interviewee said that they 'knew everything already', the course had confirmed this and they felt that there was a problem with the pitch and delivery:

> You've got it pitched incorrectly…I mean the person who was taking it…she was a really sweetie she's lovely, but…and she was following instructions that they've all got from these books, but it's pitched really. I mean I should think it's pitched for a teenager…It's not pitched for intelligent adults…Either the pace or the way they actually talk to you or…you know, you need to be much more…For a start you need a lot more examples up your own sleeves in your own heads that you can bring out when you try to get a group to talk, you know. I mean you need a lot of teaching skills really and you haven't got them…It's partially

the content and it's partially the way it's put over. It's both. [Interviewee 23]

One interviewee did not like the therapist's approach:

> I didn't like him. I thought it was patronising, arrogant and I thought he was a **** to be honest with you because about what goals I had and they talk to you like you're a kid. Do you know what I mean, which I didn't like?…I turned round and I said I wanted to run a marathon and he slapped me down. [Interviewee 28]

This interviewee also knew the information given in the group.

An interviewee who only attended two sessions because of work commitments and felt they had stopped learning from the group sessions:

> I missed out two or three sessions…and some of it I found a little bit boring…Well like the… well…when they were saying right what sort of pain is there, there's severe pain, there's mediocre pain, there's little pain…and I was like 'well yes if you want to know more…deeper into backs it's great but that was irrelevant for what…for me if you like' but sometimes it's nice to talk to people about their back but… it weren't getting to the point you know?... And it was great, I mean six sessions I realised I did three or four and then the sessions I did do…it was great but then I said 'well I'm not learning here' and you think to make my back better or though it was interesting what other people do so it…if you give it a mark out of 10, 5 or 6. Yes for the course generally…The first one (assessment) the back 10 out of 10 and I'd go to that again…that was brilliant. [Interviewee 34]

These four people were asked how useful they felt the groups would be for other people. Three felt that other people may benefit from this type of intervention; the other did not comment.

Conclusion

The CBA group intervention was added value for the trial participants over AM. Almost all participants were already familiar with the AM approach.

Most of the interviewees in the CBA intervention arm of the trial and who attended at least one session picked up key messages from the intervention and two-thirds talked about a reduction in fear avoidance and changes in their behaviour. Over half found the exercises helpful and many of these had incorporated exercise into their daily lives. Other aspects of the intervention were useful to some and not others, suggesting that offering the range of techniques is important.

Although participants of the BeST trial were considered to have received the intervention only if they had attended three or more sessions, the interview data suggest that fewer than three sessions may still be useful for some participants.

A minority of interviewees were unhappy with certain aspects of the group intervention and several of these felt they knew the content of the intervention already.

Issues that were raised by the interviews that should be considered in translating the intervention into practice were as follows:

- The individual assessment, although an unusual component of CBA, sets the agenda for the groups, begins the CBA and allows a relationship to be established with the therapist. It is an important element of the intervention.
- Exercises were considered an important component by most interviewees and demonstration and tailoring of exercises was valued. Great emphasis could be placed on tailoring and demonstrating exercises during the sessions.
- Participants can benefit even if they choose to use only certain aspects of the intervention or attend a limited number of groups. Translation into practice should consider giving participants more information about the sessions ahead of time, so that people are able to choose what to engage with and when. Although not mentioned specifically, a rolling programme of group meetings may mean that participants have a greater choice about being able to join when they choose.
- Group sessions where participants share experiences can provide them with reassurance, lessen isolation and enable participants to learn strategies from each other.
- Consider increasing training for therapists in group facilitation to increase sharing of experiences.

Chapter 6
Economic analysis

Introduction

We aimed to assess the cost–utility of adding a CBA programme to AM. Our primary outcome was cost–utility expressed as the incremental cost–utility ratio (ICUR),[131] the shadow 'price' of CBA, which indicates the cost of gaining one additional QALY relative to the current therapy.

We assessed cost–utility over a 12-month time frame, and the base year was 2008. Costs were expressed in UK pounds (£) and actualised to 2008 using the Office of National Statistics Retail Price Index[132] where required. Neither costs nor outcomes were discounted as the time frame for the analysis was 12 months.

We considered cost–utility from both the UK NHS and the general health-care perspective.[131] The NHS perspective included all health-care costs supported by the NHS to deliver AM or AM+CBA and to provide health care associated with back pain treatment and symptoms in the 12-month period after randomisation. The health-care perspective is broader and included both the total health-care costs to the NHS and the cost of privately purchased goods and services (medical and non-medical) related to LBP and private transport.

The base-case analysis was based on the within-trial resource consumption. To illustrate the generalisability of the cost-effectiveness analysis, we developed an alternative cost–utility scenario based on the potential resource consumption for the CBA programme delivered within NHS structures where therapists are almost entirely based at one site (and hence there is no need to allow for travel time and expenses). The within-trial analysis was the primary economic analysis and is presented in this chapter. The generalised NHS scenario was a secondary analysis and appears in Appendix 15.

Data

Outcome data

Health outcomes were expressed as QALYs calculated from utility weights[133] estimated from preference-based questionnaires (EQ-5D) completed at baseline, 3, 6 and 12 months.

The EQ-5D[107] is a generic measure of health status that includes five health dimensions: mobility, self-care, usual activities (e.g. work, study, housework, family or leisure activities), pain/discomfort and depression/anxiety. For each dimension, the respondent is asked to rate the extent of their problem, choosing between 'no problem', 'some problems' or 'unable to perform'. The combination of all potential responses gives rise to 243 health states ranging from full health to worst possible health state.

Resource utilisation data

The resources used to deliver the CBA were obtained from administration and visit records. CBA resource use included duration of the assessment visit, number and duration of scheduled CBA sessions (contact time) and non-contact time, equipment, consumables, educational materials and items and resources used during the training of CBA therapists. Non-contact time included the time used to contact participants and set up the sessions, writing clinical notes, administration and record-keeping. Support and supervision time provided by the intervention support team were incorporated. Travel time was calculated for therapists seconded to the programme using actual travel time reimbursed by the trial.

We collected other health-care resource use and participant costs from participant questionnaires at baseline, 3, 6 and 12 months. Participants were asked to keep a record of type and quantity of each resource item used, for services provided by the NHS and for services either privately purchased or funded by private health insurance.

Other NHS resource use data included the number of contacts with GPs, nurses, physiotherapists, psychologists, other health-care consultations, diagnostic tests [including X-ray, magnetic resonance imaging (MRI) scan, computerised tomography (CT) scan and blood tests], accident and emergency (A&E) attendances, and hospital admissions.

We also collected data on the provision of drugs used in the treatment of back pain from participants' questionnaires. These included painkillers, anti-inflammatory tablets, anti-inflammatory gels and creams, sleeping tablets and antidepressants, and other drugs indicated by participants as having been prescribed for back pain.

We sought data on out-of-pocket expenses, as well as on back care sourced from the private (non-NHS) sector. This included the resource use and costs of services such as aromatherapy, chiropractic, counselling, massage, private orthopaedic surgery, osteopathy, psychology, physiotherapy and the number of items and cost of any equipment item, housing adaptations and aids. We asked participants to indicate the type and quantity and, where appropriate, unit cost for each item of privately purchased health-care resources. We also asked participants to indicate where these costs had been paid for either in total or in part by a private insurance policy.

We verified both NHS and private hospital admissions data. A researcher (E.W.) contacted the patients who had declared any hospital admission and collected data on cause of admission, ward of admission (to determine the Health Resource Group), procedures received and length of stay.

Unit costs

The total cost of health care was calculated by multiplying resource use data by their respective unit costs. Unit costs were the cost of AM or AM+CBA, the cost of primary care and community-based services, the cost of hospital-based services, admissions and A&E services, the cost of drug prescriptions, and the cost of private health-care items and equipment. All unit costs reported in this section are 2006 prices, with the exception of private consultations and tests (*Table 36*), and were actualised to the year 2008 for the cost–utility analysis using the appropriate inflation index.

NHS health-care unit costs

Unit costs for any of the resources consumed and consultations within the NHS were obtained from published sources pertinent to the UK.[134–136] Unit costs for these items are reported in *Table 36*.

Unit costs for pharmacological agents were the average cost for one prescription of each drug type consumed in the trial, including painkillers, anti-inflammatory drugs, anti-inflammatory gels and creams, sleeping tablets and antidepressants. Unit costs were calculated based on the typical drugs commonly prescribed for back pain, based on a consensus exercise amongst six academic GPs working in the localities from which we recruited the sample. The average cost of the prescriptions was then computed from the Prescription Cost Analysis (PCA) database.[136]

Participants were asked to report if they were dispensing any drugs in addition to the categories described above. Costs for these additional drugs were calculated using the frequency of use reported

TABLE 36 *Unit costs for NHS consultations and drugs (2006 prices)*

Item	Unit cost (£)	Source
GP visit (surgery)	34.00	Curtis 2007[134]
Nurse visit (surgery)	9.00	Curtis 2007[134]
Physiotherapy visit	31.80	Curtis 2007[134]
Outpatient consultation (back pain problems)	112.70	NHS Reference Costs[135]
Psychologist consultation	67.00	Curtis 2007[134]
Painkillers	4.57	PCA database[136]
Anti-inflammatory drugs	8.22	PCA database[136]
Gels, creams and ointments	5.75	PCA database[136]
Sleeping pills	3.66	PCA database[136]
Antidepressants	5.86	PCA database[136]
PCA, Prescription Cost Analysis.		

by respondents, when available, or assuming occasional consumption of one dispensing unit (prescription). These additional items were yearly treatment with paracetamol at £12.00 assuming one box per week, pain control (fentanyl) patches, at the cost of £86.70 per prescription, and muscle relaxants at £11.90 per prescription.[136]

The costs of diagnostic tests and of hospital and A&E admissions were obtained from the NHS Reference Costs database.[135] The cost of blood tests was calculated using the average cost of blood tests (Speciality codes DAP823 and DAP839). This was £3.10. The costs of other diagnostics were CT scan (£117.90), MRI scan (£203.80) and X-ray (£28.00).

The unit cost of hospital admissions was obtained from the category HD26C Musculoskeletal Signs and Symptoms Without Complications. The cost of a day case was £529.50 and the cost of an extended-stay case was £572.00. The cost of an A&E attendance without a subsequent admission was £170.10.

Private health-care unit costs

Private costs were estimated based on resource consumption indicated in participants' questionnaires multiplied by the respective unit cost.

The unit costs of private consultations included a range of services (shown in *Table 37*). These costs were obtained from a telephone survey of six providers of each type of service, based in Coventry, Manchester, Newcastle, Essex, Liverpool and London, conducted between 1 February and 5 February 2008 (*Table 37*).

Private costs also included the cost of privately paid diagnostic tests, including X-ray, MRI scan, CT scan and blood testing. Unit costs for private tests and diagnostics were obtained from the same telephone survey and are detailed in *Table 37*.

Medications (painkillers, anti-inflammatory drugs, anti-inflammatory gels and creams, sleeping tablets and antidepressants) purchased privately were valued at the same NHS cost for similar preparations obtained from the PCA database.[136]

TABLE 37 *Unit costs of community- and hospital-based private consultations*

Item	Unit cost (£)	Source
Hospital-based fees		
Outpatient consultation with NHS consultant	182.50	Phone survey of six consultants' private consultation fees for patients with LBP, at BMI Alexandra Hospital (Cheadle); BMI Meriden Hospital (Coventry); BMI Sarum Road Hospital (Winchester); Spire Bristol; Spire Gatwick Park; Spire Leicester. Conducted in February 2008. Estimates are the average cost
X-ray	86.20	
CT scan	551.60	
MRI scan	597.90	
Blood tests	109.80	
Community-based fees		
Physiotherapy	38.20	Phone survey of six specialists' private consultation fees for patients with LBP, at Coventry, Essex, Liverpool, London, Manchester and Newcastle. Conducted between 1 February and 5 February 2008. Estimates are the average cost
Osteopath	44.30	
Chiropractor	35.30	
Psychologist	70.40	
Counsellor	50.00	
Massage therapist	24.80	
Aromatherapist	25.30	
Dietician	55.80	
Acupuncture	34.50	

CT, computerised tomography; MRI, magnetic resonance imaging.

For hospital consultations, participants were asked to indicate whether the cost was disbursed directly by the participant or reimbursed by health insurance, while equipment costs, housing adaptations and aids, all purchased privately, were estimated using the amounts declared by participants only. Finally, we computed participant travel cost for all visits, consultations and hospital admissions declared as either NHS or private services using unit costs obtained from one published study for the UK.[137] Travel to community-based services was estimated at £3.50 and that to hospital-based services was estimated at £6.50 per trip.

The cost of cognitive behavioural therapy in the randomised controlled study (within-trial analysis)

Unit costs for the AM+CBA intervention were estimated from the trial data, using resource use described above and other staff cost information retrieved from published sources.[134] The unit costs for the components of the CBA programme were staff salary costs (including overheads and capital costs), training costs, consumables and equipment and travel costs. The total cost per CBA cycle was then computed for each group and allocated to each participant in relation to the number of sessions attended and the number of participants per session.

In the cost–utility analysis, CBA was estimated using the actual resource used to deliver the programme, i.e. the total working time provided within the context of the trial. Staff salary costs of one CBA cycle were then calculated as the cost of the total number of contact and non-contact hours spent by a therapist to deliver CBA multiplied by the normal salaried staff hourly rate.

The effective staff hourly rates paid in the trial were not likely to represent the normal salaried cost of staff. As with many trials, some of the activities were paid for under casual working arrangements. Although these include a holiday enhancement, they do not account for the broader costs of employment if undertaken on a salaried basis. Therefore the total normal staff hourly cost was computed, inflating the effective salary rates paid in the trial to include gross salary, employers' and overhead costs, capital costs and capital overheads. Gross salaries were calculated based on

effective seniority for each therapist combined with published NHS pay scales.[138] Salaries were inflated with 8% employers' National Insurance costs and 14% for employers' contribution to superannuation pay.[134] Salaries were then inflated at the year 2008 using percentage pay increases for the year 2006–7 (5.5%) reported in Curtis.[134] As salary increase data for the year 2007–8 are not available the same percentage increase was compounded for that period.

Overheads were applied to total staff time in a proportion of 5% of the salary for direct revenue overheads and £2904 per year for indirect overheads.[134] Capital costs and overheads were valued at £2752 per year.[134] Hourly rates were then computed from the total salary costs, assuming a total working time of 5 days and 52 weeks, less 27–33 days of holiday per year, depending on the therapist's salary band, 8 days for statutory holidays and an average of 12 days' sick leave and 3 days' training.[138] Hourly rates used in the cost-effectiveness are summarised in *Table 38*.

Finally, the total salary cost of one cycle of CBA was computed by multiplying the number of worked hours per cycle by the therapists' normal hourly salary rates. The total working time was the sum of contact and non-contact time observed for each therapist in the trial. Therapists' travel time was included in non-contact time, as the intervention was delivered by therapists seconded to the trial from other institutions where they had a permanent position.

The total cost of training, supervision, consumables and equipment was allocated top-down to each CBA cycle, based on the number of groups in the CBA programme.

The cost of consumables and equipment was computed by multiplying the number of items bought for the trial by their acquisition costs.

Training costs were estimated by summing the cost of external lecturing fees, intervention materials, lecture room fees, and residential expenses, including accommodation, travel and subsistence costs. Salary costs of therapists attending training were not added, to avoid double counting as working time spent on training was already included in the computation of the therapists' hourly rate. Training costs were allocated by CB cycle rather than as a component of salaries, as we requested that the staff did not deliver CB therapy outside the trial context. The CBA training course

TABLE 38 *Hourly salary rates calculated for the CBA programme*

Therapist	Band	Base salary (£)	Staff total cost (£)[a]	Days worked per year	Hourly rate (£)
1	6/4	23,789	39,283	210	24.90
2	6/7	26,720	43,426	210	27.60
3	6/8	27,622	44,701	210	28.40
4	6/9	28,524	45,976	210	29.20
5, 6	6/11	31,004	49,481	210	31.40
7–10	7/7	31,906	50,756	208	32.50
11–19	7/11	36,416	57,132	204	37.30

a Includes National Insurance and superannuation, capital and overhead costs; base year: 2008.

lasted 2 days. We assumed that therapists would have refresher training/mentoring for an average of 2 days a year, therefore we assumed that the costs of training would be repeated yearly. This seemed a reasonable approximation which accounts for the cost of continuous training for specialist groups, but excludes other types of training that may be unrelated to the CBA programme.[139]

Finally, therapists' travel expenses were computed from actual travel mileage declared by therapists and paid at £0.40/mile. Travel costs were allocated based on the actual travelled mileage for each group.

We did not incorporate a separate cost for space used within NHS physiotherapy departments. The space used for physiotherapy conducted on NHS premises (community and secondary care) comprises treatment cubicles, office space and a gym space with the space being used flexibly depending on the need for privacy, equipment, etc. Some patients may be treated in the gym and others in a treatment cubicle. We considered that the overheads in the Personal Social Services Research Unit costs would include the cost of accessing these spaces (on average). In the case of CBA, sessions were run for small groups (up to eight people) in spaces comparable to the gym or office used in normal NHS physiotherapy practice. From our experience, these two spaces are likely to be used for the majority of the patients, therefore we chose to use the estimated overheads of the Personal Social Services Research Unit as they incorporate space requirements. Although it could be argued that revising the cost of capital upwards to exclude the use of cubicles should be undertaken, we believe this is likely to have negligible impact on the cost of the CBA.

The total cost of one session was then obtained as a proportion (one-sixth) of the total cost of one CBA cycle, including supervision, training, consumables, equipment and travel time. The cost of one session was allocated to participants in proportion to session attendance, i.e. dividing the cost of one session by the number of participants in each group and session. Finally, the cost of CBA was computed for each participant multiplying the cost per patient of each session by the number of sessions attended.

The cost of the assessment visit was the cost of 1.5 hours' contact time at each therapist's hourly rate, and the cost of consumables and of CBA materials given to the participant (£2.60 in total per participant assessed). The cost of assessment was attributed to those participants who were assessed.

The cost of active management

At the start of the trial, all individuals were scheduled with a 15-minute nurse consultation at the time of recruitment and given *The Back Book*, a self-help advice booklet. The total cost of AM was £14.05 per participant. This included the salary cost of a practice nurse (£13.75), based on the cost per contact hour,[134] and the duration of the consultation. The cost of *The Back Book* was £1.00 (assuming that the books are purchased in bulk quantities of 24 or more). The cost of AM was actualised to the year 2008 using the Office for National Statistics Retail Price Index.[132]

Methods of analysis

The base-case economic evaluation was conducted using the sample of participants who had

completed questionnaires at baseline and at least at 3 months.

Missing data

For individuals who had missing cost data, unconditional mean imputation methods were used.[140] For NHS costs, data were imputed only if some resource use items were present. In the case of private costs, cost data were also imputed for self-funded items. We did not undertake imputation if respondents failed to return the entire follow-up questionnaire.

Although unconditional mean imputation is recognised to underestimate the variability of estimates, we used this method because of simplicity and because the number of missing items was low for each resource consumption item.

Missing EQ-5D scores were estimated using multiple imputation techniques.[141] Missing data were imputed only for those individuals who provided at least one item response for the EQ-5D and not for individuals where all items were missing. The cost-effectiveness incremental analysis was therefore conducted on the cases who had completed questionnaires at least at 3 months. This included the cases who had completed and returned a questionnaire with some missing values. For these cases, we then imputed the missing EQ-5D items. For the full economic evaluation, we used all the cases for which at least one measurement for costs was available, provided that the 3-month data were available.

Total costs of care

Total NHS costs for each participant were obtained by adding the cost of each health-care cost component described previously.

The total cost of care from the generic health-care viewpoint was calculated as the sum of the cost of private health care, transport and the cost of NHS care.

A descriptive analysis of resource use and the total annual cost of care was conducted using cases who provided complete follow-up at 12 months. Individuals who completed questionnaires at 6 or 12 months but not at 3 months were excluded from this analysis. Mean resource use and costs were tabulated by type of health-care services. Differences in mean costs between AM and AM+CBA were tested using a *t*-test for differences

in means. Standard errors for mean resource use were also reported. As the distribution of costs is positive and skewed, we constructed confidence intervals for mean costs using a bootstrap approach, sampling 1000 random samples of costs with samples of size equal to that of the original number of participants in each group. The 95% confidence limits were then calculated from the empirical distribution of the mean costs in each group and tabulated. We analysed differences in cost by sex, age, duration of LBP and RMQ scores using analysis of variance (ANOVA) for the total sample and both arms of the trial.

Quality-adjusted life-years

Utility weights were estimated transforming quality of life data (EQ-5D) into an index on the interval [0,1], using an econometric model developed from time-trade-off health valuations provided by a sample of the general population in the UK.[131,133] A utility weight represents the relative value to the individual of a certain health state, described by the combination of EQ-5D scores (see Chapter 3, Clinical outcomes, Secondary outcomes). The two extreme values of the interval indicate the utility weight for death and perfect health respectively. Compared with perfect health, a lower utility weight indicates a lower preference for less desirable health states.

Quality-adjusted life-years were then calculated for each participant as the 'area under the curve', the weighted sum of utility weights measured at baseline and 3, 6 and 12 months, and length of follow-up between each measurement, expressed in years. To compute the area under the curve, we assumed that utility between two periods was equal to the average of utility scores at two consecutive measurements.

We present a descriptive analysis of utility weights and total QALYs using participants who, at a minimum, provided at least some EQ-5D items and had completed follow-up at 3 months. Summary utility weights and QALYs were calculated at baseline, 3, 6 and 12 months, using *t*-tests for differences in means, and explored the variations in QALYs as a function of sex, age, duration of LBP and RMQ scores, using ANOVA.

We examined the association between costs or utility weight and commonly used prognostic factors, including age, sex and duration of back pain at entry, as these factors are easily identifiable

and may offer useful indications for clinical practice.

Furthermore, we examined the impact of subdividing the study population into two groups, using a threshold RMQ score of ≥ 4 versus < 4. This threshold has been used by several large trials of LBP treatments as an entry criterion (excluding those with a score < 4).

Incremental analysis

We calculated the ICUR as the ratio of the difference in mean costs of care (incremental costs) and of the difference in mean QALYs (incremental QALYs) between AM and AM+CBA.

The mean differences in costs and QALYs for AM+CBA were estimated using a regression approach, including a treatment term in the regression for costs and QALYs, controlling for utility and other relevant baseline characteristics. Therefore the incremental costs and QALYs are the regression coefficient for the treatment term. A positive cost coefficient indicates a positive incremental cost associated with AM+CBA. Likewise, incremental QALYs indicate a positive or a negative gain in quality-adjusted survival. The ICUR is then the ratio of incremental costs and incremental QALYs, i.e. the ratio of the coefficients of the cost regression and the QALY regression respectively.

Mean costs and QALYs were estimated as the inverse probability weighted mean of the total quality-adjusted survival and cost of each participant in the two groups.[140] The use of inverse probability weighting is justified because the rate of accrual of costs and QALYs varies across participants, although no deaths were observed during the study. Therefore the accrual of costs and QALYs may differ between patients who were followed up for the whole duration of the trial and those who were lost to follow-up at earlier dates.

Furthermore, a regression approach controls for factors that may be important in the prediction of costs and quality of life. The estimation of mean costs and QALYs should be adjusted a priori by utility at baseline. This is because the value of utility at baseline correlates with the total QALY as it enters its calculation directly. Any randomised comparison of two or more treatments is likely to show a difference in utility by group at baseline. Any imbalance in the utility at baseline, regardless of statistical significance, should always be regarded

as a source of bias in the computation of the total QALY difference between the two groups. In addition, such analysis also allows for the incorporation of adjustments for control factors depending on the results of the cost and QALYs analysis, which may reveal additional significant predictors of costs and QALYs.

To investigate variations around the cost–utility ratio, we used non-parametric bootstrap techniques, sampling 1000 random samples of costs and QALYs with samples of size equal to that of the original number of participants in each group. The incremental costs and QALYs were then computed using the inverse-weighted regression approach for each sample.

The bootstrapping process consisted of two steps. First, a sample was drawn from each treatment group. These samples were sized proportionately to the randomised groups, and the bootstrap also randomly sampled baseline characteristics. The second step consisted of rerunning the original analysis on the bootstrapped data. This included recomputing the inverse probability weights and rerunning the regression on the samples generated by the bootstrap. Therefore the variation in the baseline characteristics is adjusted for in the regression and the variation in the costs and QALYs is summarised in the parameters of the regression coefficients.

Incremental costs and QALYs were plotted on the cost-effectiveness plane, the plot of the joint distribution of the values of incremental costs and incremental QALYs.

There are four potential combinations of incremental costs and QALYs:

- CBA is more effective and more costly than AM. This combination identifies points on quadrant I of the cost-effectiveness plane. In this case AM+CBA would be considered cost-effective if the incremental cost–utility ratio is lower than the societal decision-maker's willingness to pay. This is a monetary value that the decision-maker is willing to pay for one additional QALY, and as the decision-maker's willingness to pay threshold has proven empirically difficult to set,[142] we calculated the cost–utility over the range £0 to £35,000. The decision-maker's cost-effectiveness threshold is indicated with the symbol λ.
- AM+CBA is less costly and less effective than AM (points on quadrant III of the cost-

effectiveness plane). Then CBA would be considered cost-effective if the ICUR is lower than the decision-maker's cost-effectiveness threshold.

- CBA is less expensive and more effective than AM (quadrant IV). Then CBA is 'dominant' because the decision-maker's choice would always be for CBA.
- AM+CBA is more costly and less effective than AM alone (quadrant II). Then CBA is said to be 'dominated' by AM as there is no cost-effectiveness threshold at which the decision-maker would be willing to pay to implement CBA.

The cost-effectiveness plane allows visual assessment of the extent of cost-effectiveness or dominance combinations for the comparison of two interventions.

The cost–utility helps decision-making around the adoption of CBA. Because confidence intervals cannot be constructed for the ICUR, because of the presence of dominance combinations, we investigated the empirical probability that CBA is cost-effective using the net benefit statistic to estimate cost-effectiveness acceptability curves for CBA.[143] The net benefit statistic,

> Net benefit $= \lambda \times$ incremental QALY $-$ incremental cost

compares the monetary value of QALYs with the costs of the programme and is a summary indicator of the net contribution of CBA to health gain, expressed in monetary terms. Therefore AM+CBA is cost-effective if net benefit is greater than zero, where λ is the net health gain.

Net benefit was calculated for each bootstrap sample. Using the empirical frequency of positive net benefit we obtained the probability that AM+CBA is cost-effective. The probability of CBA being cost-effective indicates the uncertainty around the cost–utility of CBA and therefore the degree of confidence associated with recommending the intervention. As the probability that CBA is cost-effective depends on the health-care cost-effectiveness threshold, we plotted the probability that CBA is cost-effective as a function of λ on the cost-effectiveness acceptability plot.

The results from the bootstrap process were similar to those of the regression model run on the original data set (what we would call the 'deterministic' analysis in other circumstances). The bootstrap allowed estimation of the variability of the incremental cost-effectiveness ratio (ICER) to construct cost-effectiveness acceptability curves. As a by-product of the bootstrap we used the bootstrap estimated for the regression coefficients to estimate their variability and distribution, although we report the exact estimates. This is because the inverse weight procedure works by subdividing costs over periods, therefore both the exact coefficients and the bootstrapped coefficients are derived from three separate regressions and the derivation of confidence intervals analytically is unyielding.

Predictors of costs and utility and subgroup analysis

The analysis of predictors was carried out using ANOVA controlled for treatment allocation. Although normally the stratification of cost-effectiveness results should be driven by predictors of costs and quality of life, the extent to which predictors drive cost-effectiveness is generally unrelated to statistical significance. Therefore, to test the robustness of potential recommendations in favour of CBA, we conducted the cost–utility analysis separately for males and females, for individuals older than 60 or younger then 60 years and for individuals with RMQ scores of < 4 or ≥ 4. The latter analysis was also conducted to ensure the comparability of our results to results of other studies of LBP treatments. These findings are intended to assess the generalisability of the cost-effectiveness analysis.

Sensitivity analysis

As there were cost outliers, we conducted a sensitivity analysis excluding the cases with the highest costs (above the 90th percentile of the distribution).

To assess the impact of inverse probability weights in the cost-effectiveness analysis we also conducted a sensitivity analysis including baseline adjustment and adjustment for predictors in the regression used to estimate the incremental costs and QALYs but not inverse weighting.

Results

Cases included in the economic evaluation

The proportion of returned questionnaires valid for the economic evaluation at 3, 6 and 12 months of follow-up was between 70% and 77% (*Figure 16*).

The cost–utility analysis was conducted using the cases with complete follow-up at least for 3 months, $n = 528$. This was the majority of cases in the trial (75%). Individuals who completed questionnaires at 6 or 12 months but not at 3 months were excluded from the cost-effectiveness analysis.

For presentation purposes only, the descriptive analysis of mean resource use, costs and quality of life scores over a 1-year period was conducted on cases with complete follow-up at 12 months, 70% of the participants in the trial ($n = 490$).

There was no difference in length of follow-up between the AM+CBA and the AM groups for cases included in the economic evaluation. Mean follow-up for cases included was 360 days (SD 62) in the AM group and 365 days (SD 52) in the AM+CBA group. Cases excluded had shorter follow-up: 85 days (SD 124) and 68 days (SD 88) in the AM and AM+CBA groups respectively.

Baseline characteristics of sample included and not included in the economic evaluation

The majority of the sample included in the economic evaluation was female (59% in both AM and AM+CBA), with equal age in the two groups (55 years on average), equal duration of LBP at recruitment (13 years) and equal proportion of individuals with RMQ scores ≥ 4 (84% in the AM group and 83% in the AM+CBA group). RMQ scores were significantly higher in women, with 88% of females having an RMQ score ≥ 4, compared with 77% in men ($p = 0.001$).

The cases included in the economic analyses differed in some respects from the cases excluded (*Table 39*). In both groups, cases excluded were younger than cases included. There were also differences in the mean duration of LBT between cases included and excluded in the AM+CBA group, with lower duration of back pain in cases excluded from the economic evaluation. There were no differences in the severity of LBP between cases included and excluded (RMQ score ≥ 4: 84% in both groups). Mean utility score at baseline was with lower utility at entry for those excluded.
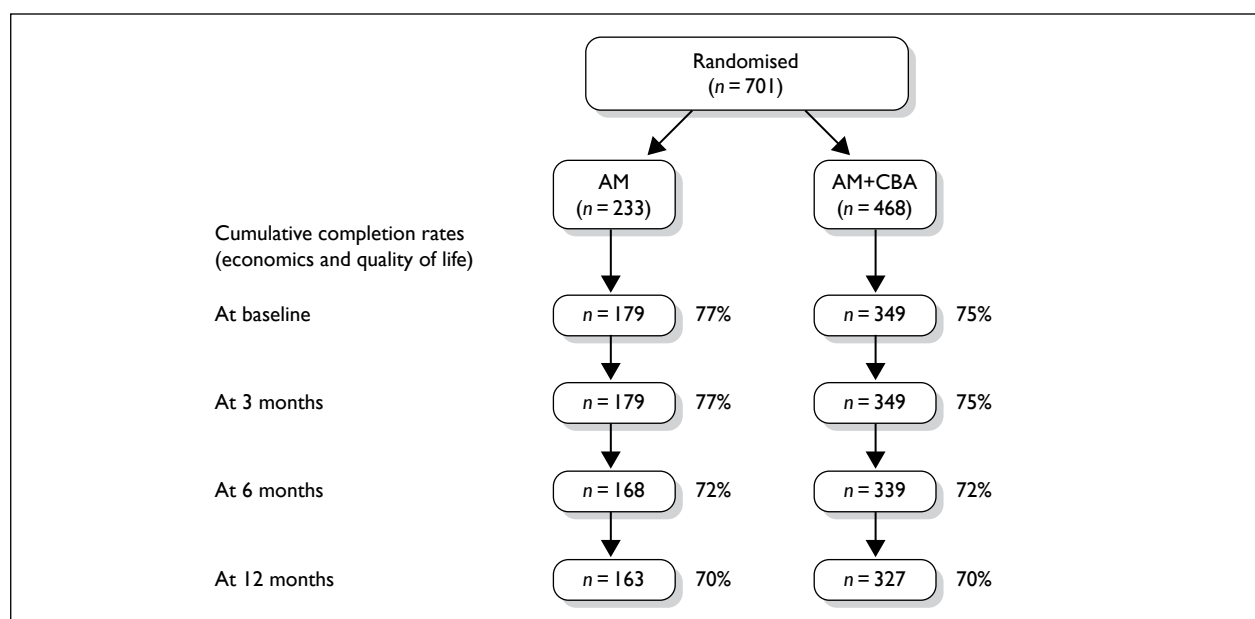

FIGURE 16 *Flow chart of loss to follow-up – economic data.*

Utility scores

There were some differences in mean baseline utility score between AM (0.606) and the AM+CBA arm of the trial (0.574), although these differences were not statistically significant (data shown in *Table 40*). At baseline women expressed worse utility (0.569) than men (0.607), although differences were not statistically significant ($p = 0.11$). As would be expected, baseline utility differed according to baseline severity. Participants with RMQ scores ≥ 4 or more had a mean baseline utility of 0.552 whereas those with RMQ scores < 4 had a baseline utility of 0.750 (mean difference 0.198; $p < 0.001$).

Figure 17 shows the mean utility scores for AM+CBA at baseline and follow-up time points. Utility scores improved during follow-up for the AM+CBA group, with changes evident at 3 months and sustained to 12 months. By the end of follow-up, the mean utility scores had risen by 0.066,

TABLE 39 *Baseline characteristics of cases included or excluded from economic evaluation*

Characteristics at baseline	Individuals included (mean, standard error)		Individuals excluded (mean, standard error)		
	AM (*N*=179)	AM+CBA (*N*=349)	AM (*N*=54)	AM+CBA (*N*=119)	*p*-value
Age (years)	54 (1.1)	55 (0.8)	50 (2.2)	50 (1.4)	0.001
% female	59% (3.6%)	59% (2.6%)	63% (6.6%)	57% (4.6%)	0.910
Duration of LBP (years)	13 (0.9)	13 (0.9)	12 (2.0)	9 (1.4)	0.030
Utility scores	0.606 (0.019)	0.574 (0.014)	0.481 (0.045)	0.525 (0.026)	0.002

TABLE 40 *Mean utility scores at baseline, 3, 6 and 12 months*

	AM[a]		AM+CBA[a]		
	Mean	SE	Mean	SE	Mean difference
Baseline (*n*=528)	0.606	0.019	0.574	0.014	−0.032
3 months (*n*=528)	0.567	0.022	0.628	0.014	0.061
6 months (*n*=527)	0.593	0.021	0.630	0.016	0.037
12 months (*n*=490)	0.592	0.023	0.640	0.016	0.048

SE, standard error.
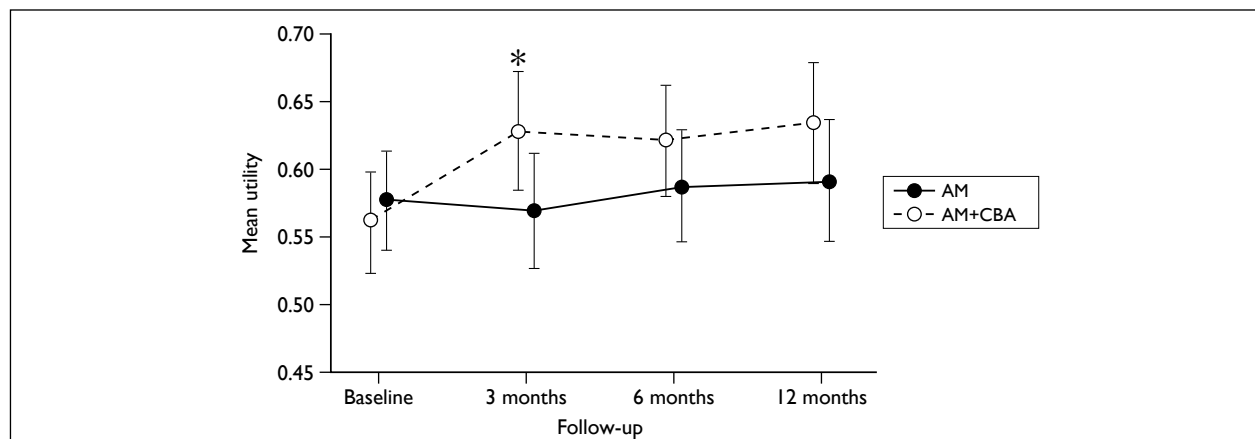a For numbers of participants in sample, see *Figure 16*.

FIGURE 17 *Mean utility scores at baseline, 3, 6 and 12 months. Vertical bars show 95% confidence intervals; data points are offset to improve visibility. *Statistically significant difference between AM and AM+CBA, p = 0.001.*

whereas in the AM group mean utility dropped initially at 3 months but improved in the follow-up, and remained unchanged over the 12 months, with a drop of −0.014 at 12 months in comparison with baseline.

Quality-adjusted life-years

We calculated the QALYs as the weighted mean of utility weights between two measurements and time spent in the study. *Figure 18* gives the cumulative QALYs over 3, 6 and 12 months. These are the total QALYs from baseline up to each time point. AM+CBA accumulated 0.662 mean QALYs and AM accumulated 0.624 mean QALYs over the 12-month follow-up, with an unadjusted difference of 0.038 QALYs at 12 months (*Figure 18*). These are crude estimates and are the mean of the area under the curve, obtained from the crude QALY scores multiplied by the length of follow-up. These estimates are illustrated here only for reference because they are not the final estimates of incremental QALYs based on the regression approach used to estimate the cost-effectiveness of CBA.

Incremental quality-adjusted life-years

The adjusted estimate of the incremental QALYs used in the cost-effectiveness analysis was obtained by fitting an ordinary least squares regression to the cumulative QALYs and adjusting for utility scores at baseline and for sex, and weighted by the inverse probability of follow-up. This section details

the results of the regression model adjusted for the predictors for QALYs, first without and then including the inverse probability weighting.

The adjusted regression equation included a term for baseline utility scores and two dummy terms for female gender and treatment.

Regression coefficients were then estimated using the inverse probability weighting method described in *Tables 41* and *42*.

This regression was weighted by the inverse probability of follow-up. With this approach, the mean total QALY with AM was 0.603 and the incremental QALY associated with treatment with AM+CBA was +0.099.

NHS resource consumption

A large proportion of trial participants, 44%, had no contacts with primary-care services during the study, with the exception of the CBA programme. The most frequently used NHS services were GP and physiotherapy consultations (*Table 43*). GPs were consulted by 50% of the trial participants, with 17% of the trial participants consulting more than three times over the course of follow-up. Physiotherapy was used by 19% of participants. Two-thirds of trial participants who were seen by a GP were prescribed pharmacological agents. Fifty per cent of the sample received more than three prescriptions over the follow-up period. The use of diagnostics tests was limited, as was use of hospital care. There were 11 admissions overall: five in the
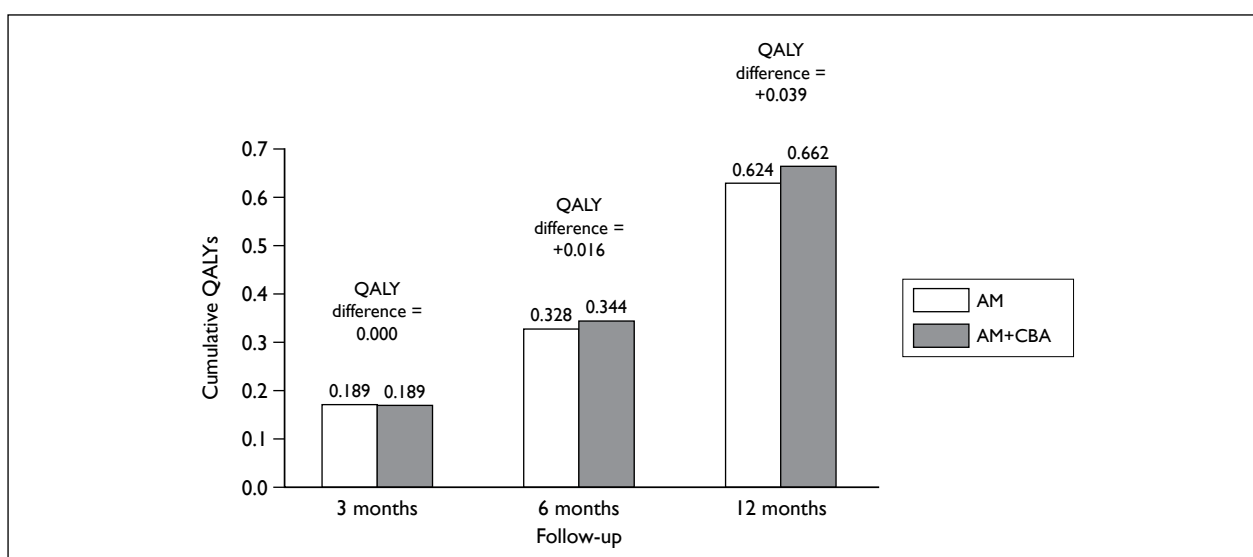

FIGURE 18 *Cumulative quality-adjusted life-years (QALYs) – unadjusted.*

TABLE 41 *Regression coefficients, QALYs, unadjusted by inverse probability weighting*

	Coefficient	SE	*p*>*t*	95% CI
Gender	−0.02	0.02	0.333	−0.05 to 0.02
Utility at baseline	0.66	0.03	0.000	0.60 to 0.72
Treatment (CBA)	0.06	0.02	0.000	0.03 to 0.10
Constant	0.21	0.03	0.000	0.16 to 0.26

SE, standard error.

TABLE 42 *Regression coefficients, QALYs, adjusted by inverse probability weighting*

	Coefficient	SE	*p*>*t*	95% CI
Gender	−0.04	0.02	0.047	−0.09 to 0.01
Utility at baseline	0.64	0.05	0.000	0.54 to 0.73
Treatment (CBA)	0.10	0.03	0.000	0.04 to 0.16
Constant	0.25	0.04	0.000	0.18 to 0.33

SE, standard error.

TABLE 43 *Mean resource consumption, NHS, by type*

Service	Item	AM (*N*=163)		AM+CBA (*N*=327)	
		Mean no.	SE	Mean no.	SE
Primary-care consultations	General practitioner	1.86	0.017	2.06	0.011
	Practice nurse	0.11	0.003	0.16	0.003
	Physiotherapist	0.90	0.016	0.91	0.008
Hospital care	A&E visits	0.02	0.001	0.03	0.001
	Outpatient	0.21	0.004	0.29	0.003
	Psychologist	0.09	0.004	0.10	0.002
	Admissions	0.03	0.000	0.02	0.000
Diagnostic tests	X-ray	0.28	0.005	0.17	0.002
	CT scan	0.01	0.001	0.03	0.001
	MRI scan	0.04	0.001	0.10	0.001
	Blood tests	0.50	0.007	0.63	0.007
Drug prescriptions	Pain killers	2.22	0.028	2.01	0.010
	Anti-inflammatory drugs	2.02	0.079	1.09	0.007
	Gels and creams	0.24	0.006	0.20	0.003
	Sleeping pills	0.48	0.018	0.28	0.004
	Antidepressants	0.37	0.007	0.40	0.004

A&E, Accident and Emergency department; CT, computerised tomography; MRI, magnetic resonance imaging; SE, standard error.

AM and six in the AM+CBA group. Six admissions were day cases, three in each group.

Overall there was no difference in the mean number of each type of service accessed in the two groups. None of the differences in NHS resource use was statistically significant.

TABLE 44 *Mean resource consumption, private health-care expenditure, by type*

Service	Item	AM (N=163)		AM+CBA (N=327)	
		Mean no.	SE	Mean no.	SE
Primary-care and community-care consultations	Physiotherapy	0.32	0.009	0.40	0.007
	Osteopath	0.53	0.014	0.28	0.006
	Chiropractor	0.45	0.017	0.83	0.020
	Psychologist	–	–	0.03	0.002
	Counselling	–	–	0.01	0.001
	Massage therapy	0.40	0.013	0.47	0.007
	Aromatherapy	–	–	0.09	0.003
	Acupuncture	0.09	0.005	0.22	0.004
Equipment	Exercise equipment	0.24	0.004	0.20	0.002
	Back support items	0.16	0.003	0.13	0.001
	Aids	0.03	0.001	0.02	0.001
	Small house furniture	0.07	0.002	0.05	0.001
	Beds and mattresses	0.22	0.003	0.24	0.002
	Other equipment	0.07	0.002	0.07	0.001
Hospital care	Outpatient	0.06	0.002	0.08	0.002
	Admissions	0.01	0.000	0.01	0.000
Diagnostic tests	X-ray	0.01	0.001	0.04	0.001
	CT scan	–	–	0.01	0.000
	MRI scan	0.01	0.001	0.02	0.000
	Blood tests	0.01	0.001	0.09	0.002
	Other tests	0.01	0.000	–	–
Drug purchases	Pain killers	4.99	0.065	3.65	0.024
	Anti-inflammatory drugs	2.94	0.049	1.77	0.012
	Gels and creams	0.88	0.012	0.72	0.006
	Other drugs	0.27	0.005	0.28	0.004

CT, computerised tomography; MRI, magnetic resonance imaging; SE, standard error.

Private resource consumption

There were no differences in the use of privately paid health-care services by treatment (*Table 44*). Overall, 23% of participants reported using private health-care services, and 16% of all participants accessed these services more than four times. A substantial proportion of participants (63%) opted to purchase medications over the counter. The number of over the counter purchases was greater than the number of NHS prescriptions, with over two-thirds of those individuals purchasing over the counter medications reporting purchasing four or more items.

Access to primary and hospital care was mainly through NHS services, whereas equipment, aids and adaptations were entirely paid for privately.

Purchases of equipment, aids and adaptations were reported by 36% of participants.

Costs
The within-trial cost of the AM+CBA programme

The AM+CBA programme was administered to 62 groups attended by 7.6 participants (minimum four, maximum 12) on average, and run by 19 therapists. Overall the programme delivered 372 sessions, with a total number of attendants equal to 161. For each group, there were 9 hours of contact time, and 8.4 hours on average for non-contact time, including 6.15 hours' support time (minimum 1, maximum 11.5 hours) and 2.25 hours' travel time (minimum 0, maximum 14 hours). Therefore the mean contact to non-

contact time ratio was 1:1.9. The mean salary cost of 1 contact hour (including non-contact time) was £33.65.

The mean total cost per group of the CBA programme was £826.08 (minimum £584.09, maximum £1294.35). This amount comprised £583.38 for salary costs, £84.21 for supervision costs, £39.50 for disposables and equipment, £17.30 for travel costs (40 miles on average per group) and £101.69 for training costs. Assessment cost was £53.45 including consumables and patient information material, and the cost of the AM advice at recruitment was £16.32 (2008 prices). The mean cost per patient for attending a cycle of CBA was £187 (SE 0.266).

Total health-care costs – NHS perspective

Total NHS costs were approximately £247 for the AM group and £421 for the CBA group. The difference was almost entirely attributable to the cost of CBA, £187, with the cost of NHS care other than attending the CBA programme being very similar for both groups. Mean health-care costs, excluding AM and CBA, were approximately £207 for the AM and £217 for the CBA group. The greatest cost was for consultations in primary care (GPs and physiotherapists) and for outpatient consultations and hospital admissions. In the trial, one patient initially allocated to AM received AM+CBA instead, at a cost of £179.

Table 45 presents mean programme costs for individuals with complete data at 12 months.

None of the cost differences were statistically significant with the exception of other consultations ($p = 0.045$), CBA costs and as a consequence of the latter, total costs.

TABLE 45 *Mean costs of care (£), NHS*

Service	Item	AM (*N*=163)		AM+CBA (*N*=327)	
		Mean cost (£)	95% CI (bootstrap)	Mean cost (£)	96% CI (bootstrap)
Primary-care consultations	General practitioner	63.20	49.85 to 78.95	69.96	57.27 to 84.74
	Practice nurse	0.99	0.44 to 1.66	1.46	0.74 to 2.45
	Physiotherapist	28.55	16.35 to 41.94	28.89	19.63 to 39.67
	Other consultations	2.43	0.00 to 6.107	0.00	0.00 to 0.00
Hospital care	A&E visits	4.62	0.00 to 11.55	5.76	1.15 to 11.79
	Outpatient	24.19	13.82 to 37.67	33.08	22.40 to 45.83
	Psychologist	5.75	0.41 to 13.15	6.67	2.37 to 12.76
	Admissions	22.44	7.19 to 41.42	11.18	3.58 to 20.57
Diagnostic tests	X-ray	8.73	5.32 to 12.72	5.42	3.54 to 7.65
	CT scan	1.60	0.00 to 4.01	3.99	1.59 to 6.78
	MRI scan	9.88	2.78 to 19.07	22.95	13.79 to 34.03
	Blood tests	2.15	1.46 to 3.03	2.15	1.45 to 3.12
	Other diagnostics	0.00	–	1.04	0.26 to 2.34
Drug prescriptions	Pain killers	10.27	7.43 to 13.71	9.30	7.80 to 11.16
	Anti-inflammatory drugs	16.77	6.46 to 36.61	9.03	7.15 to 11.27
	Gels and creams	1.41	0.65 to 2.43	1.19	0.68 to 1.82
	Sleeping pills	1.78	0.38 to 3.61	1.04	0.52 to 1.66
	Antidepressants	2.18	1.15 to 3.51	2.35	1.55 to 3.29
	Other drugs	0.86	0.23 to 1.83	1.50	0.22 to 3.47
All NHS other care (mean)		207.23	160.09 to 262.90	217.53	178.75 to 262.21
	AM	16.32	–	16.32	–
	CBA	1.10[a]	0.00 to 3.31	187.67	178.45 to 196.80
Overall mean NHS costs		224.65	176.99 to 275.66	421.52	378.11 to 468.70

A&E, Accident and Emergency department; CT, computerised tomography; MRI, magnetic resonance imaging.
a   One patient assigned to the AM group in fact received CBA sessions.

From the descriptive analysis in the previous section, there is no apparent strong predictor of differences in accrual of total costs and QALYs by group with the exception of RMQ scores. There were no differences in the mean cost of the CBA programme by age, sex, severity or duration of low back pain.

Total cost of NHS care was predicted by the RMQ score and, to a lesser extent, by sex. An RMQ score of ≥ 4 was associated with a statistically significant increase in mean expenditure of £185.42. This difference was attributable to NHS care other than the CBA programme. Individuals with higher scores spent more in GP consultations (on average, + £54.37, $p = 0.000$), physiotherapy (+ £25.58, $p = 0.012$), hospitalisations (+ £31.49, $p = 0.005$), painkillers (+ £4.83, $p = 0.019$), antidepressants (+ £2.02, $p = 0.027$), and diagnostic tests such as MRI (+ £22.44, $p = 0.027$) and X-ray (+ £6.53, $p = 0.007$).

Other health-care costs tended to be larger for women than for men in both treatment groups, although not statistically significantly so. The cost difference by sex was £64.70 ($p = 0.098$). Women tended to have higher costs for some NHS health-care items, albeit this difference was often more marked in the AM group. There were sex differences in the cost generated from drug therapies (sleeping pills, – £2.90, $p = 0.09$), use of X-rays (+ £4, $p = 0.021$) and hospital admissions (+ £20, $p = 0.024$). There were no sizeable differences in costs by age. The cost of care increased with age by a factor of £1.13 per year of age ($p = 0.4$).

The duration of LBP did not have an impact on the cost of care.

Total health-care costs, general health-care perspective

There was no significant difference in private costs between AM and AM+CBA although there was a trend toward higher private costs in the AM+CBA arm [by approximately + £130 on average (*Table 46*)]. The majority of private costs were generated by equipment and house adaptations, which cost £135 and £163 in total in the AM and AM+CBA group respectively, and consultations with medical and health-care professionals. The costs of these consultations were £65 for AM and £82 for AM+CBA. Overall, hospital admissions were low, but there were more admissions in the AM+CBA arm, and as these are expensive

resources, the costs associated with hospitalisation were also higher in the AM+CBA group.

Private health-care costs were higher in participants with a baseline score ≥ 4 on the RMQ (+ £197.68, $p = 0.09$). This difference, although not statistically significant, is likely to assume economic significance. There were no particular services that explained this increased expenditure, apart from travel costs (+ £13.90, $p = 0.01$). Private expenditure was weakly associated with sex, with higher average costs for women than men, + £90 ($p = 0.38$). The impact of age was larger for private costs compared with NHS costs. Expenditure on chiropractic increased with age (+ £1.18 per additional year of patient age; $p = 0.068$), acupuncture costs increased by a factor of + £0.35 ($p = 0.057$) and cost of aids increased by + £0.28 ($p = 0.037$). However, these effects were not economically significant given the extent of the total expenditure. The duration of LBP also had no impact on costs with only negligible differences in expenditure per year of LBP.

Overall, when broader health-care costs were considered, the total cost of AM+CBA was just under twice that of AM only. This difference arose from two sources – private expenditure and the additional costs of the AM+CBA programme (*Table 47*).

Incremental costs

The adjusted estimate of the incremental costs used in the cost-effectiveness analysis was obtained by fitting an ordinary least squares regression to the cumulative cost of care, using a regression model similar to that reported for QALYs (see Incremental QALYs).

The regression model included adjustments for utility scores at baseline and for sex, and was weighted by the inverse probability of follow-up. The results of the regression model adjusted for the predictors for costs, first without and then including the inverse probability weighting, are reported in *Tables 48* and *49*. The adjusted regression equation included a term for baseline utility scores and two dummy terms for female gender and treatment. These tables report the exact coefficient estimates, rather than expected value obtained from the bootstrap procedure.

Regression coefficients were then estimated using the inverse probability weighting method.

TABLE 46 *Mean costs (£) of private health care and related costs*

Service	Item	AM (*N*=163)		AM+CBA (*N*=327)	
		Mean cost (£)	95% CI (bootstrap)	Mean cost (£)	95% CI (bootstrap)
Primary-care consultations	Physiotherapy	12.19	4.45 to 21.56	15.42	7.13 to 25.93
	Osteopath	23.64	10.33 to 40.09	12.19	4.61 to 22.90
	Chiropractor	15.81	3.90 to 34.22	29.47	10.20 to 60.13
	Psychologist	0.00	–	2.37	0.00 to 7.10
	Counselling	0.00	–	0.61	0.00 to 1.83
	Massage therapy	10.04	3.04 to 18.33	11.76	6.26 to 18.16
	Aromatherapy	0.00	–	2.17	0.23 to 5.11
	Acupuncture	3.17	0.00 to 8.25	7.49	3.11 to 13.08
	All primary care (mean)	64.85		81.48	
Equipment	Equipment (TENS)	6.80	3.65 to 10.43	9.30	4.95 to 15.75
	Back support items	4.29	1.97 to 7.11	4.28	2.45 to 6.66
	Aids	1.12	0.06 to 2.72	3.30	0.21 to 7.47
	Small house furniture	23.17	4.41 to 48.70	28.95	12.09 to 48.55
	Beds and mattresses	96.60	60.22 to 137.49	113.64	75.90 to 158.33
	Other equipment	2.53	0.78 to 4.67	3.79	1.18 to 7.88
	All equipment (mean)	134.51		163.26	
Hospital care	Outpatient consultations	11.20	2.24 to 22.39	15.07	6.14 to 26.79
	Admissions, paid by patient	3.53	0.00 to 10.58	56.04	0.00 to 146.94
	Admissions, paid by health insurance	3.53	0.00 to 10.58	2.91	0.00 to 8.72
	All hospital care (mean)	18.26		74.02	
Diagnostic tests	X-ray	1.06	0.00 to 3.17	3.69	1.05 to 7.64
	CT scan	0.00	–	3.37	0.00 to 8.43
	MRI scan	7.34	0.00 to 18.34	9.14	1.83 to 18.28
	Blood tests	1.35	0.00 to 3.37	9.74	4.03 to 16.79
	Other	0.52	0.00 to 1.83	0.00	0.00 to 0.00
	All diagnostics (mean)	10.27		25.94	
Drug prescriptions	Painkillers	6.50	4.48 to 9.08	6.87	4.87 to 9.18
	Anti-inflammatory	4.99	3.09 to 7.18	9.22	4.90 to 14.84
	Topical gels and creams	4.01	2.32 to 6.05	7.91	2.65 to 15.59
	Other drugs	2.76	1.35 to 4.49	2.69	1.52 to 4.17
	Overall drugs (mean)	18.26		26.69	
Transport costs		24.50	19.53 to 30.05	29.17	23.70 to 35.14
Overall mean cost of private health care and related costs		270.65	205.87 to 350.63	400.55	292.16 to 541.27

CT, computerised tomography; MRI, magnetic resonance imaging; TENS, transcutaneous electrical nerve stimulation.

The inverse weighting had no impact on the regression as the coefficients were almost identical to the unadjusted analysis. With this approach, the mean total cost with AM was £224.94 and the incremental cost of treatment with AM+CBA was + £181.55.

The cost coefficients calculated from the health-care perspective are reported in *Table 49*.

TABLE 47 *Mean and total NHS and private health-care costs (£) – NHS and general health-care perspectives*

Service	AM		AM+CBA	
	Mean cost (£)	95% CI (bootstrap)	Mean cost (£)	95% CI (bootstrap)
Total cost initial intervention (AM, AM+CBA) (a)	17.42		203.99	
Total other NHS costs (b)	207.23	160.09 to 262.90	217.53	178.75 to 262.21
Total NHS costs (c = a + b)	224.65	176.99 to 275.66	421.52	378.11 to 468.70
Total cost of private health care (d)	270.65	205.87 to 350.63	400.55	292.16 to 541.27
Total costs, general health-care perspective (e = c + d)	493.68	405.08 to 590.37	821.71	695.11 to 964.48

TABLE 48 *Regression coefficients, QALYs, unadjusted by inverse probability weighting – NHS perspective*

	Coefficient (£)	SE (£)	p > t	95% CI (£)
Gender	32.72	33.98	0.000	113.69 to 247.22
Utility at baseline	−365.90	32.79	0.319	−31.70 to 97.14
Treatment (CBA)	180.46	60.77	0.000	−485.29 to −246.51
Constant	419.48	51.03	0.000	319.23 to 519.72
SE, standard error.				

TABLE 49 *Regression coefficients, QALYs, adjusted by inverse probability weighting – general health-care perspective*

	Coefficient (£)	SE (£)	p > t	95% CI (£)
Gender	56.88	102.41	0.002	113.85 to 516.23
Utility at baseline	−590.10	98.83	0.565	−137.26 to 251.03
Treatment (CBA)	315.03	183.15	0.001	−949.91 to −230.30
Constant	797.04	153.78	0.000	494.95 to 1099.14
SE, standard error.				

Cost-effectiveness

Separate models are presented for the NHS and the general health-care perspectives. Expected incremental costs and incremental QALYs are reported in *Tables 50* and *51*.

NHS perspective
From the NHS perspective, CBA was associated with an increase in health-care costs, + £178.06, and an improvement in QALYs, + 0.099. The ICUR was £1786, indicating that CBA is cost-effective at the currently accepted decision-maker's cost-effectiveness threshold.

The cost–utility was not sensitive to cost outliers. The ICUR obtained excluding the cases with costs higher than the 90th percentile was £1797, with an incremental cost of £162.44.

The cost–utility was sensitive to the inverse weighting method. Excluding inverse weighting, the model estimated + 0.061 incremental QALYs and + £177.43 incremental costs (from the bootstrap procedure), yielding an ICUR of £2909. This ICUR remains nevertheless well below the recognised decision-maker's cost-effectiveness threshold.

Uncertainty
To assess the variability of this estimate, we plotted the incremental costs and incremental QALYs on the cost-effectiveness plane (*Figure 19*) calculated for each of the 1000 bootstrap estimates upon

TABLE 50 *Incremental costs and QALYs, AM+CBA compared with AM – NHS perspective*

	AM	AM+CBA	Difference
Total NHS costs	£278.99	£457.05	+£178.06
Total QALYs	0.604	0.703	+0.099
ICUR			£1786
ICUR, incremental cost–utility ratio.			

TABLE 51 *Incremental costs and QALYs, AM+CBA compared with AM – NHS perspective, by subgroup*

	AM		AM+CBA		Incremental cost (£)	Incremental QALYs	ICER (£)
	Cost (£)	QALY	Cost (£)	QALY			
Males (n=214)	186.72	0.640	397.47	0.727	210.75	0.087	2422
Females (n=314)	251.34	0.583	413.56	0.694	162.22	0.111	1461
Older than 60 years (n=220)	218.53	0.563	454.15	0.690	235.62	0.127	1855
Younger than 60 years (n=308)	228.11	0.620	372.65	0.714	144.54	0.094	1538
Duration of pain ≤3 years (n=154)	259.35	0.681	383.74	0.749	124.39	0.068	1829
Duration of pain >3 years (n=374)	210.74	0.559	415.23	0.688	204.49	0.129	1585
RMQ score at baseline ≥ 4 (n=442)	236.76	0.583	427.20	0.708	190.44	0.125	1524
RMQ score at baseline <4 (n=86)	151.53	0.729	302.18	0.722	150.65	−0.007	AM+CBA dominated
ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; RMQ, Roland Morris Disability Questionnaire.							

which the estimation of the ICUR was made. *Figure 19* shows that the incremental cost and QALY of CBA are both always positive. Therefore CBA is never dominant (i.e. less costly and more effective).

To visually assess the range of variation for the ICER, we also plotted the cost-effectiveness thresholds at £500 and £4000. These are the dotted and dashed lines in *Figure 19*.

As the ICUR is the ratio of incremental costs and QALYs, the slope of the line joining any of the points with the origin is a graphical representation of the ICER. Therefore all points above the £500 line and below the £4000 line are points associated with an ICER of between £500 and £4000.

We summarised the variations of the ICUR in a cost-effectiveness acceptability curve (*Figure 20*).

This is the probability that CBA is cost-effective at the decision maker's cost-effectiveness threshold λ, the willingness to pay for one QALY, plotted here for the range £0–£35,000. The probability of CBA being cost-effective reaches 90% at about £3000 and remains at that level or higher above that threshold. At £30,000 CBA has an almost 100% probability of being considered cost-effective.

Subgroup analysis
We estimated the cost–utility of CBA by age and sex to test the robustness of recommendations within the general population with LBP. The descriptive analysis of costs and QALYs (see Costs) showed that costs and QALYs are not likely to vary by sex or age. However, back pain severity (RMQ scores) was shown to be associated with higher costs. The subgroup analysis reported here (*Table 51*) shows confirmatory evidence that age, sex and duration of back pain do not have a large impact
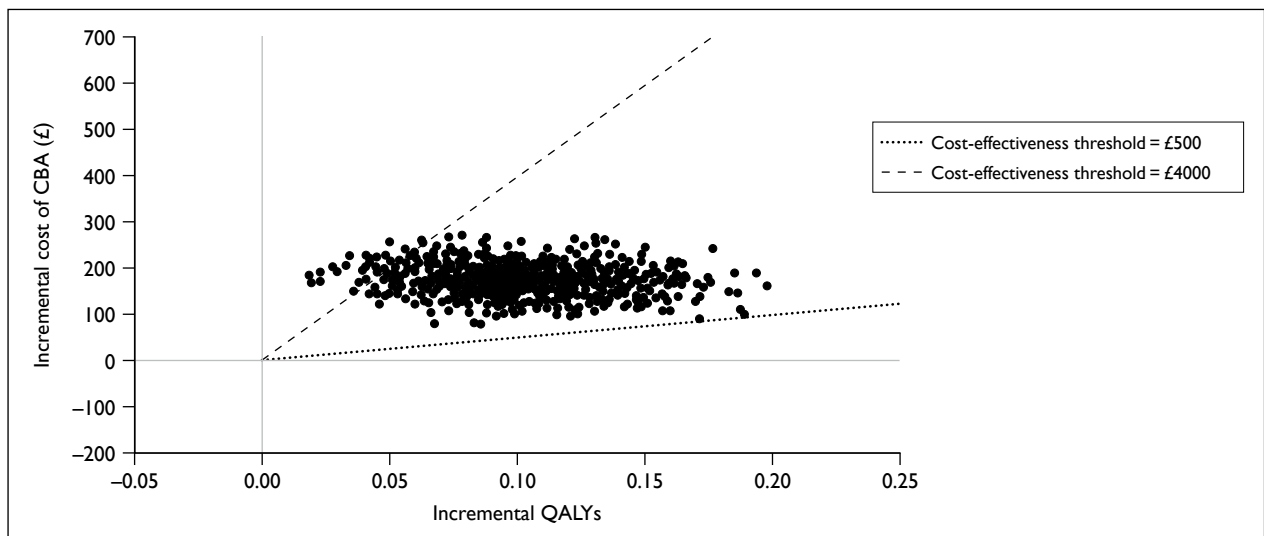
FIGURE 19 *Cost-effectiveness plane, incremental costs and incremental QALYs, AM+CBA versus AM – NHS perspective.*
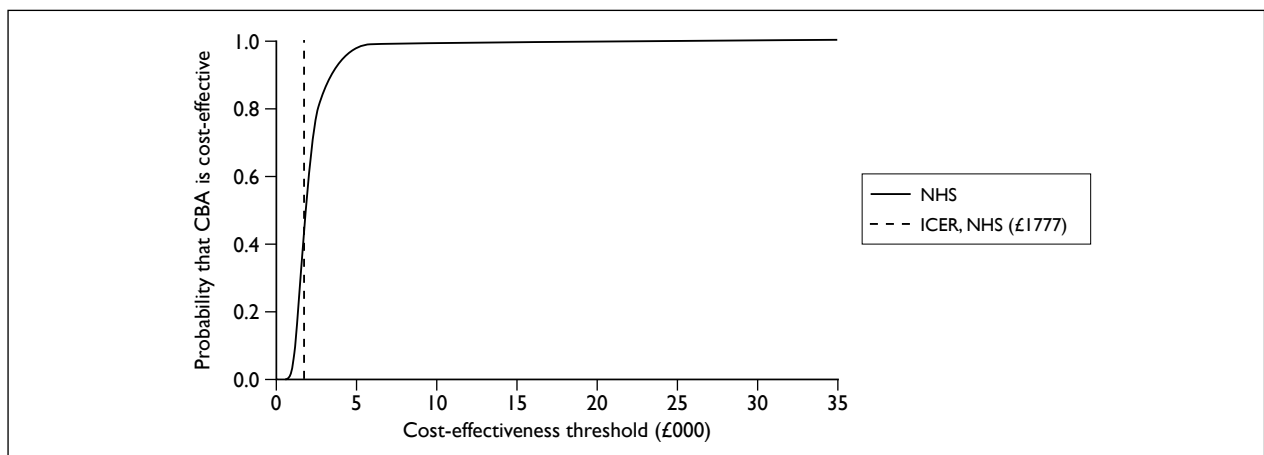

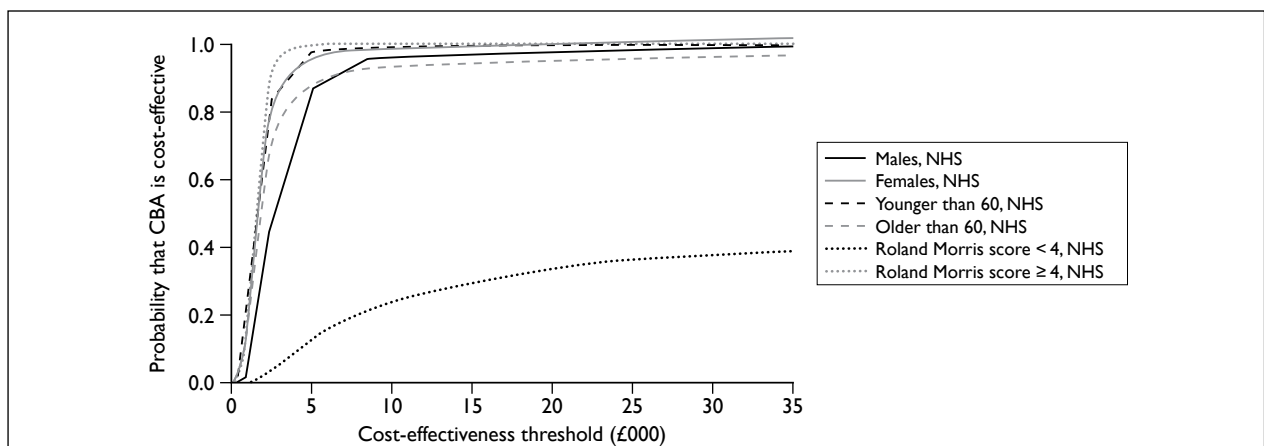**FIGURE 20** *Cost-effectiveness acceptability curves, AM+CBA versus AM – NHS perspective.*

FIGURE 21 *Cost-effectiveness acceptability curves, AM+CBA versus AM – NHS perspective, by subgroup.*

on the cost-effectiveness of CBA, which remains well below currently recognised cost-effectiveness thresholds. However, in the subgroup analysis for RMQ scores we found that CBA was associated with positive incremental costs whilst incremental QALYs were negative in the low-score range (RMQ < 4); therefore CBA was 'dominated' by AM in this group, suggesting the CBA may not be cost-effective in less severe back pain.

The cost-effectiveness acceptability curves by subgroup (*Figure 21*) show that the probability of CBA being cost-effective is between 80% and 99% for age and sex at cost-effectiveness thresholds of about £5000. Over this threshold, the probability of CBA being cost-effective remains constant. For individuals with less severe problems from their back pain (RMQ scores < 4) the probability that CBA is cost-effective is less than 40% over the customary range of decision-makers' willingness to pay.

General health-care perspective
From the health-care perspective, CBA was more expensive by approximately £314, when calculated from within-trial costs. With an improvement in

QALYs of + 0.099, the ICUR was £3093, with CBA still cost-effective at the currently accepted decision-makers' cost-effectiveness threshold (*Table 52*).

The cost–utility analysis was not sensitive to cost outliers. The ICUR computed using cases with costs lower than the 90th percentile was £2098, with an incremental cost of £189.62.

Uncertainty
The incremental costs and QALYs of CBA under the general health-care perspective remain positive, indicating no dominance for CBA (*Figure 22*).

The probability that the ICUR is below the accepted cost-effectiveness threshold is lower than that under the health-care perspective for low levels of willingness to pay.

At a threshold of £5000, the probability that CBA is cost-effective is 89% and this increases to 99% at about £10,000, after which it remains constant (*Figure 23*).

TABLE 52 *Incremental costs and QALYs, AM+CBA compared with AM – general health-care perspective*

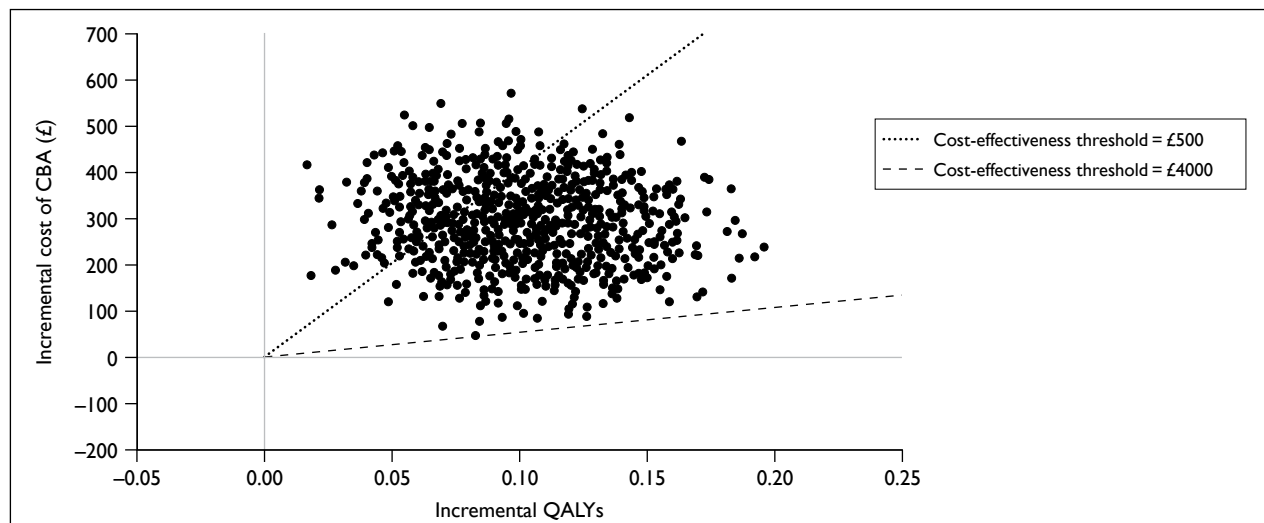|	AM	AM+CBA	Difference
Total health-care costs	£723.41	£1037.78	+£314.37
Total QALYs	0.604	0.703	+0.099
ICUR			£3093
ICUR, incremental cost–utility ratio; QALY, quality-adjusted life-year.			

FIGURE 22 *Cost-effectiveness plane, AM+CBA versus AM – general health-care perspective.*
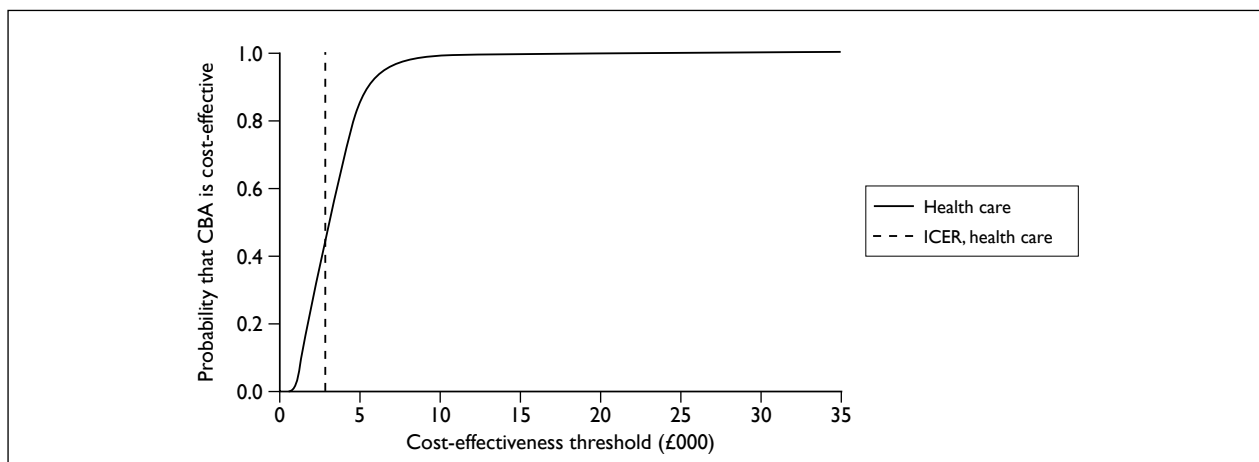
FIGURE 23 *Cost-effectiveness acceptability curves, AM+CBA versus AM – general health-care perspective.*

TABLE 53 *Incremental costs and QALYs, AM+CBA compared with AM – general health-care perspective, by subgroup.*

	AM		AM+CBA		Incremental cost (£)	Incremental QALYs	ICER (£)
	Cost (£)	QALY	Cost (£)	QALY			
Males (*n* = 214)	433.89	0.640	774.22	0.727	340.33	0.087	3912
Females (*n* = 314)	522.26	0.583	817.20	0.694	294.94	0.111	2657
Older than 60 years (*n* = 220)	469.61	0.563	938.46	0.690	468.85	0.127	3692
Younger than 60 years (*n* = 308)	499.96	0.620	705.33	0.714	205.37	0.094	2185
Duration of pain ≤ 3 years (*n* = 154)	424.64	0.681	653.55	0.749	228.91	0.068	3366
Duration of pain > 3 years (*n* = 374)	512.74	0.559	866.76	0.688	354.02	0.129	2744
RMQ score at baseline ≥ 4 (*n* = 442)	499.10	0.583	861.95	0.708	362.85	0.125	2903
RMQ score at baseline < 4 (*n* = 86)	405.15	0.729	506.48	0.722	101.34	−0.007	AM+CBA dominated

ICER, incremental cost-effectiveness ratio; QALY, quality-adjusted life-year; RMQ, Roland Morris Disability Questionnaire.
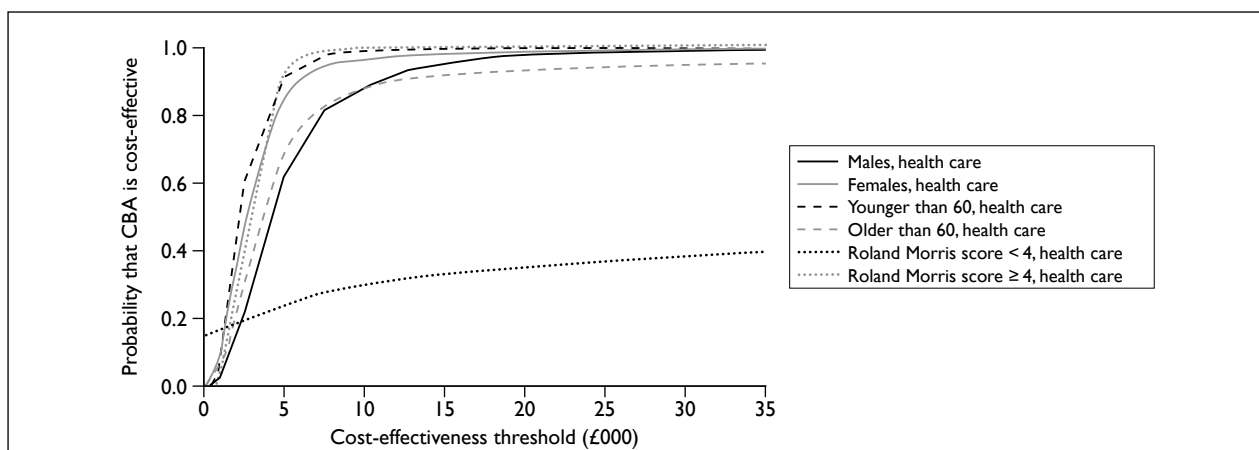

FIGURE 24 *Cost-effectiveness acceptability curves, AM+CBA versus AM – general health-care perspective, by subgroup.*

Subgroup analysis

As for the NHS perspective, the subgroup analysis (*Table 53*) shows that age, sex and duration of pain do not have a large impact on the cost-effectiveness of CBA, well below currently recognised cost-effectiveness thresholds; however for individuals with low back pain severity, CBA is dominated, i.e. more costly and less effective than current practice.

At the £10,000 cost-effectiveness threshold, CBA is cost-effective with a probability of at least 80% for all age and sex subgroups, and remains constant above that threshold (*Figure 24*). However, as for the NHS perspective, the probability that CBA is cost-effective in individuals with RMQ scores < 4 is low, below 40% at all accepted willingness-to-pay thresholds.

Chapter 7
Discussion

Aims and overview of findings

The discussion focuses on the interpretation of the findings, internal and external validity of the trial and associated analyses, comparison with other trial data, implications for clinical practice in the NHS and further research.

Low back pain is a common problem. Our aim was to optimise the design of a CBA package that could be delivered within the NHS, and to estimate the effectiveness, cost-effectiveness and acceptability of CBA in addition to best practice advice in primary care using a pragmatic trial design.

This was a definitive large-scale randomised controlled trial, which has demonstrated the long-term effectiveness and cost-effectiveness of CBA in treating subacute and chronic LBP. The clinical and cost-effectiveness outcomes are likely to make this intervention attractive to patients, clinicians and purchasers. Our short-term (3-month) clinical effects are similar to those found in high-quality studies of other therapies including manipulation, exercise and acupuncture.[144–146] Strikingly, and in contrast to many previous studies, the benefits we observed were maintained over the long term (12 months). The intervention is extremely cost-effective from an NHS and a societal perspective; cost per QALY is less than half that of competing interventions for LBP. Finally, since the intervention can be delivered by existing NHS staff following a brief, 2-day training session, the back skills training programme could be implemented into the NHS with relative ease.

External validity and generalisability of findings

The external validity of the trial is good. The trial sample was recruited from a range of general practices, including single-handed practices. The regions we recruited ranged from inner city to rural areas, and included areas of significant deprivation. The intervention was delivered by NHS staff and as such, the trial achieved the aim of testing the intervention in an everyday setting and in a sample that was representative of a range of NHS users and providers.

The average age of participants was somewhat older than seen in previous trials. This may be attributable to the ageing of the population. However, in contrast to many previous trials of LBP we did not specify an upper age limit to our entry criteria. Concerns about osteoporosis often predicate the exclusion of older people from trials of spinal manipulation.

The sample is representative of people who will accept the invitation to participate in CBA. This cannot be disentangled from the invitation to participate in the trial. People who were potentially eligible but declined were somewhat younger, but no different in other respects. The most common reason for declining was that people did not want to complete questionnaires during follow-up, and that despite reporting troublesome LBP, people did not consider it bad enough to engage in treatment. Neither of these factors has a significant impact on the interpretation of the findings. There is no suggestion of bias arising from selective loss to follow-up or withdrawal.

Overall, the trial sample was broadly representative of the ethnic mix of the UK.[147] Four per cent of people recruited were of Asian origin, although this ethnic group was predominantly recruited from the Birmingham cluster.

Critique of methods and threats to internal validity

We raised concerns with regard to the psychometric properties of the RMQ before starting the trial, and chose to adopt two primary outcome measures at the outset (the RMQ and the MVK scores). Difficulties relating to the ceiling effect of the RMQ have been observed in several studies, and more recent trials of back pain have chosen to define eligibility criteria of having an RMQ score of > 4 to avert some of these problems.[94,148,149] However, this approach reduces external validity – the RMQ is not used in clinical practice to triage or characterise LBP. Any estimates of the cost-

effectiveness using a higher RMQ score as an entry criterion should also incorporate an estimate of the costs of screening all people on the RMQ and the quality of life consequences of misclassification with the RMQ. We are not aware of any studies that do. We have presented an analysis of the subgrouping by RMQ score to enable closer comparison with other studies that have used the threshold approach. Interestingly, we report that the CBA intervention is unlikely to be cost-effective in people with low RMQ scores at baseline. This analysis should be treated as exploratory – the difference is almost entirely on differences in cost-expenditure and not associated with clinical outcomes.

Instead of using an RMQ cut-off point, we chose to include people who reported their back pain as at least moderately troublesome. The simplicity and clinical relevance of the troublesome question is widely accepted.[150,151] The BeST trial included people who have troublesome back pain but who scored < 4 points on the RMQ. Hence, we had greater potential to encounter analytical problems relating to ceiling effects in the RMQ. We provided strong justification for the between-group difference that we wished to detect at the trial protocol stage because we anticipated that the difference between groups would be smaller than in previous trials because of the score range within which we were operating. This point has been supported by Lauridsen *et al.*,[125] who observed that for individuals who scored < 6 on the RMQ, an MCID was estimated to be 2, but for those individuals with scores between 6 and 12, the MCID was in the order of 6. There have been a number of data-driven attempts to determine the MCID for the RMQ, although these should be interpreted with caution because many are based on samples that have used a threshold of > 4 RMQ points to determine eligibility.

The scaling properties of the RMQ also make calculation of numbers needed to treat difficult. Recommendations suggest that a threshold of 30% change should be used to determine a minimally important change on the measure,[124] but because the RMQ is a categorical scale, substantial errors are incurred in the calculation (because of rounding errors). We also calculated the numbers needed to treat for the MVK. There is no consensus on the MCID for the MVK, and we used guidance in the chronic pain literature that a 30% change in a 10-point numeric rating scale is clinically significant.[152–154] All estimates of numbers needed to treat have to be interpreted with caution.

We specified in the original protocol that we would undertake an interim analysis to compare the psychometric properties of the two primary outcome measures. Standard psychometric approaches did not, however, yield any useful data on which to base a choice – the main difficulty with the RMQ is the skewness in the distribution of raw scores, which severely limits what type of statistical methods can be applied to investigate between-group differences, particularly where these involve multilevel modelling. We opted to retain two primary outcomes and, reassuringly, the findings are consistent across both.

A potential criticism is that although we randomised individuals to the treatment options, we did not randomly allocate therapists to participants. It was impossible to achieve this logistically. Also, the method of allocation we studied is reflective of the intervention delivery mechanism if generalised into primary care.

How have we determined that this is a clinically important result?

Interpretation of any trial is complex. The first step is to rule out that the differences we observed between treatment groups were the result of chance. The study was powered to be definitive, and the statistical significance of the comparisons we drew across a range of measures supports rejecting the null hypothesis (there is no difference between the groups) at low levels of uncertainty. Steps were taken to minimise type I (false-positive) error by including prespecified analysis plans, setting the alpha to 0.01, and prespecification of primary outcome measures.

Determining clinical significance is more challenging. We specified a priori (protocol version 1) that we wished to detect a difference of 1.4 RMQ change score points between two treatment comparators (i.e. for the new treatment to be improved by about half as much again when compared with the control group). For the purposes of the sample size estimate, this approximated to a standardised difference of 0.35 (assuming data were normally distributed and an SD of 4.0) at 12 months. We modified the trial design before starting recruitment to an unbalanced randomisation, and chose to retain the sample size at the original 700 patients. One eventuality of this scenario was that we might have reduced power by a small amount, or that

we would only be able to detect larger effect sizes. Ultimately, with retention remaining higher than anticipated and little or no clustering in the data, there was minimal loss of power to detect the differences that we specified originally. We were able to demonstrate a statistically significant effect for our primary outcomes within the range we prespecified as the MCID. Participants who were randomised to CBA received on average, twice as much improvement in outcome across a range of measures. As a consequence, we are confident that we have demonstrated a difference that is both clinically important and statistically significant. The effect size is similar in magnitude to those found in the more robust trials used to inform the draft National Institute for Health and Clinical Excellence (NICE) guidance on LBP. Estimates of the standardised difference for the RMQ have to be interpreted with caution because the distribution of scores was significantly skewed. When we looked at scores integrated over the entire 12 months, the treatment differences were a little smaller. This was because differences in the early phase of the follow-up were smaller than those being observed at the later stages.

Comments on best practice advice

Recommendations to support best practice advice are based largely on expert opinion supported by epidemiological data highlighting the importance of physical activity and a limited amount of trial evidence.[36,155] A trial comparing sham and biomedical advice demonstrated a small short-lived effect of advice on subacute LBP.[38]

The quantitative and qualitative data collected in the best practice advice arm provide insight into the natural history of LBP when managed with a low-intensity intervention. The intervention we selected for the control arm was consistent with international LBP guidance for primary care, and allows comparison across a range of studies that have used a similar control. Back pain improved in the best practice arm. Just over one-quarter of the people who received best practice improved in their symptoms at 1 year (28%). This is broadly consistent with the natural history of back pain in people – approximately 27% will be pain-free or improved at 12 months.[156–158]

Comparisons between epidemiological data and the BeST trial data are difficult to draw – we targeted people who had subacute and chronic

LBP and experienced trouble with their backs and in whom the recovery rate might be expected to be lower than in the general population with back pain. Within our trial, *The Back Book* and brief session of advice had no lasting effect on beliefs about back pain or confidence to deal with the pain. This is disappointing; *The Back Book* was designed to target these beliefs and clearly fails to achieve any lasting change in mindset for the great majority of people. Reinforcing advice at regular intervals might improve the efficacy of the best practice, but evidence is needed to demonstrate this.

Comments on the cognitive behavioural approach tested in BeST

Cognitive behavioural interventions take a variety of guises, varying in formulation, intensity, depth and integration with other treatments. The CB method is based on accessing and modifying beliefs that are conceptualised at three levels – negative automatic thoughts, 'assumptions' or 'rules', and core beliefs. The latter are deeply held core beliefs. We included the negative automatic thoughts, but not the other belief levels, because their relationship to LBP is not known; and the management of complex beliefs requires specialist psychological expertise and was beyond the scope of group setting we proposed. Guided discovery is the key skill required to elicit beliefs, and is often accompanied by education in skills such as pacing and goal setting.

Just over half of people who were randomised to the CBA intervention reported improvements – this is substantially greater than would be expected from natural recovery or from the provision of AM alone. CBA is used to treat a range of conditions, and we tailored the approach to LBP by using CB principles to target health beliefs and behaviours associated with poor outcome in this condition. The targets were avoiding movement and activity through fear of pain and further damage, promoting steady build up in physical, leisure and occupational activity. The tailoring involved fusing knowledge on risk factors and effective treatments. It is generally accepted that increasing physical activity is an essential part of the pathway to recovery in LBP, and therefore, we ensured that therapists were trained in up to date knowledge about activity and back pain, as well as CBA. This was particularly important for therapists who were recruited from a psychological discipline. Given

the importance of physical activity, we stipulated that one of the goals set at the initial assessment should be related to physical activity or exercise. This was well received by participants and in the pilot evaluations we responded to participant comments that they would like more demonstration and checking of exercise and activity. That said, only very limited amounts of time were spent on direct supervision of exercise, and this was very much up to individual choice. We estimate that on average direct supervision of exercise occurred in less than 20% of participants, for less than 5% of the intervention time.

Other literature: comparisons of cognitive behavioural therapy with advice interventions in primary care

Cognitive behavioural approaches have been applied in a variety of ways in back pain – in isolation, alongside as opposed to integrated with other interventions, integrated with other treatments (notably exercise), and in formats in which the educational skills are used but scant attention is paid to eliciting beliefs. The recent draft NICE guidance on LBP has attempted to classify interventions, distinguishing between psychological interventions and combined psychological/physical interventions.[159,160] As our primary intention was to challenge beliefs that would effect a change in a range of behaviours, and over 95% of the intervention contact time was directed toward psychological goals, we would label our intervention as psychological.

During the lifespan of the BeST study, several variants of CB approaches have been tested in comparison with best practice advice. Two additional trials provide insight into the effectiveness of best practice advice as a comparator.

Johnson *et al.*[149] selected people if they had an RMQ > 5 and back pain of longer than 3 months' duration, but excluded those who had consulted for symptom management in the last 6 months. The interventions tested were a booklet and audio advice about back pain (based on CB principles) in comparison with the advice plus group CBA sessions. The estimates of between-group differences were smaller than we observed in BeST although they bordered on statistical

and clinical significance at some time points. The sample size was small, making interpretation very difficult. Many trials of LBP have chosen unrealistically large effect sizes, and have resulted in trials underpowered to detect smaller differences that are substantially important when the public-health impact of LBP is considered. In comparison with BeST, there are some differences in the intervention – the training and intervention was provided by physiotherapists, and the degree of psychological input and compliance with British Association for Counselling and Psychotherapy definitions of a CB intervention is unclear. The control advice intervention may have been of a greater intensity, sufficient to match the group treatments. The participants of the Johnson trial reported more chronic symptoms, although our subgroup data indicate that this should not be an important variant in the treatment response.

Jellema *et al.*[161] trained GPs to identify and intervene on psychosocial factors. The intervention was a 20-minute CB session, in addition to the original consultation. GPs were trained to use standardised questions to elicit information on fear avoidance, beliefs about the causes of LBP, worries, catastrophising and other behaviours. Treatment techniques included information giving, and goal setting, supplemented by *The Back Book*. A follow-up appointment was made if persistent LBP was anticipated. GPs were given 5 hours of training in the method. The control arm received the usual care of 'wait and see', graded uptake of activities and pain medication. There was no difference in the effectiveness of the strategies, and no change in either fear avoidance or coping. The intervention may have been too brief, and process evaluation suggests that the GPs found difficulty in identifying psychosocial risk factors. The intervention was also less intensive, and some may question whether it is a CB intervention at all.

Comparison of cognitive behavioural interventions with other physical interventions in primary care

The Hands on, Hands off trial of Hay *et al.*[148] describes a pain management programme for primary care in Staffordshire, UK, that was delivered on a one-to-one basis that included some of the types of education skills used in BeST. The overall duration of the programme was much

shorter, suggesting that belief elicitation may have been a smaller component of the programme. The intervention was no more effective than the comparator, which was physiotherapy including manipulation. This makes interpretation of this trial difficult. Both treatments may have been equally effective, or equally ineffective. Frost *et al.*'s Oxfordshire Low Back Pain Trial[37] reported that physiotherapy delivered within the NHS is no more effective than a best practice advisory session. Comparison with BeST results is also complicated because Hay *et al.*[148] recruited people with back pain of short duration, excluding those with pain for longer than 12 weeks. The one-to-one CB intervention tested in the Hands on, Hands off trial was more expensive than routine physiotherapy.[162]

Two studies from the Netherlands have tested interventions that are very intensive. Smeets *et al.*[47,162] recruiting people with chronic LBP reported that a highly intensive CB intervention was more effective than a waiting list control, but of similar effectiveness to an intensive exercise training protocol. An average of 22 group CB therapy sessions were delivered per participant. Van de Roer *et al.*[163] drew a comparison between physiotherapy and an intensive cognitive group programme (up to 30 sessions for the group-based intervention, and an average of nine sessions of physiotherapy). There was no difference in cost-effectiveness between the two approaches (clinical outcomes have not been reported to date).

Critchley *et al.*[86] investigated the effectiveness of a pain management programme that was predominantly supervised exercise, and additional sessions on goal setting and positive coping strategies. There is no mention of eliciting and challenging beliefs. There were no differences between individual sessions of physiotherapy, pain management groups, or spine stabilisation exercises, with all groups demonstrating improvement. Again it is difficult to draw strong comparisons with the BeST trial or conclusions on effectiveness, as there was no usual care or best practice arm.

Comparison of other physical treatments with advice only in primary care

Our short-term (3-month) clinical effects are similar to those found in high-quality studies of other therapies including manipulation exercise

and acupuncture.[86] Strikingly, and in contrast to many previous studies, the benefits we observed were maintained over the long term (12 months).

The UK BEAM trial compared exercise and manipulation (alone and in combination) with best practice advice.[94] They found that a spinal manipulation package produced a small to moderate benefit at 3 months and by a smaller but still statistically significant margin at 1 year, that exercise produced a small benefit at 3 months but not at 1 year, and that manipulation followed by exercise produced a small to moderate benefit at 3 months and a smaller benefit at 1 year.

Unlike acupuncture, CBA had a broad range of effects. In a well-conducted definitive trial, acupuncture reduced pain, but did not impact on disability outcomes.[143] The CBA tested in BeST impacted on a range of outcomes including disability, pain, health-related quality of life and general health status. We detected a larger effect in global health measures and health-related quality of life than in other trials of physical interventions, suggesting that the CBA has effects outside the spine and so has potential for greater overall benefit than those more localised treatments.

Cost-effectiveness

Despite a reasonable number of reports on the cost of behavioural interventions in the literature, relatively few studies are of sufficient quality to guide policy decisions. In the absence of well-conducted comprehensive decision analyses, studies of cost–utility, conducted alongside randomised controlled trials provide the best evidence.[86,94,164–167] When drawing comparisons with trials that have tested interventions against a best practice advice or usual care arm, the BeST intervention is extremely cost-effective from both an NHS and a patient perspective; cost per QALY is less than half that of competing interventions for LBP (*Table 54*).

The Oxfordshire Low Back Pain trial concluded that best practice advice was more cost-effective than routine physiotherapy.[168] There is little difference in cost between CB and alternative intensive physical interventions. Critchley *et al.*[86] and Johnson *et al.*[149] have both demonstrated that cost-effectiveness can be attained using group sessions even when the additional clinical benefits of the intervention are small or negligible.

TABLE 54 *Cost-effectiveness data from trials testing interventions for back pain in primary care*

	Intervention	Comparator	Perspective, *N*, time frame	Cost/cost-effectiveness
Whitehurst 2007[165]	Brief pain management programme addressing psychosocial risk factors	Physiotherapy (mobilisation, manipulation and soft tissue treatment)	Generic health care; *N* = 299; TF = 1 year	Brief pain management (CB) not cost-effective; ICER = £2800 for physiotherapy
Jellema 2007[167]	Minimal intervention aimed at psychosocial factors	Usual care	NHS; MIS = 116; UC = 134; TF = 1 year	Inconclusive
van der Roer 2008[165]	Intensive group training – physiotherapy + behavioural component	Guideline individual physiotherapy sessions	Societal; *N* = 102; TF = 1 year	ICER = €500 to €5150 depending on assumptions
Rivero-Arias 2006[166]	Active management advice	Physiotherapy	NHS; *N* = 286; TF = 1 year	ICER = £3010
BEAM 2004[94]	Exercise Spinal manipulation Manipulation and exercise	Active management and *The Back Book*	Health care; *N* = 1287; TF = 1 year	AM + exercise dominated; AM + manipulation + exercise £3800 BC + manipulation £8700
Ratcliffe 2006[168]	Acupuncture	Usual care	Societal; *N* = 241; TF = 2 years	ICER = £4241

BC, best care; ICER, incremental cost-effectiveness ratio; MIS, minimal intervention aimed at psychosocial factors; TF, time frame; UC, usual care.

Addressing concerns about training and delivery

We trained NHS therapists and nurses from a variety of professional backgrounds, although NHS physiotherapists were the predominant professional group delivering the intervention. Despite concerns from the practice community that the training course was short (2 days), and that non-psychological disciplines should not or cannot be taught CB skills, the evidence generated by the trial demonstrates improvements in the psychological traits we were targeting. The professional training for many allied health and nursing professions includes motivation, self-management, health education and provision of group treatments. There was no indication that the professional background of therapists was a determinant of therapist effects. We provided mentoring support to all professionals, although many therapists were largely self-sufficient in the treatment delivery. Future implementation will need to address not only training but provision of mentoring, which could be achieved by specialist therapists or in collaboration with local psychological services. The pattern of outcome across the intermediary outcomes and the disease-specific outcomes is consistent with, although not confirmatory of, the treatment mechanism being mediated by change

in beliefs about the benefits of physical activity, and in confidence to participate in activities despite pain. An additional concern is whether the health-service contacts that were generated by the research project (the two research nurse appointments) would influence the effectiveness of the CBA. As both arms received the two assessments and the advice session (which was included in the second assessment) there is no basis to believe that the findings are not attributable to CBA.

Other things we have learnt about cognitive behavioural approach interventions

We gained some insight into how CBA might work in LBP. Changes in intermediary outcomes were consistent with a hypothesis that CBA reduces fear avoidance and improves pain self-efficacy. However, within the quantitative data set, no solid inference can be made about a mechanism of effect as there is no information on the temporal sequence of changes. The qualitative data set provides further data to support the hypothesis that recognition of negative thoughts and behaviours is a key to enabling recovery, and the importance of re-establishing routine physical, leisure and occupational activity.

The relationship with the therapist was raised by a number of individuals who were interviewed. Most comments were in a positive light, although on occasion, this was not the case. However, within the quantitative analysis, we found very little evidence that variation in treatment outcome was influenced by individual therapists. There are a number of potential explanations. Although there was quite a large number of therapists involved in the delivery of the intervention, in practice a core of therapists delivered to a large number of groups. As a consequence the variance structure was complex and modelling required extending current methods and in some instances failed to achieve a good fit. Group and therapist effects were to a degree confounded. We had structured the intervention purposefully so that the same therapist would be responsible for delivering all assessments and sessions within each cycle of CBA. Additionally, each group was discrete. Only on rare occasions did a participant swap between group/therapist. As a consequence, the effects of participant, group and therapist are challenging to differentiate.

We measured the competence of most therapists in delivering the intervention by audio-taping sessions and assessing competence against prespecified and internationally agreed criteria. Although competence varied between therapists, therapist effects were still not influential. Possible explanations are the structured approach to the intervention in both the participant training manual and the format of the group sessions, which means that participants may be exposed to cognitive training aspects regardless of the ability of the therapists to use skills such as Socratic questioning.

Previous qualitative research has highlighted the potential importance of 'group' effects in determining outcome, and the therapeutic effect of both talking with people with a similar condition and drawing comparison with others with a similar diagnostic label.[169] Similar themes emerged from the qualitative analysis, but the quantitative analysis mitigates against group effects as being a major factor in explaining how the intervention works. We made no attempt to group participants of similar backgrounds together (for example men and women), meaning that the variability in participant profile was high in all groups.

We prespecified a per protocol analysis to explore dose dependency. We hypothesised that individuals would need to attend the assessment and three sessions to ensure the main messages of the intervention were embedded. Compliance with the intervention at this prespecified level was reasonable (65%), but effectiveness was not influenced by compliance in the way that we had measured it.

We ran a number of subgroup analyses to determine whether pain severity, duration or fear avoidance at baseline were predictors of treatment outcomes at 12 months. These analyses were all prespecified and based on stringent interpretation of interaction tests to minimise false-positive findings. Nevertheless, the findings should be treated as exploratory. The factors which emerged were fear avoidance at baseline and then impact was seen only in MVK (disability) scores – those people who showed least fear avoidance at baseline had larger responses to the intervention. Also, pain severity at baseline had a weak association with treatment outcomes measured by the RMQ at 12 months – the treatment effect measured by the RMQ may be larger in those with moderate pain at baseline. Both observations may be useful for generating hypotheses for future research, but should be used with caution in informing health technology appraisal.

Within one cluster there were several general practices that had a high proportion of people from minority ethnic groups. These practices were also based in areas of high socioeconomic deprivation. Participants who were referred into groups from these practices had a lower rate of attendance on the programme (50% compliance compared with 67% in the trial overall). The therapists involved in facilitating these programmes reported that although there was enthusiasm to attend, participants were often unable to attend because of difficult work and social situations, such as child-care cover. Even though these practices had high numbers of people from ethnic minorities, it became apparent that within the trial it was not practical to be able to fill a group with participants who spoke the same language and to be able to find and train enough therapists to cover languages that might be used. We considered using a translator but felt that the discursive nature of the group intervention would have been compromised as the therapist would not have been easily able to facilitate discussion between group participants. As a result of the low number of health professionals from ethnic minority backgrounds, these issues are likely to be present even outside a trial environment and a flexible approach will be needed to deliver a CBA in some populations. It may be that alternative

programmes requiring fewer visits overall may overcome difficulties in attendance. In addition, to meet cultural or language needs, the intervention may need to be run on a one-to-one basis or via different mediums such as more comprehensive written materials, video format or the use of internet interventions that seek to teach the same self-management skills.

Future research questions

Future research on implementation of the CBA programme will help to ensure that the benefits we found can be translated into a reduction in back pain disability. Further work is needed to assess the added value of adding the group activity to the assessment session alone. This may be more acceptable and may have similar effectiveness and be more cost-effective than our current CBA package. Our CBA approach was developed specifically for LBP; however, this is rarely seen in isolation. Further work is needed to test this approach for more widespread musculoskeletal pain. We hypothesise that the BeST approach could be adapted to treat a range of musculoskeletal conditions. Our sample included many people who experience pain in other areas of the body, not just the back. The substantial impact on health-related quality of life might be explained by participants using the skills learnt to manage pain for other regions of the body.

Chapter 8

Conclusion

The BeST trial confirms the findings of efficacy trials testing very similar interventions:[19,42,45,170–173] that a tailored group CBA is effective in the management of LBP in primary care. The results extend the knowledge base to demonstrate sustained clinical effects over a 1-year period in a broad range of outcomes, and that a range of health professionals with appropriate training can deliver the intervention. Our short-term (3-month) clinical effects are similar to those found in high-quality studies of other therapies, including manipulation and exercise.[94] Strikingly, and in contrast with many previous studies, the benefits we observed were maintained over the long term (12 months). The intervention is extremely cost-effective from an NHS and a societal perspective; cost per QALY is less than half that of competing interventions for LBP. Finally, since the intervention can be delivered by existing NHS staff following a brief, 2-day training session, the back skills training programme could be implemented into the NHS with relative ease. Our analyses were completed after the draft NICE guidelines on LBP were published. We anticipate that any future revision of the guidelines would include this intervention. There now appears to be a strong case to roll the training programme out to NHS practitioners for implementation within the current structures and pathways used to manage back pain.

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Appendix 1

Participant initial
approach questionnaire

BEST/040

In confidence

Potential participant study ID number

Back Skills Training (BeST) Trial

Participant initial approach questionnaire

Back Skills Training (BeST) Trial

Back Skills Training (BeST) Trial

Please complete the following information. It will tell us whether you may be able to take part in this study of treatments for back pain.

1. On what date are you completing this questionnaire?

|__|__| |__|__| |__|__|
day   month   year

2. What is your date of birth? |__|__| |__|__| |__|__|
day   month   year

3. What is your sex?

Male   ☐ 1
Female   ☐ 2

4. Have you had any low back pain or symptoms in the past 6 weeks?

Yes   ☐ 2   *(Please tick one)*
No   ☐ 1   *If No, please go to question 10*

5. How often have you had back problems during the past 6 weeks?

Everyday   ☐ 1   *(Please tick one)*
Between everyday and three quarters of the days   ☐ 2
Between three quarters of the days and half of the days   ☐ 3
Between half of the days and a quarter of the days   ☐ 4
Rarely   ☐ 5

6. How troublesome has your back been during the past 6 weeks?

Not at all troublesome   ☐ 1   *(Please tick one)*
Slightly troublesome   ☐ 2
Moderately troublesome   ☐ 3
Very troublesome   ☐ 4
Extremely troublesome   ☐ 5

7. Are you currently being treated for back pain at a hospital or elsewhere by a consultant, physiotherapist, chiropractor or osteopath?

Yes   ☐ 2   *(Please tick one)*
No   ☐ 1

8. Women only: Are you pregnant?

　　　　　　　Yes　　　　☐ 2
　　　　　　　No　　　　　☐ 1

The following questions are so that we can ensure we have asked a broad range of people to participate. They do not determine whether you will be eligible to participate.

9. What is your ethnic origin?　　　　　*(Please tick one)*

White

　　01 ☐ British

　　02 ☐ Irish

　　03 ☐ Any other White background, please
specify…………………………………

Mixed

　　04 ☐ White and Black Caribbean

　　05 ☐ White and Black African

　　06 ☐ White and Asian

　　07 ☐ Any other Mixed background, please
specify…………………………….…..

Asian or Asian British

　　08 ☐ Indian

　　09 ☐ Pakistani

　　10 ☐ Bangladeshi

　　11 ☐ Any other Asian background, please
specify…………………………………….

Black or Black British

　　12 ☐ Caribbean

　　13 ☐ African

　　14 ☐ Any other Black background, please
specify……………………………….…

Chinese or other ethnic group

　　15 ☐ Chinese

　　16 ☐ Any other background, please
specify…………………………………….……..

10. How old were you when you left full-time education (e.g. school, college or university)?

Age 16 or less ☐ 1   *(Please tick one)*

Age 17–19 ☐ 2

Age 20 or over ☐ 3

I am still in full-time education ☐ 4

11. Are you currently working (either self-employed or in paid employment)?

Yes ☐ 2   *(Please tick one)*

No ☐ 1

12. Are you interested in taking part in this study of back pain?

Yes ☐ 2   *(Please tick one)*

No ☐ 1

13. If you do **NOT** want to take part in this study, please can you tell us why?

(Please tick as many boxes as apply)

I do not want to get just ordinary treatment from my GP ☐ 1

I do not want to attend the back skills course ☐ 2

Going for treatment will take up too much of my time ☐ 3

I do not want to fill in questionnaires ☐ 4

I do not want my treatment to be chosen at random ☐ 5

I do not want to participate in a group treatment ☐ 6

My back pain is not very bad at the moment ☐ 7

My back pain is too bad at the moment ☐ 8

Other (please specify)…………………………………………… ☐ 9

14. If you do NOT want us to contact you again about this study, please tick this box. ☐ 1

15. We would like to look at the records held at the surgery for some patients with back pain. This is so we can be sure that the people with back pain who take part in the study are similar to those who do not take part. If you are prepared to let us to examine your records, please tick this box

....……….. ☐ 1

16. If you are interested in taking part in the study, please give your telephone number/s, including the area code and the research nurse will contact you shortly.

Home: .(.............)....................................………………….

Work: .(.............)....................................………………….

Mobile: …………………………………………………………

E-mail: …………………………………………………………

Thank you for filling in the questionnaire. Please return it to the surgery in the envelope provided.

Appendix 2
First nurse assessment questionnaire

BEST/041

In confidence

Potential participant study ID number

Back **S**kills **T**raining **(BeST)** Trial

First nurse assessment form

Back Skills Training (BeST) Trial

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK

GPRF

MRC General Practice Research
Framework

A randomised study of treatments for back pain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

First, please check that the participant study number is correct.
Then ask the potential participant the following questions:

1. On what date are you completing this questionnaire?	|__|__| |__|__| |__|__| day month year
2. What is your date of birth?	|__|__| |__|__| |__|__| day month year

To enter the trial potential participants must be 18 years or older when they attend the randomisation assessment.

First I would like to ask you some questions about your back pain and symptoms.

By back pain we mean pain in the back anywhere between the bottom of the chest and the top of the legs. This area includes the lower back and buttocks. (*Show patient laminated card*) This is the area marked on this card.

An attack of back pain can last for just a few hours, or may be for much longer. Some people may also experience stiffness, discomfort, anxiety, fatigue, moodiness, numbness or tingling due to the back pain.

	Yes	No
3. Are you still being troubled by your back pain?	$\square_2$	$\square_1$

4. How often have you had back pain or symptoms in the **past six weeks**?

Everyday	$\square_1$
Between everyday and three quarters of the days	$\square_2$
Between three quarters of the days and half of the days	$\square_3$
Between half of the days and a quarter of the days	$\square_4$
Rarely	$\square_5$

5. How troublesome has your back pain or symptoms been during the **past six weeks**?

Not at all troublesome	$\square_1$
Slightly troublesome	$\square_2$
Moderately troublesome	$\square_3$
Very troublesome	$\square_4$
Extremely troublesome	$\square_5$

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6. What back symptoms have you experienced over the **past six weeks**? [Tick all that apply]		
Pain in back or buttock	$\square_1$	
Pain down the leg	$\square_2$	
Stiffness or restricted motion	$\square_3$	
Anxiety or mood changes due to the back problems	$\square_4$	
Fatigue due to the back problems	$\square_5$	
Numbness or tingling	$\square_6$	
Other, please specify …………………………………………………	$\square_7$	

	Yes	**No**
7. Have you lost weight significantly over the last 6 months? By how much was this? [ ] Kg or St&lbs (please circle)	$\square_2$	$\square_1$
Were you trying to lose weight?	$\square_2$	$\square_1$
8. Are you having any problems passing water or moving your bowels? *By this we mean symptoms related to their back pain, not long standing problems such as constipation or stress incontinence.* *If **NO**, please go to question 9.*	$\square_2$	$\square_1$
*If **YES**, has the GP given consent to join the study?* *If GP is satisfied that there is not a serious cause for these symptoms, they can still join the study.*	$\square_2$	$\square_1$
If answered 'yes' to questions 7 and lost more than 10kg/1.7 stone or 'yes' to question 8, refer the patient to their GP for further screening.		
9. Are you currently being treated for back pain at a hospital or elsewhere by a hospital consultant, physiotherapist, chiropractor or osteopath or are you about to start treatment for your back pain?	$\square_2$	$\square_1$
10. If you joined this study and were allocated to the Back Skills Training would you be willing and able to attend for the training? *You will need to explain the likely times, place and frequencies of the training. They need to be able and willing to attend to be eligible for the trial.*	$\square_2$	$\square_1$
11. In the past have you ever attended a pain clinic or a pain management programme for your back pain or have you ever received prolonged psychological treatment for your back pain? *By pain clinic we do not mean an ordinary orthopaedic/neurosurgery/ rheumatology clinic but a clinic providing a multi-disciplinary approach to the management of back pain.*	$\square_2$	$\square_1$

	Yes	No
12. Do you understand the trial?	$\square_2$	$\square_1$
13. Are you interested in taking part in this study of back pain treatments?	$\square_2$	$\square_1$

If YES to Q13 and there are no responses in a shaded box:

*Ask the potential participant to book another appointment to see you **at least a week later** for a randomisation assessment. Explain that to enter the study when they see you next they must have had back pain or symptoms in the few days before they see you.*

If they do not think they will be eligible then they should cancel their appointment. They may book a fresh appointment if their pain becomes more persistent and they want to enter the study. (tell them when the study is due to end)

If NO to Q13:

Explain that this will not affect their care from the practice in any way. However, the researchers would like to know the reasons why they do not want to take part in the study.

14. Please can you tell why you do not want to take part in the study? [Tick all that apply]	
I do not want to get just treatment from my GP	$\square_1$
I do not want to attend the Back Skills Training course	$\square_2$
Going for treatment will take up too much of my time	$\square_3$
I do not want to fill in questionnaires	$\square_4$
I do not want my treatment to be chosen at random	$\square_5$
I do not want to participate in a group treatment	$\square_6$
My back pain is not very bad at the moment	$\square_7$
My back pain is too bad at the moment	$\square_8$
Other, please specify ……………………………………………………	$\square_9$

PTO

If the patient appears eligible ensure that the doctors' consent form is completed before their next appointment.
The randomisation assessment should be booked at least one week later, but no longer than four weeks from when the doctor signed the form.

If the only responses in shaded boxes are:

- *That their pain is present on less than half of the days (question 4)*
- *That their pain is not troublesome enough (question 5)*
- *That they are currently receiving treatment for their back pain or about to start treatment (question 9)*

they are not, at present, eligible for the trial. However, if their pain continues and/or they have finished the treatment they can contact you to book a randomisation appointment. Give them a temporary exclusion letter.

Comments

Appendix 3
Temporary exclusion letter

BEST/035

Study number: …………………………………

Date: ………………………………………….

Dear

Thank you for offering to take part in the study of back pain at the surgery. Your help is greatly appreciated. The information you have already given us will help us with our research.

At present you are not eligible for the study. The reason(s) why you are not eligible is/are:

☐ Your back pain is present for less than half of the days

☐ Your back pain is not at all troublesome or slightly troublesome

☐ You are currently receiving treatment or are about the start treatment for your back pain

☐ You are not interested to take part in this study or you are unable to attend the treatment sessions

If your back pain continues you may become suitable for the study. You may be eligible if:

- you have back pain on more than half of the days
- your back pain is at least moderately troublesome
- you have finished your back pain treatment

If this happens, we would be most grateful if you would contact us again. Please contact the surgery and ask for an appointment to be assessed for the *BeST back pain trial*.

Thank you once again

Yours sincerely

Back **S**kills **T**raining (**BeST**) Trial

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK

GPRF

MRC General Practice Research
Framework

A randomised study of treatments for back pain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

Appendix 4

Nurse randomisation assessment questionnaire

BEST/042

In confidence

Potential participant study ID number

Back Skills Training (**BeST**) Trial

Nurse randomisation assessment form

*Back Skills Training (**BeST**) Trial*

First, please check that the participant study number is correct. Then ask the potential participant all of the following questions.

Some of these questions are the same as those I asked you last time I saw you.
This is to make sure that you are still suitable for the study.

1. On what date are you completing this form?	|___|___| |___|___| |___|___| day month year
2. What is your date of birth?	|___|___| |___|___| |___|___| day month year

To enter the trial potential participants must be 18 years or older when they attend the randomisation assessment.

First I would like to ask you some questions about your back pain and symptoms.

By back pain we mean pain in the back anywhere between the bottom of the chest and the top of the legs. This area includes the lower back and buttocks. (*Show patient laminated card*) This is the area marked on this card.

An attack of back pain can last for just a few hours, or may be for much longer. Some people may also experience stiffness, discomfort, anxiety, fatigue, moodiness, numbness or tingling due to the back.

	Yes	No
3. Are you still being troubled by your back pain?	$\square_2$	$\square_1$

4. How often have you had back pain or symptoms in the last six weeks?		
Everyday	$\square_1$	
Between everyday and three quarters of the days	$\square_2$	
Between three quarters of the days and half of the days	$\square_3$	
Between half of the days and a quarter of the days	$\square_4$	
Rarely	$\square_5$	
5. How troublesome has your back pain or symptoms been during the past 6 weeks?		
Not at all troublesome	$\square_1$	
Slightly troublesome	$\square_2$	
Moderately troublesome	$\square_3$	
Very troublesome	$\square_4$	
Extremely troublesome	$\square_5$	

	Yes	No
6. Have you lost weight significantly over the last 6 months? By how much was this? [ ] Kg or St&lbs (please circle)	☐₂	☐₁
Were you trying to lose weight?	☐₂	☐₁
7. Are you having any problems passing water or moving your bowels? *By this we mean symptoms related to their back pain, not long standing problems such as constipation or stress incontinence.* If **NO**, please go to question 8.	☐₂	☐₁
If **YES**, *has the GP given consent to join the study?* *If GP is satisfied that there is not a serious cause for these symptoms, they can still join the study.*	☐₂	☐₁
If answered 'yes' to questions 6 and lost more than 10kg/1.7 stone or 'yes' to question 7, refer the patient to their GP for further screening.		
8. Are you currently being treated for back pain at a hospital or elsewhere by a consultant, physiotherapist, chiropractor or osteopath or are you about to start treatment for your back pain?	☐₂	☐₁
9. If you joined this trial and were randomised to the Back Skills Training would you be willing and able to attend for treatment? *You will need to explain the likely times, places and frequencies of the training. They need to be able and willing to attend to be eligible for the trial.*	☐₂	☐₁
10. In the past have you ever attended a specialised pain clinic or pain management programme for back pain or have you ever received prolonged psychological treatment for your back pain? *By pain clinic we do not mean an ordinary orthopaedic/neurosurgery/ rheumatology clinic but a clinic providing a multi-disciplinary approach to the management of back pain.*	☐₂	☐₁
11. **Women only:** Are you pregnant at the moment? If you join the trial and find out that you are pregnant during the first three months please let me know as soon as possible. *Although the back skills training is believed to be safe in early pregnancy we do not want pregnant women to have any trial treatments because a different treatment approach may be needed.*	☐₂	☐₁
12. Do you want to join this study of back pain treatments?	☐₂	☐₁
Check from your records for the following information		
13. Has the GP signed consent for the patient to enter the trial?	☐₂	☐₁

PTO

The patient is eligible if there are no responses to questions in a shaded box.

If the patient appears eligible but does not wish to take part, explain that this will not affect their care from the practice in any way. Please ask them their reasons and enter them in the comments section below.

If potential participants are temporarily not eligible for the trial give them a temporary exclusion letter and explain that if they become eligible and they wish to enter the trial then they can book a randomisation appointment with you.

If they are eligible for the trial:
    1. *ask them to sign the consent form*
    2. *ask them to complete the baseline questionnaire.*

After the baseline questionnaire has been completed:
- *complete the randomisation form*
- *randomise the patient*

Tell the participant their randomised treatment. If randomised to the Back Skills Training you need to send a notification letter to the therapist. Please advise the patient that the therapist will then contact the participants to arrange a time to start their treatments. Please ensure we have a contact number.

*Please give **all** randomised participants a copy of 'The Back Book'. Reinforce its message and tell them how important it is that they read it and follow its advice. Take time to answer their questions and refer them back to their GP if they still have any queries.*

Give the participant:
- *An address change form and reply paid envelope to notify address and telephone number changes.*

Comments

Appendix 5

Consent form

Study Number: _____

CONSENT FORM

A research trial into the effectiveness of different treatments for people experiencing low back pain.

Please initial box

1. I confirm that I have read and understand the Information sheet dated 2 February 2005 version 5 for the above study and have had the opportunity to ask questions.

2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.

3. I understand that my GP and other health professionals involved in my care will be informed of my participation in the study, and I consent to researchers where it is relevant to have access to my medical records.

4. I agree to take part in the above study.

5. I am happy to be invited for an interview during the follow up period of the trial. I understand that if I wish not be interviewed I can still participate in the trial.

Name of Patient   Date   Signature

_____   _____   _____

Name of Researcher   Date   Signature
taking consent

_____   _____   _____

Back Skills Training (BeST) Trial

The University of Warwick   THE UNIVERSITY OF   MRC General Practice Research
Centre for Primary Health Care   WARWICK   GPRF   Framework

A randomised study of physical treatments for back pain in primary care, funded by the NHS R&D HTA programme
(ISRCTN54717854)

Appendix 6
Baseline questionnaire

BEST/043

In confidence

Potential participant study ID number

Back **S**kills **T**raining **(BeST)** Trial

Baseline Questionnaire

Back Skills Training (BeST) Trial

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out if the treatments you get are helpful for your back problems.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car?	**Yes**	☒
	No	☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?' Where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy or unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

1	2	③	4	5

Please use a BLACK or BLUE pen. Please do not use a pencil.

<u>**Section 1**</u>
This section is to determine the level of back pain and employment status.
Please answer the following questions.

Firstly, please enter the date you are completing this questionnaire: |__|__| |__|__| |__|__|
                                                                          day   month   year

1. How long have you been troubled by back pain? This means when your back pain first ever started.

   _____weeks _____ months _____ years

2. Since your back pain first started which of the following statements describes your back pain? [Tick only one box]

My back pain comes and goes over time	☐	1
My back pain is fairly constant	☐	2
My back pain is getting worse	☐	3
My back pain is getting better	☐	4

3. Have you received any treatment for your back pain in the past 6 months?

   Yes ☐ 1

   No ☐ 2

   If Yes, please specify _____

4. Are you currently receiving any benefit payments?

	Yes	No		Yes	No
Statutory Sick Pay	☐ 1	☐ 2	Working Family Tax Credit	☐ 1	☐ 2
Incapacity Benefit	☐ 1	☐ 2	Council Tax Benefit	☐ 1	☐ 2
Disability living allowance	☐ 1	☐ 2	Housing Benefit	☐ 1	☐ 2
Disabled persons tax credit	☐ 1	☐ 2	Attendance allowance	☐ 1	☐ 2
Invalid Care Allowance	☐ 1	☐ 2 (includes if paid to someone who looks after you)			
Other	☐ 1	☐ 2 (please specify) _____			

5. Are you currently working? (If you are a full-time student but also work, please complete this section and also tick question 9)

        Yes, full time   ☐ 1

        Yes, part time   ☐ 2

        No   ☐ 3   *Please go to question 9*

6. Is this work: Paid   ☐ 1

                    Unpaid   ☐ 2

7. How many hours a week do you work?

        Less then 10   ☐ 1

        10-25   ☐ 2

        25-40   ☐ 3

        More than 40   ☐ 4

8. Which of the following categories do you think best describes your work?

        Unskilled manual   ☐ 1

        Skilled manual   ☐ 2

        Unskilled non-manual   ☐ 3

        Skilled non-manual   ☐ 4

        Professional   ☐ 5   Please describe: _____

        Other   ☐ 6   Please describe: _____

        Decline to answer   ☐ 7

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9. If you are **not** currently working which of the following applies to you?

Retired ☐ 1

At home and not looking for paid work ☐ 2
(eg looking after home, family or others)

Unable to work due to low back pain ☐ 3

Unable to work due to other illness ☐ 4

Unemployed and looking for work ☐ 5

In full time education ☐ 6

Other ☐ 7 Please describe: _____

_____

10. What factors are important to you when receiving treatment? [Tick all that apply]

	Yes	No
Getting rid of the pain and/or moving about better	☐ 1	☐ 2
Re-assurance that there is nothing serious wrong	☐ 1	☐ 2
Receiving trustworthy information	☐ 1	☐ 2
Having an opportunity to talk to a Dr, Nurse or therapists	☐ 1	☐ 2
Having an opportunity to talk to people with back pain	☐ 1	☐ 2
Someone taking an interest in me	☐ 1	☐ 2
Helping me to manage my back problem	☐ 1	☐ 2

Other: _____

_____

Which is the most important? : _____

_____

Section 2

This section is about your back pain <u>today</u>. When your back hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you today.

As you read the list, think of yourself <u>today</u>. When you read a sentence that describes you today, <u>place a cross in the box beside it</u>. If the sentence does not describe you, then leave the box blank and go on to the next one. Remember, only place a cross if you are sure that it describes you <u>today</u>.

1. I stay at home most of the time because of my back. .... ☐
2. I change positions frequently to try and get my back comfortable. .... ☐
3. I walk more slowly than usual because of my back. .... ☐
4. Because of my back, I am not doing any of the jobs that I usually do around the house. .... ☐
5. Because of my back, I use a handrail to get upstairs. .... ☐
6. Because of my back, I lie down to rest more often. .... ☐
7. Because of my back, I have to hold on to something to get out of an easy chair. .... ☐
8. Because of my back, I try to get other people to do things for me. .... ☐
9. I get dressed more slowly than usual because of my back. .... ☐
10. I only stand up for short periods of time because of my back. .... ☐
11. Because of my back, I try not to bend or kneel down. .... ☐
12. I find it difficult to get out of a chair because of my back. .... ☐
13. My back is painful almost all the time. .... ☐
14. I find it difficult to turn over in bed because of my back. .... ☐
15. My appetite is not very good because of my back pain. .... ☐
16. I have trouble putting on my socks (or stockings) because of the pain in my back. .... ☐
17. I only walk short distances because of my back pain. .... ☐
18. I sleep less well because of my back. .... ☐
19. Because of my back pain, I get dressed with help from someone else. .... ☐
20. I sit down for most of the day because of my back. .... ☐
21. I avoid heavy jobs around the house because of my back. .... ☐
22. Because of my back pain, I am more irritable and bad tempered with people than usual. ... ☐
23. Because of my back, I go upstairs more slowly than usual. .... ☐
24. I stay in bed most of the time because of my back. .... ☐
25. **None of the above**. .... ☐

Section 3

This section is about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

For the next six questions please <u>circle</u> the number which represents how your back pain has made you feel over the last <u>4 weeks</u>.

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?

   0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

   0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

   0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

   0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

   0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>.

   0   1   2   3   4   5   6   7   8   9   10

Section 4

This section is to determine what you believe about back pain. Here are some of the things which other patients have told us about their pain. For each statement please <u>circle</u> the number from 0 to 6 to say how much physical activities such as bending lifting walking or driving affect or would affect your back pain.

Please circle one number for each line

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

Section 5

This section is to determine how much your low back pain has troubled you lately.

1. During the **past 4 weeks**, about how many days did low back pain keep you from going to work or school/college/university? _____days

2. During the **past 4 weeks**, about how many days did you have to cut down on the things you usually do for more than half the day because of back pain? _____days

Section 6

This questionnaire asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please <u>place a cross in the one box that best describes your answer</u>.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

3. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section 7

The following questions are to ask about your general health state <u>at the moment</u>. By placing a tick ('✓') in one box in each group below, please indicate which statement best describes your own health state <u>today.</u>

Do not tick more than one box per question.

1. Mobility:

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

2. Self-Care:

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

3. Usual Activities (e.g. work, study, housework, family or leisure activities)**:**

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

4. Pain / Discomfort:

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

5. Anxiety / Depression:

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

Your own health state today

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale **how good or bad is your own health today, in your opinion.**

Please do this by <u>drawing a line from the box below</u>, to whichever point on the scale indicates how good or bad your current health state is **today**.

Your own health state TODAY

Best
imaginable
health state

100

9●0

8●0

7●0

6●0

5●0

4●0

3●0

2●0

1●0

0

Worst
imaginable
health state

143

Section 8

This section is about how you are feeling at the moment. Please <u>place a cross in the box</u> that comes closest to how you have been feeling <u>in the past week</u>.

Do not take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought out response.

1. **I feel tense or 'wound up':**

   Most of the time $\square_3$

   A lot of the time $\square_2$

   From time to time, occasionally $\square_1$

   Not at all $\square_0$

2. **I still enjoy the things I used to enjoy:**

   Definitely as much $\square_0$

   Not quite as much $\square_1$

   Only a little $\square_2$

   Hardly at all $\square_3$

3. **I get a sort of frightened feeling as if something awful is about to happen:**

   Very definitely and quite badly $\square_3$

   Yes, but not too badly $\square_2$

   A little, but it doesn't worry me $\square_1$

   Not at all $\square_0$

4. **I can laugh and see the funny side of things:**

   As much as I always could $\square_0$

   Not quite as much now $\square_1$

   Definitely not so much now $\square_2$

   Not at all $\square_3$

5. **Worrying thoughts go through my mind:**

   A great deal of the time $\square_3$

   A lot of the time $\square_2$

   From time to time but not too often $\square_1$

   Only occasionally $\square_0$

6. **I feel cheerful:**

   Not at all $\square_3$

   Not often $\square_2$

   Sometimes $\square_1$

   Most of the time $\square_0$

7. **I can sit at ease and feel relaxed:**

   Definitely $\square_0$

   Usually $\square_1$

   Not often $\square_2$

   Not at all $\square_3$

8. **I feel as if I am slowed down:**

   Nearly all the time $\square_3$

   Very often $\square_2$

   Sometimes $\square_1$

   Not at all $\square_0$

9. **I get a sort of frightened feeling like 'butterflies' In the stomach:**

Not at all $\square_0$

Occasionally $\square_1$

Quite often $\square_2$

Very often $\square_3$

10. **I have lost interest in my appearance:**

Definitely $\square_3$

I don't take as much care as I should $\square_2$

I may not take quite as much care $\square_1$

I take just as much care as ever $\square_0$

11. **I feel restless as if I have to be on the move:**

Very much indeed $\square_3$

Quite a lot $\square_2$

Not very much $\square_1$

Not at all $\square_0$

12. **I look forward with enjoyment to things:**

As much as I ever did $\square_0$

Rather less than I used to $\square_1$

Definitely less than I used to $\square_2$

Hardly at all $\square_3$

13. **I get sudden feeling of panic:**

Very often indeed $\square_3$

Quite often $\square_2$

Not very often $\square_1$

Not at all $\square_0$

14. **I can enjoy a good book or radio or TV programme:**

Often $\square_0$

Sometimes $\square_1$

Not often $\square_2$

Very seldom $\square_3$

Section 9

Please rate how <u>confident</u> you are that you can do the following things at present, <u>despite the pain</u>. To answer <u>circle</u> one of the numbers on the scale under each item, where 0 = 'not at all confident' and 6 = 'completely confident'.

For example

      0   (**1**)   **2**   **3**   **4**   **5**   **6**
Not at all   Completely
Confident   confident

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather <u>how confident you are that you can do them at present, despite the pain</u>.

	Not at all Confident						Completely Confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain. ('work' includes housework, paid and unpaid work).	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any general comments about your back pain, or this questionnaire, please write them overleaf.

Your comments:

Appendix 7
Randomisation form

RANDOMISATION FORM

Patient study number:_____

Patient Name:_____

Address:_____ _____

_____

_____   Post Code:_____

Phone Number:_____   Patient DOB: _____/_____/_____
                                                                                            DD   MM   YY

Inclusion criteria   *Please tick:*

	Yes	No
1. Aged 18 and older?		
2. Has low back pain lasted for at least 6 weeks?		
3. Patient reports at least moderately troublesome LBP?		

If any shaded box is ticked, the patient is not eligible

Randomisation information

1. GP Practice or triage service: _____

2. How troublesome is your back pain been during the past week?

   Moderately troublesome   ☐

   Very/extremely troublesome   ☐

Treatment allocation

The patient has been allocated to receive:

   A: Active management   ☐

   B: Active management + cognitive behavioural approach   ☐

Name …………………………….……… **Randomisation date:** _____/_____/_____
                                                                                          DD   MM   YY

Signed:

Please send this form via special delivery to the co-ordinating centre

Appendix 8
Follow-up questionnaires

In confidence

Potential participant study ID number

Back **S**kills **T**raining **(BeST)** Trial

Trial Participant Three Month Follow Up Questionnaire

*B**ack S**kills T**raining (**BeST**) Trial*

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK

GPRF

MRC General Practice Research
Framework

A randomised study of treatments for back pain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out if the advice or treatment you have had for your back as part of the study has been helpful.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

Please follow the instructions for each section carefully.

For example in the following question, if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car?　　　　　　**Yes**　☒

　　　　　　　　　　　　　　　　No　☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?' Where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy or unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

　　　　　　1　　　　　　**2**　　　　　（**3**）　　　　　**4**　　　　　**5**

Please use a BLACK or BLUE pen. Please do not use a pencil.

All the responses you give will be kept strictly confidential.

Firstly, please enter the date you are completing this questionnaire: |__|__| |__|__||__|__|

day   month   year

Section 1

By placing a cross ('X') in one box for each question below, please indicate which statement best describes your feelings towards the advice or treatment you have received for your lower back pain as part of the study.

1. How satisfied are you with the advice or treatment you received?

Very dissatisfied	☐ 1
Somewhat dissatisfied	☐ 2
Neither satisfied nor dissatisfied	☐ 3
Somewhat satisfied	☐ 4
Very satisfied	☐ 5

2. How much benefit have you gained from the advice or treatment you have received for your lower back pain as part of the study.

Substantial benefit	☐ 1
Moderate benefit	☐ 2
No benefit	☐ 3
Moderate harm	☐ 4
Substantial harm	☐ 5

Section 2

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you <u>today</u>.

As you read the list, think of yourself <u>today</u>. When you read a sentence that describes you <u>today</u>, place a cross in the box beside it. If the sentence does not describe you, then leave the box blank and go on to the next one. Remember, only place a cross if you are sure that it describes you <u>today</u>.

1. I stay at home most of the time because of my back. .... ☐

2. I change positions frequently to try and get my back comfortable. .... ☐

3. I walk more slowly than usual because of my back. .... ☐

4. Because of my back, I am not doing any of the jobs that I usually do around the house. .... ☐

5. Because of my back, I use a handrail to get upstairs………………………………………….. ☐

6. Because of my back, I lie down to rest more often. .... ☐

7. Because of my back, I have to hold on to something to get out of an easy chair. .... ☐

8. Because of my back, I try to get other people to do things for me. .... ☐

9. I get dressed more slowly than usual because of my back. .... ☐

10. I only stand up for short periods of time because of my back. .... ☐

11. Because of my back, I try not to bend or kneel down. .... ☐

12. I find it difficult to get out of a chair because of my back. .... ☐

13. My back is painful almost all the time. .... ☐

14. I find it difficult to turn over in bed because of my back. .... ☐

15. My appetite is not very good because of my back pain. .... ☐

16. I have trouble putting on my socks (or stockings) because of the pain in my back. .... ☐

17. I only walk short distances because of my back pain. .... ☐

18. I sleep less well because of my back. .... ☐

19. Because of my back pain, I get dressed with help from someone else. .... ☐

20. I sit down for most of the day because of my back. .... ☐

21. I avoid heavy jobs around the house because of my back. .... ☐

22. Because of my back pain, I am more irritable and bad tempered with people than usual. ... ☐

23. Because of my back, I go upstairs more slowly than usual. .... ☐

24. I stay in bed most of the time because of my back. .... ☐

Section 3

This section is about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

For the next six questions please circle the number which represents how your back pain has made you feel over the last <u>4 weeks</u>.

For example:

          0   1   2   3   4   (5)   6   7   8   9   10

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?

      0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

      0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

      0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

Section 4

Please rate how <u>confident</u> you are that you can do the following things at present, <u>despite the pain</u>. To answer circle one of the numbers on the scale under each item, where 0 = 'not at all confident' and 6 = 'completely confident'.

For example

0	1	2	③	4	5	6

Not at all Confident   **Completely Confident**

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather <u>how confident you are that you can do them at present, despite the pain</u>.

	Not at all Confident						Completely Confident
1. I can enjoy things, despite the pain.	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain.	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain.	0	1	2	3	4	5	6
4. I can cope with my pain in most situations.	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain ('work' includes housework, paid and unpaid work).	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain.	0	1	2	3	4	5	6
7. I can cope with my pain without medication.	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain.	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain.	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain.	0	1	2	3	4	5	6

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Section 5

These are some things people have told us about their back pain. For each statement please circle a number from 0 to 6 to say how much physical activity such as bending, lifting, or driving affects your pain.

Please circle one number for each line

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

Section 6

This section is to determine how much your low back pain has changed since you started the study.

1. In what way has your back pain changed in the <u>past three months</u>?

(Please cross one box)

Completely recovered	☐ 1
Much improved	☐ 2
Slightly improved	☐ 3
No change	☐ 4
Slightly worsened	☐ 5
Much worsened	☐ 6
Vastly worsened	☐ 7

Section 7

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please place a cross in the one box that best describes your answer.

---

1. In general, would you say your health is:

Excellent	**Very good**	**Good**	**Fair**	**Poor**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

2. The following questions are about activities you might do during a typical day.
    Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

3. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

<u>**Section 8**</u>

The following questions are to ask about your general health state <u>at the moment</u>. By placing a cross ('X') in one box in each group below, please indicate which statement best describes your own health state <u>today.</u>

Do not cross more than one box per question.

1. **Mobility:**

    I have no problems in walking about ☐

    I have some problems in walking about ☐

    I am confined to bed ☐

2. **Self-Care:**

    I have no problems with self-care ☐

    I have some problems washing or dressing myself ☐

    I am unable to wash or dress myself ☐

3. **Usual Activities** (e.g. work, study, housework, family or leisure activities)**:**

    I have no problems with performing my usual activities ☐

    I have some problems with performing my usual activities ☐

    I am unable to perform my usual activities ☐

4. **Pain / Discomfort:**

    I have no pain or discomfort ☐

    I have moderate pain or discomfort ☐

    I have extreme pain or discomfort ☐

5. **Anxiety / Depression:**

    I am not anxious or depressed ☐

    I am moderately anxious or depressed ☐

    I am extremely anxious or depressed ☐

Your own health state today

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale **how good or bad is your own health today, in your opinion.**

Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your current health state is **today**.

```
          Best
       imaginable
       health state
          1 0 0

          9 0

          8 0

          7 0

          6 0

          5 0

          4 0

          3 0

          2 0

          1 0

           0
          Worst
       imaginable
       health state
```

Your own health state TODAY

Section 9

This section is about health care you have received for your back pain. There are separate parts for NHS treatment, private treatment, products/equipment, normal activities and any benefits/entitlements. Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0'.

NHS Treatment

1. In the **last 3 months**, how often have you attended the following **NHS services** for lower back pain? *(Please do not include any sessions or treatments that you attended as part of the study).*

Number of times

Your GP or another GP   *if none enter '0'*

Practice nurse   *if none enter '0'*

Physiotherapist   *if none enter '0'*

Doctor/nurse in an accident and emergency department
(Casualty)   *if none enter '0'*

Hospital specialist (consultant or one of his/her team)   *if none enter '0'*

Psychologist/Counsellor   *if none enter '0'*

Other (please specify) _____   *if none enter '0'*

Other (please specify) _____   *if none enter '0'*

2. In the **last 3 months** have you been admitted to an **NHS hospital** because of back pain?

Yes ☐1
No ☐2

If Yes, in total, how many days were you in hospital?

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3. In the **last 3 months** have you had any of the following tests in a **NHS hospital** in relation to lower back pain?

Number of times

X-ray ☐☐ *if none enter '0'*

CT Scan ☐☐ *if none enter '0'*

MRI Scan ☐☐ *if none enter '0'*

Blood tests (count all blood tests done on one day, as one test) ☐☐ *if none enter '0'*

Other (please specify) _____ ☐☐ *if none enter '0'*

4. In the **last 3 months** has your **doctor** prescribed any of the following medications for your back?

Pain killers ☐☐ *if none enter '0'*

Anti-inflammatory drugs (for example ibuprofen, naproxen) ☐☐ *if none enter '0'*

Gels/Creams (for example ibuleve or movelat) ☐☐ *if none enter '0'*

Sleeping pills ☐☐ *if none enter '0'*

Anti-depressants ☐☐ *if none enter '0'*

Other (please specify) _____ ☐☐ *if none enter '0'*

5. Do you qualify for free prescriptions?

Yes ☐ 1
No ☐ 2

Private Treatment

6. For the **last 3 months** please detail total treatment costs **you paid for yourself**; **or paid for by private insurance**; <u>please do not include any treatments paid for by the NHS</u>. Please round the amounts to the nearest pound. *If none enter '0'*

	Number Of times	Medical Insurance Contribution	Personal Contribution
Physiotherapist	☐	£ ☐	£ ☐
Hospital specialist (consultant)	☐	£ ☐	£ ☐
Osteopath	☐	£ ☐	£ ☐
Chiropractor	☐	£ ☐	£ ☐
Psychologist	☐	£ ☐	£ ☐
Counsellor	☐	£ ☐	£ ☐
Massage therapist	☐	£ ☐	£ ☐
Aromatherapist	☐	£ ☐	£ ☐
Acupuncturist	☐	£ ☐	£ ☐
Other (please specify) _____	☐	£ ☐	£ ☐
Other (please specify) _____	☐	£ ☐	£ ☐

7. In the **last 3 months**, have you been admitted to a **private hospital** because of lower back pain?

Yes ☐ 1

No ☐ 2

If **Yes**, in total, **how many days were you in hospital?** ☐☐☐☐

If **Yes**, what were the **total costs paid by your medical insurance?** £ ☐☐☐☐
Please give the total costs to the nearest pound.*

If **Yes**, what were the **total costs paid by you?** £ ☐☐☐☐
Please give the total costs to the nearest pound.*

*If you do not know the actual cost please give us your best estimate of the costs.

8. In the **last 3 months,** have you had any of the following tests in a **private hospital** in relation to lower back pain?

Number of times

X-ray ☐☐ *if none enter '0'*

CT Scan ☐☐ *if none enter '0'*

MRI Scan ☐☐ *if none enter '0'*

Blood tests (please count all tests done on one day, as one test) ☐☐ *if none enter '0'*

Other (please specify) _____ ☐☐ *if none enter '0'*

9. In the **last 3 months have you bought (other than by a prescription)** any of the following treatments for your back pain? Please estimate the total cost to the nearest pound.

	Number of times	Total cost to you
Pain killers (for example paracetamol/anadin)	☐☐	£☐☐☐
Anti-inflammatory drugs (for example ibuprofen/neurofen)	☐☐	£☐☐☐
Gels/Creams (for example ibuleve or movelat)	☐☐	£☐☐☐
Other (please specify) _____	☐☐	£☐☐☐
Other (please specify) _____	☐☐	£☐☐☐

Products / equipment.

10. In the **last three months**, have you bought items such as braces or aids, a new bed or mattress, a chair, a massage machine, or any other products or equipment **because of your back pain**? (please list the item below and estimate the cost to the nearest pound)

Item bought

1. _____ . £ ☐☐☐☐

2. _____ . £ ☐☐☐☐

3. _____ . £ ☐☐☐☐

4. _____ . £ ☐☐☐☐

5. _____ . £ ☐☐☐☐

Normal activities.

11. Over the **last 3 months** has your back pain stopped you doing your **normal activities**?

Please cross any that apply and enter the total number of days your back pain stopped you getting on with your normal activities.

Number of days

☐ Employment ☐☐
If none enter '0'

☐ Education (i.e. College or University) ☐☐
If none enter '0'

☐ Housework ☐☐
If none enter '0'

☐ Childcare or care of a relative ☐☐
If none enter '0'

Changes in work status in the last three months

12. Have you had to take any days off sick from work in the last three months due to your low back pain?

        Yes   ☐ 1

        No   ☐ 2

        Not applicable   ☐ 3

    If **Yes,** how many days?   ☐☐

13. Have your hours of employment altered in the last three months because of changes in your back pain?

        No, stayed the same   ☐ 1

        Yes, increased   ☐ 2

        Yes, decreased   ☐ 3

        Not applicable   ☐ 4

    If **Yes,** by how many hours per week has your employment changed? _____

    When did this change occur? |__|__| |__|__| |__|__|

14. If you were off work when you joined the study, have you returned to work?

        ☐ 1 I am still off work

        ☐ 2 I returned to work on |__|__| |__|__| |__|__|

Benefits and entitlement to free prescriptions

15. Has your benefit status changed in the last three months?

Yes ☐1

No ☐2

If **yes**, please cross all benefits that you are currently receiving.

Statutory Sick Pay	☐1	Income support	☐8
Incapacity Benefit	☐2	Working tax credit	☐9
Disability living allowance	☐3	Child tax credit	☐10
Severe disablement allowance	☐4	Council tax benefit	☐11
Disabled persons tax credit	☐5	Housing benefit	☐12
Carers allowance	☐6	Attendance allowance	☐13
Job seekers allowance	☐7	Pension credit	☐14
		Other (please specify)	☐15

_____

_____

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any comments, please write them overleaf.

Your comments:

In confidence

Potential participant study ID number

Back **S**kills **T**raining **(BeST)** Trial

Trial Participant Six Month Follow Up Questionnaire

Back Skills Training (BeST) Trial

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK

GPRF

MRC General Practice Research
Framework

A randomised study of treatments for back pain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out if the treatment you have had for your back since you joined the study has been helpful.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick.

For example, in the following question if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car?　　　　**Yes**　☒

　　　　　　　　　　　　　　　　No　☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?', where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy nor unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

　　　　1　　　　　2　　　　Ⓐ③　　　　4　　　　　5

Please use a BLACK or BLUE pen. Please do not use a pencil.

All the responses you give will be kept strictly confidential.

Firstly, please enter the date you are completing this questionnaire: |__|__| |__|__||__|__|

day   month   year

Section 1

By placing a cross in one box for each question below, please indicate which statement best describes your feelings towards the treatment or advice you have received for your lower back pain since you joined the study.

1. How satisfied are you with the treatment you received?

    Very dissatisfied   ☐ 1

    Somewhat dissatisfied   ☐ 2

    Neither satisfied nor dissatisfied   ☐ 3

    Somewhat satisfied   ☐ 4

    Very satisfied   ☐ 5

2. How much benefit have you gained from the treatment or advice **you have received for your lower back pain since you joined the study**.

    Substantial benefit   ☐ 1

    Moderate benefit   ☐ 2

    No benefit   ☐ 3

    Moderate harm   ☐ 4

    Substantial harm   ☐ 5

Section 2

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you <u>today</u>.

As you read the list, think of yourself <u>today</u>. When you read a sentence that describes you <u>today</u>, place a cross in the box beside it. If the sentence does not describe you, then leave the box blank and go on to the next one. Remember, only place a cross if you are sure that it describes you <u>today</u>.

1. I stay at home most of the time because of my back. .... ☐

2. I change positions frequently to try and get my back comfortable. .... ☐

3. I walk more slowly than usual because of my back. .... ☐

4. Because of my back, I am not doing any of the jobs that I usually do around the house. .... ☐

5. Because of my back, I use a handrail to get upstairs……………………………………….. ☐

6. Because of my back, I lie down to rest more often. .... ☐

7. Because of my back, I have to hold on to something to get out of an easy chair. .... ☐

8. Because of my back, I try to get other people to do things for me. .... ☐

9. I get dressed more slowly than usual because of my back. .... ☐

10. I only stand up for short periods of time because of my back. .... ☐

11. Because of my back, I try not to bend or kneel down. .... ☐

12. I find it difficult to get out of a chair because of my back. .... ☐

13. My back is painful almost all the time. .... ☐

14. I find it difficult to turn over in bed because of my back. .... ☐

15. My appetite is not very good because of my back pain. .... ☐

16. I have trouble putting on my socks (or stockings) because of the pain in my back. .... ☐

17. I only walk short distances because of my back pain. .... ☐

18. I sleep less well because of my back. .... ☐

19. Because of my back pain, I get dressed with help from someone else. .... ☐

20. I sit down for most of the day because of my back. .... ☐

21. I avoid heavy jobs around the house because of my back. .... ☐

22. Because of my back pain, I am more irritable and bad tempered with people than usual. ... ☐

23. Because of my back, I go upstairs more slowly than usual. .... ☐

24. I stay in bed most of the time because of my back. .... ☐

Section 3

This section is about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

For the next six questions please circle the number which represents how your back pain has made you feel over the last <u>4 weeks</u>.

For example:

     0   1   2   3   4   (5)   6   7   8   9   10

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?

    0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

    0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

    0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

    0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

    0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

    0   1   2   3   4   5   6   7   8   9   10

Section 4

Please rate how <u>confident</u> you are that you can do the following things at present, <u>despite the pain</u>. To answer, circle one of the numbers on the scale under each item, where 0 = 'not at all confident' and 6 = 'completely confident'.

For example

	0	1	(2)	3	4	5	6
Not at all Confident							**Completely confident**

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather <u>how confident you are that you can do them at present, despite the pain</u>.

	Not at all Confident						Completely Confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain. ('work' includes housework, paid and unpaid work).	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

Section 5

These are some things people have told us about their back pain. For each statement please circle a number from 0 to 6 to say how much physical activity such as bending, lifting, driving affect your pain.

Please circle one number for each line

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

Section 6

This section is to determine how much your low back pain has troubled you lately.

1. During the **past 4 weeks**, about how many days did low back pain keep you from going to work or school/college/university? _____days

2. During the **past 4 weeks**, about how many days did you have to cut down on the things you usually do for more than half the day because of back pain? _____days

3. How would you describe your back pain compared to when you started the study?

   Very much improved (or completely recovered)   ☐ 1

   Much improved   ☐ 2

   Minimally (or slightly) improved   ☐ 3

   No change   ☐ 4

   Minimally worse   ☐ 5

   Much worse   ☐ 6

   Very much worse   ☐ 7

<u>Section 7</u>

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please place a cross in the one box that best describes your answer.

---

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

2. The following questions are about activities you might do during a typical day.
    Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

3. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section 8

The following questions are to ask about your general health state <u>at the moment</u>. By placing a cross ('X') in one box in each group below, please indicate which statement best describes your own health state <u>today.</u>

Do not cross more than one box per question.

1. **Mobility:**

   I have no problems in walking about ☐

   I have some problems in walking about ☐

   I am confined to bed ☐

2. **Self-Care:**

   I have no problems with self-care ☐

   I have some problems washing or dressing myself ☐

   I am unable to wash or dress myself ☐

3. **Usual Activities** (e.g. work, study, housework, family or leisure activities)**:**

   I have no problems with performing my usual activities ☐

   I have some problems with performing my usual activities ☐

   I am unable to perform my usual activities ☐

4. **Pain / Discomfort:**

   I have no pain or discomfort ☐

   I have moderate pain or discomfort ☐

   I have extreme pain or discomfort ☐

5. **Anxiety / Depression:**

   I am not anxious or depressed ☐

   I am moderately anxious or depressed ☐

   I am extremely anxious or depressed ☐

Your own health state today

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale **how good or bad is your own health today, in your opinion.**

Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your current health state is **today**.

Best
imaginable
health state

100

9 0

8 0

7 0

6 0

5 0

4 0

3 0

2 0

1 0

0

Worst
imaginable
health state

┌─────────────────────┐
│   │
│ **Your own health state** │
│ **TODAY**   │
│   │
└─────────────────────┘

Section 9

This section is about health care you have received for your back pain. There are separate parts for NHS treatment, private treatment, products/equipment, normal activities and any benefits/entitlements. Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0'.

NHS Treatment

1. In the **last 3 months**, how often have you attended the following **NHS services** for lower back pain? *(Please do not include any sessions or treatments that you attended as part of the study).*

Number of times

Your GP or another GP   ☐☐   *if none enter '0'*

Practice nurse   ☐☐   *if none enter '0'*

Physiotherapist   ☐☐   *if none enter '0'*

Doctor/nurse in an accident and emergency department   ☐☐   *if none enter '0'*
(Casualty)

Hospital specialist (consultant or one of his/her team)   ☐☐   *if none enter '0'*

Psychologist   ☐☐   *if none enter '0'*

Counsellor   ☐☐   *if none enter '0'*

Other (please specify) _____   ☐☐   *if none enter '0'*

Other (please specify) _____   ☐☐   *if none enter '0'*

2. In the **last 3 months** have you been admitted to an **NHS hospital** because of back pain?

Yes ☐ 1
No   ☐ 2

If Yes, in total, how many days were you in hospital?   ☐☐

3. In the **last 3 months** have you had any of the following tests in an **NHS hospital** in relation to lower back pain?

Number of times

X-ray   ☐☐ *if none enter '0'*

CT Scan   ☐☐ *if none enter '0'*

MRI Scan   ☐☐ *if none enter '0'*

Blood tests (count all blood tests done on one day as one test)   ☐☐ *if none enter '0'*

Other (please specify) _____   ☐☐ *if none enter '0'*

4. In the **last 3 months** has your **doctor** prescribed any of the following medications for your back?

Pain killers   ☐☐ *if none enter '0'*

Anti-inflammatory drugs (for example ibuprofen, naproxen)   ☐☐ *if none enter '0'*

Gels/Creams (for example ibuleve or movelat)   ☐☐ *if none enter '0'*

Sleeping pills   ☐☐ *if none enter '0'*

Anti-depressants   ☐☐ *if none enter '0'*

Other (Please specify) _____

Private Treatment

5. For the **last 3 months** please detail total treatment costs **you paid for yourself**; **or paid for by private insurance**; please do not include any treatments paid for by the NHS. Please round the amounts to the nearest pound.

	Number Of times	Medical Insurance Contribution	Personal Contribution
Private physiotherapist	☐	£ ☐	£ ☐
Private hospital specialist (consultant)	☐	£ ☐	£ ☐
Private osteopath	☐	£ ☐	£ ☐
Private chiropractor	☐	£ ☐	£ ☐
Private psychologist	☐	£ ☐	£ ☐
Private counsellor	☐	£ ☐	£ ☐
Private massage therapist	☐	£ ☐	£ ☐
Private aroma therapist	☐	£ ☐	£ ☐
Private acupuncturist	☐	£ ☐	£ ☐
Other (please specify) _____	☐	£ ☐	£ ☐
Other (please specify) _____	☐	£ ☐	£ ☐

6. In the **last 3 months**, have you been admitted to a **private hospital** because of lower back pain?

Yes ☐ 1
No ☐ 2

If **Yes**, in total, **how many days were you in hospital?** ☐

If **Yes**, what were the **total costs paid by your medical insurance?** £ ☐
Please give the total costs to the nearest pound*.

If **Yes**, what were the **total costs paid by you?** £ ☐
Please give the total costs to the nearest pound.*

*If you do not know the actual cost please give us your best estimate of the costs.

7. In the **last 3 months,** have you had any of the following tests in a **private hospital** in relation to lower back pain?

Number of times

X-ray   ☐☐   *if none enter '0'*

CT Scan   ☐☐   *if none enter '0'*

MRI Scan   ☐☐   *if none enter '0'*

Blood tests (please count all blood tests done on one day as one test) ☐☐   *if none enter '0'*

Other (please specify) _____   ☐☐   *if none enter '0'*

8. In the **last 3 months have you bought (other than by a prescription)** any of the following treatments for your back pain? Please estimate the total cost to the nearest pound.

	Number of times	Total cost to you
Pain killers	☐☐	£☐☐☐
Anti-inflammatory drugs (for example ibuprofen/nurofen)	☐☐	£☐☐☐
Gels/Creams (for example ibuleve or movelat)	☐☐	£☐☐☐

Other (Please specify)_____

Products / equipment.

9. In the **last three months**, have you bought items such as braces or aids, a new bed or mattress, a chair, a massage machine, or any other products or equipment **because of your back pain**? (please list the item below and estimate the cost to the nearest pound)

Item bought

1. _____ . £ ☐☐☐☐

2. _____ . £ ☐☐☐☐

3. _____ . £ ☐☐☐☐

4. _____ . £ ☐☐☐☐

5. _____ . £ ☐☐☐☐

Normal activities.

10. Over the **last 3 months** has your back pain stopped you doing your **normal activities**?

Please cross any that apply and enter the total number of days your back pain stopped you getting on with your normal activities.

Number of days

☐   Employment ☐☐
If none enter '0'

☐   Education (i.e. college or University) ☐☐
If none enter '0'

☐   Housework ☐☐
If none enter '0'

☐   Childcare or care of a relative ☐☐
If none enter '0'

Changes in work status in the last three months

11. Have you had to take any days off sick from work in the last three months due to your low back pain?

Yes ☐ 1

No ☐ 2

Not applicable ☐ 3

If **Yes,** how many days? ☐☐

12. Have you had to change your occupation in the last three months due to your back pain?

Yes ☐ 1

No ☐ 2

Not applicable ☐ 3

If **Yes,** what is your new job? _____

When did this change occur? |__|__| |__|__| |__|__|

13. Have your hours of employment changed in the last three months because of back pain getting better or worse?

Yes ☐ 1

No ☐ 2

Not applicable ☐ 3

If **Yes,** by how many hours per week has your employment changed? _____

When did this change occur? |__|__| |__|__| |__|__|

14. If you were off work when you joined the study, have you returned to work?

☐ 1 I am still off work

☐ 2 I returned to work on |__|__| |__|__| |__|__|

Benefits and entitlement to free prescriptions

15. Do you qualify for free prescriptions?

Yes ☐ 1
No ☐ 2

16. Has your benefit status changed in the last three months?

Yes ☐ 1
No ☐ 2

If **yes**, please cross all benefits that you are currently receiving.

Statutory Sick Pay	☐ 1	Child Tax Credit	☐ 8
Incapacity Benefit	☐ 2	Council Tax Benefit	☐ 9
Disability living allowance	☐ 3	Housing Benefit	☐ 10
Disabled persons tax credit	☐ 4	Attendance allowance	☐ 11
Invalid Care Allowance	☐ 5 (includes if paid to someone who looks after you)		
Other	☐ 6 please specify_____		
Working Tax Credit	☐ 7		

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any comments, please write them overleaf.

Your comments:

In confidence

Potential participant study ID number

Back **S**kills **T**raining **(BeST)** Trial

Trial Participant Twelve Month Follow Up Questionnaire

Back Skills Training (BeST) Trial

PLEASE READ ALL THE INSTRUCTIONS BEFORE COMPLETING THE QUESTIONNAIRE

Thank you for agreeing to take part in this study. The responses you give in this questionnaire will help us find out if the treatment you have had for your back since you joined the study has been helpful.

Please answer all the questions. Although it may seem that questions are asked more than once, it is still important that you answer every one.

Please follow the instructions for each section carefully.

For each section, if you are asked to put a cross in the box, please use a cross rather than a tick.

For example, in the following question if your answer to the question is yes, you should place a cross firmly in the box next to yes.

Do you drive a car?   **Yes**   ☒

                                 No   ☐

If you are asked to circle a number, please use a circle rather than underlining a number.

For example, in the following question if you are asked 'how happy are you today?', where '1' is 'very unhappy' and '5' is 'very happy'. If you feel neither happy nor unhappy you may wish to answer '3'. You do this by clearly circling the number 3.

| **1** | **2** | **③** | **4** | **5** |

Please use a BLACK or BLUE pen. Please do not use a pencil.

All the responses you give will be kept strictly confidential.

Firstly, please enter the date you are completing this questionnaire: |__|__| |__|__||__|__|

day   month   year

Section 1

By placing a cross in one box for each question below, please indicate which statement best describes your feelings towards the treatment or advice you have received for your lower back pain since you joined the study.

1. How satisfied are you with the treatment you received?

Very dissatisfied	☐ 1
Somewhat dissatisfied	☐ 2
Neither satisfied nor dissatisfied	☐ 3
Somewhat satisfied	☐ 4
Very satisfied	☐ 5

2. How much benefit have you gained from the treatment or advice **you have received for your lower back pain since you joined the study**.

Substantial benefit	☐ 1
Moderate benefit	☐ 2
No benefit	☐ 3
Moderate harm	☐ 4
Substantial harm	☐ 5

Section 2

When your back hurts, you may find it difficult to do some of the things you normally do. This list contains some sentences that people have used to describe themselves when they have back pain. When you read them, you may find that some stand out because they describe you <u>today</u>.

As you read the list, think of yourself <u>today</u>. When you read a sentence that describes you <u>today</u>, place a cross in the box beside it. If the sentence does not describe you, then leave the box blank and go on to the next one. Remember, only place a cross if you are sure that it describes you <u>today</u>.

1. I stay at home most of the time because of my back. .... ☐
2. I change positions frequently to try and get my back comfortable. .... ☐
3. I walk more slowly than usual because of my back. .... ☐
4. Because of my back, I am not doing any of the jobs that I usually do around the house. .... ☐
5. Because of my back, I use a handrail to get upstairs…………………………………………….. ☐
6. Because of my back, I lie down to rest more often. .... ☐
7. Because of my back, I have to hold on to something to get out of an easy chair. .... ☐
8. Because of my back, I try to get other people to do things for me. .... ☐
9. I get dressed more slowly than usual because of my back. .... ☐
10. I only stand up for short periods of time because of my back. .... ☐
11. Because of my back, I try not to bend or kneel down. .... ☐
12. I find it difficult to get out of a chair because of my back. .... ☐
13. My back is painful almost all the time. .... ☐
14. I find it difficult to turn over in bed because of my back. .... ☐
15. My appetite is not very good because of my back pain. .... ☐
16. I have trouble putting on my socks (or stockings) because of the pain in my back. .... ☐
17. I only walk short distances because of my back pain. .... ☐
18. I sleep less well because of my back. .... ☐
19. Because of my back pain, I get dressed with help from someone else. .... ☐
20. I sit down for most of the day because of my back. .... ☐
21. I avoid heavy jobs around the house because of my back. .... ☐
22. Because of my back pain, I am more irritable and bad tempered with people than usual. ... ☐
23. Because of my back, I go upstairs more slowly than usual. .... ☐
24. I stay in bed most of the time because of my back. .... ☐

Section 3

This section is about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

For the next six questions please circle the number which represents how your back pain has made you feel over the last <u>4 weeks</u>.

For example:

      0   1   2   3   4   (5)   6   7   8   9   10

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?

      0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

      0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

      0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

      0   1   2   3   4   5   6   7   8   9   10

Section 4

Please rate how <u>confident</u> you are that you can do the following things at present, <u>despite the pain</u>. To answer, circle one of the numbers on the scale under each item, where 0 = 'not at all confident' and 6 = 'completely confident'.

For example

| | 0 | 1 | (2) | 3 | 4 | 5 | 6 |

**Not at all   Completely
Confident   confident**

Remember, this questionnaire is not asking whether or not you have been doing these things, but rather <u>how confident you are that you can do them at present, despite the pain</u>.

	Not at all Confident						Completely Confident
1. I can enjoy things, despite the pain	0	1	2	3	4	5	6
2. I can do most of the household chores (e.g. tidying-up, washing dishes, etc.), despite the pain	0	1	2	3	4	5	6
3. I can socialise with my friends or family members as often as I used to do, despite the pain	0	1	2	3	4	5	6
4. I can cope with my pain in most situations	0	1	2	3	4	5	6
5. I can do some form of work, despite the pain. ('work' includes housework, paid and unpaid work).	0	1	2	3	4	5	6
6. I can still do many of the things I enjoy doing, such as hobbies or leisure activity, despite the pain	0	1	2	3	4	5	6
7. I can cope with my pain without medication	0	1	2	3	4	5	6
8. I can still accomplish most of my goals in life, despite the pain	0	1	2	3	4	5	6
9. I can live a normal lifestyle, despite the pain	0	1	2	3	4	5	6
10. I can gradually become more active, despite the pain	0	1	2	3	4	5	6

Section 5

These are some things people have told us about their back pain. For each statement please circle a number from 0 to 6 to say how much physical activity such as bending, lifting, driving affect your pain.

Please circle one number for each line

	Completely Disagree			Unsure			Completely Agree
1. My pain was caused by physical activity	0	1	2	3	4	5	6
2. Physical activity makes my pain worse	0	1	2	3	4	5	6
3. Physical activity might harm my back	0	1	2	3	4	5	6
4. I should not do physical activities which (might) make my pain worse	0	1	2	3	4	5	6
5. I cannot do physical activities which (might) make my pain worse	0	1	2	3	4	5	6

Section 6

This section is to determine how much your low back pain has troubled you lately.

1. During the **past 4 weeks**, about how many days did low back pain keep you from going

   to work or school/college/university? _____days

2. During the **past 4 weeks**, about how many days did you have to cut down on the things

   you usually do for more than half the day because of back pain? _____days

3. How would you describe your back pain compared to when you started the study?

   Very much improved (or completely recovered) ☐ 1

   Much improved ☐ 2

   Minimally (or slightly) improved ☐ 3

   No change ☐ 4

   Minimally worse ☐ 5

   Much worse ☐ 6

   Very much worse ☐ 7

Section 7

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

For each of the following questions, please place a cross in the one box that best describes your answer.

---

1. In general, would you say your health is:

Excellent	**Very good**	**Good**	**Fair**	**Poor**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

2. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

3. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

4. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

5. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

6. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Section 8

The following questions are to ask about your general health state <u>at the moment</u>. By placing a cross ('X') in one box in each group below, please indicate which statement best describes your own health state <u>today.</u>

Do not cross more than one box per question.

1. **Mobility:**

    I have no problems in walking about ☐

    I have some problems in walking about ☐

    I am confined to bed ☐

2. **Self-Care:**

    I have no problems with self-care ☐

    I have some problems washing or dressing myself ☐

    I am unable to wash or dress myself ☐

3. **Usual Activities** (e.g. work, study, housework, family or leisure activities)**:**

    I have no problems with performing my usual activities ☐

    I have some problems with performing my usual activities ☐

    I am unable to perform my usual activities ☐

4. **Pain / Discomfort:**

    I have no pain or discomfort ☐

    I have moderate pain or discomfort ☐

    I have extreme pain or discomfort ☐

5. **Anxiety / Depression:**

    I am not anxious or depressed ☐

    I am moderately anxious or depressed ☐

    I am extremely anxious or depressed ☐

Your own health state today

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked by 100 and the worst state you can imagine is marked by 0.

We would like you to indicate on this scale **how good or bad is your own health today, in your opinion.**

Please do this by drawing a line from the box below, to whichever point on the scale indicates how good or bad your current health state is **today**.

**Your own health state
TODAY**

Best
imaginable
health state

100

90

80

70

60

50

40

30

20

10

0

Worst
imaginable
health state

Section 9

This section is about health care you have received for your back pain. There are separate parts for NHS treatment, private treatment, products/equipment, normal activities and any benefits/entitlements. Please read each question carefully. For each question, if you have had no treatments or visits, please enter '0'.

NHS Treatment

1. In the **last 6 months**, how often have you attended the following **NHS services** for lower back pain? *(Please do not include any sessions or treatments that you attended as part of the study).*

Number of times

Your GP or another GP   ☐☐   *if none enter '0'*

Practice nurse   ☐☐   *if none enter '0'*

Physiotherapist   ☐☐   *if none enter '0'*

Doctor/nurse in an accident and emergency department   ☐☐   *if none enter '0'*
(Casualty)

Hospital specialist (consultant or one of his/her team)   ☐☐   *if none enter '0'*

Psychologist   ☐☐   *if none enter '0'*

Counsellor   ☐☐   *if none enter '0'*

Other (please specify) _____   ☐☐   *if none enter '0'*

Other (please specify) _____   ☐☐   *if none enter '0'*

2. In the **last 6 months** have you been admitted to an **NHS hospital** because of back pain?

Yes   ☐ 1
No   ☐ 2

If Yes, in total, how many days were you in hospital?   ☐☐

3. In the **last 6 months** have you had any of the following tests in an **NHS hospital** in relation to lower back pain?

Number of times

X-ray ☐☐ *if none enter '0'*

CT Scan ☐☐ *if none enter '0'*

MRI Scan ☐☐ *if none enter '0'*

Blood tests (count all blood tests done on one day as one test) ☐☐ *if none enter '0'*

Other (please specify) _____ ☐☐ *if none enter '0'*

4. In the **last 6 months** has your **doctor** prescribed any of the following medications for your back?

Pain killers ☐☐ *if none enter '0'*

Anti-inflammatory drugs (for example ibuprofen, naproxen) ☐☐ *if none enter '0'*

Gels/Creams (for example ibuleve or movelat) ☐☐ *if none enter '0'*

Sleeping pills ☐☐ *if none enter '0'*

Anti-depressants ☐☐ *if none enter '0'*

Other (Please specify) _____

Private Treatment

5. For the **last 6 months** please detail total treatment costs **you paid for yourself**; **or paid for by private insurance**; please do not include any treatments paid for by the NHS. Please round the amounts to the nearest pound.

	Number Of times	Medical Insurance Contribution	Personal Contribution
Private physiotherapist	☐☐	£ ☐☐☐	£ ☐☐☐
Private hospital specialist (consultant)	☐☐	£ ☐☐☐	£ ☐☐☐
Private osteopath	☐☐	£ ☐☐☐	£ ☐☐☐
Private chiropractor	☐☐	£ ☐☐☐	£ ☐☐☐
Private psychologist	☐☐	£ ☐☐☐	£ ☐☐☐
Private counsellor	☐☐	£ ☐☐☐	£ ☐☐☐
Private massage therapist	☐☐	£ ☐☐☐	£ ☐☐☐
Private aroma therapist	☐☐	£ ☐☐☐	£ ☐☐☐
Private acupuncturist	☐☐	£ ☐☐☐	£ ☐☐☐
Other (please specify) _____	☐☐	£ ☐☐☐	£ ☐☐☐
Other (please specify) _____	☐☐	£ ☐☐☐	£ ☐☐☐

6. In the **last 6 months**, have you been admitted to a **private hospital** because of lower back pain?

Yes ☐ 1

No ☐ 2

If **Yes**, in total, **how many days were you in hospital?** ☐☐

If **Yes**, what were the **total costs paid by your medical insurance?** £ ☐☐☐☐
Please give the total costs to the nearest pound*.

If **Yes**, what were the **total costs paid by you?** £ ☐☐☐☐
Please give the total costs to the nearest pound.*

*If you do not know the actual cost please give us your best estimate of the costs.

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7. In the **last 6 months,** have you had any of the following tests in a **private hospital** in relation to lower back pain?

Number of times

X-ray ☐☐ *if none enter '0'*

CT Scan ☐☐ *if none enter '0'*

MRI Scan ☐☐ *if none enter '0'*

Blood tests (please count all blood tests done on one day as one test) ☐☐ *if none enter '0'*

Other (please specify) _____ ☐☐ *if none enter '0'*

8. In the **last 6 months have you bought (other than by a prescription)** any of the following treatments for your back pain? Please estimate the total cost to the nearest pound.

	Number of times	Total cost to you
Pain killers	☐☐	£ ☐☐☐
Anti-inflammatory drugs (for example ibuprofen/nurofen)	☐☐	£ ☐☐☐
Gels/Creams (for example ibuleve or movelat)	☐☐	£ ☐☐☐

Other (Please specify)_____

Products / equipment.

9. In the **last 6 months**, have you bought items such as braces or aids, a new bed or mattress, a chair, a massage machine, or any other products or equipment **because of your back pain**? (please list the item below and estimate the cost to the nearest pound)

Item bought

1. _____ . £ [ ][ ][ ][ ]

2. _____ . £ [ ][ ][ ][ ]

3. _____ . £ [ ][ ][ ][ ]

4. _____ . £ [ ][ ][ ][ ]

5. _____ . £ [ ][ ][ ][ ]

Normal activities.

10. Over the **last 6 months** has your back pain stopped you doing your **normal activities**?

Please cross any that apply and enter the total number of days your back pain stopped you getting on with your normal activities.

Number of days

☐   Employment   [ ][ ]
                                              If none enter '0'

☐   Education (i.e. college or University)   [ ][ ]
                                              If none enter '0'

☐   Housework   [ ][ ]
                                              If none enter '0'

☐   Childcare or care of a relative   [ ][ ]
                                              If none enter '0'

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Changes in work status in the last six months

11. Have you had to take any days off sick from work in the last 6 months due to your low back pain?

        Yes   ☐ 1

        No   ☐ 2

        Not applicable   ☐ 3

If **Yes,** how many days?   ☐☐

12. Have you had to change your occupation in the last 6 months due to your back pain?

        Yes   ☐ 1

        No   ☐ 2

        Not applicable   ☐ 3

If **Yes,** what is your new job?   _____

When did this change occur? |__|__| |__|__| |__|__|

13. Have your hours of employment changed in the last 6 months because of back pain getting better or worse?

        Yes   ☐ 1

        No   ☐ 2

        Not applicable   ☐ 3

If **Yes,** by how many hours per week has your employment changed? _____

When did this change occur? |__|__| |__|__| |__|__|

14. If you were off work when you joined the study, have you returned to work?

        ☐ 1 I am still off work

        ☐ 2 I returned to work on |__|__| |__|__| |__|__|

Benefits and entitlement to free prescriptions

15. Do you qualify for free prescriptions?

Yes	☐ 1
No	☐ 2

16. Has your benefit status changed in the last 6 months?

Yes	☐ 1
No	☐ 2

If **yes**, please cross all benefits that you are currently receiving.

Statutory Sick Pay	☐ 1	Child Tax Credit	☐ 8
Incapacity Benefit	☐ 2	Council Tax Benefit	☐ 9
Disability living allowance	☐ 3	Housing Benefit	☐ 10
Disabled persons tax credit	☐ 4	Attendance allowance	☐ 11

Invalid Care Allowance ☐ 5 (includes if paid to someone who looks after you)

Other ☐ 6 please specify_____

Working Tax Credit ☐ 7

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

If you have any comments, please write them overleaf.

Your comments:

Appendix 9
Core outcome questionnaires

BeST

Core Outcome measures for 3 Month questionnaire non-responders

Participant Study Number:

Date of telephone interview:

The first questions are about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?
    0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?
    0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?
    0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
    0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
    0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
    0   1   2   3   4   5   6   7   8   9   10

7. In what way has your back pain changed in the <u>past three months</u>?

Completely recovered	❑ 1	Much improved	❑ 2
Slightly improved	❑ 3	No change	❑ 4
Slightly worsened	❑ 5	Much worsened	❑ 6
Vastly worsened	❑ 7		

The next questions are about your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

---

8. In general, would you say your health is:

Excellent	**Very good**	**Good**	**Fair**	**Poor**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

9. The following questions are about activities you might do during a typical day.
   Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

10. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

11. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

12. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are to ask about your general health state <u>at the moment</u> please let me know which statement best describes your own health state <u>today.</u>

15. Mobility:

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

16. Self-Care:

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

17. Usual Activities (e.g. work, study, housework, family or leisure activities)**:**

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

16. Pain / Discomfort:

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

17.   Anxiety / Depression:

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

<u>Changes in work status in the last three months</u>

20. Have you had to take any days off sick from work in the last three months due to your low back pain?

Yes   ☐ 1   If **Yes,** how many days? ☐☐

No   ☐ 2

Not applicable? ☐ 3

21. Have your hours of employment altered in the last three months because of changes in your back pain?

No, stayed the same   ☐ 1

Yes, increased   ☐ 2

Yes, decreased   ☐ 3

Not applicable   ☐ 4

If **Yes,** by how many hours per week has your employment changed? _____

When did this change occur? |__|__| |__|__| |__|__|

22. If you were off work when you joined the study, have you returned to work?

☐ 1 I am still off work

☐ 2 I returned to work on |__|__| |__|__| |__|__|

☐ 3 Not applicable?

Advise patient of 6 month questionnaire and importance of   ☐
completing it and returning it in pre-paid envelope

BeST

Core Outcome measures for 6 Month questionnaire non-responders

Participant Study Number:

Date of telephone interview:

The first questions are about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?
   0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?
   0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?
   0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
   0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
   0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?
   0   1   2   3   4   5   6   7   8   9   10

7. How would you describe your back pain compare to when you started the study?

Very much improved (or completely recovered)	☐1	Much improved	☐2
Minimally (or slightly) improved	☐3	No change	☐4
Minimally worse	☐5	Much worse	☐6
Very much worse	☐7		

The next questions are about your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

---

8. In general, would you say your health is:

Excellent	**Very good**	**Good**	**Fair**	**Poor**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

9. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

10. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

11. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

12. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are to ask about your general health state <u>at the moment</u> please let me know which statement best describes your own health state <u>today.</u>

15. Mobility:

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

16. Self-Care:

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

17. Usual Activities (e.g. work, study, housework, family or leisure activities)**:**

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

16. Pain / Discomfort:

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

17.   Anxiety / Depression:

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

Changes in work status in the last three months

20. Have you had to take any days off sick from work in the last three months due to your low back pain?

Yes   ☐ 1   If **Yes,** how many days?   ☐☐

No   ☐ 2

Not applicable? ☐ 3

21. Have your hours of employment altered in the last three months because of changes in your back pain?

No, stayed the same   ☐ 1

Yes, increased   ☐ 2

Yes, decreased   ☐ 3

Not applicable   ☐ 4

If **Yes,** by how many hours per week has your employment changed? _____

When did this change occur? |__|__| |__|__| |__|__|

22. If you were off work when you joined the study, have you returned to work?

☐ 1 I am still off work

☐ 2 I returned to work on |__|__| |__|__| |__|__|

☐ 3 Not applicable?

Advise patient of 12 month questionnaire and importance of   ☐
completing it and returning it in pre-paid envelope

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BeST

Core Outcome measures for 12 Month questionnaire non-responders

Participant Study Number:

Date of telephone interview:

The first questions are about how much your back trouble has been interfering with your daily activities in <u>recent weeks</u>.

1. In the **past 4 weeks**, how much has your back pain interfered with your daily activities on a scale of 0-10 where <u>0 is 'no interference'</u> and <u>10 is 'unable to carry out any activities at all'</u>?

  0   1   2   3   4   5   6   7   8   9   10

2. In the **past 4 weeks**, how much has your back pain changed your ability to take part in recreational, social and family activities on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

  0   1   2   3   4   5   6   7   8   9   10

3. In the **past 4 weeks**, how much has your back pain changed your ability to work (including housework) on a scale of 0-10 where <u>0 is 'no change'</u> and <u>10 is 'extreme change'</u>?

  0   1   2   3   4   5   6   7   8   9   10

4. In the **past 4 weeks**, how bad has your <u>worst</u> back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

  0   1   2   3   4   5   6   7   8   9   10

5. In the **past 4 weeks**, on <u>average</u> how bad has your back pain been on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

  0   1   2   3   4   5   6   7   8   9   10

6. How would you rate your back pain **today** on a scale of 0-10 where <u>0 is 'no pain'</u> and <u>10 is 'as bad as a pain could be'</u>?

  0   1   2   3   4   5   6   7   8   9   10

7. How would you describe your back pain compare to when you started the study?

Very much improved (or completely recovered)	❏1	Much improved	❏2
Minimally (or slightly) improved	❏3	No change	❏4
Minimally worse	❏5	Much worse	❏6
Very much worse	❏7		

The next questions are about your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

---

8. In general, would you say your health is:

Excellent	**Very good**	**Good**	**Fair**	**Poor**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

9. The following questions are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

	Yes, limited a lot	**Yes, limited a little**	**No, not limited at all**
a) **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	☐ 1	☐ 2	☐ 3
b) Climbing **several** flights of stairs	☐ 1	☐ 2	☐ 3

---

10. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

11. During the **past 4 weeks**, how much of the time have you had any of the following problems with your work or other regular activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

	All of the time	**Most of the time**	**Some of the time**	**A little of the time**	**None of the time**
a) **Accomplished less** than you would like	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Were limited in the **kind** of work or other activities	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

---

12. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

Not at all	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

13. These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling. **How much of the time during the past 4 weeks**:

	All of the time	Most of the time	Some of the time	A little of the time	None of the time
a) Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b) Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c) Have you felt downhearted and low?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

14. During the **past 4 weeks**, how much of the time has your physical health OR emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following questions are to ask about your general health state <u>at the moment</u> please let me know which statement best describes your own health state <u>today.</u>

15. Mobility:

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

16. Self-Care:

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

17. Usual Activities (e.g. work, study, housework, family or leisure activities)**:**

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

16. **Pain / Discomfort:**

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

17. **Anxiety / Depression:**

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

I am extremely anxious or depressed ☐

Changes in work status in the last three months

20. Have you had to take any days off sick from work in the last three months due to your low back pain?

Yes	☐ 1	If **Yes,** how many days? ☐☐
No	☐ 2	
Not applicable?	☐ 3	

21. Have your hours of employment altered in the last three months because of changes in your back pain?

No, stayed the same	☐ 1
Yes, increased	☐ 2
Yes, decreased	☐ 3
Not applicable	☐ 4

If **Yes,** by how many hours per week has your employment changed? _____

When did this change occur? |__|__| |__|__| |__|__|

22. If you were off work when you joined the study, have you returned to work?

☐ 1 I am still off work

☐ 2 I returned to work on |__|__| |__|__| |__|__|

☐ 3 Not applicable?

Thank patient for taking part in the study and advise that this ☐
Was their final questionnaire

Appendix 10

Event notification form

BEST/045

BEST Study, Event notification form

Telephone Warwick immediately with any notification of withdrawal, death, serious adverse event or complaint

Emma Withers on 024 0000 0000

Completed by .... Date of completion …../…../..…....

Participant details:

Participant ID number |__|__|__| |__|__| |__|__|__|__|

Date of birth |__|__| |__|__| |__|__|

***Only include the participant's name or address if used to notify a name or address change**

Old name   New name

…………………………………………   …………………………………………

Old address   New address

…………………………………………   …………………………………………

…………………………………………   …………………………………………

…………………………………………   …………………………………………

…………………………………………   …………………………………………

*B*ack *S*kills *T*raining (*BeST*) *Trial*

The University of Warwick
Centre for Primary Health Care

THE UNIVERSITY OF
WARWICK

GPRF

MRC General Practice Research
Framework

A randomised study of physical treatments for back pain in primary care, funded by the NHS R&D HTA programme (ISRCTN54717854)

1. Patient request for withdrawal from *treatment* (see also next item '2')

Date request received |__|__| |__|__| |__|__|

Reason for request (if given)

………………………………………………………………………………………..

Date Warwick informed |__|__| |__|__| |__|__| *Phone Emma at*
                                                    Warwick as soon as possible
                                                    with this information

2. Patient request for withdrawal from *follow-up* (i.e., from receiving questionnaires)

Date request received |__|__| |__|__| |__|__|

Reason for request (if given)

....

Date Warwick informed |__|__| |__|__| |__|__| *Phone Emma at*
                                                    Warwick as soon as possible
                                                    with this information

3. Practice request for patient to be withdrawn from *follow-up* (i.e., from receiving questionnaires)

Date request received |__|__| |__|__| |__|__|

Reason for request (if given)

....

 Date Warwick informed |__|__| |__|__| |__|__| *Phone Emma at*
                                                    Warwick as soon as possible
                                                    with this information

4. Death notification

Date of death |__|__| |__|__| |__|__| *Phone Emma at Warwick as soon as possible with this information*

Cause of death (if known)………...……............…………

Date Warwick informed |__|__| |__|__| |__|__|

Message taken by (at Warwick)

....…..……

5. Serious adverse event notification

Date of event |__|__| |__|__| |__|__| *Phone Emma at Warwick as soon as possible with this information*

Nature of possible adverse event...….....…...

....

Date Warwick informed |__|__| |__|__| |__|__|

Source of notification of possible adverse event..…………………………………………

Message taken by (at Warwick).....…………………………………….............…...………….

6. Complaint notification

Date of notification |__|__| |__|__| |__|__|

Nature of complaint...….......…

....

Date Warwick informed |__|__| |__|__| |__|__| *Phone Emma at Warwick as soon as possible with this information*

Source of notification of complaint…………......…...………………………………………….

Message taken by (at Warwick)

……………………………………………..…...……………………

Completed by ……………………………………… (Block capitals)

Date of completion |__|__| |__|__| |__|__|

7. Pregnancy

Completed by   ………………………………………… (Block capitals)

Date of completion |__|__| |__|__| |__|__|

Participant details

Participant ID number |__|__|__| |__|__| |__|__|__|__|

Date of birth |__|__| |__|__| |__|__|

Due date |__|__| |__|__| |__|__|

Appendix 11
Demography and baseline assessments

TABLE 55 *Baseline characteristics by case level missingness (using the status at 3 months)*

		Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
		Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
Age (years)	N	514	31	545	7	22	116	9	154	3.60
	Mean	54.91	46.16	54.48	59.43	59.82	47.87	60.00	50.81	(0.98 to 6.22)
	Median	57.00	45.00	56.00	68.00	58.50	46.00	60.00	50.00	
	SD	14.37	12.72	14.42	18.37	12.35	14.98	11.04	15.34	
	Range	20–85	19–76	19–85	30–76	34–81	18–85	48–79	18–85	
	Missing	0	0	0	0	1	1	0	2	
Sex	Male	201 (39.1%)	13 (41.9%)	214 (39.3%)	4 (57.1%)	5 (21.7%)	51 (43.6%)	5 (55.6%)	65 (41.7%)	–
	Female	312 (60.7%)	18 (58.1%)	330 (60.6%)	3 (42.9%)	17 (73.9%)	66 (56.4%)	4 (44.4%)	90 (57.7%)	
	Missing	1 (0.2%)	0	1 (0.2%)	0	1 (4.3%)	0	0	1 (0.6%)	
RMQ score	N	513	31	544	7	23	117	9	156	–0.26
	Mean	8.59	9.23	8.62	7.14	8.87	8.97	9.11	8.88	(–1.14 to 0.26)
	Median	8.00	9.00	8.00	9.00	9.00	8.00	10.00	8.00	
	SD	4.83	4.87	4.83	3.84	4.45	5.40	4.31	5.14	
	Range	0–23	2–21	0–23	0–10	1–18	0–23	3–15	0–23	
	Missing	1	0	1	0	0	0	0	0	
MVK (disability)	N	502	30	532	6	21	115	9	151	–2.47
	Mean	46.77	54.33	47.20	51.11	44.92	50.95	43.33	49.67	(–6.78 to 1.85)
	Median	50.00	55.00	50.00	53.33	43.33	53.33	33.33	46.67	
	SD	23.73	20.99	23.63	28.41	24.62	24.29	26.87	24.52	
	Range	0–100	13.3–90	0–100	10–83.3	6.67–100	0–100	16.67–83.33	0–100	
	Missing	12	1	13	1	2	2	0	5	
MVK (pain)	N	510	30	540	7	22	115	9	153	–4.54
	Mean	57.99	64.33	58.34	59.05	63.79	63.45	56.29	62.88	(–8.00 to –1.08)
	Median	56.67	65.00	56.67	66.67	65.00	63.33	53.33	63.33	
	SD	19.40	16.07	19.28	28.40	18.50	18.77	18.59	19.11	
	Range	10–100	40–96.77	0–100	6.67–96.67	33.3–100	23.33–100	23.33–83.33	6.67–100	
	Missing	4	1	5	0	1	2	0	3	
Physical activity (Fear Avoidance Beliefs)	N	488	30	518	6	22	108	8	144	–0.30
	Mean	13.65	14.67	13.71	12.33	15.36	13.98	11.88	14.01	(–1.46 to 0.87)
	Median	14.00	14.50	14.00	13.00	15.50	15.00	11.50	15.00	

		Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
		Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
	SD	6.25	6.02	6.24	5.89	5.05	6.59	9.79	6.54	
	Range	0–24	3–24	0–24	4–21	0–24	0–24	0–24	0–24	
	Missing	26	1	27	1	1	9	1	12	
Pain self-efficacy score	N	497	31	528	7	20	112	9	148	2.56
	Mean	40.91	36.29	40.64	42.29	41.40	37.88	29.78	38.07	(0.17 to 4.95)
	Median	43.00	41.00	43.00	41.00	43.5	40.00	25.00	40.00	
	SD	12.72	14.81	12.88	8.10	11.15	14.58	10.32	13.84	
	Range	2–60	4–57	2–60	35–59	21–56	2–60	20–48	2–60	
	Missing	17	0	17	0	3	5	0	8	
Health status	N	506	28	534	7	23	116	9	155	3.01
	Mean	65.77	56.50	65.29	61.43	60.26	62.65	63.33	62.28	(–0.33 to 6.35)
	Median	70.00	60.0	70.00	60.0	65.00	63.0	70.00	63.00	
	SD	18.26	22.78	18.61	12.15	17.98	19.14	21.79	18.74	
	Range	7–100	17–90	7–100	50–80	30–85	0–100	25–95	0–100	
	Missing	8	3	11	0	0	1	0	1	
SF-12 (physical aggregate score)	N	470	29	499	6	20	105	8	139	–0.14
	Mean	37.23	36.75	37.20	33.67	35.71	37.85	37.43	37.34	(–1.94 to 1.67)
	Median	37.33	37.93	37.41	30.37	34.50	37.46	38.12	36.95	
	SD	9.76	8.98	9.70	8.45	6.16	9.59	9.75	9.12	
	Range	7.17–61.25	20.03–53.21	7.17–61.25	26.11–47.92	26.71–47.00	19.64–57.81	24.28–53.52	19.64–57.81	
	Missing	44	2	46	1	3	12	1	17	
SF-12 (mental aggregate score)	N	470	29	499	6	20	105	8	139	2.88
	Mean	45.87	41.83	45.63	48.79	44.10	42.54	37.43	42.74	(0.76 to 5.02)
	Median	45.78	41.80	45.56	49.23	42.28	42.44	40.24	42.56	
	SD	11.41	12.22	11.49	7.02	11.68	10.56	9.89	10.64	
	Range	11.10–72.10	17.4–60.4	11.10–72.11	38.00–57.48	24.01–62.65	14.07–69.98	22.06–48.23	14.07–68.98	
	Missing	44	2	46	1	3	12	1	17	

MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12-item health survey.

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TABLE 56 *Baseline characteristics by case level missingness (using the status at 6 months)*

		Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
		Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
Age (years)	N	529	52	581	8	29	74	7	118	2.57
	Mean	54.53	49.25	54.06	64.25	57.38	46.84	61.57	51.48	(−0.33 to 5.48)
	Median	56.00	46.00	55.00	60.50	57.00	44.50	61.00	51.50	
	SD	14.47	13.45	14.45	11.68	13.90	15.26	11.82	15.69	
	Range	19–85	27–85	19–85	51–84	22–81	18–82	48–79	18–84	
	Missing	0	1	1	0	1	0	0	1	
Sex	Male	209 (39.5%)	23 (43.4%)	232 (39.9%)	3 (37.5%)	10 (33.3%)	30 (40.5%)	4 (57.1%)	47 (40%)	—
	Female	319 (60.3%)	30 (56.6%)	349 (60.0%)	5 (62.5%)	19 (63.3%)	44 (59.5%)	3 (42.9%)	71 (59.7%)	
	Missing	1 (0.2%)	0	1 (0.2%)	0	1 (3.3%)	0	0	1 (0.8%)	
RMQ score	N	528	53	581	8	30	74	7	119	−0.71
	Mean	8.53	8.81	8.56	9.75	8.83	9.42	9.00	9.27	(−1.68 to 0.26)
	Median	8.00	9.00	8.00	7.50	9.00	9.00	10.00	9.00	
	SD	4.80	4.93	4.81	7.11	4.16	5.70	3.83	5.31	
	Range	0–23	0–23	0–23	0–22	1–18	0–23	3–13	0–23	
	Missing	1	0	1	0	0	0	0	0	
MVK (disability)	N	515	52	567	7	28	74	7	116	−1.54
	Mean	47.14	50.90	47.48	43.33	43.57	52.39	40.95	49.02	(−6.31 to 3.23)
	Median	50.0	53.33	50.00	43.33	40.00	53.33	33.33	50.00	
	SD	23.42	25.02	23.55	33.61	24.44	24.13	28.65	25.14	
	Range	0–100	10–100	0–100	3.33–100	6.67–100	0–100	16.67–83.33	0–100	
	Missing	14	1	15	1	2	0	0	3	
MVK (pain)	N	525	52	577	7	29	73	7	116	−4.38
	Mean	58.10	63.72	58.62	61.43	63.10	63.74	56.17	62.99	(−8.23 to −0.53)
	Median	56.67	63.33	56.67	66.67	66.67	63.33	53.33	63.33	
	SD	19.49	15.39	19.19	27.81	19.49	18.98	19.19	19.60	
	Range	6.67–100	33.33–96.67	6.67–100	20–100	20–100	23.33–100	23.33–83.33	20.00–100	
	Missing	4	1	5	1	1	1	0	3	

		Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
		Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
Physical activity (Fear Avoidance Beliefs)	N	502	47	549	8	29	70	6	113	–1.42
	Mean	13.50	13.91	13.53	13.00	16.07	14.94	12.33	14.96	(–2.70 to –0.15)
	Median	14.00	14.00	14.00	15.50	16.00	15.00	11.50	15.00	
	SD	6.35	6.39	6.35	9.17	4.83	5.67	9.44	5.99	
	Range	0–24	1–24	0–24	0–22	0–24	3–24	0–24	0–24	
	Missing	27	6	33	0	1	4	1	6	
Pain self-efficacy score	N	510	53	563	7	27	72	7	113	3.37
	Mean	40.96	37.57	40.64	38	39.93	36.79	31.14	37.27	(0.73, 6.02)
	Median	43.00	39.00	42.00	41.00	40.00	39.50	25.00	40.00	
	SD	12.79	13.37	12.88	18.07	11.26	14.78	11.44	14.02	
	Range	2–60	4–60	2–60	7–58	21–56	2–60	20–48	2.0–60.00	
	Missing	19	0	19	1	3	2	0	6	
Health status	N	521	51	572	8	30	72	7	117	2.02
	Mean	65.00	64.51	64.95	62.5	60.53	63.43	68.57	62.93	(–1.70 to 5.74)
	Median	70.00	64.00	70.00	55.00	67.00	68.00	75.00	69.00	
	SD	18.55	17.89	18.47	18.83	17.67	20.42	21.93	19.58	
	Range	7–100	17–95	7–100	41–95	30–85	0–100	25–95	0–100	
	Missing	8	2	10	0	0	2	0	2	
SF-12 (physical aggregate score)	N	486	47	533	6	27	66	6	105	–0.23
	Mean	37.26	36.48	37.19	30.94	37.73	38.75	36.82	37.42	(–2.23 to 1.78)
	Median	37.39	37.37	37.37	26.33	35.07	38.36	38.12	36.95	
	SD	9.82	7.87	9.66	12.62	5.91	9.57	10.99	9.19	
	Range	7.17–61.25	20.03–53.13	7.17–61.25	22.78–56.15	26.25–47.00	18.96–54.54	24.28–53.52	18.96–56.15	
	Missing	43	6	49	2	3	8	1	14	
SF-12 (mental aggregate score)	N	486	47	533	6	27	66	6	105	3.27
	Mean	45.66	44.24	45.54	40.09	43.65	42.15	39.60	42.27	(0.90 to 5.64)
	Median	45.54	44.38	45.32	43.99	41.22	42.82	41.83	42.44	
	SD	11.36	10.68	11.29	13.69	11.97	11.23	9.11	11.35	
	Range	11.10–72.11	18.76–66.21	11.10–72.11	21.80–57.16	24.01–62.65	17.27–68.98	24.17–48.23	17.27–68.98	
	Missing	43	6	49	2	3	8	1	14	

MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12-item health survey.

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TABLE 57 Baseline characteristics by case level missingness (using the status at 12 months)

		Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
		Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
Age (years)	N	500	97	597	4	37	61	–	102	1.54
	Mean	55.22	47.11	53.85	46.75	56.81	49.93	–	52.30	(–1.53 to 4.63)
	Median	57.00	45.00	55.00	46.50	56.00	44.00	–	53.00	
	SD	14.07	14.23	14.39	24.10	15.54	15.96	–	16.33	
	Range	20–85	19–85	19–85	18–76	19–85	23–84	–	18–85	
	Missing	0	1	1	0	1	0	–	1	
Sex	Male	192 (38.4%)	49 (50.0%)	241 (41.1%)	2 (50.0%)	13 (34.2%)	23 (37.7%)	–	38 (36.9%)	–
	Female	307 (61.4%)	49 (50.0%)	356 (58.9%)	2 (50.0%)	24 (63.2%)	38 (62.3%)	–	64 (62.1%)	
	Missing	1 (0.2%)	0	1 (0.2%)	0	1 (2.6%)	0	–	1 (1.0%)	
RMQ score	N	500	98	598	4	38	60	–	102	–1.00
	Mean	8.44	9.0	8.54	4.0	9.47	9.28	–	9.54	(–2.03 to 0.02)
	Median	8.00	9.0	8.00	13.0	9.5	8.0	–	9.00	
	SD	4.74	5.32	4.84	6.32	4.94	5.18	–	5.16	
	Range	0–22	0–23	0–23	8–22	1–21	0–22	–	0–22	
	Missing	0	0	0	0	0	1	–	1	
MVK (disability)	N	487	98	585	4	36	58	–	98	–4.26
	Mean	46.02	52.69	47.13	64.17	45.56	54.14	–	51.39	(–9.36 to 0.84)
	Median	46.67	53.33	50.00	68.34	43.33	53.33	–	53.33	
	SD	23.52	23.95	23.71	37.45	26.08	21.94	–	24.41	
	Range	0–100	10–100	0–100	20–100	3.33–100	0–93.33	–	0–100	
	Missing	13	0	13	0	2	3	–	5	
MVK (pain)	N	496	98	594	4	37	58	–	99	–5.48
	Mean	57.61	63.37	58.56	74.16	64.50	63.05	–	64.04	(–9.58 to –1.38)
	Median	56.67	61.67	58.33	78.34	21.61	65.00	–	66.67	
	SD	19.17	17.47	19.01	30.60	66.67	19.33	–	20.55	
	Range	6.67–100	16.67–100	6.67–100	40–100	20–100	23.33–100	–	20–100	
	Missing	4	0	4	0	1	3	–	4	

	Cases with some or no missing data			Cases with all missing data					Mean difference (95% CI)
	Return (by post)	Return (by core)	Total	Return (by blank)	Withdrawal	Non-response	Others	Total	
Physical activity (Fear Avoidance Beliefs)									
N	472	91	563	4	37	58	–	99	–1.53
Mean	13.42	14.21	13.55	19.75	15.62	14.41	–	15.08	(–2.88 to –0.19)
Median	14.00	16.00	14.00	20.00	16.00	14.50	–	15.00	
SD	6.33	6.93	6.43	4.03	5.22	5.44	–	5.39	
Range	0–24	0–24	0–24	15–24	0–24	3–24	–	0–24	
Missing	28	7	35	0	1	3	–	4	
Pain self-efficacy score									
N	482	95	577	4	34	61	–	99	3.77
Mean	41.24	37.49	40.63	21	37.18	37.72	–	36.86	(0.98 to 6.56)
Median	43.0	41.00	43.00	20.00	37.50	37.00	–	37.00	
SD	12.64	14.33	13.00	18.17	14.07	12.41	–	13.48	
Range	2–60	3–60	2–60	4–40	2–58	5–60	–	2–60	
Missing	18	3	21	0	4	0	–	4	
Health state									
N	494	94	588	4	38	59	–	101	4.23
Mean	66.15	60.39	65.23	45.50	57.26	64.46	–	61.00	(0.29 to 8.17)
Median	70.00	60.00	70.00	52.50	57.50	69.00	–	63.00	
SD	18.09	19.08	18.36	23.19	20.55	19.01	–	20.10	
Range	7–100	15–95	7–100	12–65	0–95	17–98	–	0–98	
Missing	6	4	10	0	0	2	–	2	
SF-12 (physical aggregate score)									
N	458	90	548	4	33	53	–	90	1.39
Mean	37.46	37.24	37.43	30.05	35.18	37.01	–	36.03	(–0.74 to 3.53)
Median	37.63	37.45	37.62	30.05	34.98	36.95	–	35.30	
SD	9.84	8.85	9.68	5.01	8.12	9.35	–	8.84	
Range	7.17–61.25	18.96–54.38	7.17–61.25	24.00–36.11	19.11–56.15	20.65–54.55	–	19.11–56.15	
Missing	42	8	50	0	5	8	–	13	
SF-12 (mental aggregate score)									
N	458	90	548	4	33	53	–	90	2.65
Mean	46.10	41.67	45.37	36.88	43.76	42.53	–	42.73	(0.12 to 5.18)
Median	45.81	41.30	45.06	36.09	43.19	42.68	–	42.50	
SD	11.30	10.92	11.35	13.95	11.42	11.04	–	11.25	
Range	11.10–72.11	17.27–66.21	11.10–72.11	21.80–53.55	24.01–62.65	18.94–63.01	–	18.93–63.01	
Missing	42	8	50	0	5	8	–	13	

MVK, Modified Von Korff Scale; RMQ, Roland Morris Disability Questionnaire; SF-12, Short Form 12-item health survey.

Appendix 12

Missing data and characteristics of the randomised sample

TABLE 58 Missing data for the Roland Morris Questionnaire score

Time point	Therapy	No. of participants (%) (total score can be derived)	Missing data (%)			Total of any missing cases/questionnaires/items (%)
			Cases	Questionnaires	Items	
Baseline	AM	232 (99.5)	0	1 (0.4)	0	1 (0.4)
	AM+CBA	468 (100)	0	0	0	0
	Total	700 (99.9)	0	1 (0.1)	0	1 (0.1)
3 months	AM	179 (76.8)	54 (23.2)	0	0	54 (23.2)
	AM+CBA	335 (71.6)	133 (28.4)	0	0	133 (28.4)
	Total	514 (73.3)	187 (26.7)	0	0	187 (26.7)
6 months	AM	177 (76.0)	56 (24.0)	0	0	56 (24.0)
	AM+CBA	352 (75.2)	116 (24.8)	0	0	116 (24.8)
	Total	529 (75.5)	172 (24.5)	0	0	172 (24.5)
12 months	AM	159 (68.2)	72 (30.9)	2 (0.9)	0	74 (31.7)
	AM+CBA	339 (72.4)	129 (27.6)	0	0	129 (28.0)
	Total	498 (71.0)	201 (28.7)	2 (0.3)	0	203 (29.2)

TABLE 59 Missing data for the MVK (disability) questionnaire score

Time point	Therapy	No. of participants (%) (total score can be derived)	Missing data (%)		Items		Total of any missing cases/questionnaires/items (%)
			Cases	Questionnaires	2 items	1 item	
Baseline	AM	228 (97.9)	0	1 (0.4)	0	4 (1.7)	5 (2.1)
	AM+CBA	455 (97.2)	0	0	1 (0.2)	12 (2.6)	13 (2.8)
	Total	683 (97.4)	0	1 (0.1)	1 (0.1)	16 (2.3)	18 (2.6)
3 months	AM	187 (80.3)	43 (18.5)	2 (0.9)	0	1 (0.4)	46 (19.7)
	AM+CBA	345 (73.7)	113 (24.1)	0	0	10 (2.1)	123 (26.3)
	Total	532 (75.9)	156 (22.3)	2 (0.3)	0	11 (1.6)	169 (24.0)
6 months	AM	183 (78.5)	44 (18.9)	1 (0.4)	0	5 (2.1)	50 (21.5)
	AM+CBA	381 (81.4)	75 (16.0)	2 (0.4)	0	10 (2.1)	87 (18.6)
	Total	564 (80.4)	119 (17.0)	3 (0.4)	0	15 (2.1)	137 (19.5)
12 months	AM	189 (81.1)	34 (14.6)	3 (1.3)	0	7 (3.0)	44 (18.9)
	AM+CBA	374 (78.5)	69 (14.7)	1 (0.2)	3 (0.7)	21 (4.5)	94 (20.1)
	Total	563 (78.7)	103 (14.7)	4 (0.6)	3 (0.5)	28 (4.0)	138 (19.7)

TABLE 60 Missing data for the MVK (pain) questionnaire score

Time point	Therapy	No. of participants (%) (total score can be derived)	Missing data (%)			Total of any missing cases/ questionnaires/items (%)
			Cases	Questionnaires	Items (1 item)	
Baseline	AM	230 (98.7)	0	1 (0.4)	2 (0.9)	3 (1.3)
	AM+CBA	463 (98.9)	0	1 (0.2)	4 (0.9)	5 (1.1)
	Total	693 (98.9)	0	2 (0.3)	6 (0.9)	8 (1.1)
3 months	AM	189 (81.1)	43 (18.5)	1 (0.4)	0	44 (18.9)
	AM+CBA	354 (75.6)	113 (24.1)	0	1 (0.2)	114 (24.4)
	Total	543 (77.5)	156 (22.2)	1 (0.1)	1 (0.1)	158 (22.5)
6 months	AM	187 (80.3)	44 (18.9)	1 (0.4)	1 (0.4)	46 (19.7)
	AM+CBA	387 (82.7)	75 (16.0)	3 (0.6)	3 (0.6)	81 (17.3)
	Total	574 (81.9)	119 (16.9)	4 (0.6)	4 (0.6)	127 (18.1)
12 months	AM	195 (83.7)	34 (14.6)	3 (1.3)	1 (0.5)	38 (16.3)
	AM+CBA	392 (83.8)	69 (14.7)	1 (0.2)	6 (1.4)	76 (16.2)
	Total	587 (83.7)	103 (14.7)	4 (0.6)	7 (1.1)	114 (16.3)

TABLE 61 Missing data for the physical activity (Fear Avoidance Beliefs) questionnaire score

Time point	Therapy	No. of participants (%) (total score can be derived)	Missing data (%)		Items			Total of any missing cases/ questionnaires/ items (%)
			Cases	Questionnaires	3 items	2 items	1 item	
Baseline	AM	219 (94.0)	0	1 (0.4)	2 (0.9)	1 (0.4)	10 (4.3)	14 (6.0)
	AM+CBA	443 (94.7)	0	4 (0.9)	6 (1.3)	2 (0.4)	13 (2.8)	25 (5.3)
	Total	662 (94.4)	0	5 (0.7)	8 (1.1)	3 (0.4)	23 (3.3)	39 (5.6)
3 months	AM	173 (74.2)	54 (23.2)	2 (0.9)	1 (0.4)	0	3 (1.3)	60 (25.8)
	AM+CBA	319 (68.1)	133 (28.4)	2 (0.4)	0	2 (0.4)	12 (2.6)	149 (31.8)
	Total	492 (70.2)	187 (26.7)	4 (0.6)	1 (0.1)	2 (0.3)	15 (2.1)	209 (29.8)
6 months	AM	168 (72.1)	56 (24.0)	1 (0.4)	1 (0.4)	1 (0.4)	6 (2.6)	65 (27.9)
	AM+CBA	336 (71.8)	116 (24.8)	4 (0.9)	0	2 (0.4)	10 (2.1)	132 (28.2)
	Total	504 (71.9)	172 (24.5)	5 (0.7)	1 (0.1)	3 (0.4)	16 (2.3)	197 (28.1)
12 months	AM	152 (65.2)	72 (30.9)	3 (1.3)	0	1 (0.5)	5 (2.1)	81 (34.8)
	AM+CBA	320 (68.4)	129 (27.6)	5 (1.1)	2 (0.4)	0	12 (2.6)	148 (31.6)
	Total	472 (67.3)	201 (28.7)	8 (1.1)	2 (0.3)	1 (0.1)	17 (2.4)	229 (32.7)

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TABLE 62 Missing data for pain self-efficacy questionnaire score

Time point	Therapy	No. of participants (%) (total score can be derived)	Missing data (%)								Total of any missing cases/ questionnaires/ items (%)
			Cases	Questionnaires	Items						
					9 items	4 items	3 items	2 items	1 item		
Baseline	AM	223 (95.7)	0	2 (0.9)	0	0	0	0	8 (3.4)	10 (4.3)
	AM+CBA	453 (96.7)	0	1 (0.2)	1 (0.2)	0	0	3 (0.6)	10 (2.1)	15 (3.2)
	Total	676 (96.4)	0	3 (0.4)	1 (0.1)	0	0	3 (0.4)	18 (2.6)	25 (3.6)
3 months	AM	173 (74.2)	54 (23.2)	2 (0.9)	0	0	0	0	4 (1.7)	60 (25.8)
	AM+CBA	325 (69.4)	133 (28.4)	0	0	0	0	3 (0.6)	7 (1.5)	143 (30.6)
	Total	498 (71.0)	187 (26.7)	2 (0.3)	0	0	0	3 (0.4)	11 (1.6)	203 (29.0)
6 months	AM	170 (73.0)	56 (24.0)	0	0	0	0	1 (0.4)	6 (2.6)	63 (27.0)
	AM+CBA	333 (71.2)	116 (24.5)	4 (0.9)	0	1 (0.2)	1 (0.2)	3 (0.6)	10 (2.1)	135 (28.8)
	Total	503 (71.8)	172 (24.5)	4 (0.6)	0	1 (0.1)	1 (0.1)	4 (0.6)	16 (2.2)	198 (28.2)
12 months	AM	155 (66.5)	72 (30.9)	2 (0.9)	0	0	0	0	4 (2.0)	78 (33.5)
	AM+CBA	317 (67.7)	129 (27.6)	2 (0.5)	1 (0.2)	0	2 (0.4)	2 (0.4)	15 (3.1)	151 (32.3)
	Total	472 (67.3)	201 (28.7)	4 (0.6)	1 (0.1)	0	2 (0.3)	2 (0.3)	19 (2.7)	229 (32.7)

TABLE 63 Missing data for the SF-12 (physical and mental) questionnaire scores

| Time point | Therapy | No. of participants (%) (total score can be derived) | Missing data (%) | | Items (%) | | | | | | | | Total (%) |
			Cases	Qs	8 items	7 items	6 items	5 items	4 items	3 items	2 items	1 item	
Baseline	AM	217 (93.1)	0	0	0	2 (0.9)	0	1 (0.4)	0	0	2 (0.9)	11 (4.7)	16 (6.9)
	AM+CBA	421 (90.0)	0	0	1 (0.2)	8 (1.7)	0	4 (0.9)	1 (0.2)	3 (0.6)	10 (2.1)	20 (4.3)	47 (10.0)
	Total	638 (91.0)	0	0	1 (0.1)	10 (1.4)	0	5 (0.7)	1 (0.1)	3 (0.4)	12 (1.7)	31 (4.4)	63 (9.0)
3 months	AM	176 (75.5)	43 (18.5)	3 (1.3)	0	0	0	0	0	1 (0.4)	0	10 (4.2)	57 (24.5)
	AM+CBA	332 (70.9)	113 (24.1)	3 (0.6)	0	0	0	2 (0.4)	2 (0.4)	1 (0.2)	3 (0.6)	12 (2.6)	136 (29.1)
	Total	508 (72.5)	156 (22.2)	6 (0.9)	0	0	0	2 (0.3)	2 (0.3)	2 (0.3)	3 (0.4)	22 (3.1)	193 (27.5)
6 months	AM	177 (76.0)	44 (18.9)	1 (0.4)	0	0	0	0	1 (0.4)	0	2 (0.9)	8 (3.4)	56 (24.0)
	AM+CBA	362 (77.4)	75 (16.7)	3 (0.6)	0	1 (0.2)	1 (0.2)	0	1 (0.2)	2 (0.4)	4 (0.8)	19 (4.1)	106 (22.6)
	Total	539 (76.9)	119 (17.5)	4 (0.6)	0	1 (0.1)	1 (0.1)	0	2 (0.2)	2 (0.2)	6 (0.9)	27 (3.9)	162 (23.1)
12 months	AM	187 (80.3)	34 (14.6)	1 (0.4)	1 (0.5)	0	1 (0.5)	0	0	0	3 (1.5)	6 (3.0)	46 (19.7)
	AM+CBA	375 (80.1)	69 (14.7)	2 (0.4)	1 (0.2)	0	0	0	—	4 (0.9)	6 (1.4)	10 (2.4)	93 (19.9)
	Total	562 (80.2)	103 (14.7)	3 (0.4)	2 (0.3)	0	1 (0.2)	0	—	4 (0.6)	9 (1.5)	16 (2.6)	139 (19.8)

TABLE 64 Missing data for the health status score

| Time point | Therapy | No. of participants (%) (total score can be derived) | Missing data (%) | | Total of any missing cases/questionnaires (%) |
			Cases	Questionnaires	
Baseline	AM	228 (97.9)	0	5 (2.1)	5 (2.1)
	AM+CBA	461 (98.5)	0	7 (1.5)	7 (1.5)
	Total	689 (98.3)	0	12 (1.7)	12 (1.7)
3 months	AM	176 (75.5)	54 (23.2)	3 (1.2)	57 (24.5)
	AM+CBA	329 (70.3)	133 (28.4)	6 (1.3)	139 (29.7)
	Total	505 (72.0)	187 (26.7)	9 (1.3)	196 (28.0)
6 months	AM	174 (74.7)	56 (24.0)	3 (1.3)	59 (25.3)
	AM+CBA	340 (72.6)	116 (24.8)	12 (2.6)	128 (29.4)
	Total	514 (73.3)	172 (24.5)	15 (2.1)	187 (26.7)
12 months	AM	138 (59.2)	72 (30.9)	2 (0.9)	74 (31.8)
	AM+CBA	289 (61.8)	129 (27.6)	11 (2.4)	140 (29.9)
	Total	427 (60.9)	201 (28.7)	13 (1.9)	214 (30.5)

Appendix 13

Data on employment, sickness and benefit status

TABLE 65 *Hours of employment altered*

	Month		AM	AM+CBA	*p*-value[a]
Hours of employment altered	3	No	77 (33.1%)	151 (32.3%)	0.6973
		Yes, increased	1 (0.4%)	1 (0.2%)	
		Yes, decreased	5 (2.2%)	7 (1.5%)	
		Not applicable	93 (39.9%)	173 (37.0%)	
		Missing	57 (24.5%)	136 (29.1%)	
	6	No	12 (5.2%)	33 (7.1%)	0.2860
		Yes, increased	68 (29.2%)	159 (34.0%)	
		Yes, decreased	92 (39.5%)	157 (33.6%)	
		Not applicable	8 (3.4%)	24 (5.1%)	
		Missing	53 (22.8%)	95 (20.3%)	
	12	No	23 (9.9%)	36 (7.7%)	0.5627
		Yes, increased	69 (29.6%)	163 (34.8%)	
		Yes, decreased	82 (35.2%)	148 (31.6%)	
		Not applicable	11 (4.7%)	26 (5.6%)	
		Missing	48 (20.6%)	95 (20.3%)	
If yes:	3	*N*	6	8	
		Mean	9.5	10.1	
		SD	8.0	6.9	
		Median	7.5	9.0	
		Range	3–25	2–23	
		Missing	227	460	
	6	*N*	3	10	
		Mean	13	10.8	
		SD	10.1	7.1	
		Median	15.0	10.0	
		Range	2–22	0–20	
		Missing	230	458	
	12	*N*	1	8	
		Mean	50	9.6	
		SD	–	2.9	
		Median	50	10.0	
		Range	50	5–14	
		Missing	232	460	

a Based on chi-squared test.

TABLE 66 *Days off sick*

	Month		AM	AM+CBA	*p*-value
Days off sick from work	3	Yes	18 (7.7%)	30 (6.4%)	0.1987
		No	69 (29.6%)	153 (32.7%)	
		Not applicable	94 (40.3%)	156 (33.3%)	
		Missing	52 (22.3%)	129 (27.6%)	
	6	Yes	13 (5.6%)	34 (7.3%)	0.6366
		No	75 (32.2%)	175 (37.4%)	
		Not applicable	94 (40.3%)	166 (35.5%)	
		Missing	51 (21.9%)	93 (19.9%)	
	12	Yes	29 (12.5%)	37 (7.9%)	0.0818
		No	69 (29.6%)	177 (37.8%)	
		Not applicable	89 (38.2%)	167 (35.7%)	
		Missing	46 (19.7%)	87 (18.6%)	
No. of days sick	3	*N*	17	30	
		Mean	12.2	15.6	0.8754
		SD	21.4	25.2	
		Median	5.0	4.0	
		Range	1–90	1–92	
		Missing	216	438	
	6	*N*	12	29	
		Mean	6.1	19.1	0.5110
		SD	4.4	25.8	
		Median	5.5	7.0	
		Range	0–14	1–90	
		Missing	221	439	
	12	*N*	27	33	
		Mean	10.2	24.9	0.8979
		SD	12.9	46.5	
		Median	5.0	4.0	
		Range	1–49	0–180	
		Missing	206	435	
Benefit status	3	Yes	11 (4.7%)	28 (6.0%)	
		No	155 (66.5%)	276 (59.0%)	
		Missing	67 (28.8%)	164 (35.0%)	
	6	Yes	8 (3.4%)	24 (5.1%)	
		No	158 (67.8%)	312 (66.7%)	
		Missing	67 (28.8%)	132 (28.2%)	
	12	Yes	7 (3.0%)	18 (3.9%)	
		No	132 (56.7%)	277 (59.2%)	
		Missing	94 (40.3%)	173 (37.0%)	

TABLE 67 *Benefit and entitlement status – 3 months*

		AM (%)	AM+CBA (%)
Statutory Sick Pay	No	34 (14.6)	65 (13.9)
	Yes	1 (0.4)	2 (0.4)
	Missing	198 (85)	401 (85.7)
Incapacity Benefit	No	26 (11.2)	54 (11.5)
	Yes	9 (3.9)	12 (2.6)
	Missing	198 (85)	402 (85.9)
Disability Living Allowance	No	26 (11.2)	44 (9.4)
	Yes	9 (3.9)	23 (4.9)
	Missing	198 (85)	401 (85.7)
Severe Disablement Allowance	No	34 (14.6)	65 (13.9)
	Yes	1 (0.4)	1 (0.2)
	Missing	198 (85)	402 (85.9)
Disabled Persons Tax Credit	No	35 (15.0)	66 (14.1)
	Yes	0	0
	Missing	198 (85.0)	402 (85.9)
Carer's Allowance	No	34 (14.6)	61 (13.0)
	Yes	1 (0.4)	5 (1.1)
	Missing	198 (85)	402 (85.9)
Jobseeker's Allowance	No	32 (13.7)	63 (13.5)
	Yes	3 (1.3)	3 (0.6)
	Missing	198 (85.0)	402 (85.9)
Income Support	No	31 (13.3)	53 (11.3)
	Yes	4 (1.7)	14 (3.0)
	Missing	198 (85)	401 (85.7)
Working Tax Credit	No	31 (13.3)	64 (13.7)
	Yes	4 (1.7)	2 (0.4)
	Missing	198 (85)	402 (85.9)
Child Tax Credit	No	31 (13.3)	58 (12.4)
	Yes	4 (1.7)	8 (1.7)
	Missing	198 (85.0)	402 (85.9)
Council Tax Benefit	No	20 (8.6)	47 (10.0)
	Yes	15 (6.4)	19 (4.1)
	Missing	198 (85.0)	402 (85.9)
Housing Benefit	No	26 (11.2)	51 (10.9)
	Yes	9 (3.9)	15 (3.2)
	Missing	198 (85.0)	402 (85.9)
Attendance Allowance	No	32 (13.7)	58 (12.4)
	Yes	3 (1.3)	8 (1.7)
	Missing	198 (85.0)	402 (85.9)
Pension Credit	No	25 (10.7)	55 (11.8)
	Yes	10 (4.3)	11 (2.4)
	Missing	198 (85.0)	402 (85.9)
Other	No	31 (13.3)	57 (12.2)
	Yes	4 (1.7)	9 (1.9)
	Missing	198 (85.0)	402 (85.9)

TABLE 68 *Benefit and entitlement status – 6 months*

		AM (%)	AM+CBA (%)
Statutory Sick Pay	No	40 (17.2)	68 (14.5)
	Yes	2 (0.9)	11 (2.4)
	Missing	191 (82.0)	389 (83.1)
Incapacity Benefit	No	31 (13.3)	64 (13.7)
	Yes	11 (4.7)	15 (3.2)
	Missing	191 (82.0)	389 (83.1)
Disability Living Allowance	No	32 (13.7)	61 (13.0)
	Yes	10 (4.3)	18 (3.9)
	Missing	191 (82.0)	389 (83.1)
Severe Disablement Allowance	No	42 (18.0)	79 (16.9)
	Yes	0	0
	Missing	191 (82.0)	389 (83.1)
Disabled Persons Tax Credit	No	40 (17.2)	76 (16.2)
	Yes	2 (0.9)	3 (0.6)
	Missing	191 (82.0)	389 (83.1)
Carer's Allowance	No	30 (12.9)	63 (13.5)
	Yes	12 (5.2)	16 (3.4)
	Missing	191 (82.0)	389 (83.1)
Jobseeker's Allowance	No	39 (16.8)	72 (15.4)
	Yes	3 (1.3)	7 (1.5)
	Missing	191 (82.0)	389 (83.1)
Income Support	No	35 (15)	64 (13.7)
	Yes	7 (3.0)	15 (3.2)
	Missing	191 (82.0)	389 (83.1)
Working Tax Credit	No	24 (10.3)	51 (10.9)
	Yes	18 (7.7)	28 (6.0)
	Missing	191 (82.0)	389 (83.1)
Child Tax Credit	No	30 (12.9)	61 (13.0)
	Yes	12 (5.2)	18 (3.9)
	Missing	191 (82.0)	389 (83.1)
Council Tax Benefit	No	38 (16.3)	68 (14.5)
	Yes	4 (1.7)	11 (2.4)
	Missing	191 (82.0)	389 (83.1)
Housing Benefit	No	0	0
	Yes	0	0
	Missing	233 (100.0)	468 (100.0)
Attendance Allowance	No	0	0
	Yes	0	0
	Missing	233 (100.0)	468 (100.0)
Pension Credit	No	0	0
	Yes	0	0
	Missing	233 (100.0)	468 (100.0)
Other	No	0	0
	Yes	0	0
	Missing	233 (100.0)	468 (100.0)

TABLE 69 *Benefit and entitlement status – 12 months*

		AM (%)	AM+CBA (%)
Statutory Sick Pay	No	37 (15.9)	76 (16.2)
	Yes	0	2 (0.4)
	Missing	196 (84.1)	390 (83.3)
Incapacity Benefit	No	26 (11.2)	60 (12.8)
	Yes	11 (4.7)	18 (3.9)
	Missing	196 (84.1)	390 (83.3)
Disability Living Allowance	No	25 (10.7)	57 (12.2)
	Yes	12 (5.2)	21 (4.5)
	Missing	196 (84.1)	390 (83.3)
Severe Disablement Allowance	No	37 (15.9)	77 (16.5)
	Yes	0	1 (0.2)
	Missing	196 (84.1)	390 (83.3)
Disabled Persons Tax Credit	No	33 (14.2)	78 (16.7)
	Yes	3 (1.3)	0
	Missing	197 (84.6)	390 (83.3)
Carer's Allowance	No	31 (13.3)	67 (14.3)
	Yes	6 (2.6)	11 (2.4)
	Missing	196 (84.1)	390 (83.3)
Jobseeker's Allowance	No	32 (13.7)	72 (15.4)
	Yes	5 (2.2)	5 (1.1)
	Missing	196 (84.1)	391 (83.6)
Income Support	No	32 (13.7)	67 (14.3)
	Yes	5 (2.2)	11 (2.4)
	Missing	196 (84.1)	390 (83.3)
Working Tax Credit	No	23 (9.9)	47 (10.0)
	Yes	14 (6.0)	31 (6.6)
	Missing	196 (84.1)	390 (83.3)
Child Tax Credit	No	30 (12.9)	56 (12.0)
	Yes	7 (3.0)	22 (4.7)
	Missing	196 (84.1)	390 (83.3)
Council Tax Benefit	No	32 (13.7)	66 (14.1)
	Yes	5 (2.2)	12 (2.6)
	Missing	196 (84.1)	390 (83.3)

Appendix 14

Qualitative interview schedule

3/4/06 Interview Schedule for BeST version 7

Hi my name is … and I work at the Medical School at the University of Warwick doing research into back pain.

This study is looking at people with back pain which has lasted for more than 6 weeks. We are interested in their experience over a 12-month period.

Have you had an opportunity to read the information sheet? Do you have any questions or issues you wish me to clarify?

Would you mind if I recorded this interview?

Anything you say will remain entirely confidential to the research team and if used in any reports will be anonymised.

At the end of the interview we will discuss whether there is anything you would prefer to remove from the interview. I'll be jotting a few things down as we go along.

1. We'll be talking about your back a bit later but I'd like you to tell me a bit about yourself.
    a. First your work or daily activities?
    b. Your family
    c. Your social activities
        - Is there anyone at home normally/now?
        - What do you do in a normal day?
        - Are there activities you particularly enjoy?
        - Have you been in/are you in paid employment?
        - What social activities do you participate in?
        - What voluntary work/caring do you undertake?
        - Are there things you have not mentioned that are particularly important in your life?

2. Can you tell me about your back? Perhaps you could start right from the beginning?
    - e.g. Over time? What do you do? What do

you think? What happens?
- Attribution
- Beliefs re: progression (past/present)
- Coping strategies (passive/active)
- Controllability (internal/external)
- Advice or explanations from anyone.

3a. Can you tell me what kind of things affect your back?

3b. How well do you cope with your back?

3c. How do you manage life with your back?
- Anything make it better or worse?
- Benefits
- Barriers/obstacles
- Reflect on intervention received.

4. You have talked about ………… Are there any other people you can think of with whom you've talked about your back?
- Family/friends
- HCP (formal/informal consultations)
- Investigations
- Care pathways
- Explanations given.

5a. If you think back to the practitioners you've seen about your back, are there any that you really remember and why?

5b. How did you feel? What did you think of …?
- Was the patient listened to?
- Given adequate time in appointments (not rushed)?
- Feel respected in their decisions?
- Received what they perceive to be adequate and appropriate information?
- Shared decision-making and control?

6a. What have you received to help your back?

6b. Which treatment did you have on this trial? Could you tell me what you thought of that? Any views? What was most/least helpful? Are there any changes you would make?
- Expectations
- Psychological component
- Experience before.

7. Were you given any written material to do with you back?
   - *The Back Book*/other
   - Read it?
   - What information retained?
   - Critique (good/bad)
   - Influenced behaviour?

8. We're going to draw a time line about your back.
   - Timeline with events and treatments, get patient to suggest anything in the area representing the last 4 months
   - What would you say is the greatest change in your chart? (*highlight*)

9. Can you read this and pick A or B? (*show laminated sheet*)
   - What would you like from a treatment of your back?
     - A. I would like immediate relief, which might not last.
     - B. I would like to gradually improve over 12 months, and stay that way.

10. What would you do if you did not have back pain?

For cognitive behavioural group only
We may have already covered some of these questions but could I check with you about:

1. What do you think about physical activity for your back?
   - Past/present.

2. How do you decide when to go back to work/ normal activities?
   - Barriers
   - Beliefs.

3. How do you feel about the whole process of back skills training?
   - Initial assessment
   - Useful/not.

4. How did you feel about the logbooks and goal setting?
   - Content/format
   - Useful/not
   - Good bits/bits to change.

5. How did you feel about being in a group?
   - Dynamics
   - Interaction
   - Anecdotes.

6. Any other comments about the sessions?
   - Heat/light
   - Facilities
   - General comments.

Closing the interview
Do you have any further comments you would like to make?

What you have said in this interview will be kept strictly confidential.

Do you have any concerns about the interview being transcribed for use in the research? (anonymised)

Any future queries regarding the trial, you have contact details on your information sheet.

Thank you for taking part in this interview study.

Appendix 15

Generalised NHS scenario as a secondary analysis

The cost of cognitive behavioural therapy in the NHS setting

We modelled two versions of the CBA delivery. The cost of CBA included the cost of services initiated because of the health-care delivery arrangements in the trial. For example, the assumption that staff could be seconded from other institutions and travel costs were then paid was a specific consequence of the experimental nature of the CBA programme.

An alternative cost–utility scenario was developed based on the potential resource consumption for the CBA programme delivered within NHS structures. As therapists with salaried contracts are almost entirely based at one site and as travel to venues was a sizeable proportion of non-contact time, an alternative CBA resource consumption basket was profiled assuming that the delivery of CBA occurs within the existing NHS structures.

This resource consumption profile was constructed using information from both experts and published sources[136] and represents an estimate of the true cost of the intervention if implemented into the NHS.

We calculated the cost of CBA as if it were delivered by the NHS incorporating the following assumptions:

- We assumed the programme delivery used site-based staff and therefore there were no travel or mileage costs.
- We then recomputed the contact to non-contact ratio excluding total travel time.
- We assumed supervision is less intensive in NHS settings than it is in a trial; therefore reduced the supervision time to 30 minutes per CBA cycle.
- Finally, we assumed that initial training would require a refresher every 3 years, and we assumed that the cost of refreshers would be equal to that of the original training. Therefore, we assigned the cost of training in

proportion to the number of cycles provided by a therapist over a period of 3 years.

The cost of the AM+CBA programme in the NHS setting

Subtracting travel time from the total worked time for each cycle in the trial, we calculated that the total working time to deliver one CBA cycle in the NHS would be 15.35 hours, or 2.62 hours per session. Therefore each therapist would be able to deliver about 2.28 cycles per week, or 94.40 groups per year, based on the average number of days worked per year. The cost of CBA under the alternative NHS scenario considered was £605.90 per cycle, or £126.46 per participant.

Cost-effectiveness of CBA in the NHS routine delivery setting

In this section the cost–utility analysis is calculated under the assumption that CBAs were delivered in routine care within NHS existing structures. We computed incremental costs and QALYs and incremental cost–utility ratios for the overall population and by back pain severity using the RMQ-score subgroups.

NHS perspective

A cognitive behavioural approach was cost-effective from the NHS perspective, yielding 0.099 incremental QALYs at an incremental cost of £95.64, therefore with an incremental cost–utility ratio of £966. The cost-effectiveness of CBA for individuals with severe back pain (RMQ > 4) was similar (ICUR = £856); however, CBA remained dominated for the low-severity group (RMQ ≥ 4) (*Table 70*). The cost-effectiveness acceptability curves showed that for customary cost-effectiveness thresholds, CBA was cost-effective with probability nearing 1 in the whole population, but not in the low-severity population (*Figure 25*).

General health-care perspective – NHS generalisable costs

The cost-effectiveness of CBA from the health-care perspective using NHS generalisable costs was not

TABLE 70 *Incremental costs and QALYs, AM+CBA compared with AM, assuming NHS routine delivery, overall study population and by Roland Morris Questionnaire scores, NHS perspective*

	AM		AM+CBA		Incremental cost (£)	Incremental QALYs	ICER (£)
	Cost (£)	QALY	Cost (£)	QALY			
Overall study population	224.98	0.604	320.62	0.703	95.64	0.099	966
RMQ score at baseline < 4	237.58	0.584	342.90	0.707	105.32	0.123	856
RMQ score at baseline ≥ 4	153.59	0.729	214.39	0.721	60.80	−0.008	Dominated

QALY, quality-adjusted life-years; RMQ, Roland Morris Disability Questionnaire.
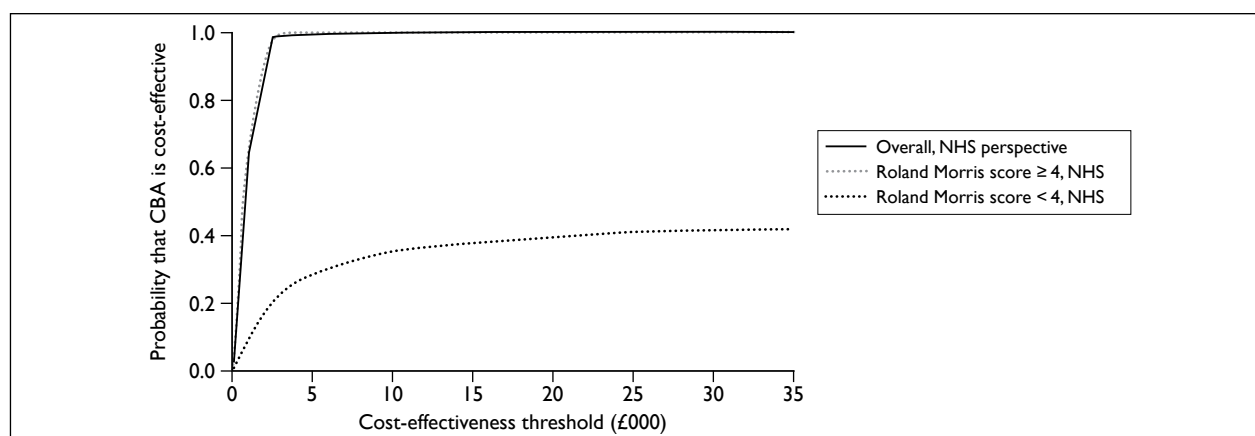
FIGURE 25 *Cost-effectiveness acceptability curves, AM+CBA versus AM – NHS perspective, assuming NHS routine delivery, overall study population and by Roland Morris Questionnaire scores.*

very different, at an incremental cost–utility ratio of £2307, yielding 0.099 incremental QALYs at an incremental cost of £228.40. The cost-effectiveness of CBA remained unfavourable for individuals with low-severity back pain (*Table 71*) and again, the cost-effectiveness acceptability curves showed that for customary cost-effectiveness thresholds, CBA was cost-effective with high probability in the whole population, but not in the low-severity population (*Figure 26*).

TABLE 71 *Incremental costs and QALYs, AM+CBA compared with AM, assuming NHS routine delivery, overall study population and by Roland Morris Questionnaire scores, health-care perspective*

	AM		AM+CBA		Incremental cost (£)	Incremental QALYs	ICER (£)
	Cost (£)	QALY	Cost (£)	QALY			
Overall study population	487.34	0.604	715.74	0.703	228.40	0.099	2307
RMQ score at baseline < 4	498.96	0.580	779.02	0.707	280.10	0.123	2277
RMQ score at baseline ≥ 4	404.03	0.729	418.12	0.721	14.09	−0.008	Dominated

QALY, quality-adjusted life-years; RMQ, Roland Morris Disability Questionnaire.
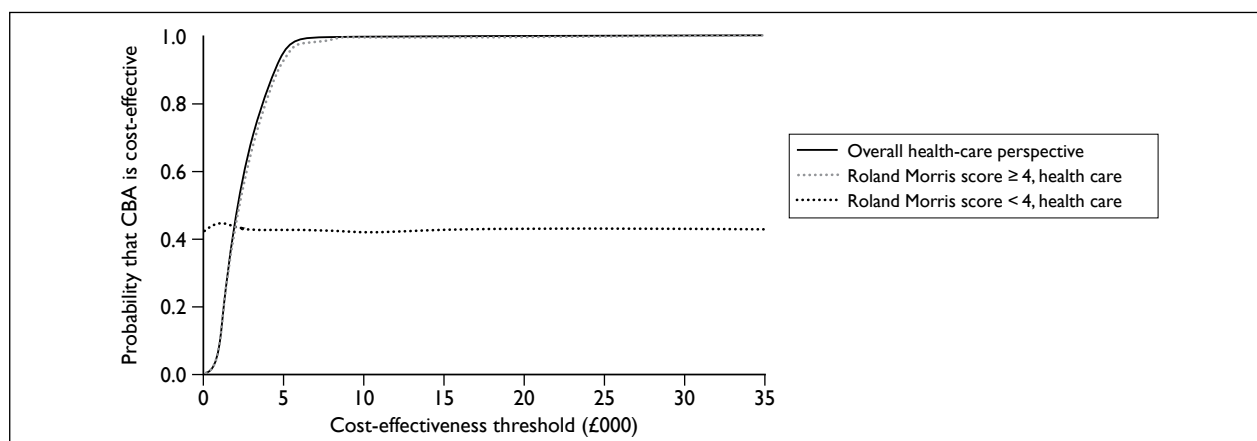
FIGURE 26 *Cost-effectiveness acceptability curves, AM+CBA versus AM, assuming NHS routine delivery, overall study population and by Roland Morris Questionnaire scores, health-care perspective.*

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