A primary care-based cognitive behavioural programme for low back pain – the BeST trial

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

SE Lamb,[1]* R Lall,[1] Z Hansen,[1]
E Castelnuovo,[2] EJ Withers,[1] V Nichols,[1]
F Griffiths,[1] R Potter,[1] A Szczepura[3]
and M Underwood,[1] on behalf of the
BeST trial group

[1]Warwick Clinical Trials Unit, Warwick Medical School,
University of Warwick, Coventry UK
[2]Centre for Health Economics, University of York, York, UK
[3]Health Sciences Research Institute, Warwick Medical School,
University of Warwick, Coventry, UK

*Corresponding author

Executive summary

Health Technology Assessment 2010; Vol. 14: No. 41
DOI: 10.3310/hta14410

Health Technology Assessment
NIHR HTA programme
www.hta.ac.uk

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.

Publication

Lamb SE, Lall R, Hansen Z, Castelnuovo E, Withers EJ, Nichols V, *et al.* A multicentred randomised controlled trial of a primary care-based cognitive behavioural programme for low back pain. The Back Skills Training (BeST) trial. *Health Technol Assess* 2010;**14**(41).

How to obtain copies of this and other HTA programme reports
An electronic version of this title, in Adobe Acrobat format, is available for downloading free of charge for personal use from the HTA website (www.hta.ac.uk). A fully searchable DVD is also available (see below).

Printed copies of HTA journal series issues cost £20 each (post and packing free in the UK) to both public **and** private sector purchasers from our despatch agents.

Non-UK purchasers will have to pay a small fee for post and packing. For European countries the cost is £2 per issue and for the rest of the world £3 per issue.

How to order:

– fax (with **credit card details**)
– post (with **credit card details** or **cheque**)
– phone during office hours (**credit card** only).

Additionally the HTA website allows you to either print out your order or download a blank order form.

Contact details are as follows:

Synergie UK (HTA Department)
Digital House, The Loddon Centre
Wade Road
Basingstoke
Hants RG24 8QW

Email: orders@hta.ac.uk

Tel: 0845 812 4000 – ask for 'HTA Payment Services' (out-of-hours answer-phone service)

Fax: 0845 812 4001 – put 'HTA Order' on the fax header

Payment methods

Paying by cheque
If you pay by cheque, the cheque must be in **pounds sterling**, made payable to *University of Southampton* and drawn on a bank with a UK address.

Paying by credit card
You can order using your credit card by phone, fax or post.

Subscriptions

NHS libraries can subscribe free of charge. Public libraries can subscribe at a reduced cost of £100 for each volume (normally comprising 40–50 titles). The commercial subscription rate is £400 per volume (addresses within the UK) and £600 per volume (addresses outside the UK). Please see our website for details. Subscriptions can be purchased only for the current or forthcoming volume.

How do I get a copy of *HTA on DVD*?

Please use the form on the HTA website (www.hta.ac.uk/htacd/index.shtml). *HTA on DVD* is currently free of charge worldwide.

The website also provides information about the HTA programme and lists the membership of the various committees.

NIHR Health Technology Assessment programme

The Health Technology Assessment (HTA) programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA programme is needs led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, from the public and consumer groups and from professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA programme then commissions the research by competitive tender.

Second, the HTA programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Third, through its Technology Assessment Report (TAR) call-off contract, the HTA programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

The final reports from HTA projects are peer reviewed by a number of independent expert referees before publication in the widely read journal series *Health Technology Assessment*.

Criteria for inclusion in the HTA journal series

Reports are published in the HTA journal series if (1) they have resulted from work for the HTA programme, and (2) they are of a sufficiently high scientific quality as assessed by the referees and editors.

Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA programme as project number 01/75/01. The contractual start date was in October 2003. The draft report began editorial review in January 2009 and was accepted for publication in August 2009. As the funder, by devising a commissioning brief, the HTA programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

The views expressed in this publication are those of the authors and not necessarily those of the HTA programme or the Department of Health.

ISSN 1366-5278

Published by Prepress Projects Ltd, Perth, Scotland (www.prepress-projects.co.uk), on behalf of NETSCC, HTA.

Printed on acid-free paper in the UK by Henry Ling Ltd, The Dorset Press, Dorchester.