

Title A Multicentred Randomized Controlled Trial of a Primary-

> Care Based Cognitive Behavioral Program for Low Back Pain. The Back Skills Training (Best) Trial

Agency NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre

Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;

Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

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Aim

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

Conclusions and results

Between April 2005 and April 2007, 701 participants (420 female) were randomized: 233 to AM and 468 to AM+CBA. The mean age was 54 years and mean baseline Roland Morris Disability Questionnaire (RMQ) was 8.7. Outcome data were obtained for 85% of participants at 12 months. Benefits in a range of outcome measures favored 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 Modified Von Korff Scale (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 pounds sterling (GBP) per participant with an additional benefit in QALYs of 0.099 and an additional cost of GBP 178.06. Incremental cost-effectiveness ratio was GBP 1786. Probability of CBA being cost effective reached 90% at about GBP 3000 and remained at that level or above. At a cost-effectiveness threshold of GBP 20 000, the CBA group had nearly 100% probability of being cost effective. User perspectives on acceptability of group treatments were sought via semistructured interviews. Most were familiar with key messages of AM; most who had attended group sessions had retained key messages and two-thirds talked about reduced fear

avoidance and changes in behavior. Group sessions appeared to provide reassurance, lessen isolation, and enable participants to learn strategies from each other. Long-term effectiveness and cost effectiveness of CBA in treating subacute and chronic LBP made 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. Since the intervention can be delivered by existing NHS staff following brief training, the back skills training program could be implemented in the NHS with relative ease.

Recommendations

See Executive Summary link www.hta.ac.uk/project/1358.asp.

Methods

See Executive Summary link www.hta.ac.uk/project/1358.asp.

Further research/reviews required

Future research on implementation of the CBA program will help 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 attend sessions or gain the cognitive skills and behavioral stimulus. The effects of package on generalized physical health-related quality of life give some evidence that CBA may be of help for other musculoskeletal disorders.