Cognitive Functional Therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain (RESTORE): a randomised controlled, three-arm parallel group, phase 3, superiority clinical trial

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Abstract

Summary

Background

Low back pain (LBP) is the leading cause of years lived with disability globally but most interventions have only short-lasting, small to moderate effects. Cognitive Functional Therapy (CFT) is an individualised approach that targets unhelpful pain-related cognitions, emotions and behaviours that contribute to pain and disability. Movement sensor biofeedback may enhance treatment effects. This trial compared the effectiveness and economic efficiency of CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

Methods

This was a randomised controlled, three-arm parallel group, superiority trial. Adults with LBP lasting >3 months with at least moderate pain-related physical activity limitation, were randomised via a centralised adaptive schedule. The primary clinical outcome was activity limitation at 13 weeks, self-reported by participants using the 24-point Roland Morris Disability Questionnaire. The primary economic outcome was quality-adjusted life years (QALYs). Participants in both interventions received up to seven treatment sessions over 12 weeks plus a booster session at 26 weeks, in 20 primary care physiotherapy clinics in Australia. Physiotherapists and patients were not able to be blinded. Trial registration ACTRN12618001396213.

Findings

492 participants recruited between 23 October 2018 and 3 August 2020 were allocated to CFT-only (n=164), CFT-biofeedback (n=163) and Usual-care (n=165). Both interventions were more effective than Usual-care, with mean differences of -4.8 (95%CI: -5.9 to -3.6) and -4.8 (-6.0 to -3.6) respectively, for activity limitation at 13 weeks (primary endpoint). Effect sizes were similar at 52 weeks. Results were similar across all secondary outcomes. There were trivial, non-significant differences between the CFT-only and CFT-biofeedback treatments. Both interventions were more effective than Usual-care for QALYs, and much less costly in terms of societal costs (direct and indirect costs and productivity losses) AUD-$5276 (-$10529 to -$24) and AUD-$8211 (-$12923 to -$3500) respectively.

Interpretation

CFT can produce large and sustained improvements for people with chronic disabling LBP at considerably lower societal cost than usual care.

Funding

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Introduction

Most people with an episode of Low Back Pain (LBP) improve rapidly, but 20-30% develop chronic pain lasting >3 months with high levels of disability. [1] LBP is the greatest contributor to years lived with disability globally[2], a burden primarily resulting from people with persistent pain and high disability. [2] The societal costs of chronic pain exceed that of cancer and diabetes combined[3], and most costs from chronic LBP are due to loss of work participation and on-going care-seeking. Current treatment approaches for people with LBP are failing with LBP-related disability continuing to increase. [2]

Chronic LBP is widely considered a complex multifactorial biopsychosocial condition. [2] Guidelines recommend that both physical and psychological contributors be addressed when treating people with chronic LBP[4], yet, most interventions fail to address the range of factors contributing to an individual's pain and associated disability. Consequently, the treatment effects of most recommended interventions such as exercise or psychological therapies are modest in size and tend to be of short duration. [5,6] Even intensive multidisciplinary biopsychosocial rehabilitation programs, which are costly and resource-intensive, show small to moderate effects that are mostly short- to medium-term. [7]

Cognitive Functional Therapy (CFT) is a patient-centred approach that facilitates patients to self-manage by targeting their individual unhelpful pain-related cognitions, emotions, and behaviours that contribute to their pain and disability. A previous small trial of CFT (n=121) compared with best-practice manual therapy and exercise provided preliminary evidence of large and sustained effects (12-month disability standardised mean differences [SMD] 1.0). [8] Similarly, a larger trial of individualised CFT (n=206) compared with group-based exercise and pain education provided evidence of sustained effects (12-month disability SMD 0.6); [9] however, both trials had relatively high rates of loss to follow up. In contrast, a recent trial comparing CFT to exercise and manual therapy found a small, non-statistically significant, effect at 12 months (disability SMD 0.2). [10] As no large trial has compared CFT with usual care (current practice) and no trials have assessed cost efficiency, there was a clear need for a large rigorous trial investigating the effectiveness and economic efficiency of CFT relative to usual care.

A key distinguishing feature of CFT, compared with other psychologically informed approaches such as Cognitive Behavioural Therapy, is it addresses pain-provocative movement patterns that contribute to LBP, such as protective muscle guarding and movement avoidance. Wearable movement sensors

enable clinicians to easily measure these and explore their relationship to pain, both in the clinical setting and during patients' normal activities at work and recreation. Via biofeedback, this technology can help patients to develop an awareness of how they move during normal activities, enhancing their ability to correct unhelpful movement habits. A pilot Randomised Controlled Trial (RCT) (N=112) of patients with chronic LBP showed that individualised rehabilitation, which included wireless movement sensors, resulted in large and sustained clinical improvements compared with guideline-recommended treatment (12-month SMDs from 0.5 to 1.0). [11] No trials have investigated if wearable sensors can enhance the effects of CFT.

This three-arm RCT aimed to compare the effectiveness and economic efficiency of individualised CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

Methods

The RESTORE study was a, randomised controlled, three-arm parallel group, phase 3 superiority, clinical trial. Treatment was delivered in 20 primary care physiotherapy clinics in Perth and Sydney, Australia. The study was approved by Curtin University Human Research Ethics Committee (HRE2018-0062, 6 February 2018), registered in the Australian New Zealand Clinical Trials Registry (ACTRN12618001396213), and the published study protocol is open access (https://bmjopen.bmj.com/content/9/8/e031133). [12]

Participants

Eligible participants were adults with chronic LBP lasting more than 3 months, who had sought care from a primary care clinician for their back pain at least 6 weeks previously, had average back pain intensity of 4 or more on a 0-10 Numerical Pain Rating Scale, and had at least moderate pain-related interference with normal work or daily activities measured by item 8 of the 36-item Short Form Health Survey[13]. Exclusion criteria were serious spinal pathology (e.g. fracture, infection, cancer), any medical condition that prevented being physically active, being pregnant or having given birth within the previous 3 months, inadequate English literacy for the study's questionnaires and instructions, a skin allergy to hypoallergenic tape adhesives, surgery scheduled within 3 months, or an unwillingness to travel to trial sites.

Participants were recruited via general medical practitioners, surgeons, physiotherapists, social media and posters. Referrers were asked to advise consecutive eligible patients of the opportunity to participate in the trial. All potential participants were screened for eligibility over the phone prior to

inclusion. Participants gave informed consent during completion of an on-line baseline questionnaire prior to randomisation.

Randomisation and masking

After participants completed the baseline assessment, a research assistant phoned the NHMRC Clinical Trials Centre, that used adaptive random allocation to randomise participants to one of three groups (1:1:1 allocation ratio): Usual-care, CFT-only, or CFT-biofeedback. The centralised randomisation service used the minimisation factors of site (Perth/Sydney), sex (female/male), and baseline activity limitation (Roland Morris Disability Questionnaire[14] score dichotomised at 0-12/13-24) and ensured concealment of allocation.

Participants were told that the trial compared usual care with two evidence-based interventions and were aware of their group allocation. All outcome measures were either self-reported by participants via web-based questionnaires, collected via movement sensors, or from government registers. Unblinded physiotherapists delivered only one type of treatment and played no role in collecting data, other than performing a standardised movement protocol while the participant wore movement sensors, with the resultant movement data being automatically uploaded by the sensors to a server without physiotherapist input. Research staff who were aware of group allocation did not assess outcome measures. Statisticians were blind to groups.

Procedures

Study treatments

In the Usual-care group, the treatment was the care pathway the participant's health providers recommended, or the participant chose. For example: physiotherapy, massage, chiropractic care, medicines, injections, or surgical interventions. Usual-care participants were informed that "If you are allocated to the usual care group, your treatment options can be any of those offered by the healthcare professionals you would normally choose to see in the community. In other words, you will choose your treatment, but it is not determined by the study or funded by it." Only Usual-care participants were paid a token reimbursement (AU$30-$110 in total) for their time completing key follow-up questionnaires. Pragmatically, participants in the two CFT groups were not restricted from also receiving usual care.

In the two CFT groups, participants received up to seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks (initial consultation ~60 minutes, follow ups ~30-40 minutes). The booster session aimed to review and optimise the participant's self-management plan, including responding to future flare ups, and address any barriers. It was added because previous studies[9,15] that

included people with higher levels of activity limitation due to chronic LBP had shown a reduction in CFT treatment effects between 6 and 12 months.

The physiotherapists used a flexible clinical-reasoning approach, based on information gathered by interview and physical examination to identify movements, postures, pain-related cognitions, emotions, and lifestyle factors contributing to each individual's ongoing pain and disability. Patient-centred communication was central to this process where patients were asked to 'tell their story'. Patients' concerns were validated and their goals for seeking care explored.[16] This informed an individualised treatment plan orientated to the patient's goals, with three broad components.

Firstly, 'making sense of pain': a reflective process using the patient's own story and experiences from the examination to help them reconceptualise their LBP from a biopsychosocial perspective. Physiotherapists discussed how the patient's individual pain-related cognitions (i.e. beliefs about tissue damage), emotions (e.g. pain-related fear and distress), social factors (e.g. life stressors), and behavioural responses (e.g. protective guarding, movement and activity avoidance, poor sleep routines) contributed to set up their vicious cycle of pain and disability. Modifiable factors were identified as targets for change to break the pain/disability cycle and reach their goals. Participant's concerns were addressed, and educational resources provided if unhelpful pain beliefs were identified. Pain exacerbation plans were provided to promote self-care strategies.

Secondly, exposure with 'control': a process of functional behavioural change and pain control through graded exposure to movements and activities nominated as painful, feared or avoided. Through experiential learning, the aim was to provide individualised change strategies to reduce pain and build confidence during graded exposure to movements and activities nominated as painful, feared or avoided. This was achieved by body relaxation techniques, abolishing protective and safety behaviours, and movement control and postural modifications, as indicated. The participant was provided a daily exercise program to practise these skills, with the aim to enhance pain control and build confidence to engage in movement and valued activities related to their goals.

Thirdly, lifestyle change: coaching to develop healthy lifestyle behaviours such as paced physical activity based on preference, adopting healthy sleep and dietary habits, stress management, and social engagement where relevant.

Participants in both CFT groups wore movement sensors for the same duration and frequency, but for the CFT-only group, the movement sensors were a placebo, meaning that the sensors collected data but neither the patient nor the physiotherapist had access to it. These ViMove2 devices (DorsaVi P/L, Melbourne, Australia) consisted of two miniaturised sensors attached to the lumbar spine (sacrum and

L1) with hypoallergenic tape, that communicated wirelessly with a tablet or mobile phone for data to be automatically uploaded to a secure cloud-based server.

In the CFT-biofeedback group, physiotherapist had access to the movement sensor's data to use for assessment, movement retraining, and for providing biofeedback. That additional information could assist in guiding individualised movement retraining via three strategies. Firstly, seeing and recording movement data live while the patient moved in the clinic could assist in identifying movement patterns that might be contributing to the pain. [17] Secondly, 'live training' in the clinic provided patients and physiotherapists with real-time feedback (visual and auditory) on the participant's movement to facilitate changing functional movement and postural patterns. Thirdly, using the ViMove2 software, physiotherapists could program biofeedback alerts, such as audio 'beeps' and messages via a trial-supplied iPhone, that reinforced key principles from the treatment session while the participant went about their normal daily activities for the rest of the day. These prompts could, for example, include that a period of too much 'end range' slumped or upright sitting had occurred; that target amounts of time in various functional activities (being active, sitting, standing and lying down) needed to be or had been achieved; or reminders at pre-set time intervals to do patient-specific exercises.

Further detail about both the CFT and the movement sensor interventions is in Appendix Tables A1 and A2, and is published in detail elsewhere. [12,16] During COVID (SARS-CoV-2) pandemic lock-downs, follow-up sessions for the two trial interventions were delivered via telehealth by some physiotherapists, which meant that sensors could not be applied during those consultations. Assuming a worst-case scenario of all physiotherapists delivering telehealth for all follow-up consultations during those periods, then up to 9% (62/719) of CFT-biofeedback follow-up consultations would not have included biofeedback, though the likely number is less. No new participants were enrolled for 9 weeks during the lockdown periods to ensure all participants had their initial consultation face-to-face.

Physiotherapist recruitment and training

Eighteen physiotherapists (9 in each city, across 20 clinics) were recruited via social media advertising. They needed to have: at least 2 years' clinical experience post-graduation; experience treating people with chronic LBP; an interest in applying biopsychosocial management principles; a willingness to use movement sensors clinically; less than 4 days of prior exposure to CFT training; and a willingness to be observed and videoed while treating non-trial patients during training for mentoring and feedback purposes.

The CFT training for both physiotherapist groups consisted of three components: (i) 80 hours of clinical workshops (1 weekend per month for 5 months), including lecture presentations, live patient demonstrations, skills development and direct mentoring/feedback while treating non-trial patients, (ii) online resources (e.g. e-book and training videos), and (iii) mentoring and support via private Facebook group pages. This training was conducted by physiotherapists (POS and JPC) who had developed the CFT approach and had extensive experience using and teaching it. Clinical competency was assessed throughout the mentoring period using a checklist and in a final one-day workshop or by subsequent submission of videos of patients being treated. More detail of this training is available in Appendix Table A4. Each physiotherapist was allocated using random number generation to deliver only one CFT treatment arm to prevent contamination across groups.

All participating physiotherapist attended a 2-hour technical workshop on setting up and using the sensors, as movement sensors were worn by participants in both CFT groups. The physiotherapists in the CFT-biofeedback group received 4 additional hours of training on accessing and interpreting the movement data and on programming biofeedback. The movement sensor training was conducted by a physiotherapist (RL) with extensive clinical experience using these sensors and teaching clinicians to use them.

During the trial, private Facebook pages (one on CFT and one each on sensors for CFT-only and CFT-biofeedback) and virtual group meetings every 3 months with a clinical trainer provided a forum for the discussion of challenges faced when implementing the interventions or with technical issues related to the sensors. JPC and RL contributed to the Facebook discussions. Clinicians could request a personalised (email or phone) mentoring session with JPC (CFT) or RL (biofeedback) if required.

Approximately every seventh participant of each clinician had their treatment monitored to ensure ongoing treatment fidelity. This consisted of video recordings of three consultations (early in the treatment process, in the middle and close to the end of the treatment period) that were reviewed by a randomly selected clinician trainer (JPC or KOS) with structured feedback provided, if required.

Outcomes

The primary clinical outcome was pain-related physical activity limitation, self-reported by participants on-line using the Roland Morris Disability Questionnaire (0-24 scale) and the primary time point was 13 weeks. Secondary clinical outcomes were: mean pain intensity (three numeric rating scales - now, most severe 14-days, average 14-days, 0-10 scale) patient-specific functional limitation (Patient-Specific Functional Scale, 0-10 scale, 0-30 scale), pain catastrophisation (Pain Catastrophising Scale, [3-item 0-12 scale at all time points, 13-item 0-52 scale only at baseline]), pain self-efficacy (Pain Self-Efficacy Questionnaire, 0-60 scale), fear of movement (physical activity

subscale of the Fear Avoidance Beliefs Questionnaire, 0-24 scale), patient-perceived global improvement (1 question), patient satisfaction with care and treatment (1 question), and adverse events noted by the physiotherapists or self-reported by participants in follow-up questionnaires. Treatment expectation was measured post-randomisation by a single tailored question 'How confident are you that this treatment option will be successful in improving your back pain? Data collection occurred at baseline, 3, 6, 13, 26, 40 and 52 weeks. Participant self-rated treatment adherence was measured in the two trial intervention groups with a single question: "How would you rate your adherence to the treatment program your physiotherapist has recommended?" with response options 0=No adherence to 10=Complete adherence. More details of the outcome measures (including references), baseline measures and data collection are reported in the published protocol. [12] Adverse event data were collected as detailed in Appendix Report A2.

For the economic (cost-utility) analysis, the primary outcome of clinical effect was quality-adjusted life years (QALYs) calculated using the area under the curve approach based on responses to the EQ-5D-5L questionnaire (https://euroqol.org/eq-5d-instruments/).[18] Cost outcomes included were direct health costs attributable to consumption of all health care resources (measured using extracts from the Australian government Medicare claims data and Pharmaceutical Benefits Scheme databases provided via Services Australia, and patient questionnaires to capture other health care costs such as hospitalisations) and productivity losses (measured using the iMTA Productivity Cost Questionnaire[19]). Indirect health costs (e.g. travel to appointments) and productivity costs (including absenteeism and presenteeism) were captured in the 13, 26, 40, and 52 week participant questionnaires.

Statistical analysis

The sample size (164 per group) was calculated for the primary clinical outcome to detect a difference of 2 activity limitation points[20] (0-24 RMDQ scale) between the two CFT groups, at $p<0.05$, 80% power, a common standard deviation of 6 points and a 20% drop-out rate. As all three pairwise comparisons between Usual-care, CFT-only, or CFT-biofeedback were of primary interest, no adjustment for multiple comparisons was deemed appropriate. [21]

Analysis was by intention-to-treat. The primary analysis used a heteroscedastic, partially-nested repeated measures, three-level linear mixed model to assess the effect of group allocation on activity limitation (RMDQ score) at the primary time point of 13 weeks and additionally at 3, 6, 16, 42 and 52 weeks. The baseline RMDQ score was included as a repeated observation of the dependent outcome variable to enable the inclusion of those participants missing all follow-up data in the analysis. Linear mixed models are a likelihood-based estimation procedure whereby likely values for missing outcome data are estimated from information contained in the observed data, resulting in non-biased estimates

providing data are missing at random. Group, time (as categorical variable), and group by time were included as fixed effects. Participant was included as a random effect to account for within-person correlation, using an exchangeable covariance structure. Clinician was also included as a random effect to account for the partial nesting by clinician in the CFT-only and CFT-BF groups using the method recommended by Candlish et al. (2018). [22] The model also adjusted for covariates site and sex (minimisation variables used for randomisation), and symptom duration and pain intensity (specified in study protocol). Two sensitivity analyses were performed, as detailed in Appendix Table A12. The first used covariates from the primary analysis model plus auxiliary variables (age, BMI, baseline measures of secondary outcomes, baseline treatment expectations, education, Keele StartBack MSK Tool) for multiple imputation of missing values via chained equations, then estimates for the primary analysis model were pooled from the ten imputed datasets. The second adjusted was a two-level linear mixed model with a random effect for participant only and unadjusted for covariates. The effect of treatment on secondary outcome measures was evaluated using the equivalent heteroscedastic partially-nested repeated measures three-level linear mixed model as for the primary analysis, with baseline activity limitation included as an additional continuous covariate. We calculated both mean differences and standardised mean differences (SMD). We considered an SMD of >0.8 to represent large effects as is commonly used[23], and two points as the criterion for minimal clinically important (between-group) difference in the RMDQ from an estimate in a similarly disabled population. [20] We also calculated the number needed to treat using the proportion of people with a change of 5 RMDQ points or more as the criterion for clinically important (within-person) change. [24]

An incremental cost-utility analysis calculated the difference in costs between intervention and control groups divided by the difference in QALYs. Incremental cost-utility analyses were undertaken from a societal perspective (productivity costs were calculated from a human capital perspective in the main analysis and using a friction method in a secondary analysis). To reflect a societal perspective, we measured productivity gains and losses, included the opportunity costs of medicines for Australian society, and used community preferences to estimate the utility of health states. [25]

The approach to imputation of missing data is detailed in Appendix Report A1. Bootstrap resampling (20,000 replications in total per analysis) was used to generate a 95% confidence ellipse surrounding the incremental cost-utility estimate. [26] Productivity costs measured at specific time points were extrapolated to the full one-year period using an area under the curve approach. [27] All costs were calculated using a 2019-2020 financial base year, including hospital costs valued using the National Weighted Activity Unit calculators. More detail of the resource use data, costing approach and analysis methods is provided in Appendix Report A1. Economic data on the cost of delivery of the trial interventions would have revealed the group allocation and unblinded the analysts. Consequently, 6 data options (1 true and 5 false) for the treatment costs were created so that the analysts had to repeat the analyses 6 times, thereby retaining their blinding.

Role of the funding sources

The funders of the study had no role in the study design, data collection, analysis, interpretation, writing or submission of this paper. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

The 492 participants were recruited between 23 October 2018 and 3 August 2020. Of them, 161 (33%) declined consent for their Medicare claims data and Pharmaceutical Benefits Scheme data extractions, which were non-compulsory for ethical reasons (70/165 [42%] Usual-care; 45/164 [27%] CFT-only; 45/163 [28%] CFT-biofeedback). At 13 weeks (primary outcome time point), 418/492 (85%) participants completed the primary outcome (141/165 [85%] Usual-care; 141/164 [86%] CFT-only; 136/163 [83%] CFT-biofeedback). Figure 1 shows the trial profile, with additional detail in Appendix Tables A3 and A5.

At baseline, participants had high levels of disability (mean RMDQ score 13.5/24 [SD5.2]) [5], and pain (mean over last 14 days 6.2/10 [SD1.6]), and the median pain duration of the current episode of LBP was 260 weeks (IQR 500). The average age was 47.3 years (SD15.2, full range 19 to 87) and 292/492 (59%) were female. Table 1 provides full details the participants' baseline characteristics and the balance across groups.

In the two intervention groups, the median number of consultations was 7 (IQR 4) in both groups, recognising that the clinically appropriate number of consultations was individualised. Although this was the median number, 13/164 (8%) in the CFT-only group and 13/163 (8%) in the CFT-biofeedback group did not attend any consultations, some due to the COVID pandemic. The delay time between completion of the baseline questionnaire and the first consultation was similar between the CFT-only group (median 9 days, IQR 10) and CFT-biofeedback group (median 8 days, IQR 9).

Some information was available to describe health care behaviour in the Usual-care group. At baseline, 91/163 (56%) were taking medication for their LBP. At the 13-week time point, 134/163 (82%) answered a question about their care-seeking behaviour over the previous 3 months, with 51/134 (38%) having sought care for their LBP from a health care practitioner. Their median number of consultations during that period was 3 (IQR 5, full range 1 to 22). Some care-seeking behaviour may have been interrupted by lockdowns during the COVID pandemic. For additional detail, see Appendix Figure A1.

The main clinical effectiveness findings (Table 2, Figure 2, Appendix Table A8) for differences in activity limitation at the primary outcome time point (13 weeks) indicate that the CFT-only and CFT-biofeedback treatments were both more effective than Usual-care, with mean differences of -4.8 (95%CI: -5.9 to -3.6) and -4.8 (-6.0 to -3.6) respectively. The corresponding standardised mean differences (SMD) were large: -0.92 (-1.17 to -0.69) and -0.91 (-1.15 to -0.67), respectively (Appendix Table A8). The effect sizes remained similar up to the 52-week time point. Differences between the CFT-only and CFT-biofeedback treatments were trivial and not statistically significant: mean difference -0.1 (-1.3 to 1.1), SMD 0.01 (-0.25 to 0.23). The proportions of participants with a within-person clinically-important reduction of 5 or more points of activity limitation[24] at 13 weeks were: Usual-care 27/141 (19%), CFT-only 86/141 (61%) and CFT-biofeedback 82/136 (60%). The proportions at every outcome time point are detailed in Appendix Table A9, with those differences being broadly sustained to 52 weeks. The number needed to treat for the same threshold[24] reduction of activity limitation at 13 weeks, for the CFT-only and CFT-biofeedback groups was 2.4 (95%CI: 2.0 to 3.2) and 2.4 (2.0 to 3.3) respectively, and ranged between 2.0 and 3.0 across the follow-up period to 52 weeks (Appendix Table A9).

All the secondary clinical outcomes (Table 2, Figure 2, Appendix Tables A10-A12, Figure A2) mirrored the primary outcome, showing large and sustained effects for both the CFT-only and CFT-biofeedback treatments compared with Usual-care from 13 weeks to the end of follow up, with no difference between the two intervention groups. At 13 weeks, the proportions of participants very satisfied or satisfied were Usual-care 21%, CFT-only 68%, and CFT-biofeedback 64% (full results reported in Appendix Figure A2). Differences in self-rated treatment adherence between the two trial intervention groups were trivial and not statistically significant at any time point. The full results are shown in Appendix Table A7. Both sensitivity analyses for the primary clinical effectiveness outcome showed trivial differences from the results of the main analysis (Appendix Table A12).

Results from each pair-wise contrast in the primary cost-utility comparisons are displayed (Figure 3), along with 95% confidence ellipses. The CFT-only versus Usual-care comparison had 97% of the bootstrap replications fall into the South-East quadrant where CFT-only is more effective and less costly, with an incremental gain of 0.12 QALY per participant (95%CI 0.08 to 0.16), at a lower overall cost of $AUD -5276 (95%CI -$10529 to -$24). Similarly, 99.8% of the bootstrap replications fell into the South-East quadrant for the CFT-biofeedback versus Usual-care comparison, with an incremental gain of 0.13 QALY per participant treated (95%CI 0.01 to 0.17), and a lower overall cost of $AUD -$8211 per participant treated (95%CI -$12923 to -$3500) for the CFT-biofeedback group. Most of the between-group differences in costs were in productivity losses. There was reasonable uncertainty as to whether CFT-only was more or less cost-effective than the CFT- biofeedback. In the analyses using imputed data, 46% of the bootstrap replications fell into the South-East quadrant where

CFT-biofeedback was more effective and less costly, whereas 6% fell into the North-West quadrant where CFT-only was more effective and less costly. However, in the sensitivity analyses using complete case data, only 16% of the bootstrap replications fell into the South-East quadrant where CFT-biofeedback was more effective and less costly, whereas 33% of the bootstrap replications fell into the North-West quadrant where CFT-biofeedback was less effective and more costly than CFT-alone. Acceptability curve analysis using imputed data (Appendix Report A1) indicated CFT-biofeedback was likely to be more cost-effective compared to CFT-only with 80% to 85% probability across willingness to pay per QALY thresholds up to $(AUD) 100,000. However, sensitivity analyses using complete case data indicated this probability varied between 40% and 50%. On balance, there was insufficient evidence to support a conclusion favouring the economic efficiency of one CFT treatment over the other.

Twenty-one participants experienced low back-related serious adverse events during the 12-month trial period, with a similar (p=0.63) prevalence across groups (Usual-care 6/165 [4%], CFT-only 6/164 [4%] and CFT-biofeedback 6/163 [4%]), see Table 3. Also 279 participants experienced non-serious adverse events during the 12-month trial period, again with similar (p=0.43) prevalence across the groups (Usual-care 86/165 [52%], CFT-only 97/164 [59%] and CFT-biofeedback 89/163 [55%]). Full details are in Appendix Report A2.

Deviations from the trial protocol were (i) we measured participant self-rated adherence to treatment adherence between the two trial intervention groups and the analysis of those data was post-hoc, (ii) the STarT MSK Tool was also collected in the Usual_care group, (iii) to reduce responder burden, we used the 3-item version of the Pain Catastrophizing Scale[28], (iv) the results of the economic efficiency analysis from a health service perspective will be published in a separate paper, and (v) we also conducted a sensitivity analysis without any data imputation for the main economic efficiency analysis including only those participants (n=330) with MBS/PBS data.

Figure 1. Trial profile

465 Table 1. Baseline characteristics of the study population.

	Usual-care (n=165)		CFT-only (n=164)		CFT-biofeedback (n=163)	
Female	98	(59%)	99	(60%)	95	(58%)
Age (years; mean [SD])	47·7	(16)	47·5	(15)	46·7	(15)
University education (n [%])	89	(54%)	80	(49%)	74	(46%)
Weight (kgs; mean [SD])	82·3	(19·9)	83·2	(20·0)	83·2	(19·0)
Height (cms; mean [SD])	170·2	(10·7)	169·7	(10·0)	170·1	(10·4)
BMI (mean [SD])	28·3	(6·1)	28·9	(6·4)	28·9	(6·8)
Duration of care-seeking (years; median [IQR])	4·0	(8.7)	4·0	(10·0)	5·0	(8.6)
Length of current episode (years; median [IQR])	5·0	(8.2)	4·0	(11·0)	5·0	(9.2)
Pain-related physical activity limitation (RMDQ, mean [SD])	13·5	(4·3)	13·3	(4·4)	13·8	(4·4)
Patient-specific physical function (PSFS, mean [SD])	4·2	(1·9)	4·3	(2·0)	4·3	(2·0)
Pain: Single Item (average last 14 days NRS, mean [SD])	6·3	(1·5)	6·2	(1·5)	6·1	(1·6)
Pain: mean of now, usual, average (NRS, mean [SD])	5·8	(1·3)	5·8	(1·4)	5·7	(1·6)
Pain Self-Efficacy (PSEQ, mean [SD])	36·4	(11·0)	34·2	(11·2)	33·9	(12·1)
Pain Catastrophising (PCS-13, mean [SD], 0 to 52 score)	24.3	(12.4)	24.1	(12.8)	25.4	(12.3)
Pain Catastrophising (PCS-3, mean [SD], 0 to 12 score)	5·9	(2·7)	6·0	(2·6)	6·1	(2·6)
Fear of movement (FABQ physical activity subscale, mean [SD])	14·9	(4·8)	14·7	(5·4)	14·8	(4·6)
Cognitive Flexibility sum score (mean [SD])	51·4	(4·3)	51·5	(4·1)	51·0	(4·4)
Taking any LBP medication	91*	(56%)	104*	(65%)	103*	(65%)
Number of types of medication being taken (median, IQR, maximum)	1	(2; 6)	1	(2; 6)	1	(2; 5)
Opioids	37	(23%)	28	(17%)	27	(17%)
Analgesics	46	(28%)	49	(30%)	47	(29%)
Anti-inflammatories	43	(26%)	53	(33%)	59	(36%)
Anti-neuropathic analgesics	16	(10%)	8	(5%)	14	(9%)
Muscle relaxants	2	(1%)	4	(2%)	3	(2%)
Anti-depressants	5	(3%)	4	(2%)	6	(4%)
Keele StartBack MSK Tool categories (n [%])						
Low risk	17	(10%)	11	(7%)	19	(12%)
Medium risk	86	(52%)	95	(58%)	84	(52%)
High risk	62	(38%)	58	(35%)	59	(36%)
Confidence in treatment assigned (n [%])						
Very unconfident	14	(10.%)	1	(1%)	0	(0%)
Unconfident	27	(19%)	2	(1%)	2	(1%)
Uncertain	64	(46%)	35	(24%)	47	(32%)
Somewhat confident	9	(6%)	40	(27%)	40	(27%)
Confident	18	(13%)	47	(32%)	41	(28%)
Very confident	8	(6%)	20	(14%)	17	(12%)
Occupation (ANZCO categories)						
Managers	7	(7%)	6	(7%)	10	(10%)
Professionals	27	(28%)	23	(26%)	30	(29%)

Technicians and Trades Workers	7	(7%)	5	(6%)	4	(4%)
Community and Personal Service Workers	17	(18%)	11	(13%)	17	(17%)
Clerical and Administrative Workers	13	(14%)	12	(14%)	13	(13%)
Sales Workers	9	(9%)	8	(9%)	6	(6%)
Machinery Operators and Drivers	3	(3%)	6	(7%)	4	(4%)
Labourers	11	(11%)	13	(15%)	16	(16%)

SD=standard deviation; IQR=inter-quartile range; SMD=Standardised Mean; BMI=Body Mass Index, RMDQ=Roland Morris Disability Questionnaire, PSFS=Patient-Specific Functional Scale, NRS=Numeric Rating Scale, PSEQ=Patient Self-Efficacy Questionnaire, PCS=Pain Catastrophising Scale, FABQ=Fear Avoidance Beliefs Questionnaire, ANZCO=Australian and New Zealand Standard Classification of Occupations, Confidence in treatment measured after randomisation by a single tailored question 'How confident are you that this treatment option will be successful in improving your back pain?' *Numbers of participants answering this question about medication use: Usual-care 163 (99%), CFT-only 160 (98%), CFT-biofeedback 159 (98%).

Figure 2. Primary and secondary clinical effectiveness outcomes* (mean & 95%CI)

Activity limitation = Roland Morris Disability Questionnaire (RMDQ); Pain intensity = Numeric Rating Scales; Patient-specific function = Patient-Specific Functional Scale; Pain self-efficacy = Pain Self-efficacy Questionnaire; Pain catastrophising = 3-item Pain Catastrophising Scale; Fear avoidance beliefs = Fear Avoidance Beliefs Questionnaire (physical activity subscale); *All secondary outcomes that were measured using discrete scales. Higher scores represent worse outcomes for all measures except for patient-specific function and pain self-efficacy.

Table 2. Clinical effectiveness outcomes*

	Usual-care (n=165)	**CFT-only (n=164)**	**CFT-biofeedback (n= 163)**	**CFT-only compared with Usual-care**		**CFT-biofeedback compared with Usual-care**		**CFT-biofeedback compared with CFT-only**	
	mean[a] (SE)	mean (SE)	mean (SE)	Difference (95% CI)	p	Difference (95%CI)	p	Difference (95% CI)	p
Primary outcome									
Activity limitation (RMDQ)									
Baseline	13·3 (0.4)	13·3 (0.5)	14.0 (0.4)	0·0 (-1·2 to 1.2)		0·6 (-0·6 to 1·8)		0·6 (-0·6 to 1·9)	
13 weeks	**12·1 (0.4)**	**7·5 (0.5)**	**7·5 (0.5)**	**-4·6 (-5·9 to -3·4)**	**<0·001**	**-4·6 (-5.8 to -3·3)**	**<0·001**	**0·0 (-1·3 to 1·3)**	**0·97**
52 weeks	11·5 (0.5)	6·7 (0.5)	6·1 (0.5)	-4.8 (-6·0 to -3·5)	<0·001	-5·4 (-6·6 to -4·1)	<0·001	-0·6 (-1·9 to 0·7)	0·37
Secondary outcomes									
Physical function (PSFS)									
Baseline	4·2 (0.2)	4·2 (0.2)	4·3 (0.2)	0·0 (-0·5 to 0·4)		0·1 (-0·4 to 0·6)		0·1 (-0·4 to 0·6)	
13 weeks	**4·5 (0.2)**	**6·5 (0.2)**	**6·3 (0.2)**	**2·0 (1·5 to 2·5)**	**<0·001**	**1·9 (1·4 to 2·4)**	**<0·001**	**-0·1 (-0·6 to 0·4)**	**0·65**
52 weeks	4·9 (0.2)	6·5 (0.2)	6·9 (0.2)	1·5 (1·0 to 2·0)	<0·001	2·1 (1·5 to 2·6)	<0·001	0·5 (0·0 to 1·0)	0·05
Pain: mean of 3-item NRS									
Baseline	6·2 (0.1)	6·2 (0.2)	6·2 (0.2)	0·0 (-0.4 to 0·4)		0·0 (-0·4 to 0·4)		0·0 (-0·5 to 0·5)	
13 weeks	**5·8 (0.2)**	**4·3 (0.2)**	**4·4 (0.2)**	**-1·6 (-2·0 to -1.1)**	**<0·001**	**-1·5 (-2·0 to -1.1)**	**<0·001**	**0·0 (-0·5 to 0·5)**	**0·93**
52 weeks	5.6 (0.2)	4·2 (0.2)	3·8 (0.2)	-1·4 (-1.9 to -1.0)	<0·001	-1·8 (-2·3 to -1·4)	<0·001	-0·4 (-0·9 to 0·1)	0·09
Pain: Single Item NRS (average last 14 days)									
Baseline	5·8 (0.2)	5·9 (0.2)	5·8 (0.2)	0·2 (-0·3 to 0·6)		0·0 (-0·4 to 0·5)		-0·2 (-0·6 to 0·3)	
13 weeks	**5·5 (1·9)**	**3·9 (0.2)**	**3·9 (0.2)**	**-1·6 (-2·1 to -1·1)**	**<0·001**	**-1·6 (-2·1 to -1·2)**	**<0·001**	**0·0 (-0·5 to 0·5)**	**0·87**
52 weeks	5·2 (0.2)	3·7 (0.2)	3·4 (0.2)	-1·5 (-2·0 to -0.9)	<0·001	-1·8 (-2·3 to -1·3)	<0·001	-0·4 (-0·9 to 0·1)	0·21
Pain Self-efficacy (PSEQ)									
Baseline	36·7 (0.9)	34·0 (1.0)	34.4 (0.9)	-2·6 (-5.2 to 0·1)		-2.2 (-4.8to -0·4)		-0·4 (-2.2 to 3.0)	
13 weeks	**36.9 (1.0)**	**45·1 (1·0)**	**45.2 (1·0)**	**8·2 (5·4 to 10.9)**	**<0·001**	**8.2(5.5to 11.0)**	**<0·001**	**0.1 (-2·7 to 2.8)**	**0·96**
52 weeks	37·6 (1.0)	45·7 (1·0)	46.5 (1·0)	8·1 (5·3 to 10.9)	<0·001	8.8 (6.1 to 11·6)	<0·001	0.7 (-2.0 to 3.5)	0·61
Pain Catastrophising (PCS-3)									
Baseline	5·9 (0.2)	6·0 (0.2)	6·1 (0.2)	0·2 (-0·4 to 0·7)		0·2 (-0·3 to 0·8)		0·1 (-0·5 to 0·7)	
13 weeks	**5·8** (0.2)	**3·9 (0.2)**	**3·6 (0.2)**	**-1·9 (-2·5 to -1·3)**	**<0·001**	**-2·2 (-2·8 to -1·6)**	**<0·001**	**-0·3 (-0·9 to 0·3)**	**0·28**
52 weeks	5·6 (0.2)	3·5 (0.2)	3·7 (0.2)	-2·1 (-2·7 to -1·4)	<0·001	-1·9 (-2·5 to -1·3)	<0·001	0·2 (-0·4 to 0·8)	0·56

Fear of movement (FABQ)									
Baseline	14·9 (0.4)	14·7 (0.5)	14·6 (0.4)	-0·1 (-1·4 to 1.1)		0·0 (-1·5 to 0.9)		-0·2 (-1·4 to 1·1)	
13 weeks	**14·6 (0.5)**	**8·6 (0.5)**	**7·6 (0.5)**	**-6·0 (-7·4 to -4·7)**	**<0·001**	**-7.0 (-8·3 to -5·7)**	**<0·001**	**-1.0 (-2·3 to 0.3)**	**0·15**
52 weeks	14.0 (0.5)	7.5 (0.5)	7.7 (0.5)	-6.6 (-7.9 to -5.2)	<0·001	-6.4 (-7.7 to -5.0)	<0·001	0.2 (-1.1 to 1.5)	0.78

[a]Mean difference calculated via an intention to treat analysis; SE=standard error; CI=confidence interval; RMDQ=Roland Morris Disability Questionnaire; PSFS=Patient-Specific Functional Scale; NRS=Numeric Rating Scale; PSEQ=Pain Self-Efficacy Questionnaire; PCS-3=3-item Pain Catastrophising Scale; FABQ=Fear Avoidance Beliefs Questionnaire.

*All outcomes that were measured using discrete scales. Higher scores represent worse outcomes for all measures except for PSFS and PSEQ.

The estimate for clinician clustering for RMDQ with the CFT groups across the whole time period was 0·062 (95%CI: 0·019-0·183).

The primary time point (13 weeks) is in bold.

Figure 3. Economic efficiency

Cost-effectiveness plane for paired comparisons of treatment groups, based on 20,000 bootstrapped cost-effect pairs. QALYs=quality-adjusted life years. CFT = Cognitive Functional Therapy

Table 3. Adverse Events Summary (over the whole 12-month observation period)

	Usual-care (n=165)	**CFT-only (n=164)**	**CFT-biofeedback (n=163)**	p
Potentially trial-related serious adverse events				
Participants reporting one or more potentially trial-related adverse events (Chi Squared Test)	6 (3·6%)	6 (3·7%)	9 (5·5%)	0·63
All potentially trial-related serious adverse events:				
Pain flare requiring hospitalisation	4 (2.4%)	3 (1.8%)	3 (1.8%)	
Nerve blocks (in hospital)	2 (1.2%)	6 (3.7%)	3 (1.8%)	
Lumbar fracture requiring hospitalisation	1 (0.6%)	0 (0.6%)	0 (0·6%)	
Lumbar disc surgery	2 (1.2%)	0 (0%)	1 (0·6%)	
Lumbar fusion surgery	0 (0%)	1 (0%)	2 (1.2%)	
Injury of nerve during nerve block injection	0 (0%)	0 (0%)	1 (0.6%)	
Non-serious adverse events				
Participants reporting one or more non-serious adverse events (Chi Squared Test)	86 (52·1%)	97 (59·1%)	89 (54·6%)	0·43
Potentially trial-related:				
Low back pain	52 (31·5%)	62 (37·8%)	62 (38·0%)	
Neck or thoracic spine pain	16 (9·7%)	20 (22·6%)	10 (6·1%)	
Lower limb pain or sciatica	30 (18·2%)	37 (14·0%)	53 (32·5%)	
Prolapsed intervertebral disc	1 (0·6%)	1 (0·6%)	1 (0·6%)	
Skin reactions	0 (0%)	1 (0·6%)	6 (3·7%)	
Most common other non-serious adverse events:				
Musculoskeletal sprain or strain	17 (10·3%)	10 (6·1%)	10 (6·1%)	
Arthritis	7 (4·2%)	8 (4·9%)	6 (3·7%)	
Upper limb pain	6 (3·6%)	7 (4·3%)	7 (4·3%)	
Non-trial related surgery	4 (2·4%)	7 (4·3%)	8 (4·9%)	
Cardiovascular conditions	4 (2·4%)	4 (2·4%)	5 (3·0%)	
Fractures	4 (2·4%)	4 (2·4%)	5 (3·0%)	

Adverse Event: Any untoward medical occurrence in a participant and that does not necessarily have a causal relationship with trial-related treatment.
Serious Adverse Event: Any low back pain-related adverse event that resulted in death, was life-threatening, required hospitalisation, or resulted in persistent or significant disability or incapacity. These events do not necessarily have a causal relationship with trial-related treatment.

Discussion

CFT-only and CFT-biofeedback treatments both resulted in large clinically important effects (SMD >0.8) for the primary outcome of pain-related activity limitation, compared with Usual-care, and they were substantially less costly (dominant) from a societal perspective. Those effects were sustained until the 52-week final follow up. There was no apparent benefit when CFT was supplemented with movement sensors. The findings were similar across all the secondary clinical outcomes, increasing our confidence in the results.

At the end of the treatment period, the clinical effectiveness of our two intervention groups were larger than most interventions for chronic LBP for the outcomes of activity limitation and pain, and similar to those previously reported for the most effective combination therapies, including previous trials of CFT, identified in a recent systematic review and network meta-analysis.[29] However, our results were sustained at 52 weeks, which is unusual, in contrast to the same systematic review's findings that no treatments, nor combination of treatments, had statistically significant effects at 52 weeks for either activity limitation or pain.[29] In addition, the long-term effects we observed were much greater than more expensive multidisciplinary pain management programs compared with Usual-care for activity limitation (SMD: 0.23 [95% CI 0.06 to 0.40]) and pain (SMD: 0.21 [0.04 to 0.37])[7] even though our interventions were delivered by solo primary care physiotherapists.

Our hypothesis that CFT-biofeedback would have a larger clinical effect than CFT-only was not confirmed. We cannot be sure why no additional effect of movement sensor biofeedback was found, but it appears that in the context of CFT, an individualised intervention that already targets provocative movement patterns, additional movement information via biofeedback added no benefit. It is possible that sensor biofeedback with more feature-rich software may have resulted in different outcomes.

Both interventions were cost-effective, and resulted in larger quality adjusted life year improvements, when compared with Usual-care. The size of the societal-level estimated net cost savings per participant treated (CFT-only $AUD 5276, CFT-biofeedback $AUD 8211) were driven largely by improvements in productivity. This is noteworthy because the largest LBP costs are due to productivity losses rather than direct health costs.[30] There was consistency of results when the economic data were reanalysed by valuing productivity costs using a friction method. Both interventions involved marginally longer consultations (initial consultation 60 minutes, follow ups 30–40 minutes) than with traditional physiotherapy in Australia (approximately initial 30–45 minutes, follow ups 30 minutes), and therefore larger physiotherapy reimbursements from funders may be required to support this practice. However, the net cost saving results indicate that these marginally more expensive treatments were cheaper for society over a 12-month period. This aligns with results

from a recent case-control study that showed physiotherapist-delivered CFT to be only 7% of the cost of a multidisciplinary pain management program. [31]

There are several possible reasons why the effects in this study were larger and more sustained than most previous studies of LBP. CFT explicitly targets factors that are known to be important predictors of outcome, aiming to build self-efficacy and skills for self-management, and reduce pain catastrophising and fear avoidance. The finding that these outcomes all improved provides some evidence that individually targeting these factors is important. The training of clinicians in the trial was a key element, which included direct mentoring and feedback from experts while practising with real patients, and the requirement to formally demonstrate competency before starting to treat patients. These aspects of training are rare in clinical trials of physical or psychological medicine interventions. [32] The inclusion of a booster session at 6 months may also have contributed to the sustained effects. Future studies should explore how critical these different aspects of training are to the effectiveness of this and similar complex interventions.

Strengths of this study are that it was a large relatively pragmatic trial of a clinically challenging cohort, that included participants usually excluded from LBP trials such as people with leg pain, mental health conditions, and older age. Anecdotally, during the baseline interview, many participants reported having given up on seeking care for their LBP, due to a lack of effect. Further, it occurred in multiple primary care clinics in cities on opposite sides of the Australian continent and not in a specialised centre. We trained to competency physiotherapists with diverse previous clinical experience but minimal previous training in CFT, which shows the potential for wider implementation of CFT in primary care. Physiotherapists only delivered one of the interventions and we monitored their CFT treatment fidelity. There were also consistent effects across all clinical outcomes. Unusually for LBP research, we reported adverse events in detail and what constituted Usual-care. Collectively, these attributes of the study enhance the precision and generalisability of the results.

A limitation of this study is that 33% of participants declined consent for access to their Medicare claims and Pharmaceutical Benefits Scheme data, requiring those data to be imputed, which likely introduced some imprecision into those estimates. All clinical outcomes and some economic outcomes were self-reported, and as participants were not blinded this may have impacted expectations and produced some bias. It was also not possible to blind treating physiotherapists. However, the assessors for health economic data were blinded, as were the clinical effectiveness and health efficacy statisticians. Consistent with our pragmatic approach to usual (current) care, the amount of treatment received by the Usual-care group was not controlled, nor was it designed to match the intervention group, which may have contributed to differences in outcomes. Also, because

the fidelity videos did not record sensor data, we did not monitor biofeedback fidelity and therefore physiotherapist biofeedback fidelity cannot be determined.

Future research should investigate the same interventions in other settings and countries, and investigate CFT for other chronic musculoskeletal conditions. Better knowledge of physiological and behavioural mechanisms of change during CFT via mediation studies would be useful. Investigation of whether clinicians can be adequately trained in less time and using online resources, or a hybrid of online and face-to-face training, would inform broader implementation.

Overall, these results demonstrate that CFT resulted in large clinically important effects in both the short and long term, and was more cost-effective from a societal perspective over a 12-month period, when compared with Usual-care. The addition of wearable sensor biofeedback did not add to that effectiveness. CFT may offer a high-value, low-risk and low-cost clinical pathway for patients with persistent disabling LBP. The results of this study have ramifications for the management of LBP in primary care and may have implications for the training of all health care professionals who deliver care for people with chronic disabling LBP.

Contributors

The authors accept full responsibility for the content of this paper and were responsible for the decision to submit the manuscript. TH, POS, AS, AC, RS, JPC, RL, KOS, AMcG, JH, AV and RC conceived of and designed the study. PK, AS, TH and D-CAL accessed and verified the data. AS, TH, D-CAL and PK analysed the data. PK, MH, AS, POS and TH wrote the first draft. All authors critically revised the manuscript for important intellectual content. All collaborators had an opportunity to provide input into the study protocols, contribute to the interpretation of the results, and to critically revise the manuscript for important intellectual content.

RESTORE trial team

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Declaration of interests

POS, JPC, RS, and KOS have received speaker fees for lectures and/or workshops on the biopsychosocial management of pain, including on Cognitive Functional Therapy, from special interest physiotherapy groups and multi-disciplinary audiences of clinicians and researchers. MH and JH have received speaker fees for lectures and/or workshops on management of pain from audiences of clinicians and/or patient-representative groups. POS and JPC are clinical directors of a Physiotherapy Clinic that uses Cognitive Functional Therapy. RS has received a part-time salary from the Insurance Commission of Western Australia to work on another clinical trial of Cognitive Functional Therapy. TH has received fees as an expert witness on falls prevention, received support from the Amplifon Foundation for travel with relation to use of technology in nursing homes, and is deputy chair of the Australian Council of Deans of Health Sciences. KOS was National Director of Professional Development for the Irish Society of Chartered Physiotherapists, and a member of their national board. All other authors declare no competing interests.

Data sharing

The study protocol, participant consent and information forms, de-identified individual participant data. The data dictionary and statistical code can be made available by request to the corresponding author. Access will require submission of a protocol, approval by our review committee, and the signing of a data access agreement. Potential access will be for the period beginning 9 months and ending 36 months following publication of this article. We are not able to provide access to the Medicare Claims Data and Pharmaceutical Benefits Scheme databases, as only Services Australia (a branch of the Federal Government of Australia) has authority to provide access to those data.

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Panel: Research in context

Evidence before this study

We searched four electronic databases (Cochrane CENTRAL, CINAHL, MEDLINE, Embase) up to 27 September 2022 without date or language limits using a modified Cochrane Collaboration search strategy. That strategy used diverse search terms for low back pain ("back pain", "low back pain", "lumbago" etc), cognitive functional therapy ("Cognitive Functional Therapy", "Cognitive Behavioural Therapy" etc) and randomised controlled trials ("controlled clinical trial", "randomised" etc). Four randomised controlled trials of individualised Cognitive Functional Therapy (reported in 5 papers) were identified. All four trials were judged to be of moderate risk of bias (scores 6-7 on 0-10 PEDro scale). Control interventions included manual therapy and exercise, group-based exercise and education, no treatment). One study was inadequately powered (n=36), two showed persistent effects favouring Cognitive Functional Therapy for reducing pain-related activity limitation (disability) up to 12 months follow-up and one did not show significant effects beyond the end of the treatment period. Three studies compared CFT with other interventions. Two reported on activity limitation up to 3 months and their pooled effects were a standardised mean difference of 0.89 (95%CI -0.03 to 1.81), a potentially large effect. Three reported long-term outcomes at 12 months and their pooled effects were a standardised mean difference 0.44 (95%CI 0.01 to 0.77), a moderate effect. There was considerable heterogeneity and imprecision at both time points.

We found no high quality randomised controlled trials comparing Cognitive Functional Therapy to usual primary care, no trials that included an evaluation of economic efficiency, nor any that explored the potential added effect of movement sensor biofeedback.

Added value of this study

The RESTORE trial is the largest clinical trial of Cognitive Functional Therapy and its findings indicate that this treatment resulted in substantial clinically important effects in both the short and long term, when compared with Usual-care. It was effective for the primary outcome of activity limitation and all of the secondary outcome measures. The large effect sizes persisted to the end of the follow-up period (12 months), which is unusual in chronic low back pain. The use of wearable sensor biofeedback did not add to effectiveness. Cognitive Functional Therapy was also much more cost-effective from a societal perspective than usual care.

Implications of all the available evidence

Cognitive Functional Therapy may offer a high-value, low-risk and low-cost clinical pathway for patients with persistent disabling LBP. The results of this study have ramifications for the management of LBP in primary care and may have implications for the training of all healthcare professionals who deliver care for people with chronic disabling LBP.

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