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, clinical trial

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Summary

Background Low back pain 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 might enhance treatment effects. We aimed to compare the effectiveness and economic efficiency of CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling low back pain.

Methods RESTORE was a randomised, controlled, three-arm, parallel group, phase 3 trial, done in 20 primary care physiotherapy clinics in Australia. We recruited adults (aged ≥18 years) with low back pain lasting more than 3 months with at least moderate pain-related physical activity limitation. Exclusion criteria were serious spinal pathology (eg, fracture, infection, or 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 randomly assigned (1:1:1) via a centralised adaptive schedule to usual care, CFT only, or CFT plus biofeedback. 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. Physiotherapists and patients were not masked. This trial is registered with the Australian New Zealand Clinical Trials Registry, ACTRN12618001396213.

Findings Between Oct 23, 2018 and Aug 3, 2020, we assessed 1011 patients for eligibility. After excluding 519 (51·3%) ineligible patients, we randomly assigned 492 (48·7%) participants; 164 (33%) to CFT only, 163 (33%) to CFT plus biofeedback, and 165 (34%) to usual care. Both interventions were more effective than usual care (CFT only mean difference –4·6 [95% CI –5·9 to –3·4] and CFT plus biofeedback mean difference –4·6 [–5·8 to –3·3]) for activity limitation at 13 weeks (primary endpoint). Effect sizes were similar at 52 weeks. Both interventions were also more effective than usual care for QALYs, and much less costly in terms of societal costs (direct and indirect costs and productivity losses; –AU$5276 [–10 529 to –24) and –8211 (–12 923 to –3500).

Interpretation CFT can produce large and sustained improvements for people with chronic disabling low back pain at considerably lower societal cost than that of usual care.

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Introduction

Most people with an episode of low back pain improve rapidly, but 20–30% develop chronic pain lasting more than 3 months, with high levels of disability.[1] Low back pain 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 low back pain are due to loss of work participation and on-going care-seeking. Existing treatment approaches for people with low back pain are inadequate, with low back pain-related disability continuing to increase.[2]

Chronic low back pain is widely considered a complex multifactorial biopsychosocial condition.[2] Guidelines recommend that both physical and psychological contributors be addressed when treating people with chronic low back pain;[4] yet, most interventions do not address the various factors contributing to an individual's pain and associated disability. Consequently, the

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See Online for appendix

Research in context

Evidence before this study

We searched four electronic databases (Cochrane CENTRAL, CINAHL, MEDLINE, and Embase) from inception up to Sept 27, 2022, without language restrictions, using a modified Cochrane Collaboration search strategy. That strategy used diverse search terms for low back pain (eg, "back pain", "low back pain", and "lumbago"), cognitive functional therapy (CFT; eg, "cognitive functional therapy" and "cognitive behavioural therapy"), and randomised controlled trials (eg, "controlled clinical trial" and "randomised"). We identified four randomised controlled trials of individualised CFT (reported in five papers). 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, and no treatment. One study was inadequately powered (n=36), two showed persistent effects favouring CFT 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 of 0·44 (0·01 to 0·77), a moderate effect. We found considerable heterogeneity and imprecision at both timepoints. We found no high quality randomised controlled trials comparing CFT with usual primary care, no trials that included an analysis of economic efficiency, nor any that explored the potential added effect of movement sensor biofeedback.

Added value of this study

To the best of our knowledge, the RESTORE trial is the largest clinical trial of CFT and its findings indicate that this treatment resulted in substantial clinically important effects in both the short term and long term, when compared with usual care. CFT 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. CFT was also much more cost-effective from a societal perspective than usual care.

Implications of all the available evidence

CFT might offer a high-value, low-risk, and low-cost clinical pathway for patients with persistent disabling low back pain. The results of this study have ramifications for the management of low back pain in primary care and might have implications for the training of all health-care professionals who deliver care for people with chronic disabling low back pain.

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 programmes, 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 pain-related cognitions, emotions, and behaviours that contribute to their pain and disability. A previous small trial[8] 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 [SMDs] 1·0). 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 high rates of loss-to-follow-up. By contrast, a trial[10] comparing CFT with exercise and manual therapy found a small, non-statistically significant effect at 12 months (disability SMD 0·2). 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 that CFT addresses pain-provocative movement patterns that contribute to low back pain, such as protective muscle guarding and movement avoidance. Wearable movement sensors enable clinicians to easily measure such movements 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[11] (n=112) of patients with chronic low back pain showed that individualised rehabilitation, which included the wearing of wireless movement sensors, resulted in large and sustained clinical improvements compared with guideline-recommended treatment (12-month SMDs 0·5–1·0). No trials have investigated whether wearable sensors can enhance the effects of CFT.

This three-arm randomised controlled trial 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 low back pain.

Methods

Study design and participants

The RESTORE study was a randomised, controlled, three-arm parallel group, phase 3, clinical trial. Treatment

was delivered in 20 primary care physiotherapy clinics in Perth (WA) and Sydney (NSW), Australia.

Eligible participants were adults (aged ≥18 years) with chronic low back pain lasting more than 3 months, who had sought care from a primary care clinician for their back pain at least 6 weeks previously, had an 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.[12] Exclusion criteria were serious spinal pathology (eg, fracture, infection, or 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 by telephone before inclusion. Participants gave informed consent during completion of an online baseline questionnaire before randomisation.

The study was approved by Curtin University Human Research Ethics Committee (HRE2018-0062, Feb 6, 2018), registered in the Australian New Zealand Clinical Trials Registry, ACTRN12618001396213, and the study protocol is available online.[13]

Randomisation and masking

After participants completed the baseline assessment, a research assistant phoned the National Health and Medical Research Council Clinical Trials Centre, which used adaptive random allocation to randomly assign (1:1:1) participants to one of three groups (1:1:1 allocation ratio): usual care, CFT only, or CFT plus biofeedback. The centralised randomisation service used the minimisation factors of site (Perth or Sydney), sex (female or male), and baseline activity limitation (Roland Morris Disability Questionnaire [RMDQ][14] score dichotomised at 0–12 or 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. Unmasked physiotherapists delivered only one type of treatment and played no role in collecting data, other than facilitating the participant to perform 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 masked to group allocation.

Procedures

Study treatments

In the usual care group, the treatment was the care pathway that the participant's health providers recommended or the participant chose—eg, 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 health-care 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) 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 lasting approximately 60 min and follow-ups approximately 30–40 min). The booster session aimed to review and optimise the participant's self-management plan, including responding to future flare-ups, and address any barriers. This session was added because previous studies[9,15] that included people with higher levels of activity limitation due to chronic low back pain had shown a reduction in CFT treatment effects between 6 and 12 months.

The physiotherapists used a flexible clinical-reasoning approach, which was 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 in which patients were asked to "tell their story" (eliciting a personal narrative of the patient's pain journey to share their concerns, identify which elements of their history were important to them, and what their priorities were). Patients' concerns were validated and their goals for seeking care explored.[16] This approach informed an individualised treatment plan orientated to the patient's goals, with three broad components.

The first component was making sense of pain, a reflective process using the patient's own story and experiences from the examination to help them reconceptualise their low back pain from a biopsychosocial perspective. Physiotherapists discussed how the patient's individual pain-related cognitions (ie, beliefs about tissue damage), emotions (eg, pain-related fear and distress), social factors (eg, life stressors), and behavioural responses (eg, protective guarding,

movement and activity avoidance, and poor sleep routines) contributed to pain and disability. Modifiable factors were identified as targets for change to break the pain and 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.

The second component was 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 aim was achieved by body relaxation techniques, abolishing protective and safety behaviours, and movement control and postural modifications. The participant was provided a daily exercise programme 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.

The third component was lifestyle change, which included 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 the data. These ViMove2 devices (DorsaVi P/L, Melbourne, VIC, Australia) consisted of two miniaturised sensors attached to the lumbar spine (sacrum and L1) with hypoallergenic tape, which communicated wirelessly with a tablet or smartphone for data to be automatically uploaded to a secure cloud-based server.

In the CFT plus biofeedback group, physiotherapists 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. First, seeing and recording movement data while the patient moved in the clinic could assist in identifying movement patterns that might be contributing to the pain.[17] Second, 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. Third, using the ViMove2 software, physiotherapists could programme biofeedback alerts, such as audio beeps and messages via a trial-supplied smartphone, which 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 the suggestion 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 information about both the CFT and the movement sensor interventions is given in the appendix (pp 2–9) and is published in detail elsewhere.[12,16] During the COVID-19 pandemic lockdowns, 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, up to 9% (62/719) of follow-up consultations in the CFT plus biofeedback group would not have included biofeedback, although the true number is likely to be 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

We recruited 18 physiotherapists (nine in each city, across 20 clinics) via social media advertising. Physiotherapists needed to have at least 2 years' clinical experience after graduation, experience treating people with chronic low back pain, an interest in applying biopsychosocial management principles, a willingness to use movement sensors clinically, less than 4 days of previous 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: (1) 80 h of clinical workshops (2 days per month for 5 months), including lecture presentations, live patient demonstrations, skills development, and direct mentoring or feedback while treating non-trial patients; (2) online resources (eg, e-books and training videos); and (3) mentoring and support via private Facebook group pages. This training was done by physiotherapists (PO and JPC) who had developed the CFT approach and had extensive experience using and teaching CFT. Clinical competency was assessed throughout the mentoring period using a checklist and in a final 1-day workshop or by subsequent submission of videos of patients being treated (appendix p 11). Each physiotherapist was allocated using random number generation to deliver only one CFT treatment group to prevent contamination across groups.

All participating physiotherapist attended a 2-h technical workshop on setting up and using the sensors because movement sensors were worn by participants in both CFT groups. The physiotherapists in the CFT plus biofeedback group received an additional 4 h of training on accessing and interpreting the movement data and on

programming biofeedback. The movement sensor training was done 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 plus 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 telephone) 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 monitoring 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 KO) with structured feedback provided, if required.

Outcomes

The primary clinical outcome was pain-related physical activity limitation, self-reported by participants online using the RMDQ (0–24 scale) and the primary timepoint was 13 weeks. Secondary clinical outcomes were mean pain intensity (three numeric rating scales—now, most severe during past 14 days, and average during past 14 days, on a 0–10 scale), patient-specific functional limitation (Patient-Specific Functional Scale, 0–10 scale) pain catastrophisation (Pain Catastrophizing Scale, 3-item 0–12 scale at all timepoints and 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 (one question), patient satisfaction with care and treatment (one question), and adverse events noted by the physiotherapists or self-reported by participants in follow-up questionnaires (appendix p 41). Treatment expectation was measured after 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 programme 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.[2] Adverse event data were collected as detailed in the appendix (p 41).

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 on the basis of responses to the EQ-5D-5L questionnaire.[18] Cost outcomes that were included were direct health costs attributable to use 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 (eg, travel to appointments) and productivity costs (including absenteeism and presenteeism) were captured in the participant questionnaires at 13, 26, 40, and 52 weeks.

Statistical analysis

We calculated the sample size (164 per group) 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 value of less than 0·05, 80% power, a common SD of 6 points, and a 20% dropout rate. Because all three pairwise comparisons between usual-care, CFT only, or CFT plus 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 timepoint of 13 weeks and additionally at 3, 6, 16, 42, and 52 weeks. We included the baseline RMDQ score 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. We included group, time (as categorical variable), and group by time as fixed effects. We included participant as a random effect to account for within-person correlation, using an exchangeable covariance structure. We also included clinician as a random effect to account for the partial nesting by clinician in the CFT only and CFT plus biofeedback groups using the method recommended by Candlish and colleauges.[22] The model also adjusted for covariates site and sex (minimisation variables used for randomisation) and symptom duration and pain intensity (specified in the study protocol). We did two sensitivity analyses (appendix p 21). The first used covariates from the primary analysis model plus auxiliary variables (age, BMI, baseline measures of secondary outcomes, baseline treatment expectations, education, and the Keele STarT MSK Tool score) for multiple imputation of missing values via chained equations, then

we pooled estimates for the primary analysis model from the ten imputed datasets. The second sensitivity analysis used a two-level linear mixed model with a random effect for participant only and unadjusted for covariates. We assessed the effect of treatment on secondary outcome measures 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 (SMDs). We considered an SMD of greater than 0·8 to represent large effects, as is commonly used,[23] and 2 points as the criterion for a minimal clinically important (between-group) difference in the RMDQ score 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]

We did an incremental cost-utility analysis to calculate 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]

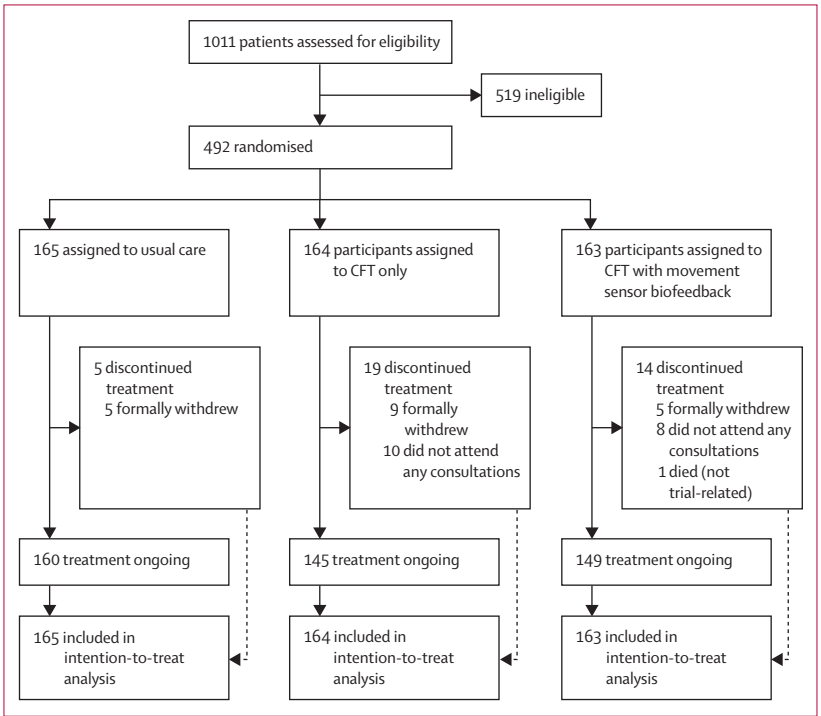

Figure 1: **Trial profile**
CFT=cognitive functional therapy.

The approach to imputation of missing data is detailed in the appendix (pp 29–31). We used bootstrap resampling (20 000 replications in total per analysis) to generate a 95% confidence ellipse surrounding the incremental cost-utility estimate.[26] We extrapolated productivity costs measured at specific timepoints to the full 1-year period using an area-under-the-curve approach.[27] We calculated all costs using a 2019–20 financial base year, including hospital costs valued using the National Weighted Activity Unit calculators (appendix p 27). Economic data on the cost of delivery of the trial interventions would have revealed the group allocation and unmasked the analysts. Consequently, six data options (one true and five false) for the treatment costs were created so that the analysts had to repeat the analyses six times, thereby retaining their masking.

Deviations from the trial protocol were that (1) we measured participant self-rated adherence to treatment between the two trial intervention groups and the analysis of those data was post-hoc; (2) the STarT MSK Tool responses were also collected in the usual care group; (3) to reduce responder burden, we used the 3-item version of the Pain Catastrophizing Scale;[28] (4) the results of the economic efficiency analysis from a health service perspective will be published in a separate paper; and (5) we also did a sensitivity analysis without any data imputation for the main economic efficiency analysis including only those participants (n=330) with Medical Benefits Scheme and Pharmaceutical Benefits Scheme data.

Role of the funding source

The funders of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between Oct 23, 2018, and Aug 3, 2020, we assessed 1011 patients for eligibility. After excluding 519 (51·3%) ineligible patients, we recruited 492 (48·7%) patients; 164 were randomly assigned to CFT only, 163 to CFT plus biofeedback, and 165 to usual care (figure 1). Of these patients, 160 (33%) declined consent for their Medicare claims data and Pharmaceutical Benefits Scheme data extractions, which were non-compulsory for ethics reasons (70 [42%] of 165 in the usual care group, 45 [27%] of 164 in the CFT only group, and 45 [28%] of 163 in the CFT plus biofeedback group; figure 1). At 13 weeks (primary outcome timepoint), 418 (85%) of 492 participants completed the primary outcome (141 [85%] of 165 in the usual care group, 141 [86%] of 164 in the CFT only group, and 136 [83%] of 163 in the CFT plus biofeedback group; figure 1; appendix pp 10, 13).

At baseline, participants had high levels of disability (mean RMDQ score 13·5 [SD 5·2]),[5] and pain (mean over past 14 days 6·2 [SD 1·6]), and the median pain duration of the current episode of low back pain was 260 weeks

	Usual care (n=165)	CFT only (n=164)	CFT plus biofeedback (n=163)
Sex			
Female	98 (59%)	99 (60%)	95 (58%)
Male	67 (41%)	65 (40%)	68 (42%)
Age, years	47·7 (16)	47·5 (15)	46·7 (15)
University education	89 (54%)	80 (49%)	74 (46%)
Weight, kg	82·3 (19·9)	83·2 (20·0)	83·2 (19·0)
Height, cm	170·2 (10·7)	169·7 (10·0)	170·1 (10·4)
BMI, kg/m²	28·3 (6·1)	28·9 (6·4)	28·9 (6·8)
Duration of care-seeking, years	4·0 (1·3–10·0)	4·0 (1·0–11·0)	5·0 (1·4–10·0)
Length of current episode, years	5·0 (1·8–10·0)	4·0 (1·0–12·0)	5·0 (1·8–11·0)
RMDQ score	13·5 (4·3)	13·3 (4·4)	13·8 (4·4)
PSFS score	4·2 (1·9)	4·3 (2·0)	4·3 (2·0)
Pain: single item, average past 14 days, NRS score	6·3 (1·5)	6·2 (1·5)	6·1 (1·6)
Pain: mean of 3-item NRS scores*	5·8 (1·3)	5·8 (1·4)	5·7 (1·6)
PSEQ score	36·4 (11·0)	34·2 (11·2)	33·9 (12·1)
PCS-13 score (0–52)	24·3 (12·4)	24·1 (12·8)	25·4 (12·3)
PCS-3 score (0–12)	5·9 (2·7)	6·0 (2·6)	6·1 (2·6)
FABQ physical activity subscale score	14·9 (4·8)	14·7 (5·4)	14·8 (4·6)
Cognitive flexibility scale sum score	51·4 (4·3)	51·5 (4·1)	51·0 (4·4)
Taking any low back pain medication	91/163 (56%)	104/160 (65%)	103/159 (65%)
Number of types of medication being taken	1 (0–2; range 0–6)	1 (0–2; range 0–6)	1 (0–2; range 0–5)
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%)
Antidepressants	5 (3%)	4 (2%)	6 (4%)
Keele STarT MSK Tool categories			
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†			
Very unconfident	14 (10%)	1 (1%)	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%)

(Table 1 continues on next page)

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	Usual care (n=165)	CFT only (n=164)	CFT plus biofeedback (n=163)
Occupation (ANZCO categories)			
Managers	7 (7%)	6 (7%)	10 (10%)
Professionals	27 (28%)	23 (26%)	30 (29%)
Technicians and trade 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%)

Data are n (%), n/N (%), mean (SD), or median (IQR). ANZCO=Australian and New Zealand Standard Classification of Occupations. CFT=cognitive functional therapy. FABQ=Fear Avoidance Beliefs Questionnaire. NRS=numeric rating scale. PCS=Pain Catastrophising Scale. PSEQ=Patient Self-Efficacy Questionnaire. PSFS=Patient-Specific Functional Scale. RMDQ=Roland Morris Disability Questionnaire. *3-item NRS score refers to the average of now, most severe during past 14 days, and average during past 14 days. †Confidence in treatment was measured after randomisation by a single tailored question: "How confident are you that this treatment option will be successful in improving your back pain?"

Table 1: **Baseline characteristics of the study population**

(IQR 72–572). The mean age was 47·3 years (SD 15·2; range 19–87), and 292 (59%) of 492 were female, and 200 (41%) were male (table 1).

In the two intervention groups, the median number of consultations was seven (IQR 4–8) in both groups, recognising that the clinically appropriate number of consultations was individualised. Although this was the median number, 13 (8%) of 164 patients in the CFT only group and 13 (8%) of 163 in the CFT plus biofeedback group did not attend any consultations, some because of the COVID-19 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 6–14]) and CFT plus biofeedback group (median 8 days [6–14]).

In terms of health-care behaviour in the usual care group, at baseline, 91 (56%) of 163 patients were taking medication for their low back pain (table 1). At the 13-week timepoint, 134 (82%) patients answered a question about their care-seeking behaviour over the previous 3 months, with 51 (38%) having sought care for their low back pain from a health-care practitioner. Of those who sought care, the median number of consultations during that period was three (IQR 2–7; range 1–22). Some care-seeking behaviour might have been interrupted by lockdowns during the COVID-19 pandemic (appendix p 14).

	Usual care (n=165)	CFT only (n=164)	CFT plus biofeedback (n=163)	CFT only compared with usual care		CFT plus biofeedback compared with usual care		CFT plus biofeedback compared with CFT only	
				Difference (95% CI)	p value	Difference (95% CI)	p value	Difference (95% CI)	p value
Primary outcome									
RMDQ score									
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)	<0·0001	–4·6 (–5·8 to –3·3)	<0·0001	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)	<0·0001	–5·4 (–6·6 to –4·1)	<0·0001	–0·6 (–1·9 to 0·7)	0·37
Secondary outcomes									
PSFS score									
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)	<0·0001	1·9 (1·4 to 2·4)	<0·0001	–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)	<0·0001	2·1 (1·5 to 2·6)	<0·0001	0·5 (0·0 to 1·0)	0·051
Pain: mean of 3-item NRS scores‡									
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)	<0·0001	–1·5 (–2·0 to –1·1)	<0·0001	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)	<0·0001	–1·8 (–2·3 to –1·4)	<0·0001	–0·4 (–0·9 to 0·1)	0·091
Pain: single item, average past 14 days, NRS score									
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)	<0·0001	–1·6 (–2·1 to –1·2)	<0·0001	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)	<0·0001	–1·8 (–2·3 to –1·3)	<0·0001	–0·4 (–0·9 to 0·1)	0·21
PSEQ score									
Baseline	36·7 (0·9)	34·0 (1·0)	34·4 (0·9)	–2·6 (–5·2 to 0·1)	..	–2·2 (–4·8 to –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)	<0·0001	8·2(5·5to 11·0)	<0·0001	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)	<0·0001	8·8 (6·1 to 11·6)	<0·0001	0·7 (–2·0 to 3·5)	0·61
PCS-3 score									
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)	<0·0001	–2·2 (–2·8 to –1·6)	<0·0001	–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)	<0·0001	–1·9 (–2·5 to –1·3)	<0·0001	0·2 (–0·4 to 0·8)	0·56
FABQ physical activity subscale score									
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)	<0·0001	–7·0 (–8·3 to –5·7)	<0·0001	–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)	<0·0001	–6·4 (–7·7 to –5·0)	<0·0001	0·2 (–1·1 to 1·5)	0·78

Data are mean (SE) unless otherwise indicated Includes 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 scores with the CFT groups across the whole time period was 0·062 (95% CI 0·019–0·183). *CFT=cognitive functional therapy. FABQ=Fear Avoidance Beliefs Questionnaire. NRS=numeric rating scale. PCS=Pain Catastrophising Scale. PSEQ=Pain Self-Efficacy Questionnaire. PSFS=Patient-Specific Functional Scale. RMDQ=Roland Morris Disability Questionnaire. Primary outcome timepoint. †Mean difference calculated via an intention-to-treat analysis. ‡3-item NRS score refers to the average of now, most severe during past 14 days, and average during past 14 days.

Table 2: **Clinical effectiveness outcomes**

The main clinical effectiveness findings for differences in activity limitation at 13 weeks indicate that the CFT only (mean difference –4·6 [95% CI –5·9 to –3·4]) and CFT plus biofeedback (–4·6 [–5·8 to –3·3]) treatments were both more effective than usual care (table 2; figure 2; appendix pp 16, 21). The corresponding SMDs were large (–0·90 [–1·11 to –0·68] for CFT only and –0·87 (–1·08 to –0·66] for CFT plus biofeedback; appendix p 16). The effect sizes remained similar up to the 52-week timepoint (appendix p 16). Differences between the CFT only and CFT plus biofeedback treatments were trivial and not significant at 13 weeks (mean difference 0·0 [–1·3 to 1·3]; SMD 0·00 [–0·22 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 27 (19%) of 141 in the usual care group, 86 (61%) of 141 in the CFT only group, and 82 (60%) of 136 in the CFT plus biofeedback group. Those differences were broadly sustained to 52 weeks (appendix p 17). The number needed to treat for the same threshold[24] reduction of activity limitation at 13 weeks was 2·4 (2·0 to 3·2) for the CFT group and 2·4 (2·0 to 3·3) for the CFT plus biofeedback groups, and ranged between 2·0 and 3·0 across the follow-up period to 52 weeks (appendix p 17).

All the secondary clinical outcome findings were similar to those of the primary outcome, showing large and sustained effects for both the CFT only and CFT plus biofeedback groups compared with usual care from

13 weeks to the end of follow-up, with no difference between the two intervention groups (table 2; figure 2; appendix pp 18–20). At 13 weeks, the numbers of participants very satisfied or satisfied were 27 (19%) of 139 in the usual care group, 119 (84%) of 141 in the CFT only group, and 107 (79%) of 135 in the CFT plus biofeedback group (appendix p 20). Differences in self-rated treatment adherence between the two trial intervention groups were trivial and not statistically significant at any timepoint (appendix p 15). Both sensitivity analyses for the primary clinical effectiveness outcome showed trivial differences from the results of the main analysis (appendix p 21).

Regarding the pair-wise contrasts in the primary cost-utility comparisons, the CFT only versus usual care comparison had 97% of the bootstrap replications fall into the lower-right quadrant, indicating that CFT only is more effective and less costly, with an incremental gain of 0·12 QALYs per participant (95% CI 0·08 to 0·16), at an overall cost of –$5276 (–10 529 to –24; figure 3). Similarly, 99·8% of the bootstrap replications fell into the lower-right quadrant for the CFT plus biofeedback versus usual plus care comparison, with an incremental gain of 0·13 QALYs per participant treated (0·01 to 0·17), and an overall cost of –$8211 per participant treated (–12 923 to –3500) in the CFT plus biofeedback group (figure 3). Most of the between-group differences in costs were in productivity losses (appendix p 33). We found reasonable uncertainty as to whether CFT only was more or less cost-effective than the CFT plus biofeedback. In the analyses using imputed data, 46% of the bootstrap replications fell into the lower-right quadrant, where CFT plus biofeedback was more effective and less costly, whereas 6% fell into the upper-left 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 lower-right quadrant, where CFT plus biofeedback was more effective and less costly, whereas 33% of the bootstrap replications fell into the upper-left quadrant, where CFT only was more effective and less costly. Acceptability curve analysis using imputed data indicated that CFT plus biofeedback was likely to be more cost-effective compared with CFT only, with 80–85% probability across willingness to pay per QALY thresholds up to $100 000 (appendix p 35). However, sensitivity analyses using complete case data indicated this probability varied between 40% and 50% (appendix p 36). On balance, we found insufficient evidence to support a conclusion favouring the economic efficiency of one CFT treatment over the other.

21 participants had low back-related serious adverse events during the 12-month trial period, with a similar prevalence across groups (six [4%] of 165 in the usual-care group, six [4%] of 164 in the CFT only group, and nine [6%] of 163 in the CFT plus biofeedback group; table 3). 279 participants had non-serious adverse events during the 12-month trial period, also with similar prevalence across the groups (86 [52%] of 165 in the usual care group, 97 [59%] of 164 in the CFT only group, and 89 [55%] of 163 in the CFT plus biofeedback group; table 3).

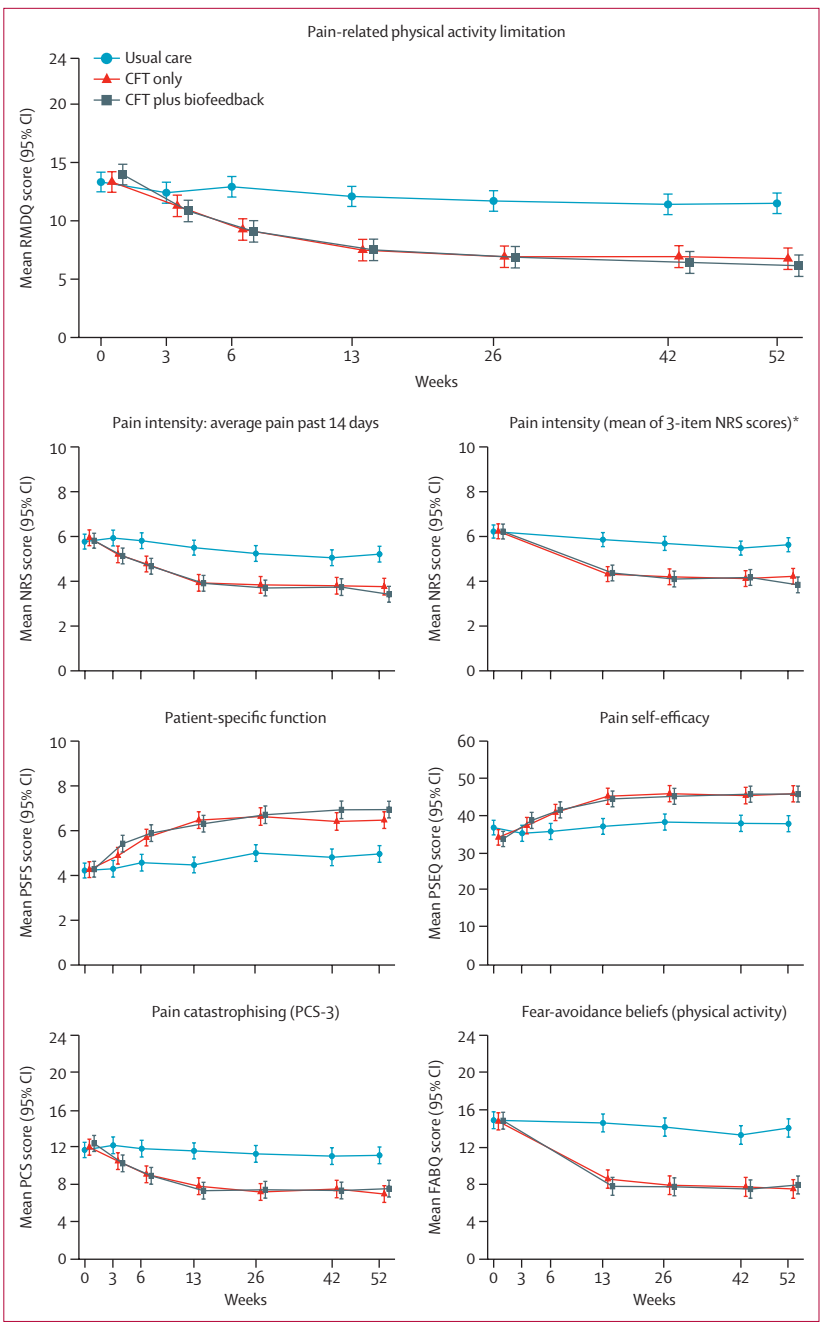

Figure 2: **Primary and secondary clinical effectiveness outcomes**
Includes all secondary outcomes that were measured using discrete scales. Higher scores represent worse outcomes for all measures except for patient-specific function and pain self-efficacy. CFT=cognitive functional therapy. FABQ=Fear Avoidance Beliefs Questionnaire (physical activity subscale). NRS=numeric rating scale. PCS=Pain Catastrophizing Scale. PSEQ=Pain Self-Efficacy Questionnaire. PSFS=Patient-Specific Functional Scale. RMDQ=Roland Morris Disability Questionnaire. *3-item NRS score refers to the average of now, most severe during past 14 days, and average during past 14 days.

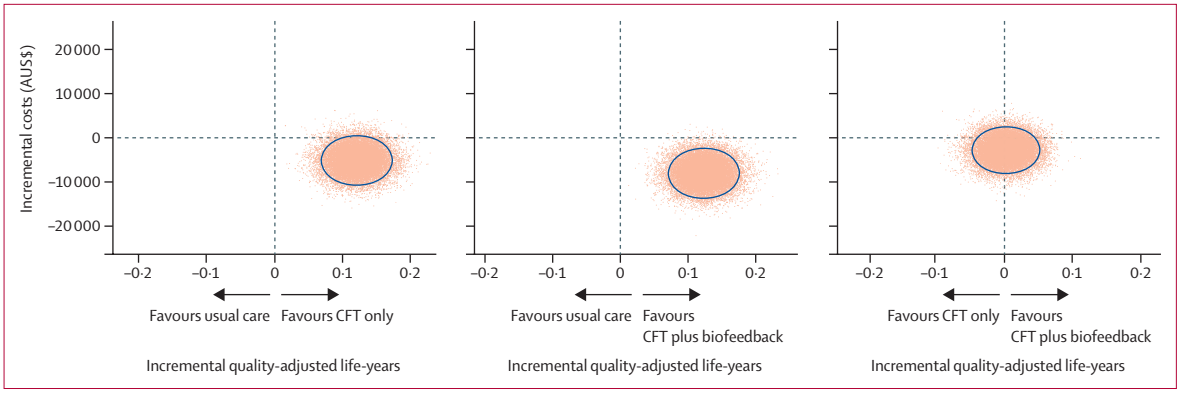

Figure 3: **Economic efficiency**
Cost-effectiveness plane for paired comparisons of treatment groups, based on 20 000 bootstrapped cost-effect pairs. CFT=cognitive functional therapy.

	Usual care (n=165)	CFT only (n=164)	CFT plus biofeedback (n=163)
Potentially trial-related serious adverse events			
Participants reporting one or more potentially trial-related adverse events	6 (4%)	6 (4%)	9 (6%)
Pain flare requiring hospitalisation	4 (2%)	3 (2%)	3 (2%)
Nerve blocks (in hospital)	2 (1%)	6 (4%)	3 (2%)
Lumbar fracture requiring hospitalisation	1 (1%)	0	0
Lumbar disc surgery	2 (1%)	0	1 (1%)
Lumbar fusion surgery	0	1 (1%)	2 (1%)
Injury of nerve during nerve block injection	0	0	1 (1%)
Non-serious adverse events			
Participants reporting one or more non-serious adverse events*	86 (52%)	97 (59%)	89 (55%)
Potentially trial related			
Low back pain	52 (32%)	62 (38%)	62 (38%)
Neck or thoracic spine pain	16 (10%)	20 (23%)	10 (6%)
Lower limb pain or sciatica	30 (18%)	37 (14%)	53 (33%)
Prolapsed intervertebral disc	1 (1%)	1 (1%)	1 (1%)
Skin reactions	0	1 (1%)	6 (4%)
Most common other non-serious adverse events			
Musculoskeletal sprain or strain	17 (10%)	10 (6%)	10 (6%)
Arthritis	7 (4%)	8 (5%)	6 (4%)
Upper limb pain	6 (4%)	7 (4%)	7 (4%)
Non-trial related surgery	4 (2%)	7 (4%)	8 (5%)
Cardiovascular conditions	4 (2%)	4 (2%)	5 (3%)
Fractures	4 (2%)	4 (2%)	5 (3%)

*Adverse events were any untoward medical occurrence in a participant; and serious adverse events were 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. Participants could report more than one adverse effect and might be counted more than once.

Table 3: **Adverse events (over the whole 12-month observation period)**

Discussion

CFT only and CFT plus biofeedback treatments both resulted in large clinically important effects for the primary outcome of pain-related activity limitation at 13 weeks, compared with usual care, and these treatments were substantially less costly from a societal perspective. Those effects were sustained until the 52-week final follow-up. We found 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 was larger than most interventions for chronic low back pain 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 systematic review and network meta-analysis.[29] However, our results were sustained at 52 weeks, which is unusual, by contrast with 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] Additionally, the long-term effects we observed were much greater than those of more expensive multidisciplinary pain management programmes compared with usual care for activity limitation,[7] although our interventions were delivered by solo primary care physiotherapists.

Our hypothesis that CFT plus 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 in the context of CFT, an individualised intervention that already targets provocative movement patterns, additional movement information via biofeedback added no benefit. Sensor biofeedback with more feature-rich software might have resulted in different outcomes.

Both interventions were cost-effective and resulted in larger QALY improvements when compared with usual care. The size of the societal-level estimated net cost savings per participant treated were driven largely by improvements in productivity. This finding is noteworthy because the largest low back pain costs are due to productivity losses rather than direct health costs.[30] Results were consistent when we reanalysed the

economic data by valuing productivity costs using a friction method. Both interventions involved marginally longer consultations than with traditional physiotherapy in Australia, and therefore larger physiotherapy reimbursements from funders might 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 finding aligns with results from a case-control study that showed physiotherapist-delivered CFT to be only 7% of the cost of a multidisciplinary pain-management programme.[31]

There are several possible reasons why the effects in this study were larger and more sustained than in most previous studies of low back pain. 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 show 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 might also have contributed to the sustained effects. Future studies should explore how important 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 cohort with specific clinical challenges, which included participants usually excluded from low back pain trials such as people with leg pain, mental health conditions, and older participants. Further, the study was done in multiple primary care clinics in cities on opposite sides of Australia 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. We also found consistent effects across all clinical outcomes. 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 because participants were not blinded this method might have affected expectations and produced some bias. We could also not mask treating physiotherapists. However, the assessors for health economic data were masked, as were the clinical effectiveness and health efficacy statisticians. Consistent with our pragmatic approach to usual (current) care, the amount of treatment received in the usual care group was not controlled, nor was treatment frequency designed to match the intervention group, which might 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 assessed. Lastly, we did not collect race or ethnicity data.

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 show that CFT resulted in large clinically important effects in both the short term 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 might offer a high-value, low-risk, and low-cost clinical pathway for patients with persistent disabling low back pain. The results of this study have ramifications for the management of low back pain in primary care and might have implications for the training of all health-care professionals who deliver care for people with chronic disabling low back pain.

Contributors

PK, TH, PO, AS, AC, RS, JPC, RL, KO, AM, JH, AV, and RC conceived of and designed the study. SA and RS provided clinical psychology input to the design and conduct of the trial, and were the trial managers in Sydney and Perth, respectively. AS, TH, D-CAL, and PK analysed the data. PK, MH, AS, PO, 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. All authors had full access to the data and PK, AS, TH, and D-CAL accessed and verified the data.

Declaration of interests

PO, JPC, RS, and KO have received speaker fees for lectures or workshops on the biopsychosocial management of pain, including on CFT, from special interest physiotherapy groups and multi-disciplinary audiences of clinicians and researchers. MH and JH have received speaker fees for lectures or workshops on management of pain from audiences of clinicians or patient-representative groups. PO and JPC are clinical directors of a physiotherapy clinic that uses CFT. RS has received a part-time salary from the Insurance Commission of Western Australia to work on another clinical trial of CFT. 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. KO 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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