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RESTORE—Cognitive functional therapy with or without movement sensor biofeedback versus usual care for chronic, disabling low back pain: study protocol for a randomised controlled trial

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ABSTRACT

Introduction Low back pain (LBP) is the leading cause of disability globally and its costs exceed those of cancer and diabetes combined. Recent evidence suggests that individualised cognitive and movement rehabilitation combined with lifestyle advice (cognitive functional therapy (CFT)) may produce larger and more sustained effects than traditional approaches, and movement sensor biofeedback may enhance outcomes. Therefore, this three-arm randomised controlled trial (RCT) aims to compare the clinical effectiveness and economic efficiency of individualised CFT delivered with or without movement sensor biofeedback, with usual care for patients with chronic, disabling LBP.

Methods and analysis Pragmatic, three-arm, randomised, parallel group, superiority RCT comparing usual care (n=164) with CFT (n=164) and CFT-plus-movement-sensor-biofeedback (n=164). Inclusion criteria include: adults with a current episode of LBP >3 months; sought primary care ≥6 weeks ago for this episode of LBP; average LBP intensity of ≥4 (0–10 scale); at least moderate pain-related interference with work or daily activities. The CFT-only and CFT-plus-movement-sensor-biofeedback participants will receive seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks. All participants will be assessed at baseline, 3, 6, 13, 26, 40 and 52 weeks. The primary outcome is pain-related physical activity limitation (Roland Morris Disability Questionnaire). Linear mixed models will be used to assess the effect of treatment on physical activity limitation across all time points, with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks. For the economic (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years measured across the 12-month follow-up using the EuroQol EQ-5D-5L .

Ethics and dissemination Approved by Curtin University Human Research Ethics Committee (HRE2018-0062, 6 Feb 2018). Study findings will be disseminated through publication in peer-reviewed journals and conference presentations.

Strengths and limitations of this study

► The first fully powered study comparing cognitive functional therapy (CFT) to usual care as control.
► Three-arm trial to quantify the added contribution of movement sensor biofeedback to CFT.
► Evaluation of whether cognitive or movement changes mediate improvements.
► Evaluation of economic efficiency in addition to clinical effectiveness.
► Full participant and therapist blinding not possible.

Trial registration number Australian New Zealand Clinical Trials Registry (ACTRN12618001396213).

INTRODUCTION

Globally, low back pain (LBP) carries the greatest burden of disease in terms of years lived with disability.[1] Most people with an episode of LBP improve rapidly; however, many have recurrent pain and some develop chronic LBP (pain lasting >3 months) with high levels of disability.[2] This group of patients is responsible for most of the cost and burden associated with LBP.[3] The resultant societal costs of chronic LBP are enormous, exceeding that of cancer and diabetes combined,[4 5] with the majority of these costs being due to loss of work participation and ongoing care-seeking. Current care models are failing, with LBP-related disability increasing 45% from 1990 to 2010.[6]

LBP guidelines recommend that patients seeking care for LBP are initially offered simple interventions (eg, advice and self-management strategies) and, if they do not improve quickly, then other interventions such as anti-inflammatory medication,

exercise therapy and manual therapies.[7] For those patients who fail to respond to these interventions, care is often rapidly escalated, to more invasive, expensive and potentially harmful interventions, including opioids,[8] injections[9] and surgery,[10] which have limited evidence of effectiveness despite carrying substantial risks. Furthermore, these patients frequently undergo expensive imaging, which does not improve outcomes and may actually be detrimental.[11] There is an urgent need for effective 'second line' primary care interventions for those patients who do not improve with early standard management to reduce chronicity and limit the number of people progressing to secondary care.

Exercise approaches are the most widely recommended interventions for patients with chronic disabling LBP.[12] A number of exercise approaches, including graded activity, pilates and motor control exercises, have been shown to produce small to moderate effects but with a variable duration of improvements.[13–16] One aspect this has been attributed to is a lack of individualised management of known psychological barriers to recovery and inadequate targeting of exercise to each individual's specific functional movement limitations.

Cognitive functional therapy (CFT) was developed as a physiotherapist-led, individualised cognitive and behavioural self-management approach to chronic disabling LBP that helps people to: (1) reconceptualise their pain from a biopsychosocial perspective, while dispelling unhelpful beliefs and identifying new cognitive and behavioural responses to pain; (2) build confidence to engage in functional activities related to their goals through functional movement training and (3) adopt a healthy lifestyle by targeting activity avoidance, poor sleep habits, stress management and dietary advice.[17] A Norwegian study of patients with chronic LBP (N=121) found CFT resulted in large sustained effect sizes (12-month standardised effect sizes from 0.7 to 0.9) compared with guideline-recommended manual therapy and exercise.[18] These findings suggest a large, high-quality study is now required.

With advances in technology, movement sensors enable accurate measurement and monitoring of lumbar spine movements outside the research laboratory.[19] Wearable movement sensors enable clinicians to precisely measure movement patterns, postures (functional movements) and their relationship to pain, both in the clinical setting but more importantly, during patients' normal activities (work, rest and play) outside the clinic. In addition, movement sensors could help patients to develop an awareness of how they move and the postures they use during normal activities, where changes to these habituated functional movement behaviours are most important. This technology has the potential to increase the effectiveness of therapies aimed at correcting functional movement behaviours. A recent pilot randomised controlled trial (RCT; N=112) of patients with chronic LBP showed that individualised rehabilitation, based on addressing functional movement behaviours, combined with biofeedback from wearing wireless movement sensors, resulted in large and sustained clinical improvements compared with guideline-recommended treatment (12-month effect sizes from 0.5 to 1.0).[20]

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

METHODS AND ANALYSIS

The RESTORE study is a pragmatic, three-arm, parallel group, superiority RCT comparing usual care with CFT only and CFT-plus-movement-sensor-biofeedback in patients with chronic LBP (figure 1). The trial will be conducted in Perth and Sydney, Australia. Curtin University Human Research Ethics Committee approved the study (HRE2018-0062, 6 February 2018). The protocol follows the guidelines described in the 'Standard Protocol Items: Recommendations for Interventional Trials' Statement.[21]

Participants

We will recruit 492 adult participants who meet these inclusion criteria: a current episode of non-specific LBP lasting more than 3 months (including cases with leg pain); presenting to a primary care clinician at least 6 weeks ago for this episode of LBP; scoring an average LBP intensity of 4 or more on a 0–10 Numerical Rating Scale[22] and having at least moderate pain-related interference with normal work or daily activities (measured by item 8 of the 36-item Short Form Survey).[23] Patients will be excluded if they have any diagnosed medical conditions that prevent them from being physically active; have a serious spinal pathology (eg, fracture, infection, cancer); are pregnant or have given birth within the previous 3 months; have inadequate English to comprehend the study's questionnaires and instructions; have a skin allergy to hypoallergenic band-aid or tape adhesives or are scheduled for major surgery in the next 3 months. In addition to those inclusion criteria, participants will be informed of the locations of the physiotherapy clinics for the study intervention groups and will only be included in the trial if they are willing to travel for treatment to at least one site delivering either of the possible interventions.

Patient and public involvement

Patients and the public were not directly involved in the design, recruitment to or conduct of this study. They will be involved in our plans to disseminate the study results to participants and relevant community groups by assisting in the choice of what information/results to share and in what format.

Recruitment

Trial participants will be recruited via clinicians (eg, general medical practitioners, physiotherapists, pain
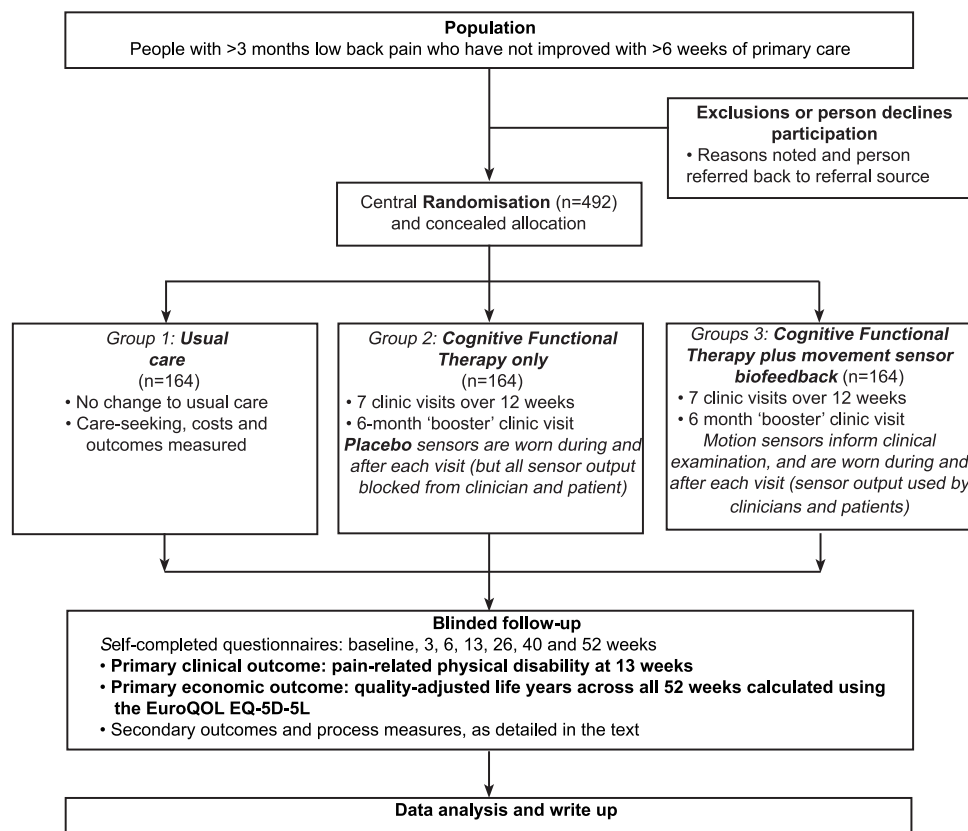
Figure 1 Flow chart.

clinics, surgeons) or directly from the community (eg, via print media and social media). Clinicians will conduct a preliminary screening of patients with LBP and inform potential trial participants about the study. Those patients who request further information about the study will be provided with a flyer, which directs them to the study website (https://www.restorebackpain.com/) where greater study detail, including the participant information sheet and consent form, are provided. Potential participants can opt to have the research team contact them or can simply take the study flyer and contact the research team directly.

Participants will also be recruited directly from the community, without a health practitioner referral. Information about the trial will be disseminated via social media (including Facebook, LinkedIn and Twitter) and print media (including flyers and newsletters) which will direct to the website and the research team.

All potential participants will be screened for eligibility over the phone by a researcher prior to inclusion. The researcher will also note in the trial database any reasons for excluding a referred patient but not any identifying details of that person. Recruitment into RESTORE commenced on 23 October 2018.

Consent process
Consent will be sought from potential participants who meet the inclusion criteria. A researcher will discuss the trial protocol and offer participants the opportunity to provide consent electronically or by mail (see online supplementary appendix 1). Electronic consent for the trial will be via a weblink to an electronic version of the consent form. The consent form also asks patients to indicate whether they are comfortable or not with videos being taken of some treatment sessions. Videos are used to monitor fidelity of the physiotherapist in delivering the individualised rehabilitation as per the study protocol. Participants can withdraw for any reason at any time.

All recruited patients will be asked to provide consent for access to their Medicare and Pharmaceutical Benefits Scheme records for the 12-month time period that they are involved in the study. These data will be only used for the analysis of economic efficiency. A paper version of the Federal Department of Human Services-supplied consent form will be sent to participants for signing and returning via a postage-paid envelope. Declining this consent will not affect eligibility to participate in the clinical effectiveness component of the trial.

Baseline assessment
Following informed consent, participants will self-complete the baseline assessment, including patient demographics and outcome measures, via the online database. A researcher will be available by phone if they require assistance. A detailed description of the baseline variables is provided in table 1.

Table 1 Trial data collected and their purpose

Construct	Measure	Time points (weeks)	Purpose
Age	Date of birth	0	Describe population
Sex	Male/female	0	Describe population
Duration of episode	Weeks	0	Describe population
Duration since care-seeking	Weeks	0	Describe population
Previous lifetime episodes	Number	0	Describe population
Height	cm	0	Describe population
Weight	kg	0	Describe population
Education	Categorical	0	Describe population
Current role	Categorical	0	Describe population
Employed	Yes/no	0	Describe population and analysis of economic efficiency
Occupation	Open text	0	Describe population and analysis of economic efficiency
Hours working	Hours	0	Describe population and analysis of economic efficiency
Days working	Days	0	Describe population and analysis of economic efficiency
Sick leave last 3/12	Yes/no	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Days of sick leave 3/12	Days	0, 12, 26, 40 and 52	Describe population and analysis of economic efficiency
Pain-related physical activity limitation	Roland Morris Disability Questionnaire[46]	0, 3, 6, 12, 26, 40 and 52	Describe population, primary outcome, analysis of economic efficiency
Functional limitation	Patient-Specific Functional Scale[47]	0, 3, 6, 12, 26, 40 and 52	Secondary outcome
Pain intensity	Numeric Pain Rating Scales[31]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome
Fear avoidance beliefs	Fear Avoidance Beliefs Questionnaire (physical activity sub-scale)[35]	0, 12, 26, 40 and 52	Describe population, secondary outcome, mediator
Analgaesic use	Participant self-report text box	0	Describe population, secondary outcome (when matched to 12 month Pharmaceutical Benefits Scheme data)
Catastrophising	Pain Catastrophizing Scale[33]	0, 3, 6, 12, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Pain self-efficacy	Pain Self-efficacy Questionnaire[34]	0, 3, 6, 13, 26, 40 and 52	Describe population, secondary outcome, mediator and moderator
Quality-adjusted life years	EuroQOL EQ-5D-5L[30]	0, 12, 26, 40 and 52	Analysis of economic efficiency outcome
Treatment expectations	A tailored question, based on Rofail et al[48]	0 (post-randomisation)	Clinical effectiveness baseline covariate
Confidence in intervention	A tailored question, based on Rofail et al[48]	3 (CFT groups only)	Mediator
Cognitive flexibility	Cognitive Flexibility Inventory[49]	0	Moderator
Therapeutic alliance	Working Alliance/ Theory of Change Inventory[44]	3 (CFT groups only)	Moderator
Risk stratification	Keele STarT MSK Tool[43]	0	Moderator

Continued

Table 1 Continued

Construct	Measure	Time points (weeks)	Purpose
Patient-perceived global improvement	Tailored question, based on Kamper et al recommendations[36]	12, 26, 40 and 52	Secondary outcome
Satisfaction with care and treatment	Tailored question, based on Client Satisfaction Questionnaire[50]	12	Secondary outcome
Productivity costs	iMTA Productivity Cost Questionnaire[38]	12, 26, 40 and 52	Analysis of economic efficiency
Direct health costs attributable to consumption of healthcare resources	Extracts from Medicare and Pharmaceutical Benefits Scheme databases and direct patient report	12, 26, 40 and 52	Analysis of economic efficiency
Functional movement	Wearable wireless sensors (DorsaVi P/L)	Every consultation (CFT groups only)	Mediator
Adverse events	Tailored question, based on recommendations of the Council for International Organisations of Medical Sciences Working Group VI[51]	3, 6, 12, 26, 40, 52 and every consultation	Monitoring adverse events

CFT, cognitive functional therapy; EQ-5D-5L, 5-level EuroQol Five Dimension.

Randomisation

After completing the baseline assessment, dynamic (adaptive) random allocation will be used to randomise participants to treatment groups. Randomisation using a 1:1:1 allocation ratio will be conducted by a research assistant by phoning the Australian National Health and Medical Research Council's Clinical Trials Centre (24 hours phone service), thereby ensuring concealment of treatment allocation. That Clinical Trials Centre will be blinded to baseline assessment. After randomisation and only for those randomised to the CFT-only and CFT-plus-movement-sensor-biofeedback groups, a research assistant will make an appointment for them with a study clinician at an accessible location in their city.

Study treatment

Group 1: usual care

This treatment will be the usual care pathway the participant's health providers recommend and/or the participant chooses. Treatment in this group will not be impacted in any way by participation in the study. Participants in this group only will be paid a token reimbursement for their time completing follow-up questionnaires (AU$30 for the 3-month questionnaire, AU$30 for the 12-month questionnaire and an additional AU$50 if they complete all the six follow-up questionnaires (3 and 6 weeks, 3, 6, 9 and 12 months).

Commonalities across the two CFT treatment groups (groups 2 and 3)

Both CFT treatment groups will have the same treatment frequency of seven treatment sessions over 12 weeks plus a 'booster' session at 26 weeks (initial consultation 60 min, follow ups 30–40 min) in physiotherapy clinics. In both groups, clinicians will use a structured approach to address the relevant cognitive, emotional and behavioural (functional and lifestyle) factors deemed relevant to the individual's presentation.[17]

Based on prior screening (Orebro Musculoskeletal Pain Questionnaire and the Patient-Specific Functional Scale) combined with a comprehensive interview and functional examination, the clinician will identify the multidimensional contributors to pain, distress and disability. This will enable the physiotherapist to design a management plan that is tailored to the person's unique clinical presentation and context.

There are three broad components to the intervention:

Making sense of pain: a reflective process that combines the person's own narrative (interview) and experience (during guided behavioural experiments) to develop a personally relevant, multidimensional understanding of pain for the patient. In this process, unhelpful beliefs and responses to pain are disconfirmed, and new helpful cognitive and behavioural responses (functional and lifestyle) to pain are identified that are linked to their personally relevant goals.[17]

Exposure with 'control': a process of behavioural change through experiential learning following a 'graded exposure' model, designed to challenge expectations of pain and damage consequences via guided behavioural experiments. Specifically, sympathetic nervous system responses (rapid upper chest breathing and body tension) and safety-seeking behaviours (protective muscle guarding, breath holding, movement avoidance and propping of the hand) that manifest during exposure to painful, feared or avoided functional tasks are explicitly targeted and controlled. This provides patients with strategies to relax, control respiration, normalise postural and movement behaviours that they nominate as painful, feared or

Hypoallergenic over-wraps are applied when used during normal daily activities. When EMG sensors are included, they are placed paraspinally at the L3 level.

Figure 2 Placement of the ViMove2 movement sensors.

avoided. The new strategies are immediately integrated into goal-orientated daily activities to build self-efficacy and body conditioning.

Lifestyle change: behavioural modification addressing unhelpful lifestyle factors aimed at increasing physical activity levels based on preference, sleep habits, regulation of stress (via relaxation techniques) and/or dietary advice, where relevant.

CFT is underpinned by a strong therapeutic alliance and motivational interviewing style (open, non-judgmental, reflective)[17] providing validation and facilitating disclosure.[24 25] An individualised progressive self-management programme will be provided, monitored and progressed that includes cognitive restructuring, progressive functional exercises and lifestyle changes, tailored to the individual's goals.

All participants in the CFT-only and CFT-plus-movement-sensor-biofeedback groups will wear the movement sensors for the same duration and frequency, but for the CFT-only group, the movement sensors will be a placebo, meaning that the sensors will collect data, but neither the patient nor the clinician will have access to it (only the researchers have access). The ViMove2 device (DorsaVi P/L, Melbourne, Australia) consists of miniaturised sensors attached to the lumbar spine with hypoallergenic tape and communicate wirelessly with a tablet or mobile phone (figure 2). At all treatment sessions, patients in both CFT groups will perform forward bending in standing and two other clinically relevant functional movements selected by the physiotherapist based in the patient specific functional scale. All three movements will be repeated three times and data recorded via the movement sensors.

Differences across the two CFT treatment groups
Group 2: CFT only
Clinicians and patients in this group will be blinded to all movement sensor output by a software block that only allows the sensors to be configured/started and for the data to be automatically uploaded to a secure cloud-based server. Participants will be told the device is being used to collect outcome data.

Group 3: CFT-plus-movement-sensor assessment and biofeedback (CFT-plus-movement-sensor-biofeedback)
Clinicians in this group will treat patients with the same CFT approach as in the CFT-only group except that in addition, these clinicians will have access to data measured by the movement sensors and be able to use these data for assessment, movement retraining and providing biofeedback. The identification of clinically relevant functional movement behaviours in this particular treatment group will also be informed by data from the movement sensors that are graphically analysed and displayed by the ViMove2 software (figure 3).

This additional information could assist in guiding individualised movement retraining incorporating the following strategies. First, 'live assessment' can assist in identifying unusual kinematic parameters or movement patterns.[26] Second, 'live training' in the clinic, allows visual interaction by observing real-time kinematic and electromyographic (EMG) on-screen data to facilitate changing functional movement behaviours. Third, using the ViMove2 software, clinicians can programme movement sensor biofeedback alerts (audio 'beeps' and messages via a trial-supplied iPhone) that will reinforce key principles from the treatment session while the participant goes about their normal daily activities for the rest of the day. The device will prompt the patient when they 'break a movement rule' that has been programmed for them by the clinician. Individualised movement 'prompts' may be time based, such as reducing long periods of sitting without getting up and moving, or may be kinematically based, such as reducing sitting in an excessively upright position.

There is no provision for trial-funded ancillary or post-trial care.

Clinician recruitment and training
Depending on recruitment and training success, approximately 16 physiotherapists (8 in each city) will deliver the interventions at private physiotherapy clinics. Each physiotherapist will deliver only one CFT treatment arm to prevent learning (contamination) from experience using the movement sensor output being applied to the CFT-only patients. Physiotherapists will be randomised into either the CFT-only group or CFT-plus-movement-sensor-biofeedback group. Up to four additional physiotherapists will be recruited and trained in each city to act as reserves if required. For physiotherapists to be considered for inclusion in the training programme, they will need to have: at least 2 years clinical experience postgraduation; experience treating people with chronic LBP; an interest in applying biopsychosocial management principles via CFT; a willingness to use movement sensors clinically; less than 4 days of prior exposure to CFT training and
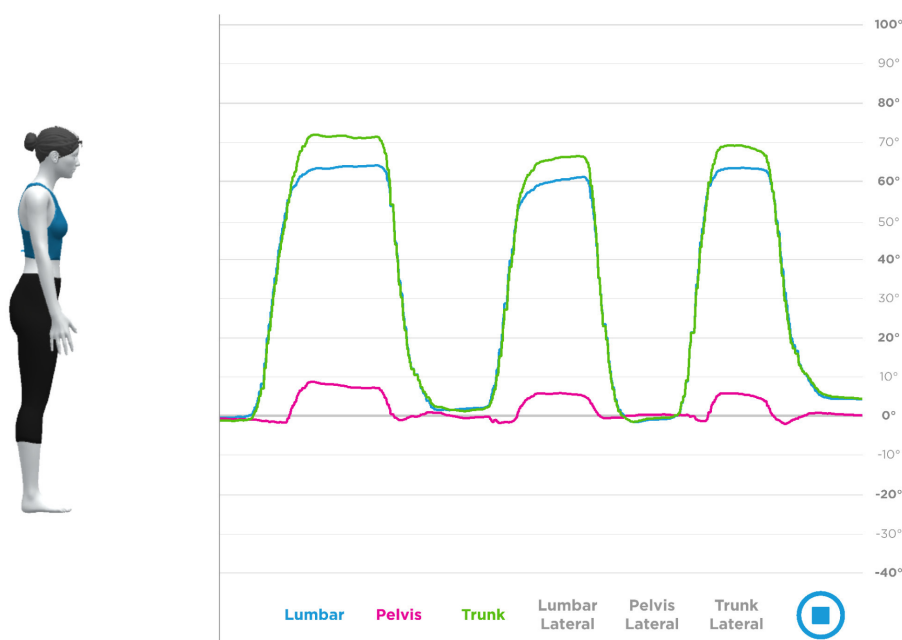
Figure 3 Example movement data (flexion) graphically analysed and displayed by the ViMove2 software.

a willingness to be observed and videoed for mentoring and feedback purposes while treating a non-trial patient with disabling LBP.

The clinician training for both the CFT-only group and CFT-plus-movement-sensor-biofeedback group will consist of three components: (1) clinical workshops including live patient demonstrations and mentoring of the physiotherapists while treating patients, (2) online resources (eg, e-book and training videos) and (3) Facebook private support group pages.

CFT training

Six clinical workshops will be conducted (a 2-day workshop every month for 6 months) in each city where both CFT-only and CFT-plus-movement-sensor-biofeedback groups will train together. A final single day workshop will be held for each group separately when clinicians will need to demonstrate a predefined level of competency, as evaluated by the CFT and movement sensor clinical trainers using a structured competency checklist before being eligible to deliver the relevant intervention in the trial. The training workshops will include an initial introductory workshop about CFT with patient involvement, a workshop to build skills regarding communication and behavioural experiments and four workshops involving observation of each physiotherapist examining and treating people with disabling LBP using CFT. The later four sessions will be observed by the clinical trainers who will provide personalised feedback using a competency checklist developed for the training. The CFT training will be conducted by physiotherapists (POS and JPC) who developed the CFT approach and have extensive experience using and teaching CFT. Clinical competency will be assessed in a final 1-day workshop or by ongoing videos of patients if required.

Movement sensor training

Because the ViMove2 movement sensors are worn by participants in both CFT groups, all participating clinicians will attend a 2-hour technical workshop on setting up and using the ViMove2 devices. This workshop will focus on sensor placement, how to test they are working and how to troubleshoot technical issues. The training will occur after the sixth training workshop and at least 2 weeks before the final single-day workshop. The clinicians in the CFT-plus-movement-sensor-biofeedback group will attend a second 4-hour workshop on accessing and interpreting the movement data (kinematic and EMG) and programming biofeedback. These movement sensor workshops will be conducted by a physiotherapist (RL) with extensive experience using these movement sensors clinically and teaching clinicians in their use. Personalised mentoring by RL will be available over the phone to each physiotherapist for up to five post hoc reviews of treatment sessions of trial participants.

Ongoing support for both clinician groups

During the trial, private Facebook pages (one on CFT, one on movement sensors for the CFT-only group and one on movement sensors for the CFT-plus-movement-sensor-biofeedback group) and virtual or face-to-face meetings every 3 months with a clinical trainer will be provided for both clinician groups separately to provide a forum for the discussion of challenges faced when implementing the intervention or with technical issues related to the sensors. The trainers will contribute to the Facebook discussion and 3 monthly meetings.

Treatment fidelity checking

Every seventh participant of each clinician will be selected, and their treatment monitored by the appropriate

clinician trainer to ensure ongoing treatment fidelity. If the seventh participant does not consent to this occurring, each subsequent participant of that clinician will be asked until one consents. This process is recommended in the Spillane et al[27] framework for implementation fidelity in trials. This will take the form of video recordings of three consultations (a consultation early in the treatment process, one in the middle and one close to the end of the treatment period) that will be reviewed by a randomly selected clinician trainer (POS, JPC or KOS) with brief feedback provided if required.

Data collection and outcome measures
Data collection will occur at baseline, and at 3, 6, 13, 26, 40 and 52 weeks. Wherever possible, all data will be completed online directly into the trial database. Alternatively, patients can complete follow-ups over the telephone with a researcher. If participants do not complete follow-ups within 2 days of the scheduled date, they will receive an email reminder and then 2 days later will be contacted by one of the study team. Data collected via the ViMove sensors at each clinical visit will be directly uploaded to a database. A detailed description of the data collected at each time point is presented in table 1.

Primary outcomes
The primary clinical outcome will be pain-related physical activity limitation measured using the Roland Morris Disability Questionnaire[28][29] (RMDQ). For the economic efficiency (cost-utility) analysis, the primary outcome of clinical effect will be quality-adjusted life years calculated using the area under the curve approach based on responses to the EQ-5D-5L questionnaire[30] across each of the assessment time points.

Secondary outcomes
The secondary outcomes include:
- ▶ Pain intensity (three numeric rating scales).[31]
- ▶ Patient-specific activity limitation (Patient-Specific Functional Scale).[32]
- ▶ Pain catastrophisation (Pain Catastrophizing Scale).[33]
- ▶ Pain self-efficacy (Pain Self-efficacy Questionnaire).[34]
- ▶ Fear of movement (physical activity subscale of the Fear Avoidance Beliefs Questionnaire).[35]
- ▶ Patient-perceived global improvement (one question).[36]
- ▶ Patient satisfaction with care and treatment (one question).[37]
- ▶ Adverse events (defined as any morbidity or events causing unwarranted distress to a participant that were potentially related to any trial-related intervention). Clinicians and follow-up questionnaires will inquire about any adverse events.
- ▶ Lumbosacral movement will be measured in both CFT treatment groups using ViMove2 wearable wireless sensors and used in the mediation analysis.
- ▶ Direct health costs attributable to consumption of healthcare resources (measured using extracts from Medicare and Pharmaceutical Benefits databases and direct patient reports) and productivity costs (measured using the Institute for Medical Technology Assessment Productivity Cost Questionnaire.[38]

Sample size calculation
The sample size was calculated for the primary outcome using the programme STATA. A total of 492 patients (164 per group) will be recruited to detect a difference of 2 points (0–24 scale) on the RMDQ between the CFT-only group and CFT-plus-movement-sensor-biofeedback group, p<0.05, 80% power, a common SD of 6 points and a worst-case scenario of 20% dropout rate. Based on our pilot study results,[18][20] we hypothesise that the CFT-plus-movement-sensor-biofeedback group would have an average score of 7.5 points on the RMDQ and the usual care group would have a score of 11.5 points. Pragmatically and arbitrarily, we assume the CFT-only group will have a mean outcome that is halfway (9.5) between the other two groups and so we will power the trial to detect this as the smallest likely between-group difference (11.5−9.5=2.0).

Blinding
Patients will not be informed of any anticipated results of the trial and will be told that the trial is comparing usual care to two evidence-based interventions. All outcome measures will be either self-reported by patients via web-based questionnaires or collected via the movement sensors or Medicare Benefits Scheme/Pharmaceutical Benefits Scheme (MBS/PBS) registers. Unblinded clinicians will deliver only one type of treatment and play no role in collecting data, other than performing a standardised movement protocol with the resultant movement data being automatically uploaded by the sensors to a server without clinician input. Statisticians will be blind to groups.

Statistical analysis
Almost all participant-reported data will be entered directly into an electronic database, where range values are automatically checked. In addition, all data will be checked for range values and outliers prior to analysis.

Treatment efficacy analysis
Repeated-measure linear mixed models will be used to assess the effect of treatment on pain-related physical activity limitation across all time points (3, 6, 13, 26, 40 and 52 weeks), with the primary comparison being a formal test of adjusted mean differences between groups at 13 weeks using intention-to-treat principles. Appropriate sensitivity analyses will be performed on multiple imputed datasets. Estimates of treatment effect will be adjusted for baseline scores of symptom duration, pain intensity, activity limitation (RMDQ score), treatment expectations and significant clinician cluster effects.

The secondary outcome measures will be evaluated using the equivalent repeated-measure linear mixed models.

As widely recommended, we will focus on reporting the size of the effect and its uncertainty (including describing compatibility intervals and p-values) rather than making judgements based on an arbitrary p-value threshold.[39–41] In the papers that report the outcomes of this clinical trial, effect sizes will be discussed relative to those obtained by other interventions in comparable populations.

Analysis of economic efficiency

Direct healthcare and indirect (productivity) costs incurred by participants will be measured over the 12-month follow-up period. Direct health costs will be collected using MBS and PBS database extractions and patient questionnaires to capture other healthcare costs (eg, hospitalisations). Indirect health costs (eg, travel to appointments) and productivity costs (including absenteeism and presenteeism) will also be captured in the 3-monthly patient questionnaires. Productivity costs will be measured using the 'iMTA Productivity Cost Questionnaire'. Productivity costs measured at specific time points will be extrapolated to the full 1-year period using an area under the curve approach. All costs will be calculated using a 2019–2020 financial base year. Hospital costs will be valued using the National Weighted Activity Unit calculators for the 2019–2020 year.

An incremental cost-utility analysis will calculate the difference in costs between intervention and control groups divided by the difference in quality-adjusted life years. Incremental cost-utility analyses will be undertaken from societal (primary analysis) and health service (secondary analysis) perspectives. There will also be analyses undertaken for valuation of productivity costs using human capital (primary analysis) and friction (secondary analysis) methods. Bootstrap resampling (2000 replications of original sample size) will be used to generate a 95% confidence ellipse surrounding the incremental cost-utility estimate. Cost-effectiveness acceptability curve analyses will be undertaken if the intervention is not found to dominate the control condition.

Moderation analysis

To investigate if treatment effect is moderated by cognitive flexibility, baseline activity limitation, baseline pain, catastrophisation or self-efficacy (all groups), the interaction term between the potential moderator and the treatment group variable will be assessed in the repeated-measure linear mixed models for pain-related activity limitation and pain intensity described above. Only in the CFT groups, similar moderation analysis will also occur using the STaRT MSK Tool[42 43] (measured at baseline), therapeutic alliance[44] (measured at 3 weeks) and participant-rated adherence to the treatment programme measured at weeks 3, 6 and 12 with a study-specific single question ('How would you rate your adherence to the treatment programme your physiotherapist has recommended?' 0–10 no adherence to complete adherence).

Mediation analysis

To investigate whether improvement in patients' activity limitation was mediated by correction of habituated functional movement behaviours, or changing patient's pain-related cognitions and emotions, a multilevel structural equation model framework will be used. Investigation of the mediation roles of cognitions and emotions will occur using data from all patients; whereas, investigation of the mediation roles of change in movement will occur using data from only patients in the CFT groups. Results will be expressed as standardised estimates of mediated treatment effect with bootstrapped 95% CIs.

Monitoring

Because this is not a drug trial and the funder has no access to the data, a data monitoring committee will not be formed and there is no planned trial audit. This does not preclude the administering institution choosing to conduct an audit. There will be no interim analysis and, due to the very low risk of harm, there are no stopping guidelines.

Ethics and dissemination

This study will be conducted in accordance with the Therapeutic Goods Administration's Note for Guidance on Good Clinical Practice, the NHMRC National Statement on Ethical Conduct in Human Research and the Australian Code for the Responsible Conduct of Research.

Authorship will be based on the Vancouver Convention[45] and no professional writers will be involved.

Any protocol amendments will be detailed in the trial registration.

Metadata and appropriate copies of publications will be deposited in the Curtin University eSpace, which is an open-access digital repository.

Results will be disseminated via publications in peer-reviewed scientific journals, popular press articles, social media and presentations to scientific and general public audiences.

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