Cognitive functional therapy for disabling non-specific chronic low back pain: A multiple case cohort study

Kieran O'Sullivan[a], Wim Dankaerts[b], Leonard O'Sullivan[a], Peter O'Sullivan[c]

[a]University of Limerick, Limerick, Ireland

[b]University of Leuven, Leuven, Belgium

[c]Curtin University of Technology, Perth, Australia

Corresponding Author:

Dr. Kieran O'Sullivan, Department of Clinical Therapies, University of Limerick, Ireland.

Tel: +353 61 234119

Fax: +353 61 234251

email: kieran.osullivan@ul.ie

Abstract

Background. Multiple dimensions across the biopsychosocial spectrum are relevant in the management of non-specific chronic low back pain (NSCLBP). Cognitive functional therapy is a behaviourally targeted intervention which combines normalisation of movement and abolition of pain behaviours with cognitive reconceptualisation of the NSCLBP problem, while also targeting psychosocial and lifestyle barriers to recovery.

Objective. To examine the effectiveness of cognitive functional therapy for people with disabling NSCLBP who are awaiting an appointment with a specialist medical consultant.

Design. A multiple case (n=26) cohort study consisting of 3 phases (A1-B-A2).

Methods. Measurement phase A1 was a baseline phase during which pain and functional disability were collected on three occasions over three months for all participants. During phase B, participants entered a cognitive functional therapy intervention program, involving approximately eight treatments over an average of 12 weeks. Finally, phase A2 was a 12 month no-treatment follow-up period. Outcomes were analysed using repeated measures ANOVA or Friedman's test (with post-hoc Bonferroni) across seven time intervals, depending on normality of data distribution.

Results. Statistically significant improvements in both functional disability ($p<0.001$) and pain ($p<0.001$) were observed immediately post-intervention, and maintained over the 12 months follow-up period. These reductions reached clinical significance for both disability and pain. Secondary psychosocial outcomes were significantly ($p<0.01$) improved after the intervention, including depression, anxiety, back beliefs, fear of physical activity, catastrophising and self-efficacy.

Limitations. Not a randomised controlled trial. While primary outcome data was self-reported, the assessor was not blinded.

Conclusions. These promising results suggest that cognitive functional therapy should be compared to other conservative interventions for the management of disabling NSCLBP in secondary care settings in large randomised clinical trials.

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Introduction

Non-specific chronic low back pain (NSCLBP) remains a costly musculoskeletal disorder, with effective treatments remaining elusive.[1] While the movement behaviours and body perceptions of people with NSCLBP differ from painfree controls,[2, 3] most physical interventions demonstrate limited effectiveness.[4-8] There is growing evidence that psychosocial factors including depression, anxiety, fear, self-efficacy, catastrophising, distress, negative beliefs and maladaptive coping are associated with disabling NSCLBP disorders.[9-15] Consequently, educational and/or psychosocial interventions have been employed in NSCLBP with some moderate success.[16-19] Furthermore, reduced disability after rehabilitation is primarily related to improvements in fear, distress, catastrophising and self-efficacy.[20, 21] However, the effect size of educational and psychologically-based behavioural therapies remains relatively small, with limited long-term effectiveness[19] and different behavioural and exercise therapies appear to be equally effective.[22]

Maladaptive movement behaviours in NSCLBP patients are associated with increased levels of fear[23] and catastrophising,[24] highlighting intimate body-mind interactions.[25] Given the inter-related, multi-dimensional nature of disabling NSCLBP, interventions which target multiple dimensions associated with a person's pain disorder have been advocated.[26, 27] The few trials employing targeted approaches to managing NSCLBP have shown encouraging findings.[28-30]

Cognitive functional therapy (CFT) is a novel, person-centered behavioural intervention which addresses multiple dimensions in NSCLBP.[26] CFT combines a functional behavioural approach of normalising provocative postures and movements

while discouraging pain behaviours, with cognitive reconceptualisation of the NSCLBP problem. In a recent randomised controlled trial (RCT) among people with moderate NSCLBP, this approach was more effective than combining manual therapy and exercise.[28] However, this approach has not yet been evaluated among people with higher levels of disabling NSCLBP, a group who consume most healthcare resources.[30] Considering the evidence that the natural history of, and specific treatment required for, people with low back pain (LBP) may differ according to the complexity or prognostic risk status of their disorder[30], there is a need to examine whether CFT has clinical utility in more disabled populations. Furthermore, the initial RCT[28] examined a limited number of secondary outcome measures, with no analysis of physical factors such as posture and physical activity. Considering the multidimensional nature of CFT, it would be useful to examine the changes in physical and/or psychological factors after CFT to better inform the choice of outcome measures to use among more disabled populations in future RCTs. Furthermore, this would help ascertain if there are specific variables (e.g. fear, stress, mood) which are not responding as anticipated to rehabilitation.

Multiple case cohort designs are advocated in the developmental stages of novel chronic pain interventions before progressing to RCT design studies.[31, 32] This allows interpretation of the changes which occur with rehabilitation, and fine-tuning of the intervention before an RCT. Therefore, this study examined the role of CFT in a multiple case cohort design, using repeated measurements of the primary outcomes at baseline in a group of patients with disabling NSCLBP on a waiting list for secondary care with a medical consultant. Secondary outcomes were assessed by a range of questionnaires along with novel, minimally invasive methods of analysing physical

factors relevant to NSCLBP such as posture and physical activity in the "real-world" outside the laboratory setting.

Methods

Study Design

A multiple case cohort study consisting of three phases (A1-B-A2) was used. Phase A1 (duration three months) was a baseline measurement phase during which no new intervention took place. During this phase, self-reported baseline measures of pain and functional disability (see section 2.3) were collected for all participants on three occasions six weeks apart. In addition, a range of other secondary outcome measures (see section 2.3) were collected once at the start of this stage. During phase B, participants participated in a CFT intervention. The length of this intervention phase varied in a pragmatic manner based on the progression of the participants, but had a minimum duration of six weeks. At the end of phase B, all (primary and secondary) outcome measures were completed once again. Formal treatment was withdrawn at the end of Phase B, but participants were expected to continue their behavioural-based modification program independently using the strategies developed during the intervention period for the duration of phase A2. Phase A2 lasted 12 months, including follow-up three, six and 12 months after completion of treatment. Ethical approval for this study was obtained from two local hospital Research Ethics Committees.

Participants

Participants were recruited from three local medical consultant clinics (two chronic pain centres, one rheumatology centre). All participants were on the public health

service waiting lists, either awaiting appointment with the medical consultant, or awaiting a medical intervention after their initial appointment. To be eligible for inclusion, participants had to report NSCLBP for at least six months, their NSCLBP had to be present in the previous week and the lower back had to be reported as their primary pain location. The NSCLBP must have interfered with their function, such that they reported reduced activity levels, or required treatment or medication, in the previous year.[13] Participants had to be aged between 18 and 65 years of age, be independently mobile, and capable of participating in a rehabilitation programme incorporating an exercise component. They had to report their NSCLBP was aggravated by changes in posture, movement or physical activity. Participants were excluded if they had evidence of specific spinal pathology (such as malignancy, fracture, infection, spinal stenosis, spondylolisthesis, or inflammatory joint or bone disease), were pregnant or < six months postpartum, had evidence of neurological compromise (i.e. reduced reflexes or motor deficits) or had undergone a pain-relieving medical procedure (e.g. facet or sacroiliac joint injection, myofascial trigger point injection, denervation procedure) in the previous three months. A total of 47 potential participants from the medical consultant waiting lists were contacted. A total of 11 people did not meet the criteria, while another nine people declined participation. The remaining 27 people fulfilled all criteria, and were invited to participate in the study. One participant then withdrew before starting the study, due to difficulty organising transport to attend. The remaining 26 people provided written informed consent, and entered the study (Fig. 1). This sample size is similar to other studies which have examined the feasibility of novel interventions or interventions in new settings.

INSERT FIGURE 1 HERE

Outcome measures

Participants provided a range of demographic information, including age, height, weight, NSCLBP duration, and the number of pain sites throughout their body during the last 12 months using the Nordic Musculoskeletal Questionnaire.[33]

The primary outcomes were (1) functional disability using the Oswestry Disability Index (ODI)[34] and (2) pain severity, scored using the average of the four (maximum in the last 24 hours, minimum in the last 24 hours, average in the last 24 hours, right now) numeric rating scales (NRS) of the Brief Pain Inventory.[35]

A range of secondary outcome measures were also collected. Depression, anxiety and stress were analysed using the subscales of the DASS21.[36] Participants beliefs and thoughts about NSCLBP were analysed using the back beliefs questionnaire (BBQ),[37] the physical activity subscale of the Fear Avoidance Beliefs Questionnaire (FABQ),[38] and the pain catastrophising scale (PCS).[39] Self-efficacy was assessed using the pain self-efficacy questionnaire (PSEQ),[40] while the STarT Back screening tool, which is a predictor of outcome,[30] was also completed. All these questionnaires have appropriate psychometric properties for use in NSCLBP research.

Several secondary physical outcome measures were evaluated in phase A1 and after treatment (end of phase B). Usual daily physical activity was analysed using an ActivPal™ (PAL Technologies, Glasgow, Scotland) accelerometer placed on the thigh.[41] This monitor uses time intervals of 15 seconds when monitoring activity. Participants logged any non-wear time using a diary, and periods of inactivity evident

on the monitor on completion of data collection were cross-checked with participants to ensure this was differentiated from sedentary behaviour. Minimum acceptable wear time for a day to be considered valid was 20 hours, as research has shown that activity measurement accuracy is strongly correlated with wear time.[42] Considering the requirement for at least 20 hours data collection, and the use of diaries, no correction or adjustment for missing deemed necessary. No distinction was made between weekdays and weekends, as most participants were not working which is the primary reason for such variation. Furthermore, the target duration of activity monitoring was one week, which would include all days of the week. Usual seated lumbo-pelvic posture (mean and standard deviation(SD)) was evaluated during a representative day (selected by participant as "typical" in terms of activity and work demands) outside the laboratory using a wireless posture monitor (BodyGuard^{TM}) (Sels Instruments, Vorselaar, Belgium) placed on the lower lumbar spine. This wireless posture monitor has established reliability and validity for monitoring lumbo-pelvic posture.[41, 43, 44] Lower lumbar spine posture during the three longest sitting periods on each day was extracted for analysis. Finally, lumbo-pelvic repositioning error was evaluated using the same posture monitoring device. This involved asking participants to reproduce, while blindfolded, a neutral sitting posture which they were first facilitated into.[45] Constant error, reflecting the degree and direction of error, was the measure of interest.

Clinical Assessment

After all baseline measurements were completed, all participants underwent a comprehensive interview and physical examination by one of the authors (KOS), who is a specialist musculoskeletal physiotherapist with 13 years of experience. The aim of

this interview was to let participants tell their story regarding their pain disorder and the impact it had on their life. During this interview participants provided information about their history of pain, pain area and nature, pain behaviour (aggravating/easing movements and activities), their primary functional impairments, disability, activity levels, lifestyle behaviours and sleep patterns. Inquiries were also made regarding their level of fear of pain and any avoidance of activities, work and social engagement. Their degree of pain focus, pain coping strategies, stress responsiveness and its relationship to pain and their pain beliefs were also questioned, as was any history of anxiety and depression. Finally their beliefs and goals regarding management of their disorder were ascertained. Key principles for building therapeutic alliance, such as expressing empathy, open and reflective questioning, summarising, identifying discrepancies, goal setting and supporting self-efficacy were utilised.[46] The physical examination involved analysis of the subject's primary reported functional impairments (pain provocative movements and functional tasks), in order to identify maladaptive behaviours including provocative postures, movement patterns, muscle guarding and pain avoidant and communicative behaviours. They were also assessed regarding their level of body control and awareness (body perception), their ability to relax their trunk muscles and normalise their movement behaviours, and the effect this had on their pain.[46]

Intervention

Formal treatment was provided in an outpatient university setting, typically once per week and reducing gradually to once every two weeks. Each patient received a specific targeted intervention directed at changing their individual cognitive, movement and lifestyle behaviours considered to be provocative and maladaptive of

their disorder.[2, 26, 47] There were four main components to the intervention. Details of the different components involved in the CFT intervention are described in detail in Supporting Information Appendix S1. These were; (1) a cognitive component focused on pain mechanisms and the factors identified from the history and examination that were considered to contribute to their pain disorder. This included discussing the multidimensional nature of persistent pain as it pertained to the individual – and how cognitive factors, beliefs, emotions and behaviours (movement and lifestyle) can reinforce a vicious pain / disability cycle; (2) specific functional movement and postural training which involved a behavioural modification approach to rehabilitation where patients were taught strategies aiming to enhance their body awareness (use of mirrors and feedback), relaxation (breathing exercises) and control (relaxing tense postures) during tasks they reported as being pain provocative. Pain control and / or reconceptualisation is a key component of this, such that patients were taught to relax and move in a normal manner while reconceptualising that pain doesn't equal harm; (3) functional integration of these new functional patterns in activities of daily life their reported they avoided or which provoked their pain and (4) physical activity and lifestyle advice (See Appendix S1). Participants were requested to practice these strategies at home, and to become increasingly aware of both physical and psychosocial dimensions to their pain, both during the treatment period (phase B), as well as after the cessation of formal treatment (phase A2).

Data Analysis

The thigh accelerometer which collected physical activity data was worn for a mean(SD) of 5.6(1.3) days before and 5.8(1.2) days after treatment. These physical activity data were analysed as steps per day for each participant. The spinal posture

monitor was worn for a mean(SD) duration of 341(123) minutes on one day during phase A1 and again for 243(96) minutes after treatment. Sitting periods while wearing the posture monitor were identified using the accelerometer placed on the thigh. Seated posture data for the three longest sustained sitting periods were then identified for each participant. The mean(SD) duration of each sitting period exported was 26(11) minutes and 25(13) minutes before and after treatment respectively.

All statistical analyses were carried out with IBM SPSS version 19.0. Statistical significance was set as $p<0.05$. The reliability of the primary outcome measures (NRS and ODI) were assessed across the three baselines using the intra-class correlation coefficient (ICC) (two-way mixed), analysis of the standard error of measurement (SEM) and the minimal detectable change at the 90% confidence interval (MDC90). Data were tested for normality of distribution. Mauchly's test indicated that the assumption of sphericity had been violated for both disability and pain, such that degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity. Drop-outs were controlled for on an intention-to-treat basis, using the last observation carried forward. The primary outcomes were compared across the seven time intervals – three baseline measurements, immediately post-intervention, as well as the three, six and 12 month follow-ups - using a general linear model repeated measures ANOVA (NRS) and Friedman's test (ODI). Post-hoc tests had a Bonferroni correction applied. The effect size of the CFT intervention on ODI and NRS was calculated using Cohen's d. The number of participants whose disability and pain remained at least 30% lower 12 months after the intervention was also evaluated, as this is considered the minimum important change (MIC).[48] The physical secondary outcome measures were compared between baseline and immediately post-intervention using paired t-

tests or Wilcoxon's signed ranks tests, depending on the normality of data distribution. The other secondary outcome measures were compared at baseline, immediately post-intervention, and after 6 and 12 months using Friedman's test, with p values adjusted for multiple comparisons to $p<0.0041$.

Results

The 26 participants (14 female) had a mean(SD) age of 44.3(9.7) years, height of 171(10) cm, mass of 88.3(18.7) kg and body mass index of 30.1(5.3) kg/m^2. Their mean(SD) NSCLBP duration was 141(120) months, and number of pain sites was 4.3(1.9). Based on their STarT Back screening score, 14 were "high risk", eight were "moderate risk" and four were "low risk" at baseline. Based on ODI values at baseline, the level of disability varied between low (ODI<20%; n=2), moderate (ODI 21-40%; n=11) and high (ODI>41%; n=13). Two participants did not complete the programme; one participant was involved in a road traffic accident after entering the study and was unable to attend for further treatment, while another participant was offered a pain-relieving medical intervention while receiving treatment such that she was no longer eligible for participation in this study. One further participant did not complete the three and 6 month follow-up, while three additional participants did not complete the 12 month follow-up (Fig. 1). The mean(SD) number of treatment sessions was 7.7(2.5), provided over 12.0(3.5)weeks, with each session lasting 60.0(6.6) minutes.

Reliability of baseline measures

The primary outcome (ODI) showed excellent association (ICC=0.84(0.72-0.92)) between measurements, with small values for both the SEM (3.4) and MDC90 **(9.5)**.

The reliability of the NRS was moderate (ICC=0.67(0.47-0.82)), while the SEM was 0.7 and the MDC90 was 2.0.

Effect of CFT intervention

Functional disability was significantly reduced, $\chi^2(6) = 65.526$, $p<0.001$. Post-hoc analysis with Wilcoxon signed-rank test was conducted with a Bonferroni correction applied, resulting in a significance level set at $p < 0.0042$. These post-hoc tests demonstrated that ODI values were significantly reduced at all four time intervals after treatment compared to each of the three baseline measurements (Fig. 2). This was a large effect size (d=0.85). Compared to median ODI values across the three baselines, median ODI values were 22 points lower after treatment, 23 points lower after three and six months, and 24 points lower 12 months later. Fifteen of the 24 participants who completed the intervention reported a reduction in functional disability greater than 30% at 12 months follow-up.

INSERT FIGURE 2 HERE

Pain was also significantly reduced, $F(3.589, 89.737) = 7.658$, $p<0.001$. Post-hoc Bonferroni tests demonstrated that NRS values at all intervals after treatment were significantly different to the middle of the three baseline measurements. In addition, NRS values were significantly lower than the first baseline measurement immediately after treatment and after 12 months ($p<0.05$). However, none of the post-treatment NRS values were significantly reduced from the third baseline measurement (all $p>0.05$) (Fig. 3). This was a medium effect size (d=0.65). Compared to mean NRS values across the three baselines, NRS values were 1.6 points lower immediately after

treatment, 1.5 points lower three months later, 1.5 points lower six months later, and 1.7 points lower 12 months later. Thirteen of the 24 participants who completed the intervention reported at least a 30% reduction in pain 12 months after the intervention was ended.

INSERT FIGURE 3 HERE

Secondary outcome measures

There were no significant differences (all $p>0.05$) between baseline and immediately post-intervention in any of the physical measures assessed, including the number of steps per day, usual sitting posture, variation in sitting posture and lumbar repositioning. However, there were statistically significant (all **$p<0.0041$**) improvements in depression, anxiety, back beliefs, fear of physical activity, catastrophising, self-efficacy as well as the STarT Back risk score at all intervals after treatment. Stress was not significantly reduced after treatment ($p=0.052$). (See Supporting Information Appendix S2 for full details of secondary outcomes).

Discussion

This multiple case cohort study demonstrated that CFT, a novel person-centred multidimensional intervention significantly reduced functional disability and pain among people with disabling NSCLBP. Furthermore, these improvements were maintained 12 months after the intervention. The results are consistent with a recent RCT[28] using CFT among a less disabled NSCLBP population. However, the absence of a control group did not allow comparison to another intervention. Notwithstanding the significant improvement from repeated baselines, the fact that this is not an RCT

means that the observed improvements could be influenced by factors such as natural recovery, regression to the mean and other non-specific effects.

The reduction in median functional disability of approximately 22 points (54% reduction from baseline) immediately after the intervention exceeded the proposed MIC value of 30%.[48] This reduction was maintained, with 15/24 participants meeting this criterion, after 12 months. This reduction also exceeded the MDC90 of 9.5 points based on ODI variation over the three repeated baselines. The reduction in mean pain of 1.5 points (31% reduction from baseline average) immediately after the intervention exceeded the proposed MIC reduction of 30%.[48] This reduction in pain was also maintained, with 13/24 participants meeting this criterion after 12 months. However, the reduction in pain did not exceed the MDC90 of two points based on NRS variation over the three repeated baselines. Overall, the reductions in functional disability and pain were both statistically and clinically significant. The improvements were larger for functional disability than for pain, as is commonly observed with NSCLBP interventions,[49, 50] and may also reflect greater variation in the repeated baseline measurements of pain.

Analysis of the secondary outcomes provides some insight into the possible mechanisms of effectiveness. The majority of the cognitive and psychosocial outcome measures demonstrated significant improvement after the intervention. In contrast, none of the physical outcome measures (usual sitting posture, variation in sitting posture, repositioning error, daily physical activity) were significantly different after the intervention. This is consistent with the previous RCT, where psychosocial measures were significantly altered after rehabilitation, but not the physical measure

used (range of motion). This is notable considering that the CFT intervention included instruction on gradually increasing levels of physical activity, and on assuming relaxed, non-provocative postures in sitting and during other functional tasks. This could suggest that changing physical factors, as measured in this study, is less relevant in this subgroup of NSCLBP, since addressing psychosocial factors and pain seem more important in reducing disability. Another possibility is that the physical components of the intervention (addressing spinal posture and physical activity) were simply inadequate, and require greater attention. Previous research has however demonstrated that seemingly quite different interventions such as cognitive behavioural therapy (CBT) and various forms of physical exercise appear to have their effect on NSCLBP disability by reducing psychological factors such as catastrophising, distress, fear and self-efficacy.[15, 20, 51-53] This hypothesis of indirectly influencing psychosocial factors through physical rehabilitation is further supported by studies demonstrating that physical rehabilitation programmes appear to be as successful as interventions like CBT at addressing factors such as catastrophising.[21, 51] The exact reasons for this are unclear. It is known that physical factors such as increased back muscle activity are closely related to psychosocial factors.[23, 25] Assessment of the trunk muscles, such as the flexion-relaxation phenomenon (FRP),[54] may be a more sensitive physical measure to assess these changes, especially considering the high baseline levels of muscle activation noted on clinical examination. However, evaluation of the FRP is time-consuming and not very feasible to perform in a large RCT. One of the aims of CFT is to facilitate patients performing painful or physically impaired activities in a more relaxed manner, with pain control and a different conceptualisation of pain, which may reduce the threat value of pain, provide hope, reassurance and encourage participation in rehabilitation.[21, 51]

Alternatively, all conservative interventions may act through a similar mechanism by decreasing central nervous system sensitivity.[55]

The magnitude of improvement on several psychosocial outcomes (Appendix S2) were greater than that observed with several interventions used among people with NSCLBP, including CBT, educational approaches and various forms of physical exercise. This includes the effect of rehabilitation programmes on catastrophising,[51, 53] back beliefs,[56-58] pain self-efficacy,[20, 59] fear,[21, 60] and depression.[61] Several of the secondary outcome measures have proposed cut-off values for risk or clinical significance applied to them. Using these recommended cut-off values, the number of participants at "risk" based on their STarT Back,[62] catastrophising,[39] depression,[36] anxiety,[36] stress,[36] pain self-efficacy[40] and fear-avoidance[63] scores reduced after the intervention (Appendix S2). While no cut-off value for the BBQ has been published, the number of participants scoring below the median baseline value (21.5) also reduced after the intervention (Appendix S2). Furthermore, the post-intervention values on measures such as the PSEQ,[40] STarT Back[62] and FABQ[15] have been associated with maintenance of rehabilitation gains, increased return to work rates, decreased risk of chronicity and reduced use of healthcare resources. Interestingly, the reduction in median fear of 50% at 12 months is remarkably similar to the reduction in fear reported in the previous RCT[28] using this approach. The magnitude of these changes in a wide range of psychosocial factors suggests the CFT intervention impacts upon several relevant psychosocial factors effectively, though the lack of a blinded assessor should be considered when interpreting these changes. The smaller effect on stress may represent a greater resistance to modification of stress[64, 65], or an inadequate emphasis on this factor during CFT rehabilitation.

A key feature of CFT is tailoring a behavioural-based intervention to each individual with NSCLBP. This is done by targeting specific physical (e.g. aggravating postures and activities, muscle guarding and pain behaviours) and related cognitive and psychosocial (e.g. the person's experience of pain, and their own thoughts, emotions, beliefs and life events) behaviours. The few studies which have examined tailoring rehabilitation to individual patient profiles across multiple domains demonstrate encouraging findings.[28-30] Simply combining conservative interventions (physical and psychosocial) in a non-integrated manner may be no more effective than either intervention provided in isolation.[66] Therefore, the benefit from an integrated CFT approach may not be from simply combining different interventions, but from integrating these different physical and psychosocial interventions to develop a greater insight into pain and associated disability in a patient-centred manner. This interlinking of contributing factors reflects their physiological interaction.[25] The aim is to challenge behaviours as a mean of changing beliefs regarding the threat of pain. Since only four participants were rated "low risk" on the STarT Back, most participants arguably required a multidimensional behaviourally targeted intervention. CFT rehabilitation can be adapted to emphasise physical or psychosocial factors according to their relative dominance in each individual. For example, CFT has previously been used with a greater emphasis on addressing physical behaviours when indicated.[67-69] While several dimensions are involved in the CFT intervention, all aspects were provided by a single therapist. This limits generalizability, though potentially reduces the risk of contradictory advice being received from different health care professionals.

There were several limitations to this study. This was not a blinded RCT. Only a small sample of participants with NSCLBP from one geographic region were included. However, the study was able to demonstrate treatment effects that were both statistically significant and clinically relevant, in a population that had not responded to primary care management. Posture was only analysed as seated posture on a single day. Several other physical factors were not examined or controlled for, including seating design and trunk muscle activation. Not measuring these physical factors, nor focussing on commonly provocative activities such as bending and lifting, may explain the lack of physical changes at follow-up. The outcome assessor was not blinded to treatment, although the primary outcomes were self-reported. Secondary outcome measures were not assessed after three months, with the physical secondary outcome measures not being assessed at all during follow-up due to logistical and time constraints. Delivery of individualised treatment is time-consuming and potentially costly, although likely to be less than invasive medical and surgical procedures. It is possible that some patients with lower disability levels and at lower risk of chronicity may not require as intensive and lengthy a rehabilitation process,[30] and whether CFT should be weighted to match such baseline characteristics requires further study. The design of the current study did not allow evaluation of whether the benefit obtained was dependent on treatment being individualised to each person, as opposed to CFT being an approach that could be provided uniformly to each individual, and this is an area worthy of further study. A detailed analysis of healthcare utilisation was not conducted as part of this study. In addition, five patients opted to undergo pain relieving procedures during Phase A2, after completion of rehabilitation. The median disability of these five patients on completion of the rehabilitation was significantly higher (median ODI=38%) than those who completed

rehabilitation and did not go on to undergo a pain relieving procedure (median ODI=15%). In addition, disability levels appear to have remained relatively static over the following 12 months irrespective of whether a patient underwent such a procedure (median ODI at end of Phase A2 = 40%) or not (median ODI at end of Phase A2 = 12%). However, it must be noted that the additional procedures provided during Phase A2 are a potential confounder of the findings.

This preliminary study was designed to determine the potential utility of CFT among NSCLBP patients with higher disability levels, to assist the development of future RCTs among people with disabling CLBP. An RCT, where CFT is compared to another active rehabilitation approach, is currently ongoing. This ongoing RCT addresses several limitations of this study, since it includes a control group, a blinded assessor and assessment of healthcare utilisation. Based on these results, the CFT intervention for the RCT has evolved to include greater emphasis on stress management, with specific resources developed to target stress where deemed relevant with patients. Furthermore, the choice of secondary outcome measures for the RCT reflects those variables which demonstrated the greatest response to rehabilitation, and includes baseline risk status as a potential moderator of outcome. Finally, reflecting some findings from this study (e.g. no change in usual physical activity levels) and the wishes of the physiotherapists participating, a series of additional resources have been developed for the ongoing RCT which provide advice on physical activity recommendations, flare-up management, the use and interpretation of diagnostic imaging tests and sleep hygiene, as these have all been linked to CLBP outcomes .

Conclusion

In this multiple case cohort study, reductions in pain and disability were observed 12 months after CFT treatment among a group of people with disabling NSCLBP. The effectiveness of CFT should be examined in an RCT among people with disabling NSCLBP.

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Author contributions

Kieran O'Sullivan, Wim Dankaerts, Leonard O'Sullivan, Peter O'Sullivan – all involved in the planning of the study, preparing protocols and obtaining ethical approval. Kieran O'Sullivan, Wim Dankaerts, Peter O'Sullivan – designed the intervention utilised. Kieran O'Sullivan recruited participants, collected the data, delivered the intervention and analysed the data. Kieran O'Sullivan, Wim Dankaerts, Leonard O'Sullivan, Peter O'Sullivan were all involved in the writing and editing the manuscript of the article. All authors discussed the results and commented on the manuscript.

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Figure Legends

Figure 1: Flowchart of participant progress through the study

Figure 2: Median (IQR) functional disability (ODI) across the three phases of the study (A1, B, A2)

Figure 3: Mean (SD) pain intensity (NRS) across the three phases of the study (A1, B, A2)

Appendices

Appendix S1: Detailed description of the four stages involved in the Cognitive Functional Therapy (CFT) Intervention

Appendix S2: Secondary outcome measures at baseline, immediately post-intervention, as well as **six** and 12 months post-intervention