Research Report

Cognitive Functional Therapy for Disabling Nonspecific Chronic Low Back Pain: Multiple Case-Cohort Study

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Background. Multiple dimensions across the biopsychosocial spectrum are relevant in the management of nonspecific chronic low back pain (NSCLBP). Cognitive functional therapy is a behaviorally targeted intervention that combines normalization of movement and abolition of pain behaviors with cognitive reconceptualization of the NSCLBP problem while targeting psychosocial and lifestyle barriers to recovery.

Objective. The purpose of this study was to examine the effectiveness of cognitive functional therapy for people with disabling NSCLBP who were awaiting an appointment with a specialist medical consultant.

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

Methods. Measurement phase A1 was a baseline phase during which measurements of pain and functional disability were collected on 3 occasions over 3 months for all participants. During phase B, participants entered a cognitive functional therapy intervention program involving approximately 8 treatments over an average of 12 weeks. Finally, phase A2 was a 12-month, no-treatment follow-up period. Outcomes were analyzed using repeated-measures analysis of variance or Friedman test (with post hoc Bonferroni correction) across 7 time intervals, depending on normality of data distribution.

Results. Statistically significant reductions in both functional disability and pain were observed immediately postintervention and were maintained over the 12-month follow-up period. These reductions reached clinical significance for both disability and pain. Secondary psychosocial outcomes, including depression, anxiety, back beliefs, fear of physical activity, catastrophizing, and self-efficacy, were significantly improved after the intervention.

Limitations. The study was not a randomized controlled trial. Although primary outcome data were self-reported, the assessor was not blinded.

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

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

Maladaptive movement behaviors in patients with NSCLBP are associated with increased levels of fear[23] and catastrophizing,[24] highlighting intimate body-mind interactions.[25] Given the interrelated, multidimensional nature of disabling NSCLBP, interventions that target multiple dimensions associated with a person's pain disorder have been advocated.[26,27] The few trials using targeted approaches to managing NSCLBP have shown encouraging findings.[28–30]

Cognitive functional therapy (CFT) is a novel, person-centered behavioral intervention that addresses multiple dimensions in NSCLBP.[26] This intervention combines a functional behavioral approach of normalizing provocative postures and movements while discouraging pain behaviors, with cognitive reconceptualization of the NSCLBP problem. In a recent randomized 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 health care 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 psychological factors after CFT to better inform the choice of outcome measures to use among more disabled populations in future RCTs. Furthermore, this examination would help ascertain if there are specific variables (eg, fear, stress, mood) that 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] These designs allow interpretation of the changes that occur with rehabilitation and fine-tuning of the intervention before an RCT. Therefore, this study examined the role of CFT with 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 with a range of questionnaires, along with novel, minimally invasive methods of analyzing physical factors relevant to NSCLBP, such as posture and physical activity, in the "real world" outside the laboratory setting.

Method

Study Design

A multiple case-cohort study consisting of 3 phases (A1–B–A2) was conducted. Phase A1 (duration of 3 months) was a baseline measurement phase during which no new intervention took place. During this phase, self-reported baseline measurements of pain and functional disability (see Outcome Measures section) were collected for all participants on 3 occasions 6 weeks apart. In addition, data for a range of other secondary outcome measures (see Outcome Measures section) were collected once at the start of this stage. During phase B, the study sample 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 6 weeks. At the end of phase B, all outcome measures (primary and secondary) were completed again. Formal treatment was withdrawn at the end of phase B, but participants were expected to continue their behaviorally based modi-

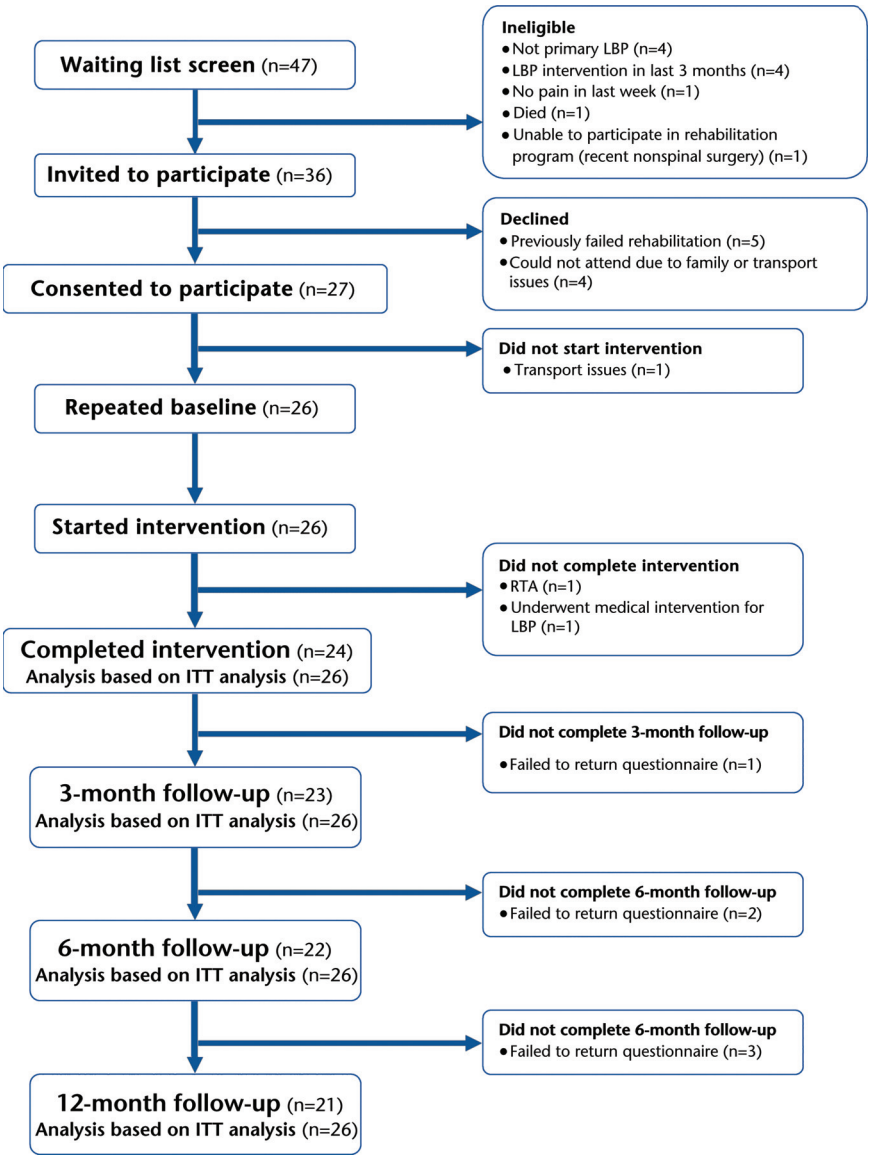

Figure 1.
Flowchart of participants' progress through the study. LBP=low back pain, RTA=road traffic accident, NSCLBP=nonspecific chronic low back pain, ITT=intention to treat.

fication program independently using the strategies developed during the intervention period for the duration of phase A2. Phase A2 lasted 12 months, including follow-ups at 3, 6, and 12 months after completion of treatment.

Participants

Participants were recruited from 3 local medical consultant clinics (2 chronic pain centers, 1 rheumatology center). 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 of at least 6 months' duration, 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 between 18 and 65 years of age, independently mobile, and capable of participating in a rehabilitation program 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 (eg, malignancy, fracture, infection, spinal stenosis, spondylolisthesis, inflammatory joint or bone disease), were pregnant or less than 6 months postpartum, had evidence of neurological compromise (ie, reduced reflexes or motor deficits), or had undergone a pain-relieving medical procedure (eg, facet or sacroiliac joint injection, myofascial trigger point injection, denervation procedure) in the previous 3 months.

A total of 47 potential participants from the medical consultant waiting lists were contacted. Eleven people did not meet the criteria, and another 9 people declined participation. The remaining 27 people fulfilled all criteria and were invited to participate in the study. One participant withdrew before starting the study due to difficulty organizing transport to attend. The remaining 26 people provided written informed consent and entered the study (Fig. 1). This sample size is similar to those of other studies that have examined the feasibility of novel interventions or interventions in new settings.

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 previous 12 months using the Nordic Musculoskeletal Questionnaire.[33]

The primary outcomes were: (1) functional disability, as assessed with the Oswestry Disability Index (ODI),[34] and (2) pain severity, scored as the average of the 4 numeric rating scales (NRSs) for pain (maximum pain in the last 24 hours, minimum pain in the last 24 hours, average pain in the last 24 hours, and pain right now) of the Brief Pain Inventory.[27]

Data for a range of secondary outcome measures also were collected. Depression, anxiety, and stress were analyzed using the subscales of the 21-item Depression Anxiety and Stress Scale (DASS-21).[35] Participants' beliefs and thoughts about NSCLBP were analyzed using the Back Beliefs Questionnaire (BBQ),[36] the physical activity subscale of the Fear-Avoidance Beliefs Questionnaire (FABQ),[37] and the Pain Catastrophizing Scale (PCS).[38] Self-efficacy was assessed using the Pain Self-Efficacy Questionnaire (PSEQ),[39] and the STarT Back screening tool, which is a predictor of outcome,[30] also was completed. All of 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 analyzed using an ActivPal (PAL Technologies, Glasgow, Scotland) accelerometer placed on the thigh.[40] 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 inactivity was differentiated from sedentary behavior. 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.[41] Considering the requirement for at least 20 hours of data collection and the use of diaries, no correction or adjustment for missing data was 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 1 week, which would include all days of the week.

Usual seated lumbopelvic posture (mean and standard deviation) 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, Sels Instruments, Vorselaar, Belgium) placed on the lower lumbar spine. This wireless posture monitor has established reliability and validity for monitoring lumbopelvic posture.[40,42,43] Lower lumbar spine posture during the 3 longest sitting periods on each day was extracted for analysis. Finally, lumbopelvic repositioning error was evaluated using the same posture monitoring device. This evaluation involved asking participants to reproduce, while blindfolded, a neutral sitting posture, into which they were first facilitated.[44] 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 (K.O.S.), who is a musculoskeletal physical therapy specialist 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 behavior (aggravating/easing movements and activities), primary functional impairments, disability, activity levels, lifestyle behaviors, and sleep patterns. Inquiries also were 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, and stress responsiveness and its relationship to pain and their pain beliefs also were 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, summarizing, identifying discrepancies, goal setting, and supporting self-efficacy, were utilized.[45] The physical examination involved analysis of each participant's primary reported functional impairments (pain provocative movements and functional tasks) to identify maladaptive behaviors, including provocative postures, movement patterns, muscle guarding, and pain avoidant and communicative behaviors. They also were assessed regarding their level of body control and awareness (body perception), their ability to relax their trunk muscles and normalize their movement behaviors, and the effect that this relaxation and awareness training had on their pain.[45]

Intervention

Formal treatment was provided in an outpatient university setting, typically once per week and reducing gradually to once every 2 weeks. Each participant received a specific targeted intervention directed at changing his or her individual cognitive, movement, and lifestyle behaviors considered to be provocative and maladaptive of his or her disorder.[2,26,46] The intervention had 4

main stages: (1) cognitive training, (2) functional movement training, (3) functional integration, and (4) physical activity and lifestyle training (eAppendix, available at ptjournal.apta.org). Details of the different components involved in the CFT intervention are described in the eAppendix. The cognitive training stage focused on pain mechanisms and the factors identified from the history and examination that were considered to contribute to the participant's pain disorder. This stage included discussing the multidimensional nature of persistent pain as it pertained to the individual and how cognitive factors, beliefs, emotions, and behaviors (movement and lifestyle) can reinforce a vicious pain/disability cycle. The second stage focused on specific functional movement and postural training that involved a behavioral 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 or reconceptualization is a key component of this stage, such that patients were taught to relax and move in a normal manner while reconceptualizing that pain does not equal harm. The third stage focused on functional integration of these new functional patterns in activities of daily life that they reported they avoided or that provoked their pain. The fourth stage focused on physical activity and lifestyle advice. 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), and after the cessation of formal treatment (phase A2).

Data Analysis

The thigh accelerometer used to collect physical activity data was worn for a mean of 5.6 days (SD=1.3) before treatment and for a mean of 5.8 days (SD=1.2) after treatment. These physical activity data were analyzed as steps per day for each participant. The spinal posture monitor was worn for a mean duration of 341 minutes (SD=123) on one day during phase A1 and again for a mean duration of 243 minutes (SD=96) after treatment. Sitting periods while wearing the posture monitor were identified using the accelerometer placed on the thigh. Seated posture data for the 3 longest sustained sitting periods were then identified for each participant. The mean duration of each sitting period exported was 26 minutes (SD=11) minutes before treatment and 25 minutes (SD=13) after treatment.

All statistical analyses were carried out with IBM SPSS version 19.0 (IBM Corp, Armonk, New York). Statistical significance was set at $P<.05$. The reliability of the primary outcome measures (NRS and ODI) was assessed across the 3 baseline measurements using the intraclass correlation coefficient (ICC) (2-way mixed), the standard error of measurement (SEM), and the minimal detectable change at the 90% confidence interval (MDC_{90}). Data were tested for normality of distribution. The Mauchly 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. Dropouts were controlled for on an intention-to-treat basis using the last observation carried forward. The primary outcomes were compared across the 7 time intervals—the 3 baseline measurements, immediately postintervention, and the 3-, 6-, and 12-month follow-ups— using a general linear model repeated-measures analysis of variance (NRS) and the Friedman test (ODI). Post hoc tests had a Bonferroni correction applied. The effect size of the CFT intervention on ODI and NRS scores was calculated using Cohen *d*. The number of participants whose disability and pain remained at least 30% lower 12 months after the intervention also was evaluated, as this is considered the minimum important change (MIC).[47] The physical secondary outcome measures were compared between baseline and immediately postintervention using paired *t* tests or Wilcoxon signed rank tests, depending on the normality of data distribution. The other secondary outcome measures were compared at baseline, immediately postintervention, and after 6 and 12 months using the Friedman test, with *P* values adjusted for multiple comparisons to $P<.0041$.

Role of the Funding Source

The Health Research Board of Ireland sponsored the study.

Results

The 26 participants (14 female, 12 male) had a mean age of 44.3 years (SD=9.7), a mean height of 171 cm (SD=10), a mean mass of 88.3 kg (SD=18.7), and a mean body mass index of 30.1 kg/m^2 (SD=5.3). Their mean NSCLBP duration was 141 months (SD=120), and their mean number of pain sites was 4.3 (SD=1.9). Based on their STarT Back screening tool score, 14 participants were considered "high risk," 8 were considered "moderate risk," and 4 were considered "low risk" at baseline. Based on ODI values at baseline, the level of disability varied from low (ODI value <20%; n=2) to moderate (ODI value 21%–40%; n=11) to high (ODI value >41%; n=13). Two participants did not complete the program: 1 participant was involved in a traffic accident after entering the study and was unable to attend for further treatment, and another participant was offered a pain-relieving

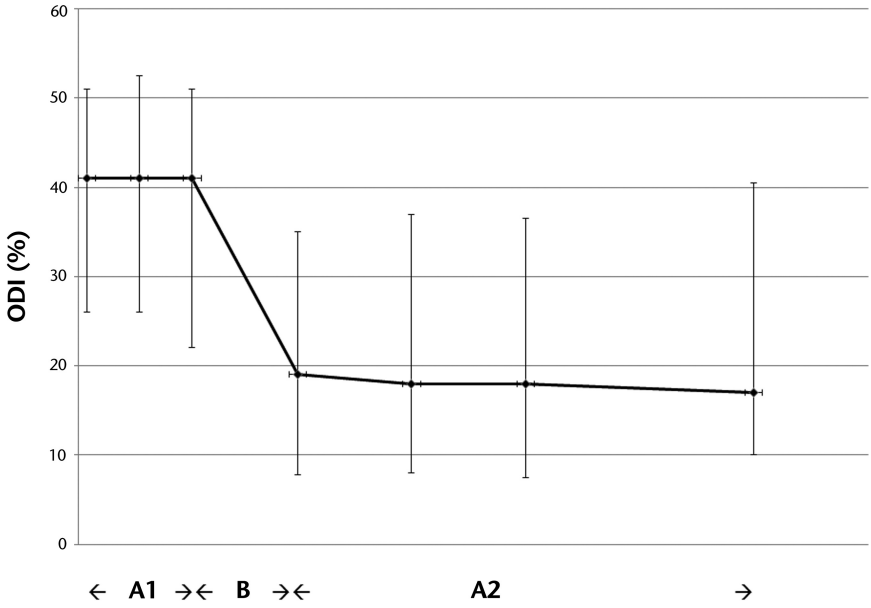

Figure 2.
Median functional disability (Oswestry Disability Index [ODI] scores) across the 3 phases of the study (A1, B, and A2). Error bars represent interquartile range.

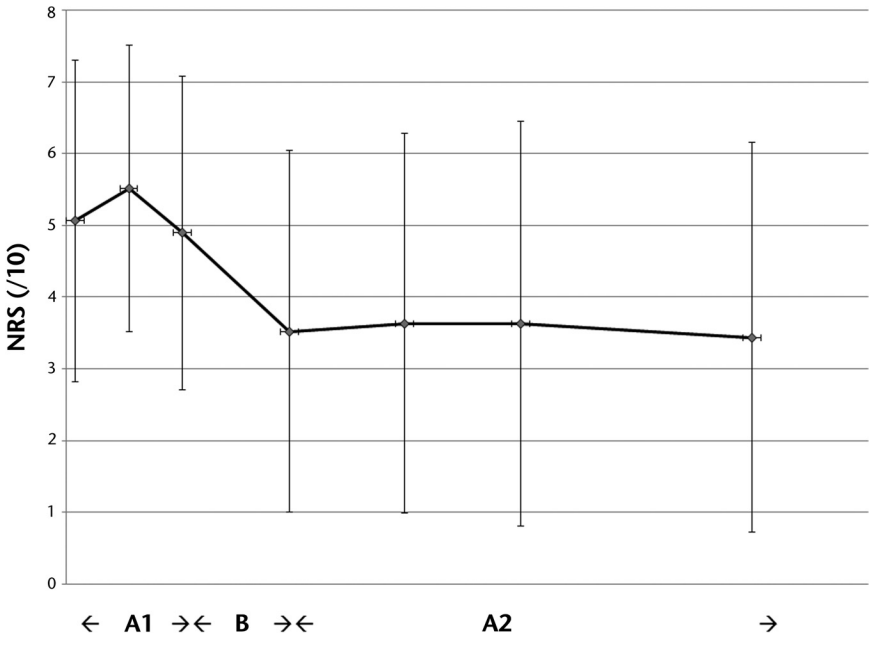

Figure 3.
Mean (SD) pain intensity (numeric rating scale [NRS] scores) across the 3 phases of the study (A1, B, and A2).

medical intervention while receiving treatment and was no longer eligible for participation in this study. In addition to the 2 participants who did not complete treatment, the 3-, 6-, and 12-month follow-ups were not completed by 1, 2, and 3 participants, respectively (Fig. 1). The mean number of treatment sessions was 7.7 (SD=2.5), provided over a mean of 12.0 weeks (SD=3.5), with each session lasting a mean of 60.0 minutes (SD=6.6).

Reliability of Baseline Measures

The primary outcome measure (ODI) showed excellent association (ICC=.84, range=.72–.92) among the measurements, with small values for both the SEM (3.4) and the MDC_{90} (9.5). The reliability of the NRS was moderate (ICC=.67, range=.47–.82); the SEM was 0.7, and the MDC_{90} was 2.0.

Effect of CFT Intervention

Functional disability was significantly reduced (χ^2_6=65.53, P<.001). Post hoc analysis with the Wilcoxon signed rank test was conducted with a Bonferroni correction applied, resulting in a significance level set at P<.0042. These post hoc tests demonstrated that ODI values were significantly reduced at all 4 time intervals after treatment compared with each of the 3 baseline measurements (Fig. 2). There was a large effect size (d=0.85). Compared with median ODI values across the 3 baseline measurements, median ODI values were 22 points lower after treatment, 23 points lower after 3 and 6 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 the 12-month follow-up.

Pain also was significantly reduced ($F_{3.59-89.7}$=7.66, P<.001). Post hoc Bonferroni tests demonstrated that NRS values at all intervals after treatment were significantly different from the middle of the 3 baseline measurements. In addition, NRS values were significantly lower than the first baseline measurement immediately after treatment and after 12 months (P<.05). However, none of the posttreatment NRS values were significantly reduced from the third baseline measurement (all P>.05) (Fig. 3). There was a medium effect

size (d=0.65). Compared with mean NRS values across the 3 baseline measurements, NRS values were 1.6 points lower immediately after treatment, 1.5 points lower 3 months later, 1.5 points lower 6 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 had ended.

Secondary Outcome Measures

There were no significant differences (all P>.05) between baseline and immediately postintervention 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<.0041) improvements in depression, anxiety, back beliefs, fear of physical activity, catastrophizing, self-efficacy, and STarT Back risk score at all intervals after treatment. Stress was not significantly reduced after treatment (P=.052) (see eTable, available at ptjournal.apta.org, for full details of secondary outcomes).

Discussion

This multiple case-cohort study demonstrated that CFT, a novel, person-centered, 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 with another intervention. Notwithstanding the significant improvement from repeated baseline measurements, the fact that the present study was not an RCT means that the observed improvements could be influenced by factors such as natural recovery, regression to the mean, and other nonspecific 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%.[47] This reduction was maintained, with 15/24 participants meeting this criterion, after 12 months. This reduction also exceeded the MDC_{90} of 9.5 points based on variation in ODI values over the 3 repeated baseline measurements. 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%.[47] This reduction in pain also was maintained, with 13/24 participants meeting this criterion after 12 months. However, the reduction in pain did not exceed the MDC_{90} of 2 points based on variation in NRS values over the 3 repeated baseline measurements. 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,[48,49] and may 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. These findings are consistent with the previous RCT,[28] where psychosocial measures were significantly altered after rehabilitation, but not the physical measure used (range of motion). This lack of change in physical factors is notable considering that the CFT intervention included instruction on gradually increasing levels of physical activity and on assuming relaxed, nonprovocative postures in sitting and during other functional tasks. This lack of change in physical factors could suggest that changing physical factors, as measured in this study, are less relevant in this subgroup of individuals with NSCLBP, as addressing psychosocial factors and pain appear to be 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 warrant greater attention.

Previous research, however, has demonstrated that seemingly quite different interventions, such as cognitive-behavioral therapy (CBT) and various forms of physical exercise, appear to have their effect on NSCLBP disability by reducing psychological factors such as catastrophizing, distress, fear, and self-efficacy.[15,20,50–52] This hypothesis of indirectly influencing psychosocial factors through physical rehabilitation is further supported by studies demonstrating that physical rehabilitation programs appear to be as successful as interventions such as CBT at addressing factors such as catastrophizing.[21,50] The exact reasons for this finding 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 assessment of the flexion-relaxation phenomenon (FRP),[53] 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 conceptualization of pain, which may reduce the threat value of pain, provide hope and reassurance, and encourage participation in rehabilitation.[21,50] Alternatively, all conservative interventions may act through a similar mechanism by decreasing central nervous system sensitivity.[54]

The magnitude of improvement on several psychosocial outcomes (eTable) was greater than that observed with several interventions used in people with NSCLBP, including CBT, educational approaches, and various forms of physical exercise. This finding includes the effect of rehabilitation programs on catastrophizing,[50,52] back beliefs,[55–57] pain self-efficacy,[20,58] fear,[21,59] and depression.[60] Several of the secondary outcome measures have proposed cutoff values for risk or clinical significance applied to them. Using these recommended cutoff values, the number of participants at risk based on their STarT Back,[61] catastrophizing,[38] depression,[35] anxiety,[35] stress,[35] pain self-efficacy,[39] and fear-avoidance[62] scores was reduced after the intervention (eTable). Although no cutoff value for the BBQ has been published, the number of participants scoring below the median baseline value (21.5) also was reduced after the intervention (eTable). Furthermore, the postintervention values on measures such as the PSEQ,[39] STarT Back,[61] and FABQ[15] have been associated with maintenance of rehabilitation gains, increased return-to-work rates, decreased risk of chronicity, and reduced use of health care 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 that the CFT intervention affects several relevant psychosocial factors effectively, although 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[63,64] or an inadequate emphasis on this factor during CFT rehabilitation.

A key feature of CFT is tailoring a behaviorally based intervention to each individual with NSCLBP. This tailoring is done by targeting specific physical behaviors (eg, aggravating postures and activities, muscle guarding and pain behaviors) and related cognitive and psychosocial behaviors (eg, the person's experience of pain and his or her own thoughts, emotions, beliefs, and life events). The few studies that have examined tailoring rehabilitation to individual patient profiles across multiple domains demonstrated encouraging findings.[28–30] Simply combining conservative interventions (physical and psychosocial) in a nonintegrated manner may be no more effective than either intervention provided in isolation.[65] 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-centered manner. This interlinking of contributing factors reflects their physiological interaction.[25] The aim is to challenge behaviors as a means of changing beliefs regarding the threat of pain. Because only 4 participants were rated "low risk" on the STarT Back screening tool, most participants arguably required a multidimensional, behaviorally targeted intervention. Rehabilitation with CFT can be adapted to emphasize 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 behaviors when indicated.[66–68] Although several dimensions are involved in the CFT intervention, all aspects were provided by a single therapist. This approach limits generalizability, although it potentially reduces the risk of contradictory advice being received from different health care professionals.

There were several limitations in this study. This was not a blinded RCT. Only a small sample of participants with NSCLBP from one geographic region was 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 analyzed 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, or focusing 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 3 months, with the physical secondary outcome measures not being assessed at all during follow-up due to logistical and time constraints. Delivery of individualized treatment is time-consuming and potentially costly, although likely to be less costly 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 warrants further study. The design of the current study did not allow evaluation of whether the benefit obtained was dependent on treatment being individualized 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 health care utilization was not conducted as part of this study. In addition, 5 patients opted to undergo pain-relieving procedures during phase A2, after completion of rehabilitation. The median disability of these 5 patients on completion of the rehabilitation was significantly higher (median ODI value=38%) than that of those patients who completed rehabilitation and did not undergo a pain-relieving procedure (median ODI value=15%). In addition, disability levels appear to have remained relatively static over the following 12 months regardless of whether a patient underwent such a procedure (median ODI value at end of phase A2=40%) or did not (median ODI value 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 patients with NSCLBP and higher disability levels to assist in the development of future RCTs among people with disabling CLBP. An RCT, where CFT is compared with another active rehabilitation approach, is currently ongoing. This ongoing RCT addresses several limitations of this study, as it includes a control group, a blinded assessor, and assessment of health care utilization. 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 that demonstrated the greatest response to rehabilitation and includes baseline risk status as a potential moderator of outcome. Finally, reflecting some findings from this study (eg, no change in usual physical activity levels) and the wishes of the participating physical therapists, a series of additional resources had been developed for the ongoing RCT that 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.

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.

All authors participated in planning of the study, preparing protocols, and obtaining ethical approval. All authors also provided writing and editing of the manuscript, discussed the results, and commented on the manuscript. Dr K. O'Sullivan, Dr Dankaerts, and Dr P.B. O'Sullivan designed the intervention utilized. Dr K. O'Sullivan recruited participants, delivered the intervention, and collected and analyzed the data.

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Ethical approval for this study was obtained from 2 local hospital research ethics committees.

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References

1 Dagenais S, Caro J, Haldeman S. A systematic review of low back pain cost of illness studies in the United States and internationally. *Spine J.* 2008;8:8–20.

2 Dankaerts W, O'Sullivan P, Burnett A, et al. Discriminating healthy controls and two clinical subgroups of nonspecific chronic low back pain patients using trunk muscle activation and lumbosacral kinematics of postures and movements: a statistical classification model. *Spine (Phila Pa 1976).* 2009;34:1610–1618.

3 Bray H, Moseley GL. Disrupted working body schema of the trunk in people with back pain. *Br J Sports Med.* 2011;45:168–173.

4 van Tulder M, Malmivaara A, Esmail R, Koes B. Exercise therapy for low back pain: a systematic review within the framework of the Cochrane collaboration back review group. *Spine (Phila Pa 1976).* 2000;25:2784–2796.

5 Furlan AD, van Tulder M, Cherkin D, et al. Acupuncture and dry-needling for low back pain: an updated systematic review within the framework of the Cochrane collaboration. *Spine (Phila Pa 1976).* 2005;30:944–963.

6 Assendelft WJ, Morton SC, Yu EI, et al. Spinal manipulative therapy for low back pain: a meta-analysis of effectiveness relative to other therapies. *Ann Intern Med.* 2003;138:871–881.

7 Ferreira ML, Ferreira PH, Latimer J, et al. Comparison of general exercise, motor control exercise and spinal manipulative therapy for chronic low back pain: a randomized trial. *Pain.* 2007;131:31–37.

8 Schaafsma FE, Schonstein E, Whelan KM, et al. Physical conditioning programs for improving work outcomes in workers with back pain. *Cochrane Database Syst Rev.* 2010;1:CD001822.

9 Carroll LJ, Cassidy JD, Côté P. Depression as a risk factor for onset of an episode of troublesome neck and low back pain. *Pain.* 2004;107:134–139.

10 Ramond A, Bouton C, Richard I, et al. Psychosocial risk factors for chronic low back pain in primary care: a systematic review. *Fam Pract.* 2011;28:12–21.

11 Main CJ, Foster N, Buchbinder R. How important are back pain beliefs and expectations for satisfactory recovery from back pain? *Best Pract Res Clin Rheumatol.* 2010;24:205–217.

12 Jarvik JG, Hollingworth W, Heagerty PJ, et al. Three-year incidence of low back pain in an initially asymptomatic cohort: clinical and imaging risk factors. *Spine (Phila Pa 1976).* 2005;30:1541–1548.

13 Mitchell T, O'Sullivan PB, Burnett A, et al. Identification of modifiable personal factors that predict new-onset low back pain: a prospective study of female nursing students. *Clin J Pain.* 2010;26:275–283.

14 Gatchel RJ, Peng YB, Peters ML, et al. The biopsychosocial approach to chronic pain: scientific advances and future directions. *Psychol Bull.* 2007;133:581–624.

15 Leeuw M, Goossens ME, Linton SJ, et al. The fear-avoidance model of musculoskeletal pain: current state of scientific evidence. *J Behav Med.* 2007;30:77–94.

16 van Tulder MW, Ostelo R, Vlaeyen JW, et al. Behavioral treatment for chronic low back pain: a systematic review within the framework of the Cochrane Back Review Group. *Spine (Phila Pa 1976).* 2001;25:2688–2699.

17 Ryan CG, Gray HG, Newton M, Granat MH. Pain biology education and exercise classes compared to pain biology education alone for individuals with chronic low back pain: a pilot randomised controlled trial. *Man Ther.* 2010;15:382–387.

18 Moseley L. Combined physiotherapy and education is efficacious for chronic low back pain. *Aust J Physiother.* 2002;48:297–302.

19 Henschke NR, Ostelo RW, van Tulder MW, et al. Behavioural treatment for chronic low-back pain. *Cochrane Database Syst Rev.* 2010;7:CD002014.

20 Woby SR, Urmston M, Watson PJ. Self-efficacy mediates the relation between pain-related fear and outcome in chronic low back pain patients. *Eur J Pain.* 2007;11:711–718.

21 Mannion AF, Junge A, Taimela S, et al. Active therapy for chronic low back pain: part 3; factors influencing self-rated disability and its change following therapy. *Spine (Phila Pa 1976).* 2001;26:920–929.

22 Wetherell JL, Afari N, Rutledge T, et al. A randomized, controlled trial of acceptance and commitment therapy and cognitive-behavioral therapy for chronic pain. *Pain.* 2011;152:2098–2107.

23 Geisser ME, Haig AJ, Wallbom AS, Wiggert EA. Pain-related fear, lumbar flexion, and dynamic EMG among persons with chronic musculoskeletal low back pain. *Clin J Pain.* 2004;20:61–69.

24 Sullivan MJ, Thibault P, Andrikonyte J, et al. Psychological influences on repetition-induced summation of activity-related pain in patients with chronic low back pain. *Pain.* 2009;141:70–78.

25 Lewis S, Holmes P, Woby S, et al. The relationships between measures of stature recovery, muscle activity and psychological factors in patients with chronic low back pain. *Man Ther.* 2012;17:27–33.

26 O'Sullivan P. It's time for change with the management of non-specific chronic low back pain. *Br J Sports Med.* 2012;46:224–227.

27 Wand BM, O'Connell NE, Di Pietro F, Bulsara M. Managing chronic nonspecific low back pain with a sensorimotor retraining approach: exploratory multiple-baseline study of 3 participants. *Phys Ther.* 2011;91:535–546.

28 Vibe Fersum K, O'Sullivan P, Skouen JS, et al. Efficacy of classification based cognitive functional therapy in patients with non-specific chronic low back pain: a randomized controlled trial. *Eur J Pain.* 2013;17:916–928.

29 Asenlof P, Denison E, Lindberg P. Long-term follow-up of tailored behavioural treatment and exercise based physical therapy in persistent musculoskeletal pain: a randomized controlled trial in primary care. *Eur J Pain.* 2009;13:1080–1088.

30 Hill JC, Whitehurst DG, Lewis M, et al. Comparison of stratified primary care management for low back pain with current best practice (STarT Back): a randomised controlled trial. *Lancet.* 2011;378:1560–1571.

31 van de Meent H, Oerlemans M, Bruggeman A, et al. Safety of "pain exposure" physical therapy in patients with complex regional pain syndrome type 1. *Pain.* 2011;152:1431–1438.

32 Boersma K, Linton S, Overmeer T, et al. Lowering fear-avoidance and enhancing function through exposure in vivo: a multiple baseline study across six patients with back pain. *Pain.* 2004;108:8–16.

33 Kuorinka I, Jonsson B, Kilbom A, et al. Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms. *Appl Ergon.* 1987;18:233–237.

34 Fairbank JC, Pynsent PB. The Oswestry Disability Index. *Spine (Phila Pa 1976).* 2000;25:2940–2952.

35 Lovibond S, Lovibond P. *Manual for the Depression Anxiety and Stress Scale*. Sydney, Australia: Psychology Foundation; 1995.

36 Buchbinder R, Jolley D. Effects of a media campaign on back beliefs is sustained 3 years after its cessation. *Spine (Phila Pa 1976).* 2005;30:1323–1330.

37 Waddell G, Newton M, Henderson I, et al. A Fear-Avoidance Beliefs Questionnaire (FABQ) and the role of fear-avoidance beliefs in chronic low back pain and disability. *Pain.* 1993;52:157–168.

38 Sullivan M. *The Pain Catastrophizing Scale: User Manual*. Montreal, Quebec, Canada: McGill University; 2004.

39 Nicholas MK. The pain self-efficacy questionnaire: taking pain into account. *Eur J Pain.* 2007;11:153–163.

40 O'Sullivan K, Verschueren S, Pans S, et al. Validation of a novel spinal posture monitor: comparison with digital videofluoroscopy. *Eur Spine J.* 2012;21:2633–2639.

41 Herrmann SD, Barreira TV, Kang M, Ainsworth BE. Impact of accelerometer wear time on physical activity data: a NHANES semisimulation data approach. *Br J Sports Med.* 2014;48:278–282.

42 O'Sullivan K, O'Sullivan L, Campbell A, et al. Towards monitoring lumbo-pelvic posture in real-life situations: concurrent validity of a novel posture monitor and a traditional laboratory-based motion analysis system. *Man Ther.* 2012;17:77–83.

43 O'Sullivan K, Galleotti L, Dankaerts W, et al. The between-day and inter-rater reliability of a novel wireless system to analyse lumbar spine posture. *Ergonomics.* 2011;54:82–90.

44 O'Sullivan PB, Burnett A, Floyd AN, et al. Lumbar repositioning deficit in a specific low back pain population. *Spine (Phila Pa 1976).* 2003;28:1074–1079.

45 O'Sullivan P. Diagnosis and classification of chronic low back pain disorders: maladaptive movement and motor control impairments as underlying mechanism. *Man Ther.* 2005;10:242–255.

46 Dankaerts W, O'Sullivan PB, Burnett AF, Straker LM. The use of a mechanism-based classification system to evaluate and direct management of a patient with non-specific chronic low back pain and motor control impairment: a case report. *Man Ther.* 2007;12:181–191.

47 Ostelo RW, Deyo RA, Stratford P, et al. Interpreting change scores for pain and functional status in low back pain: towards international consensus regarding minimal important change. *Spine (Phila Pa 1976).* 2008;33:90–94.

48 Lambeek LC, van Mechelen W, Knol DL, et al. Randomised controlled trial of integrated care to reduce disability from chronic low back pain in working and private life. *BMJ.* 2010;340:c1035.

49 Guzmán J, Esmail R, Karjalainen K, et al. Multidisciplinary rehabilitation for chronic low back pain: systematic review. *BMJ.* 2001;322:1511–1516.

50 Smeets RJ, Vlaeyen JW, Kester AD, Knottnerus JA. Reduction of pain catastrophizing mediates the outcome of both physical and cognitive-behavioral treatment in chronic low back pain. *J Pain.* 2006;7:261–271.

51 Mannion AF, Müntener M, Taimela S, Dvorak J. Comparison of three active therapies for chronic low back pain: results of a randomized clinical trial with one-year follow-up. *Rheumatology (Oxford).* 2001;40:772–778.

52 Spinhoven P, Ter Kuile M, Kole-Snijders AM, et al. Catastrophizing and internal pain control as mediators of outcome in the multidisciplinary treatment of chronic low back pain. *Eur J Pain.* 2004;8:211–219.

53 Geisser ME, Ranavaya M, Haig AJ, et al. A meta-analytic review of surface electromyography among persons with low back pain and normal, healthy controls. *J Pain.* 2005;6:711–726.

54 Wand BM, O'Connell NE. Chronic non-specific low back pain: sub-groups or a single mechanism. *BMC Musculoskelet Disord*, 2008;9:11.

55 Symonds TL, Burton AK, Tillotson KM, Main CJ. Absence resulting from low back trouble can be reduced by psychosocial intervention at the work place. *Spine (Phila Pa 1976).* 1995;20:2738–2745.

56 Burton AK, Waddell G, Tillotson KM, Summerton N. Information and advice to patients with back pain can have a positive effect: a randomized controlled trial of a novel educational booklet in primary care. *Spine (Phila Pa 1976).* 1999;24:2484–2491.

57 George SZ, Teyhen DS, Wu SS, et al. Psychosocial education improves low back pain beliefs: results from a cluster randomized clinical trial (NCT00373009) in a primary prevention setting. *Eur Spine J.* 2009;18:1050–1058.

58 Williams AC, Richardson PH, Nicholas MK, et al. Inpatient vs. outpatient pain management: results of a randomised controlled trial. *Pain.* 1996;66:13–22.

59 Woby SR, Roach NK, Urmston M, et al. Outcome following a physiotherapist-led intervention for chronic low back pain: the important role of cognitive processes. *Physiotherapy*, 2008;94:115–124.

60 Della-Posta C, Drummond PD. Cognitive behavioural therapy increases re-employment of job seeking worker's compensation clients. *J Occup Rehabil.* 2006;16:223–230.

61 Hill JC, Dunn KM, Lewis M, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum.* 2008;59:632–641.

62 Poiraudeau S, Rannou F, Baron G, et al. Fear-avoidance beliefs about back pain in patients with subacute low back pain. *Pain.* 2006;124:305–311.

63 Henningsen P, Zimmermann T, Sattel H. Medically unexplained physical symptoms, anxiety, and depression: a meta-analytic review. *Psychosom Med.* 2003;65:528–533.

64 Linton SJ. Occupational psychological factors increase the risk for back pain: a systematic review. *J Occup Rehabil.* 2001;11:53–66.

65 Smeets RJ, Vlaeyen JW, Hidding A, et al. Active rehabilitation for chronic low back pain—cognitive-behavioral, physical, or both: first direct post-treatment results from a randomized controlled trial [ISRCTN22714229]. *BMC Musculoskelet Disord.* 2006;7:5.

66 Perich D, Burnett A, O'Sullivan P, Perkin C. Low back pain in adolescent female rowers: a multi-dimensional intervention study. *Knee Surg Sports Traumatol Arthrosc.* 2011;19:20–29.

67 Thorpe A, O'Sullivan P, Burnett A, et al. Assessing the efficacy of a specific physiotherapy intervention for the prevention of low back pain in female adolescent rowers: a field study. *NZ J Physio.* 2010;36:38–46.

68 Van Hoof W, Volkaerts K, O'Sullivan K, et al. Comparing lower lumbar kinematics in cyclists with low back pain (flexion pattern) versus asymptomatic controls: field study using a wireless posture monitoring system. *Man Ther.* 2012;17:312–317.