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Published in:
Pain Reports

DOI (link to publication from Publisher):
[10.1097/PR9.0000000000000802](https://doi.org/10.1097/PR9.0000000000000802)

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Publication date:
2020

Document Version
Publisher's PDF, also known as Version of record

[Link to publication from Aalborg University](#)

Citation for published version (APA):

Vaegter, H. B., Ussing, K., Johansen, J. V., Stegemejer, I., Palsson, T. S., O'Sullivan, P., & Kent, P. (2020). Improvements in clinical pain and experimental pain sensitivity after cognitive functional therapy in patients with severe persistent low back pain. *Pain Reports*, 5(1), Article e802. <https://doi.org/10.1097/PR9.0000000000000802>

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Improvements in clinical pain and experimental pain sensitivity after cognitive functional therapy in patients with severe persistent low back pain

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Abstract

Introduction: Multidisciplinary care is recommended for disabling persistent low back pain (pLBP) nonresponsive to primary care. Cognitive functional therapy (CFT) is a physiotherapy-led individualised intervention targeting psychological, physical, and lifestyle barriers to recovery, to self-manage pLBP.

Objectives: This pilot study investigated clinical outcomes and pain thresholds after a 12-week CFT pathway in patients with severe pLBP referred to a University Pain Center. Exploratory analyses compared changes in clinical outcomes, opioid consumption, and costs after CFT with changes after a multidisciplinary pain management (MPM) pathway.

Methods: In total, 47 consecutively referred pLBP patients consented to the CFT pathway. At baseline, 3 and 6 months, clinical outcomes and PPTs were assessed. Control patients (n = 99) who had completed an MPM pathway in the last 3 years were matched from the clinical pain registry used in the Pain Center in a 3:1 ratio based on propensity scores derived from relevant baseline variables of the CFT cases.

Results: Most clinical outcomes and low back pressure pain threshold were improved at 3 and 6 months after the CFT pathway. Compared with MPM, CFT patients had significantly larger reductions in disability and improved quality of life after the interventions at a lower cost (−3688€ [confidence interval: −3063 to −4314€]). Reduction in pain intensity and proportion of patients withdrawing from opioids (18.2% vs 27.8%) were similar between CFT and MPM groups.

Conclusion: Improvements in clinical and experimental pain were found after the CFT pathway. Fully powered randomized controlled trials comparing CFT with an MPM program in patients with disabling pLBP are warranted to control for the current limitations.

Keywords: Low back pain, Persistent pain, Chronic pain, Opioids, Cognitive functional therapy, Multidisciplinary pain rehabilitation

1. Introduction

Low back pain (LBP) is the leading cause of disability.⁵⁷ Despite increasing resources being spent on managing this condition, a significant proportion does not fully recover within a year.¹¹ Failure to recover often results in a trajectory of seeking pain specialist's second opinions, surgical evaluations,⁵⁸ and high use of opioid medication.²¹ Evidence suggests that persistent low back pain (pLBP) is a multidimensional biopsychosocial problem^{38,39} with various contributing factors, such as negative pain cognitions, pain-related fear and emotional distress,^{27,31,33,55,59}

avoidant and protective movement behaviors,¹⁰ and unhelpful lifestyle factors such as activity avoidance and sleep problems.²

Current guidelines recommend that patients with pLBP who do not benefit from primary care treatment should be referred to multidisciplinary pain rehabilitation in secondary care settings.^{6,37} However, such treatments are often expensive, not easily accessible, and have small effects.^{16,49} Therefore, less expensive and more accessible management strategies targeting these multidimensional barriers to recovery may facilitate earlier improvements.

Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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PR9 5 (2019) e802

<http://dx.doi.org/10.1097/PR9.0000000000000802>

Cognitive functional therapy (CFT)^{35,36} is a physiotherapy-led individualised intervention that targets physical, lifestyle, and psychological barriers to recovery, to coach people to self-manage pLBP. Cognitive functional therapy has shown promising results in patients with pLBP in primary care with low to moderate disability compared with exercise and manual therapy at 12-month⁵⁴ and 36-month¹⁹ follow-ups. A recent RCT demonstrated CFT to be more effective in reducing disability levels at 6 and 12 months, than group education and exercise in people with moderate disabling pLBP.³⁴ To date, the effectiveness of CFT has not been investigated in patients with severe pLBP and high levels of disability who have not benefited from primary care treatments, and it has not been compared with a multidisciplinary pain management program (MPM). Although cognitive and emotional factors, such as levels of fear and distress, have been observed to reduce after CFT,^{35,54} no study has yet investigated whether clinical improvements after CFT are associated with changes in pain sensitivity, which would add important knowledge regarding the possible underlying mechanisms of change associated with CFT.

As a precursor to a larger-scale randomized controlled trial comparing CFT with MPM, this pilot study investigated clinical outcomes and pressure pain thresholds (PPTs) after a 12-week CFT treatment pathway in patients with severe pLBP referred to a University Hospital Pain Center. In addition, exploratory analyses comparing changes in clinical outcomes, opioid consumption, and treatment costs in patients who took the CFT pathway with a matched cohort who took the MPM pathway were performed on clinical outcomes, opioid consumption, and treatment costs.

It was hypothesized that (1) CFT would result in improvement in clinical outcomes and pain sensitivity, and (2) improvements in clinical pain would be associated with improvements in pain sensitivity.

2. Materials and methods

The CONSORT-NPT was used as a guideline for reporting this study,³ which was conducted in accordance with the Helsinki Declaration, registered at the Danish Data Protection Agency (17/23847), approved by the local ethics committee (S-20170029), and all patients provided written informed consent.

2.1. Cognitive functional therapy participants

All patients referred to the Odense University Pain Center between June 2017 and February 2018, who reported pain (>6 months) in the lower back as their primary pain complaint, were invited to participate in the study. Patients between 18 and 75 years of age and adept in Danish were eligible. Patients were excluded if any of these criteria were present: pregnancy, former/present addictive behavior, neurological, or cardiovascular diseases. Patients included in the CFT pathway were requested not to receive other treatments while participating in the study but were allowed to continue analgesics.

2.2. Case-control patients

The Pain Center care group was retrospectively selected from 250 eligible patients in the PainData Registry used in the Pain Center, who had LBP, had completed the end of treatment questionnaire, had received the multidisciplinary intervention of interest, and had given electronic consent that data could be

used for research. For referral, patients must have had pain >6 months and report significant disability and psychological distress affecting daily life. Patients in this setting have moderate to severe pain intensity, high disability, and psychological distress, and most report pain in more than one body area.^{50,52}

2.3. Case-control matching

Each person in the CFT group was matched with 3 people in the Pain Center care group, to account for the potential diversity of treatment exposure in the control group. Case/control matching used propensity scores based on the following baseline variables: age, sex, body mass index, LBP intensity, LBP duration, number of pain areas, Pain Disability Index (PDI) score, anxiety, depression, pain catastrophization, fear of movement, health-related quality of life (QOL), and use of analgesics or opioids. After matching (*STATA psmatch2*), the distributions of the baseline variables used in the propensity scoring were not statistically different (*STATA pstest*) between the cases and controls (*t* tests $P = 0.295$ – 0.957 , likelihood-ratio test $P = 0.49$, Rubin $R = 1.28$), indicating that no selection bias was present on these measured variables.

2.4. Cognitive functional therapy pathway

The CFT pathway included treatment performed by 1 of 3 CFT-trained physiotherapists at a private physiotherapy clinic while patients were on the Pain Center waiting list (approximately 8 months from referral). Each patient received up to 8 consultations over a period of 3 months. The intervention comprised 3 components: (1) making sense of pain: context-based patient education focusing on the multidimensional nature of pain and disability, while reducing the threat of structural damage and correcting unhelpful beliefs; (2) exposure with control: graded exposure to painful, feared, or avoided activities with body relaxation and extinguishing protective behaviours; and (3) lifestyle changes: patients were encouraged to perform 20 to 30 minutes of physical activity daily based on their preference and taught strategies to manage stress and poor sleep.³⁶

2.5. Control pathway

Treatment at the Pain Center can be diverse, and control patients were only eligible if they had received a multidisciplinary intervention consisting of a combination of (1) medical treatment with a specialist pain consultant (ie, individual adjustment of analgesics to improve effect and reduce side effects) AND (2) one or more of the following: individual consultations with a pain psychologist or social worker with cognitive-behavioral therapy training or participation in a group session with relaxation therapy or mindfulness, as these represent the most comprehensive pathway. The Pain Center pathways are based on elements from cognitive-behavioral therapy, acceptance and commitment therapy, and mindfulness-based stress reduction programs (<http://www.ouh.dk/wm164091>), which have shown moderate effects in this population and thus have similarities with some of the CFT components. For this pathway, there was only 1 outcome time point, which was the end of their individualized treatment. Because this was individualized, the outcome time point was variable, with a median of 9 months (interquartile range 3–19).

2.6. Outcomes

All outcomes were blinded to study participants, physiotherapists, and researchers until after the last follow-up.

2.6.1. Pain intensity

Pain intensity was measured using Numerical Pain Rating Scale (NRS)⁷ showing good test–retest reliability in patients with chronic pain.¹⁸ Peak and average pain during the past 24 hours were rated on 2 NRSs ranging from 0 = “no pain” to 10 = “worst pain imaginable.”

2.6.2. Pain-related disability

Pain-related disability was assessed with the PDI and the Oswestry Disability Questionnaire (ODI). The PDI⁴⁰ is a generic pain-related disability scale that assesses the degree to which chronic pain interferes with daily activities. This is constructed using 11-item NRSs in which 0 = “no disability” and 10 = “worst disability.” This study used only the 5 voluntary activities items, which yielded a 0 to 50 pain-related disability score as previous psychometric analyses indicated that the obligatory activation subscale has inadequate internal reliability.⁴⁵

The ODI^{14,15} showing good validity and reliability in patients with low back pain⁵³ is a back pain–specific self-report measure comprising statements for the patient to select that reflect the patient’s ability to manage their everyday life despite their pain. Each item is scored between 0 and 5 with a total score between 0 and 50, and a percentage score is calculated based on the patients’ total score divided by the total possible score.

2.6.3. Pain-related cognitions and emotions

Catastrophic thinking related to pain was assessed using the Pain Catastrophizing Scale⁴⁷ showing acceptable test–retest reliability and internal consistency in patients with low back pain.¹⁷ The Pain Catastrophizing Scale instructions ask participants to indicate the degree to which they experienced each of 13 thoughts or feelings when experiencing pain, on a 5-point Likert scale with 0 = not at all and 4 = all the time. The score is 0 to 52 with a higher score indicating a high level of pain catastrophizing.

Fear of movement was assessed with the 17-item Tampa Scale of Kinesiophobia questionnaire²⁵ showing good reliability and acceptable concurrent validity in patients with low back pain.⁴⁸ Each item is rated on a 4-point Likert scale with 1 = “strongly disagree” and 4 = “strongly agree” with a higher score indicating higher levels of fear of movement/kinesiophobia (scale 17–68).

Depression and anxiety was assessed with the Patient Health Questionnaire-9 (PHQ-9)²⁶ and the Generalized Anxiety Disorder-7 (GAD-7) questionnaire⁴⁶ showing good validity and reliability^{29,44} and has been widely used to measure depressive and anxiety symptoms in chronic pain populations.¹ Questions are assessed on a 4-point Likert scale, ranging from 0 = “not at all” to 3 = “nearly every day” with a higher score indicating higher depression (scale 0–27) or anxiety (scale 0–21) severity.

Health-related QOL was measured on the 0 to 100 Visual Analog Scale from the EuroQol 5-D questionnaire with 100 indicating the best QOL.¹³ Assessment of QOL with the 0 to 100 Visual Analog Scale has shown good correlations with SF-36, degree of independence, and lower depression scores in patients with chronic conditions.⁴³

2.6.4. Treatment costs

Treatment costs were calculated accounting for the different number of sessions for each individual. Calculation of costs for the CFT intervention was based on the payment rates detailed in the collective agreement between the Danish Physiotherapy Association and the Danish regions. Calculation of costs for the Pain Center care group was based on rates for diagnostic-related groups (DRG rates) itemized in the collective agreement between the Danish Government and the Danish regions.

2.6.5. Outcomes available for comparison of the 2 treatment pathways

In addition to the estimates of treatment costs, the following pain-related variables were suitable for outcome comparison between CFT and the Pain Center care pathways: duration of pain, use of analgesics and opioids, intensity of average clinical pain, pain-related disability (PDI), body chart (pain drawing) body areas, and health-related QOL, sex, age, height, and weight.

2.6.6. Assessment of pressure pain sensitivity

Pressure pain thresholds that have shown good within- and between-session reliability^{22,51} were assessed by HBV who was not involved in the CFT pathway. Pressure pain thresholds were assessed locally at the right erector spinae muscle (3 cm from the fourth lumbar spinous process) and at the left upper trapezius muscle (10 cm horizontally from the acromion in direct line with the seventh cervical spinous process) using a handheld pressure algometer (Somedic Sales AB, Norra Mellby, Sweden) with a stimulation area of 1 cm², and a pressure rate of 30 kPa/s. Patients were instructed to press a button when the pressure was perceived as the first sensation of minimal pain. Two PPT assessments with 20-second intervals between assessments were completed for each site and the average used for analysis.

2.7. Statistical analyses

Two stages of analysis were performed, one to describe the change in the CFT pathway and the second for the comparison of outcomes between the 2 different pathways.

2.7.1. Analysis 1

Analysis 1 involved, first, describing the number of dropouts from the CFT pathway and comparing their baseline characteristics with those that completed the CFT pathway. For continuous scores, *P*-values were calculated using independent *t* tests for normally distributed variables and Mann–Whitney *U* tests for non-normally distributed variables. For categorical scores, *P*-values were calculated using χ^2 tests. Second, the magnitude of change from baseline to the 3- and 6-month time points was estimated for those that completed CFT pathway, using paired *t* tests for continuous outcomes (Wilcoxon rank-sum tests if not normally distributed), and the calculation of proportions and odds ratios for dichotomous outcomes. Finally, the change in PPTs between baseline and 3 months, and baseline and 6 months were calculated, and as these data were not normally distributed, Spearman rho correlations were used to describe the association between those changes and pain-related disability or pain intensity at the same outcome time points.

2.7.2. Analysis 2

Analysis 2 estimated the CFT pathway effect by comparing the CFT group outcome after treatment with that of Pain Center care pathway. Between-pathway comparisons in outcomes were analyzed using linear regression, with adjustment for baseline scores of the dependent variable. Bootstrapped standard errors were estimated to adjust for slight departures from normality due to skew, and 95% confidence intervals were constructed from those standard errors.

For all analyses of continuous data, when that data were normally distributed, effects sizes were calculated. For within-pathway change scores, those effect sizes were standardized mean changes (SMCs) using a bias-corrected bootstrap method of 1000 samples with replacement.¹² For between-pathway differences, those effect sizes were standardized mean differences (SMDs or Cohen's D) also using a bias-corrected bootstrap method of 1000 samples with replacement.¹² The strength of effect sizes was categorized using Cohen's criteria (greater than 0.8 as large, 0.5 as moderate, and smaller than 0.2 as small).⁸ The same bootstrap method was applied for dichotomous data using the Yang and Dalton method.⁶⁰

There were few missing data. Across the estimates in analysis 1, the missingness was 0.8% at baseline, 0.8% at 3 months, and 4.0% at 6 months. Across the estimates in analysis 2, the missingness for the CFT group was 0.0% at baseline, 0.6% at 3 months, and 2.5% at 6 months, and for the Pain Center group was 0.0% at baseline and 3.0% after treatment. Because of this, and that the analyses were made with statistical techniques that are unbiased in the presence of data missing at random, no data were imputed. All statistical analyses were performed using STATA version 15.1 (Stata-Corp, College Station, TX) with a *P*-value of <0.05 as the threshold for statistical significance.

3. Results

3.1. Cognitive functional therapy cases

Forty-seven patients consented to participate in the study (Fig. 1 and Table 1). Six patients were excluded after the first session of CFT, and 7 dropped out within the first 3 CFT sessions due to lack of motivation or due to other health-related issues being investigated. Thirty-four patients completed the CFT pathway; receiving a mean of 6.6 ± 1.3 treatment sessions over 12 weeks and were included in analysis 1. Most of the patients reported pain in several areas of the body (Fig. 2). At baseline, the 72.3% of patients who completed CFT had lower scores on average pain intensity, pain-related disability, and kinesiophobia compared with patients who did not complete (Table 1).

3.2. Change in clinical outcomes and pressure pain thresholds after cognitive functional therapy

In the CFT group, improvements were seen from baseline to end of treatment in disability, pain intensity, kinesiophobia, pain catastrophization, anxiety, depression, health-related QOL, and a reduction in the proportion taking opioids (%). Those effects were moderate in size, with the point estimates of SMCs ranging from 0.33 to 0.75. Also, there was an increase in lumbar PPT (Table 2). At the end of the 3-month treatment period, there was a moderate-sized association between changes in lumbar PPT and changes in pain intensity ($r_s = 0.340$, $P = 0.049$; Table 3).

In the CFT group, there were also improvements from baseline to the 6-month follow-up in disability, health-related QOL, anxiety, pain catastrophization, depression, kinesiophobia, and a reduction in the proportion taking opioids. Again, the point estimates of the SMCs were moderate size, and there continued to be an increase in lumbar PPT. At 6 months, there were moderate-sized associations between changes in lumbar PPT

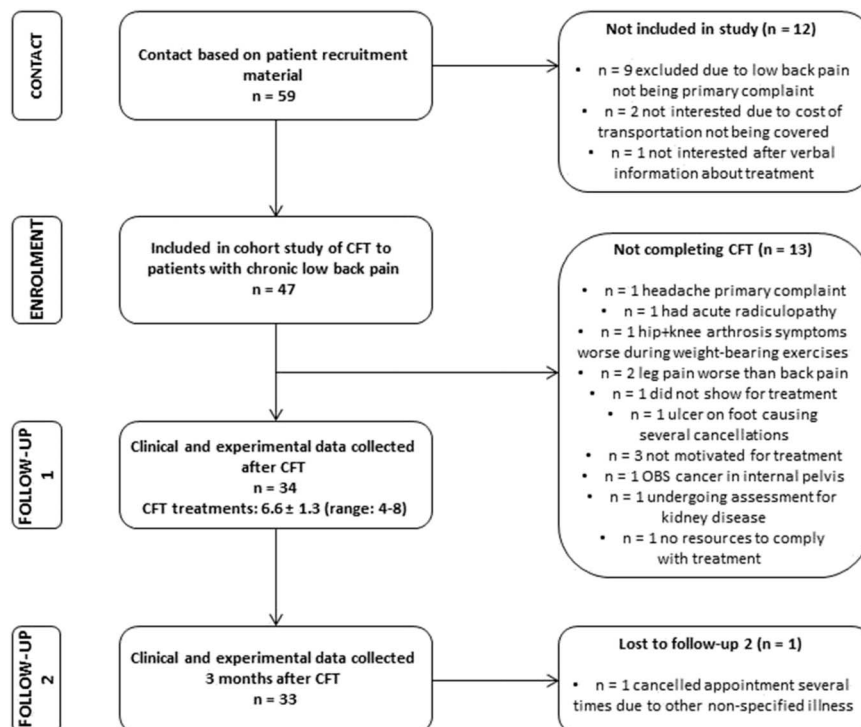


Figure 1. Flow chart.

Table 1**Baseline characteristics of the patients consenting to participate in the CFT pathway.**

Domain	Variable	Total (n = 47)	Completed CFT (n = 34)	Dropouts (n = 13)	Mean difference (95% CI)	P
Demographic characteristics	Gender (female)	30 (63.8%)	24 (70.6%)	6 (46.2%)	—	0.12*
	Marital status (married)	38 (80.9%)	26 (76.5%)	12 (92.3%)	—	0.28*
	Age (y)	52.1 ± 13.2	52.4 ± 14.0	51.2 ± 11.4	1.3 (−7.5 to 10.0)	0.77†
	BMI	27.1 ± 5.0	27.2 ± 4.3	27.0 ± 6.7	0.1 (−3.2 to 3.4)	0.49‡
	Insurance claims	9 (19.1%)	6 (17.6%)	3 (23.1%)	—	0.67*
	Sick leave (n = 30)	16 (53.3%)	9 (45.0%)	7 (70.0%)	—	0.20*
	Pension	17 (36.2%)	14 (41.2%)	3 (23.1%)	—	0.52*
Clinical pain characteristics	Pain duration (y)	13.5 ± 12.6	14.5 ± 14.0	10.8 ± 7.5	3.7 (−4.5 to 12.0)	0.96‡
	Peak pain intensity (NRS: 0–10)	7.9 ± 1.7	7.7 ± 1.8	8.6 ± 1.1	−0.9 (−2.0 to 0.1)	0.08‡
	Average pain intensity (NRS: 0–10)	6.4 ± 2.0	5.9 ± 1.9	7.3 ± 1.6	−1.3 (−2.5 to −0.04)	0.043‡
	Pain areas (0–71)	17.6 ± 15.1	19.4 ± 15.4	13.1 ± 14.0	6.3 (−3.6 to 16.1)	0.16‡
	Analgesics	44 (93.6%)	32 (91.4%)	12 (92.3%)	—	0.82*
	Opioids	30 (63.8%)	20 (58.8%)	10 (76.9%)	—	0.25*
	Disability (PDI: 0–50)	33.3 ± 8.5	31.0 ± 8.3	39.4 ± 5.8	−8.4 (−13.5 to −3.3)	0.002‡
	Disability (Oswestry: 0%–100%)	44.5 ± 13.7	41.6 ± 13.0	52.1 ± 13.1	−10.5 (−19.0 to −1.9)	0.018‡
Psychological characteristics	Quality of life (EQ5D: VAS 0–100)	44.20 ± 23.5	46.1 ± 21.4	39.5 ± 27.4	6.6 (−9.1 to 22.2)	0.40‡
	Anxiety (GAD-7: 0–21)	6.7 ± 5.5	7.0 ± 5.5	6.0 ± 5.6	1.0 (−2.6 to 4.7)	0.54‡
	Depression (PHQ-9: 0–27)	10.9 ± 5.5	10.9 ± 5.9	11.5 ± 3.9	−0.9 (−4.5 to 2.7)	0.61‡
	Pain catastrophization (PCS: 0–52)	26.2 ± 11.2	25.2 ± 10.5	28.9 ± 12.8	−3.8 (−11.1 to 3.6)	0.31‡
	Fear of movement (TSK: 17–68)	41.8 ± 8.3	40.2 ± 6.7	47.6 ± 7.4	−8.1 (−13.0 to −3.1)	0.002‡
Experimental pain sensitivity	PPT low back right side (kPa)	228 ± 129	225 ± 118	238 ± 159	−17 (−99 to 66)	0.75‡
	PPT upper trapezius (kPa)	197 ± 111	212 ± 122	156 ± 63	56.6 (−15 to 128)	0.21‡

* For categorical scores, *P*-values are based on χ^2 test.† For continuous scores, *P*-values are calculated based on independent *t*-test for normally distributed variables.‡ For continuous scores, Mann–Whitney *U*-test for non-normally distributed variables.

BMI, body mass index; CFT, cognitive functional therapy; EQ5D, EuroQOL 5-D; GAD-7, Generalised Anxiety Disorder-7; kPa, kilopascal; NRS, Numeric Pain Rating Scale; PDI, Pain Disability Index; PPT, pressure pain threshold; Oswestry, Oswestry Disability Index; PCS, Pain Catastrophising Scale; TSK, Tampa Scale of Kinesiophobia; Y/N, yes/no.

and changes in pain-related disability (ODI) scores ($r_s = 0.348$, $P = 0.048$) and pain intensity ($r_s = 0.381$, $P = 0.029$).

3.3. Comparison between cognitive functional therapy cases and pain Center care

One of the 34 patients who completed CFT could not be matched in the propensity score matching. Consequently, 33 CFT cases and 99 matched control cases were included in analysis 2 (**Fig. 2** and **Table 4**). Pain Center care patients received a mean of 16.4 ± 7.4 treatment sessions over a median of 9 months. The treatment period in the Pain Center care pathway was approximately 3 times longer and 14.7 times the cost per patient.

Greater reductions in PDI and greater improvements in health-related QOL were observed for the CFT group, but there were no differences on all other outcomes (**Table 5**).

4. Discussion

4.1. Summary of results

This is the first study comparing a CFT pathway to an MPM pathway for patients with severe and disabling pLBP. While acknowledging the limitations of the study design of this pilot case–control study without randomization, the main findings of this pilot study was significant improvements in pain intensity, pain-related disability, pain-related cognitions, emotions, QOL, use of opioids, and back PPT in patients with severe pLBP after the CFT pathway. In addition, the CFT group had larger reductions in pain-related disability and improved QOL at a markedly lower cost at the end of the treatment period compared with the MPM group.

These findings are potentially important, and somewhat surprising, given that these patients were nonresponsive to

primary care, and many were taking opioids and on sick leave. This patient profile is known to be very resistant to change. Furthermore, they were provided with a relatively small treatment dose by a single physiotherapist and had no additional booster sessions outside of the 3-month treatment period. However, randomized studies with larger samples are required to reduce the imprecision in many of the estimates of observed effects and control for the limitations of the study design.

The observed changes for pain-related disability and psychological factors are in line with the aim of CFT which directly targets personally relevant psychological, physical, and lifestyle barriers to recovery in an individualized manner, to return people to valued activities. These findings are consistent with previous CFT clinical studies^{19,35,54} reporting reductions in negative pain cognitions and emotional distress and improvements in pain coping and pain self-efficacy.^{5,35,54} This model of care is aligned to recent clinical guidelines advocating physical and psychological interventions in people with high levels of psychological distress. Typically, this is delivered in a multidisciplinary care environment, while CFT targets this in an integrated manner delivered by a single physiotherapist.

In general, the MPM group reported small to modest improvements in pain intensity, disability, and QOL of a similar magnitude as recently reported by multidisciplinary pain centers in Canada³⁸ and in a large meta-analysis.²⁴ However, the likely heterogeneity in outcome make these results somewhat challenging from a cost-effectiveness perspective, as it is difficult to predict which LBP patients will benefit from an MPM program.

A novel aspect of this study was the increase in PPT at the back after the CFT intervention. Although lower PPT's have been reported in people with pLBP and emotional distress,^{41,42} to date, no study has reported an increase in PPT at the lower back after a CFT intervention. The exact underlying mechanism for these

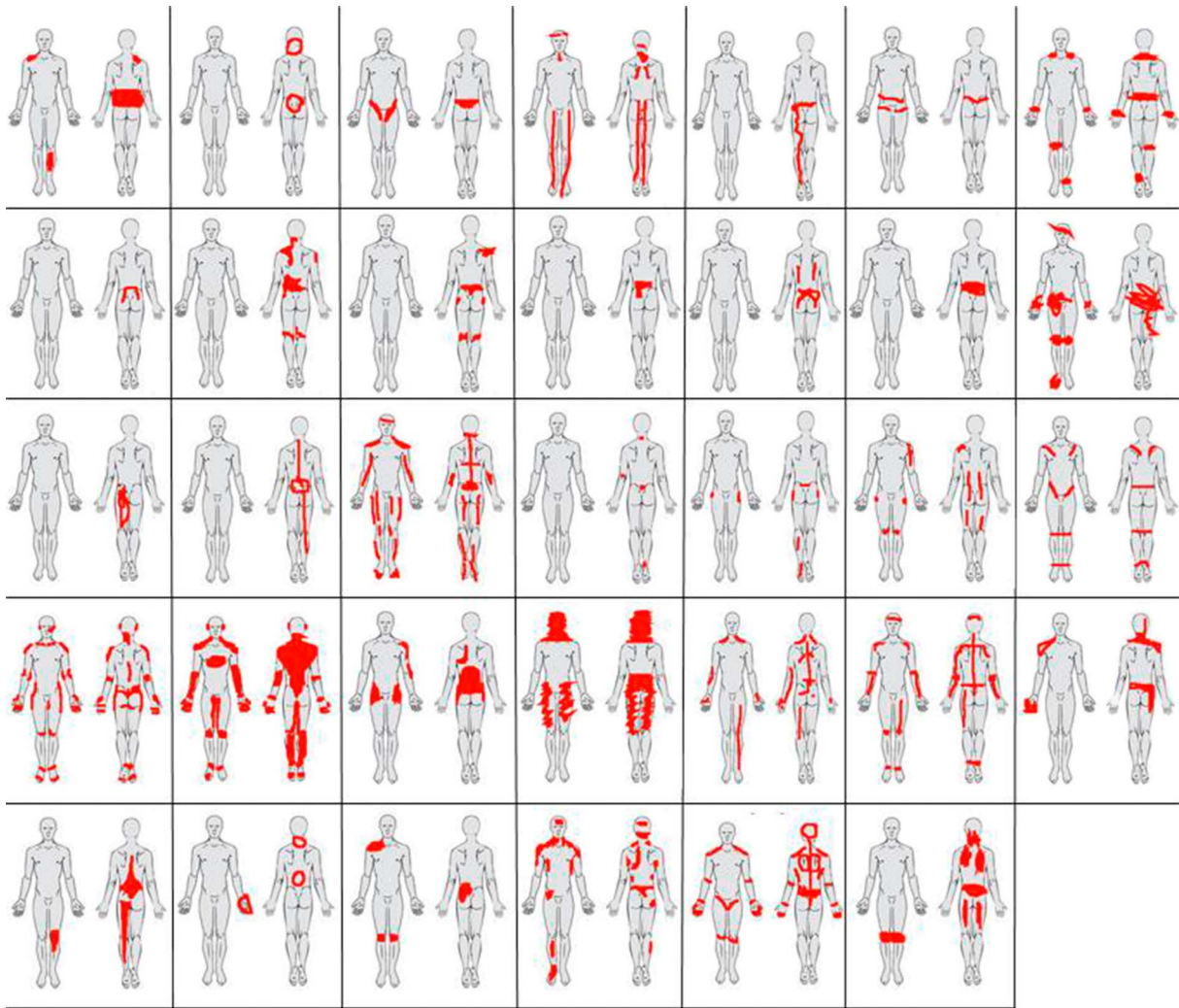


Figure 2. Pain drawings from the 34 patients who completed the cognitive functional therapy pathway.

changes are unknown; however, it is known that cognitive processes and lifestyle factors affect both pain^{9,20} and pain sensitivity,³² and it has been hypothesized that reduced fear of pain and pain-related distress may impact tissue sensitivity. Interestingly, remote trapezius PPT did not increase, suggesting that CFT did not cause a generalized change in pain sensitivity, which point to more local or segmental than systemic mechanisms. Whether these local changes reflect factors such as the normalization of spinal movement and reduced protective guarding of the low back, which are key components in the CFT intervention, is not known. The exact contribution of pain sensitivity mechanisms to spinal pain is unclear, and it has even been suggested that pain sensitivity is a poor marker for the subjective experience of pain and disability.²³ Nonetheless, these preliminary findings of an increase in PPT at the lower back after CFT intervention and an association with reduced pain intensity and pain-related disability suggest that changes in pain sensitivity should be further investigated in studies of CFT.

4.2. Results compared with previous cognitive functional therapy studies

Compared with previous studies investigating CFT in primary care patients with low to moderate disability,^{19,35,54} the present results

do not display similar large effects on pain, disability, cognitive, and emotional variables. The findings are in line with a recent RCT reported moderate and long-term reductions in disability, but not pain, in people with disabling LBP after CFT compared with group exercise and education.³⁴ Interestingly, CFT has consistently demonstrated significant long-term effect on fear in previous studies,^{5,19,35,54} and fear has been proposed as a potential mediating effect of disability within the CFT intervention.⁵ In this study, the changes in fear were relatively low, which is similar to recent findings,³⁴ but larger changes in other emotional constructs, eg, depression and anxiety were seen, indicating possible different mechanism of change in this complex cohort of patients. In a recent RCT, CFT resulted in improvements in pain self-efficacy, risk of chronicity, and pain coping compared with group education and exercise.³⁴

The explanation for the positive results of CFT in this cohort may relate to the nature of the intervention. The CFT intervention targets feared and avoided activities through behavioural experiments that involve exposure to threatening tasks while training relaxation and abolishing protective and safety behaviours. These behavioural experiments are specifically designed to challenge pain-related movement and activity avoidance beliefs and behaviours.⁴ Although speculative, this re-engagement with valued activities coupled with increased pain self-efficacy may

Table 2**Change in outcomes in the CFT group from baseline to 1 week after the CFT pathway, and at 6-month follow-up.**

Baseline		Post-treatment		6-month follow-up	
n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Oswestry Disability Index (0–100 low scores better) 34	41.6 (13.0)	34	33.0 (15.6) Improvement from baseline 20.7% or –8.7 (95% CI –4.4 to –13.0), $P < 0.01$ SMC = 0.68 (0.38–1.09)	33	34.9 (18.4) Improvement from baseline 15.3% or –6.3 (–1.47 to –11.2), $P = 0.01$ SMC = 0.50 (0.13–0.93)
Pain Disability Index (0–50 low scores better) 34	31.0 (8.3)	34	24.9 (11.6) Improvement 19.7% or –6.1 (95% CI –2.7 to –9.4), $P < 0.01$ SMC = 0.71 (0.36–1.20)	33	26.4 (12.4) Improvement 14.6% or –4.5 (–0.9 to –8.1), $P < 0.02$ SMC = 0.52 (0.12–0.98)
Low back pain (0–10, low scores better) 34	5.9 (1.9)	34	4.8 (2.2) Improvement 18.6% or –1.1 (95% CI –0.5 to –1.7), $P < 0.01$ SMC = 0.61 (0.29–1.09)	33	5.2 (2.5) Improvement 12.5% or –0.8 (–0.0 to –1.5), $P = 0.06$ SMC = 0.40 (0.04–0.85)
Health-related quality of life (0–100, high scores better) 34	46.1 (21.4)	34	62.0 (19.4) Improvement 34.5% or 15.9 (95% CI 23.1–8.7), $P < 0.01$ SMC = 0.75 (0.42–1.14)	33	61.4 (20.1) Improvement 32.0% or 14.9 (23.5–6.3), $P < 0.01$ SMC = 0.70 (0.26–1.18)
Generalised Anxiety Disorder Scale 7 (0–21 low scores better) 33	7.0 (5.5)	33	5.2 (4.3) Improvement 25.7% or –1.8 (95% CI –0.5 to –3.2), $P < 0.01$ SMC = 0.33 (0.11–0.56)	32	5.1 (5.2) Improvement 23.9% or –1.6 (–0.2 to –3.0), $P < 0.03$ SMC = 0.29 (0.05–0.55)
Pain Catastrophization Scale (0–52 low scores better) 33	25.2 (10.5)	33	20.8 (10.9) Improvement 17.5% or –4.3 (95% CI –1.4 to –7.3), $P < 0.01$ SMC = 0.41 (0.14–0.68)	32	20.9 (11.8) Improvement 15.0% or –3.7 (–0.7 to –6.7), $P < 0.02$ SMC = 0.35 (0.08–0.63)
Patient Health Questionnaire-9 (depression) (0–27 low scores better) 33	10.9 (5.9)	33	8.5 (5.9) Improvement 22.5% or –2.4 (95% CI –0.9 to –3.9), $P < 0.01$ SMC = 0.41 (0.15–0.70)	32	8.6 (6.8) Improvement 17.3% or –1.8 (–0.1 to –3.4), $P < 0.02$ SMC = 0.35 (0.06–0.63)
Tampa Scale for Kinesiophobia (11–44 low scores better) 34	40.2 (6.7)	34	36.7 (6.2) Improvement 8.7% or –3.5 (95% CI –1.5 to –5.4), $P < 0.01$ SMC = 0.51 (0.23–0.86)	32	36.0 (8.0) Improvement 10.7% or –4.3 (–2.1 to –6.5), $P < 0.01$ SMC = 0.64 (0.30–1.03)
Taking opioids (yes/no) 34	Yes (20) 58.8%	34	Yes (14) 41.2% Improvement 17.6% (95% CI 4.1% to 31.2%), $P = 0.01$ SMC = 0.37 (0.12 to 0.70)	33	Yes (15) 45.5% Improvement 13.3% (2.2% to 28.1%), $P < 0.03$ SMC = 0.28 (0.05 to 0.61)

(continued on next page)

Table 2 (continued)**Change in outcomes in the CFT group from baseline to 1 week after the CFT pathway, and at 6-month follow-up.**

Baseline		Post-treatment		6-month follow-up	
n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Taking analgesia (yes/no)					
34	Yes 32 (94.1%)	34	Yes 29 (88.2%) Improvement 5.9% (95% CI −6.0% to 17.8%), $P = 0.32$ SMC = NP	33	Yes (30) 90.9% Improvement 3.2% (−0.1% to 13.8%), $P = 0.57$ SMC = NP
No. of pain areas (0–71)					
34	19.4 (15.4)	34	15.7 (11.4) Improvement −4 (95% CI −7.9 to 0.7), $P = 0.10$ SMC = 0.26 (−0.06 to 0.47)	33	15.8 (12) Improvement −3.4 (−8.1 to 1.7), $P = 0.19$ SMC = 0.22 (−0.09 to 0.51)
Baseline		Post-treatment		6-month follow-up	
n	Median (IQR)	n	Median (IQR)	n	Median (IQR)
Pressure pain threshold (local area = L5)					
34	183.3 (132.5–278.0)	34	230.3 (193.5 to 363.5) Improvement 33.75 (IQR −0.5 to 130.5), $P = 0.05$ SMC = NA	33	257.5 (192.0 to 367.0) Improvement 55.5 (IQR −6.0 to 128.0), $P = 0.05$ SMC = NA
Pressure pain threshold (distal area = upper trapezius)					
34	189.5 (121.0–251.0)	34	208.75 (152.0 to 296.5) Improvement 19.5 (IQR −21.5 to 92.0), $P = 0.16$ SMC = NA	32	218.0 (160.5 to 308.0) Improvement 31.0 (IQR −20.0 to 69.5), $P = 0.12$ SMC = NA

CFT, cognitive functional therapy; IQR, interquartile range; NP, a standardised mean change was not calculable in this dichotomous data due to too few improvements; NA, a standardised mean change was not calculable as these data were not normally distributed; SMC, standardised mean change (mean change/baseline SD).

result in positive effects on mood and emotional status. The present findings are in line with previous research on management of LBP involving exposure treatments.^{28,56} Interestingly, patients who did not complete the CFT intervention also showed higher disability and kinesiophobia than patients who completed the intervention, which may indicate that they could be the individuals who might benefit most from CFT core components. However, not all patients are willing or ready to actively engage in this treatment approach.

4.3. Limitations

This is a small pilot case–control study without randomization, so participants were only balanced on the measured variables. The findings may potentially be influenced by nonspecific effects as

patients receiving CFT were enrolled in a clinical trial, while patients in the usual MPM group were not. Not all potential outcome variables were available for control patients, and no evaluation of other health care services and costs outside of the study was performed, which could potentially influence the nondirect treatment-related costs. There was a high dropout rate in the beginning of the CFT pathway suggesting that the timing of the pathway was not optimal for all patients or that it did not suit the expectations of all patients. As participant motivation for choosing CFT pathway or Pain Center care was not assessed in this study, we cannot rule out that potential differences may have inflated the results. Although cases were matched at start of pathways, the long wait time for usual Pain Center care may have negative effects across a range of domains including health-related QOL and psychological well-being.³⁰ Based on the

Table 3**Correlations between change in pressure pain thresholds and change in pain intensity or pain-related disability in the CFT group.**

Spearman rho correlations	Post-treatment (n = 34)	6-month follow-up (n = 33)
Lumbar (local) PPT		
Oswestry Disability Index	$r_s = 0.252$, (95% CI: −0.094 to 0.544) $P = 0.150$	$r_s = 0.348$, (95% CI: 0.005 to 0.617) $P = 0.048$
Pain Disability Index	$r_s = 0.183$, (95% CI: −0.165 to 0.491) $P = 0.300$	$r_s = 0.284$, (95% CI: −0.065 to 0.572) $P = 0.109$
Low back pain intensity	$r_s = 0.340$, (95% CI: 0.002 to 0.61) $P = 0.049$	$r_s = 0.381$, (95% CI: 0.043 to 0.640) $P = 0.029$
Trapezius (distal) PPT		
Oswestry Disability Index	$r_s = 0.023$, (95% CI: −0.318 to 0.358) $P = 0.897$	$r_s = 0.004$, (95% CI: −0.340 to 0.347) $P = 0.983$
Pain Disability Index	$r_s = 0.156$, (95% CI: −0.192 to 0.470) $P = 0.378$	$r_s = 0.173$, (95% CI: −0.181 to 0.488) $P = 0.335$
Low back pain intensity	$r_s = 0.253$, (95% CI: −0.093 to 0.544) $P = 0.149$	$r_s = 0.318$, (95% CI: −0.029 to 0.596) $P = 0.072$

CI, confidence interval; CFT, cognitive functional therapy; PPT, pressure pain threshold.

Table 4**Baseline characteristics in 33 CFT cases and 99 matched control patients.**

	CFT group (n = 33)	Pain Center care group (n = 99)
Age, mean (SD)	51.9 (13.9)	50.2 (11.3)
Female, n (%)	23 (69.7%)	69 (69.7%)
Height (cm), mean (SD)	171.2 (8.1)	164.8 (48.3)
Weight (kg), mean (SD)	79.8 (14.7)	79.1 (20.6)
Pain duration, % (n)		
<1 yr	12.1% (4)	11.1% (11)
2–5 yrs	30.3% (10)	28.3% (28)
6–10 yrs	12.1% (4)	20.2 (20)
>10 yrs	46% (15)	40.4 (40)
Pain Disability Index (PDI: 0–50)	31.1 (10.5)	32.9 (8.9)
Low back pain intensity (NRS: 0–10)	5.9 (1.9)	6.1 (1.7)
Health-related quality of life (EQ5D-VAS: 0–100)	46.1 (21.7)	43.6 (20.1)
Taking opioids (yes)	20 (60.6%)	62 (62.6%)
Taking analgesics (yes)	32 (97.0%)	94 (96.0%)

CFT, cognitive functional therapy; EQ5D = EuroQOL 5-D; NRS, Numeric Pain Inventory; PDI, Pain Disability Index; VAS, Visual Analog Scale.

exploratory nature of several of the statistical analyses, we acknowledge the risk of Type I error.

5. Conclusions

Patients receiving CFT showed significant improvements in pain intensity, pain-related disability, pain-related cognitions, emotions, QOL, use of opioids, and PPTs. The CFT pathway produced superior outcomes for pain-related disability and QOL at a much lower cost for patients with severe disabling pLBP compared with an MPM pathway. Although we are cautious not to over interpret this case-control data, fully powered RCTs investigating these results in this setting is warranted, as there is an urgent need to identify alternative, clinically and cost-effective interventions to help people manage disabling pLBP.

Disclosures

P. O'Sullivan, K. Ussing and J.V. Johansen occasionally receive payments for clinical workshops on cognitive functional therapy (CFT). H.B. Vaegter received funding for this study by the Research and Development Fund, and the Danish Physiotherapy Research Fund. The remaining authors have no conflicts of interest to declare.

Previous presentation of research: The content of this manuscript was presented at the 10th International World Congress on Low Back and Pelvic Girdle Pain in October 2019.

Table 5**Comparisons of outcomes in the CFT and Pain Center care pathways.**

	CFT		Pain Center care		Between-group difference
	n	Mean (SD)	n	Mean (SD)	CFT—usual care (95% CI)
Pain Disability Index (0–50 low scores better)					
Baseline	33	31.1 (10.5)	99	32.9 (8.9)	−1.8 (−5.8 to 2.2), $P = 0.38$
After treatment	33	26.2 (8.6)	96	30.8 (7.5)	−4.6 (−7.6 to −1.7), $P < 0.01$
Improvement		15.8%		6.4%	SMD = 0.52 (0.15 to 0.97)
Pain intensity (0–10, low scores better)					
Baseline	33	5.9 (1.9)	99	6.1 (1.7)	−0.2 (−0.9 to 0.6), $P = 0.68$
After treatment	33	4.9 (2.0)	99	5.2 (1.7)	−0.3 (−1.0 to 0.4), $P = 0.45$
Improvement		17.0%		14.8%	SMD = 0.21 (−0.15 to 0.66)
Health-related quality of life (0–100, high scores better)					
Baseline	33	46.1 (21.7)	99	43.6 (20.1)	2.5 (−5.8 to 19.7), $P = 0.55$
After treatment	32	61.2 (17.5)	95	49.5 (21.4)	11.8 (5.4 to 18.1), $P < 0.01$
Improvement		32.8%		13.3%	SMD = 0.60 (0.23 to 0.97)
Cost of treatment (Euros)					
Saving	33	267.90€ (49.61€)	99	3956.19€ (1810.58€)	3688.29€ (CI: 3063 to 4314€), $P = 0.01$
Taking opioids (yes/no)					
Baseline	33	Yes 20 (60.6%)	99	Yes 62 (62.6%)	Odds ratio 0.92 (0.41 to 2.1), $P = 0.84$
After treatment	33	14 (42.4%)	99	31 (34.8%)	1.35 (0.60 to 3.1), $P = 0.47$
Improvement		18.2%		27.8%	SMD = −0.16 (−0.60 to 0.22)
Taking analgesics (yes/no)					
Baseline	33	Yes 32 (97.0%)	99	Yes 94 (96.0%)	Odds ratio 1.70 (0.19 to 15.3), $P = 0.63$
After treatment	33	29 (87.9%)	98	88 (89.8%)	0.82 (0.24 to 2.8), $P = 0.76$
Improvement		9.1%		6.2%	SMD = 0.09 (−0.52 to 0.84)

CI, confidence interval; CFT, cognitive functional therapy; SMD, standardised mean difference (Cohen's D).

Acknowledgements

The authors thank Prof Anne Smith for her statistical and interpretative advice.

Article history:

Received 20 August 2019

Received in revised form 22 October 2019

Accepted 9 November 2019

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