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Bibliographic Data	
Authors	Fersum KV, O'Sullivan P, Skouen JS, and et al.
Title	Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: A randomized controlled trial
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Other information if relevant	trial registration with clinicaltrials.gov

Methods	
Aim of study	To investigate the efficacy of person-centered classification-based cognitive functional therapy (CB-CFT) compared with manual therapy and exercise (MT-EX) for the management of non-specific chronic low back pain (NSCLBP).
Design	Single-blind randomized clinical trial

Participants	
Population from which participants are drawn	Recruited from private physiotherapy outpatient practices, general practitioners, and the outpatient spine clinic at the Haukeland University Hospital. In addition, six advertisements were placed in the local newspaper.
Setting (location and type of facility)	The intervention took place at 3 different private clinics in Bergen, Norway. Therapy was in the primary care setting.
Age	Adults between 18 and 65 years, mean age 41.9 years
Sex	48 females, 46 males
Total number of participants for whom outcome data were reported	94
Inclusion criteria	1. Age between 18 and 65 years 2. The presence of NSLBP for >3 months 3. >2 of 10 on Numerical Rating Scale (PINRS) for pain over the last 14 days 4. Mechanical provocation and relief of pain with postures, movement and activities 5. Oswestry Disability Index (ODI) > 14%
Exclusion criteria	Continuous sick-leave for >4 months, acute exacerbation of LBP at time of testing, specific LBP diagnosis (radicular pain, disc herniation, spondylolisthesis, stenosis, Modic changes), any low limb surgery in the last 3 months, surgery involving the lumbar spine, pregnancy, diagnosed psychiatric disorder, widespread constant non-specific pain disorder, pain without a clear mechanical behavior, active rheumatologic disease, progressive neurological disease, serious cardiac or other internal medical condition, malignant diseases, acute traumas, infections or acute vascular catastrophes.

Other information if relevant	Baseline pain intensity and disability did not differ between groups. The baseline means (SD) on the Pain Intensity Numeric Pain Rating Scale (PINRS, range 0-10) for the CB-CFT intervention group and the MT-EX control group were 4.9(2.0) and 5.3(1.9) for pain intensity, and 21.3(7.5) and 24.0 (8.0) on the Oswestry disability index, respectively. The inclusion criterion of mechanical provocation of back pain was designed to include patients whose movement behaviors had a clear association with their pain disorder, for which the CB-CFT intervention was designed.

Intervention Groups

Group 1	
Group name	Classification-based cognitive functional therapy (CB-CFT) -Intervention
Number in group	51
Description of intervention	This active intervention is a multilevel, cognitive and functionally specific, patient-centered clinical reasoning approach to broadly classify and target management for patients with NSCLBP. Each patient receives a specific targeted intervention directed at changing their individual cognitive, movement and lifestyle behaviors considered by the therapist to be maladaptive (provocative) of their disorder. The aim is for each subject to acquire self-management strategies for their disorder by developing positive back pain beliefs, pain control, developing adaptive strategies of movement that enhanced functional capacity and the ability to engage in regular physical activity. There are 4 main components; (1) cognitive, (2) specific movement exercises designed to normalize maladaptive movement behaviors, (3) targeted functional integration of provocative activities in their daily life, and (4) a physical activity program tailored to the movement classification.
Duration of treatment period	12 week intervention, initial session = 1 hour, follow-ups = 30-45 min, weekly 1st 2-3 sessions, then every 2-3 weeks, daily program
Co-interventions if reported	
Additional information if relevant	Participants were asked to complete daily diaries. The mean number of treatments was 7.7.

Group 2	
Group name	Manual therapy and exercise (MT-EX) -control group
Number in group	43
Description of intervention	Participants were treated with joint mobilization or manipulation techniques applied to the spine or pelvis consistent with best current manual therapy practice at the discretion of the treating therapist.
Duration of treatment period	12 week intervention, 1 hour for the initial consultation and 30 min for follow-ups.
Co-interventions if reported	Most patients (82.5%) in this group were given exercises or a home exercise program. This included general exercise or motor control exercises. The motor control exercises involved isolated contractions of the deep abdominal muscles in different functional positions.
Additional information if relevant	The mean number of treatments was 8.0.

Coprimary outcomes	
Outcome name and criteria for definition	(1) Self-reported pain intensity in the last 2 weeks measured by the Pain Intensity Numeric Pain Rating Scale (PINRS, range 0-10) with higher scores indicating worse pain. (2) Perceived function measured by the Oswestry Disability Index (ODI), 0 -100, low scores indicate low disability The primary end time point was the 12-month post-intervention follow-up.
Time points measured and/or reported	Baseline, at program completion at 3 months, and also at 12 months post-intervention.
Differences between groups	Both groups improved significantly from baseline. The CB-CFT group displayed superior outcomes supported by both statistically and clinically significant differences when compared with the MT-EX group both at 3 and 12-month post-intervention follow-ups for both primary and all secondary outcomes. For the CB-CFT group, improvement from baseline in the ODI score was 11.4 points at 12 months post-intervention and for the PINRS score 2.6 points. For the MT-EX group, improvement from baseline in the ODI score was 4.3 points at 12 months post-intervention and for the PINRS score 1.5 points. The mean differences between groups in the ODI score at 12 months was -8.2 (-12.6 to -3.8) and the mean difference between groups in the PINRS was -1.3(-2.1 to -0.5) both favoring the CB-CFT group. These results showed statistically and clinically significant differences between groups in both pain and function with participants in the CB-CFT group having greater reduction of pain and greater improvement in function ($P< 0.001$). At the 3- month follow-up, the significant results were similar.
Additional information if relevant	There were no statistically significant differences between the 2 groups in baseline demographics or outcome measures. A total of 94 participants completed assessments at all 3 time points. Analyses followed the intention-to-treat principle. Clinically meaningful changes for both primary outcomes as defined by the minimally important change (MIC) is >10-point change in ODI and >1.5 point change on PINRS.

Secondary outcomes	
Outcome name and criteria for definition	Depression, anxiety, fear avoidance beliefs of physical activity, lumbar spine range of motion, patient satisfaction, and number of sick leave days.
Time points measured	Baseline, at program completion at 3 months, and also at 12 months post-intervention.
Differences between groups	- The improvements for all secondary outcomes showed similar effects, with the CB-CFT group demonstrating significantly greater change when compared with the MT-EX group across all outcomes, except for total lumbar range of motion. - Although satisfaction rates were high in both groups, odds of being completely satisfied were over 3times higher in the CB-CFT group at 3 months and five times higher at 12 months. - Although it was not a primary aim of the CB-CFT intervention, the results demonstrate a 2.95-times less likelihood of taking sick leave for their LBP at 12 months compared with the MT-EX group. - The patients in the CB-CFT group also sought less additional treatment for their pain, suggesting significant cost–benefits.

Additional information if relevant	No dropouts reported adverse effects from either intervention arm.
Conclusions	
Key conclusions of study authors	- This study revealed that the CB-CFT group demonstrated superior outcomes compared with the MT-EX group across every outcome measured at post-intervention and at 12-month follow-up. Both groups showed significant improvement in short- and long-term follow-ups, but the CB-CFT group was superior based on clinically meaningful changes in both pain reduction and functional improvement. - The results of this study support that (CB-CFT), a behaviorally orientated targeted approach to manage NSCLBP, was more effective at reducing pain, disability, fear beliefs, mood and sick leave at 12 months follow-up than MT-EX. - This study showed that moving away from a biomedical 'injury' model, to viewing LBP as a multifactorial biopsychosocial disorder, and directing treatment at person-centered beliefs and behaviors that promote pain and disability, rather than simply at the signs and symptoms associated with the disorder, can result in effective treatment. - While this intervention appears to be successful for the study population tested, further studies are needed to investigate those with higher levels of pain and disability, patients that are long-term sick-listed, as well as in other cultural and occupational groups, in order to determine the generalizability of the findings.

Risk of bias assessment		
Domain	Risk of bias Low High Unclear	Comments
Random sequence generation *(selection bias)*	Low	A person independent of the study at the University of Bergen developed a randomization schedule and produced 160 sealed opaque envelopes containing each participant's allocation.
Allocation concealment *(selection bias)*	Low	Only after baseline measures were completed, the patient drew the envelope containing their allocation and details of procedure in relation to their allocation.
Blinding of participants and personnel *(performance bias)*	High	Patients were aware of which group they were in, and it was not possible to blind them. Therapists in both arms of the study were not blinded to the intervention The lack of blinding does not prejudice the conclusions.
Blinding of outcome assessment *(detection bias)*	Low	All outcome assessments were conducted by staff members blinded to intervention assignment.

Incomplete outcome data *(attrition bias)*	Low	While the 12 month follow-up was designated as the primary endpoint, confidence intervals and p values were only reported for the 3 month follow-up results, not the 12 month results. The 3 month results gave slightly better between group differences for the 2 primary outcomes.
Selective outcome reporting? *(reporting bias)*	Low	The trial was registered with clinicaltrials.gov
Other bias		Intention to treat analysis was used.

Sponsorship if reported		
Study funding sources if reported	Funded by the Norwegian Fund for Post-Graduate Training in Physiotherapy.	
Possible conflicts of interest for study authors	None declared	
Notes:		

Comments by DOWC staff

- One possible way to improve treatment efficacy in psychological research for chronic pain is to better match treatments to patient characteristics, treatment components, and patient treatment interactions. Classification-based cognitive functional therapy addresses this aim and demonstrates effective treatment results for chronic LBP.

- The classification-based cognitive functional therapy used in this study produced superior outcomes for pain and function for treating non-specific chronic low back pain compared with traditional manual therapy and exercise.

- At 12 months post-intervention, the CB-CFT group improved 11.4 points in the ODI score while the MT-EX group only improved 4.3 points. The CB-CFT group attained the minimally important change (MIC) of >10-point change in ODI, while the MT-EX group did not. Similarly, at 12 months post-intervention, the CB-CFT group improved 2.6 points in the PINRS score while the MT-EX group only improved 1.5 points. The CB-CFT group attained the minimally important change (MIC) of >1.5-point change in PINRS score, while the MT-EX group did not quite meet this. Even though the MT-EX group did improve by reducing pain and increasing function, these improvements were small, but clinically unimportant.

- While there was a comparable proportion of non-completers in each group, 8 of 59 (13.5%) of the MT-EX group failed to commence their allocated treatment, compared with only 1 of 62 (1.6%) of the CB-CFT group. Seven of these subjects had reported previous manual therapy treatment with poor effect, which would have potentially biased for a poorer outcome in the MT-EX group.

- Strengths of the study included an active control group, adequate randomization, a designated primary follow-up endpoint, clinical trial registration, a functional outcome, and long-term follow-up at 12 months.

- The active engagement required of subjects for this behavioral approach may present a barrier for those unwilling to self-manage their disorder or pain.

- Since the interventions were multidimensional in nature, no conclusion as to the specific effects of the different components of the intervention can be drawn.

- Results of participant adherence to their prescribed daily exercises or intervention regimens to conduct at home were not provided.

Assessment by DOWC staff	
Overall assessment as suitability of evidence for the guideline ☐ High quality ☒ Adequate ☐ Inadequate	This study is adequate for some evidence that in the setting of non-specific chronic low back pain, patient- centered cognitive functional therapy from physical therapists produced superior outcomes for pain reduction and functional improvement compared with traditional manual therapy and exercise at post-intervention and at 12-month follow-up.
If inadequate, main reasons for recommending that the article not be cited as evidence	

Additional references if relevant