CRITICALLY APPRAISED TOPIC

FOCUSED CLINICAL QUESTION

In **(P)** adult patients with chronic low back pain presenting to outpatient physical therapy services, does the **(I)** integration of strategies based in **psychologically informed practices (O)**better promote patient self-management (increase self- efficacy) compared with **(C)**traditional PT practice alone?

AUTHOR

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CLINICAL SCENARIO

Many physical therapists will likely be faced with patients who present with numerous psychological comorbidities, such as anxiety or depressive symptoms, poor coping skills, and maladaptive fear-avoidance beliefs surrounding physical activity. Many of these factors are associated with chronic low back pain. Chronic low back pain has notoriously poor outcomes long-term with traditional physical therapy care due to the multidimensional nature of pain. Research has indicated that addressing psychosocial factors is associated with positive outcomes. The question then, is whether the integration of strategies based in psychologically informed practice, and which address psychosocial, cognitive, and behavioral factors, would improve outcomes compared with routine PT care alone for these patients.

SUMMARY OF SEARCH

9 studies met inclusion and exclusion criteria, including 2 narrative reviews/ perspective articles, 1 case series, 5 randomized controlled trials, and 1 systematic review of randomized controlled trials

- Cognitive and Behavioral-based treatment interventions of at least 6-12 weeks in duration, as adjunct to routine care, or integrated within physical therapy care may be more effective than adjunct education or routine care for adult patients with chronic low back pain, including those post-lumbar spine surgery.
- For effective implementation of cognitive-behavioral based protocols, physiotherapists should undergo extensive training which includes didactic, experiential, and supervised training and practice with both a clinical psychologist and an experienced physiotherapist trained in psychologically informed methodologies.
- Patient-reported disability and psychosocial outcomes including pain self-efficacy appear to continue to improve over time, with effect sizes maxing out at 1-year post-treatment and the largest improvements being noted in subjective mental-health.
- Performance-based outcomes appear to be least affected by cognitive and behavioral protocols compared with routine care or education, with only small improvements noted which may have been due to natural healing.
- Patients report that the greatest strengths of these programs were the accountability, phone based treatment options, and improved self-efficacy.

CLINICAL BOTTOM LINE

The integration of cognitive and behavioral based strategies or treatment methodologies within, or as adjunct to routine physical therapy care has demonstrated greater improvements in psychosocial outcomes, subjective physical and mental health, perceived disability, and pain self-efficacy compared with adjunct education or routine care alone in adult patients with chronic low back pain. These strategies should not be passively integrated, and effective implementation should follow an evidence-based protocol and requires extensive training and experiential learning by the administering physical therapists. Research is needed to allow for generalization to other populations.

This critically appraised topic has been individually prepared as part of a course requirement and has been peer-reviewed by one other independent course instructor

The above information should fit onto the first page of your CAT

SEARCH STRATEGY

Terms used to guide the search strategy			
Patient/Client Group	**I**ntervention (or Assessment)	**C**omparison	**O**utcome(s)
Chronic health condition* Chronic health disorder* Adult* Chronic conditions* Chronic low back pain Persistent pain Chronic pain	Physical therap* Physiotherap* Cognitive behavior* CBT Psycholog* Psychologically informed Psychology informed Cognitive functional therapy CFT	Physical therap* Physio therap* Physical rehabilitation	Self management Self efficacy

Final search strategy (history) from Pubmed:

1. (("chronic low back pain" OR "chronic back pain" OR "persistent pain") OR ("chronic health condition*") OR ("chronic health disorder*") OR ("chronic condition*")) OR ("chronic disease*"))
2. ("cognitive behav*") OR (CBT)
3. ("physical therap*") OR (physiotherap*)□ (Combined Comparison)
4. ((#1) AND (#2)) AND (#3)
5. ("self management") OR ("patient self management")
6. (#4) AND (#5) □ yielded only 5 results, including CBT delivered by a psychologist
7. (#5) OR ("self efficacy")□ (Combined Outcomes)
8. (#4) AND (#7) □ yielded 15 results, improved results greatly
9. ((cognitive) **AND** (behav*)) AND ((principles) OR (strategies) OR (theories))- yielded 37,420
10. ("cognitive functional therapy") - yielded 33 results. This 'treatment' focuses on the LBP population
11. ((#1) AND (#3)) AND (#7)- yielded 200 results-□ USED to try other psychology based treatment strategies/ wording
12. (#11) AND (#9) □ yielded 15 results
13. (#9) OR (#2)
14. (#11) AND (#13) □ yielded 22 results; difference appears to be positive for more articles of relevance
15. (#11) AND (#10) □ yielded 0 results, I suspect due to patient population wording of chronic X, rather than just chronic low back pain
16. (chronic) OR ("chronic pain")
17. ((#3) AND (#7)) AND (#16)- yield 594 results as opposed to 200 when using #1
18. (#17) AND (#10)- 3 results
19. ((cognitive) **OR** (behav*)) AND ((principles) OR (strategies) OR (theories))- yielded 285,884
20. (#17) AND (#19)- yielded 100- this also looks very promising
21. (#16) OR (#1) □ (Combined Population)
22. ((#19) OR (#10)) OR (#2) □ (Combined Interventions)
23. ((((#22) AND (#21)) AND (#7)) AND (#3))□ yield 144
24. **(#23) AND (adult*)□ yielded 70 results (final search line, expanded below)**

Final Search Line: ("chronic low back pain"[All Fields] OR "chronic back pain"[All Fields] OR "persistent pain"[All Fields] OR ("chronic health condition*"[All Fields] OR "chronic health disorder*"[All Fields] OR "chronic condition*"[All Fields] OR "chronic disease*"[All Fields] OR ("chronic"[All Fields] OR "chronical"[All Fields] OR "chronically"[All Fields] OR "chronicities"[All Fields] OR "chronicity"[All Fields] OR "chronicization"[All Fields] OR "chronics"[All Fields] OR "chronic pain"[All Fields]))) AND ("self management"[All Fields] OR "patient self management"[All Fields] OR "self efficacy"[All Fields]) AND ("physical therap*"[All Fields] OR "physiotherap*"[All Fields]) AND ((("cognition"[MeSH Terms] OR "cognition"[All Fields] OR "cognitions"[All Fields] OR "cognitive"[All Fields] OR "cognitively"[All Fields] OR "cognitives"[All Fields] OR "behav*"[All Fields]) AND ("principle"[All Fields] OR "principle based ethics"[MeSH Terms] OR ("principle based"[All Fields] AND "ethics"[All Fields]) OR "principle based ethics"[All Fields] OR "principlism"[All Fields] OR "principled"[All Fields] OR "principles"[All Fields] OR ("strategie"[All Fields] OR "strategies"[All Fields] OR "strategy"[All Fields] OR "strategy s"[All Fields]) OR ("theorie"[All Fields] OR "theories"[All Fields] OR "theory"[All Fields] OR "theory s"[All Fields]))) OR ("cognitive behav*"[All Fields] OR "CBT"[All Fields]) OR "cognitive functional therap*"[All Fields]) AND "adult*"[All Fields]

Databases and Sites Searched	Number of results	Limits applied, revised number of results (if applicable)
PubMed	**70**	**Last 10 years- 61 results** **Humans only- 50 results**
Cochrane	**3**	**X**
PsycInfo	**20**	**X**
PEDro	**37**	**X**
CINAHL	**623**	**Adult- 156 results** **English, Last 10 years- 22 results**

INCLUSION and EXCLUSION CRITERIA

Inclusion Criteria
• Adults 18-65 years old with chronic low back pain or other chronic conditions • Cognitive-behavioral based interventions or strategies based in psychologically informed practice (ie. Cognitive functional therapy) • All interventions performed by a physical therapist • Can be seeking PT for their specific condition or be receiving the inclusion of health promotional and wellness- style therapies included within their PT Plan of Care • Must use a patient-reported outcome measure and must include patient self-management or self-efficacy measures • Preferred: inclusion of a specific protocol
Exclusion Criteria
• Studies not translated to English • Pediatric populations, older adult populations (> 18 years or >65 years exclusively= > 50% of population) • CBT or psychological care carried out by another provider as a standalone intervention rather than being integrated into PT care

RESULTS OF SEARCH

Summary of articles retrieved that met inclusion and exclusion criteria

Author (Year)	Risk of bias (quality score)	Level of Evidence*	Relevance	Study design
O'Sullivan et al (2018)	**JIB 6/6******	**5**	**high**	**Perspective Article- narrative review**
Ferrari et al (2016)	**JIB*** 10/10**	**4**	**high**	**Case series**
Archer et al (2016)	**PEDro** 10/11** No blinding of PT	**1b**	**Mod-** surgical specific	**RCT**
Vibe Fersum et al (2013)- original (2019)-3 year follow up	**PEDro 9/11** PT & patients not blinded; 48% attrition @ 3 yr follow-up	**2b**	**Mod**	**RCT 3 year follow up single centre, two-arm**
Hajihasani et al (2019)	**AMSTAR2**** "critically low quality"- stated it followed PRISMA guidelines but included no explicit bias assessment	**1a**	**Low-mod** addresses depression and quality of life; separates CBT & PT by different providers rather than integrating it into PT methodology	**Systematic review of RCTs;**
O'Keeffe et al (2019)	**PEDro 8/11** Lack of blinding, large attrition rate	**2b**	**Mod**	**Multicentre RCT- they did adjust to maintain power**
Sterling et al (2018)	**PEDro 9/11** Lack of blinding PTs & subjects	**1b**	**Low-mod** (acute)	**RCT**
Keefe et al (2018)	**JIB 6/6******	**5**	**High**	**Perspective article- narrative review**
Riddle et al (2019)	**PEDro 9/11** Lack of blinding of PTs & subjects	**1b**	**Mod-** surgical specific	**Multisite RCT- single blinded**

*Portney & Watkins Table 16.1 (2009)

**Shea BJ, Reeves BC, Wells G, Thuku M, Hamel C, Moran J, Moher D, Tugwell P, Welch V, Kristjansson E, Henry DA. AMSTAR 2: a critical appraisal tool for systematic reviews that include randomised or non-randomised studies of healthcare interventions, or both. BMJ. 2017 Sep 21;358:j4008.

***Munn Z, Barker T, Moola S, Tufanaru C, Stern C, McArthur A, Stephenson M, Aromataris E. Methodological quality of case series studies, JBI Evidence Synthesis, doi: 10.11124/JBISRIR-D-19-00099

**** McArthur A, Klugarova J, Yan H, Florescu S. Innovations in the systematic review of text and opinion. Int J Evid Based Healthc. 2015;13(3):188–195

Note: decisions for tools made with consideration of the following article:

Ma, L., Wang, Y., Yang, Z. *et al.* Methodological quality (risk of bias) assessment tools for primary and secondary medical studies: what are they and which is better?. *Military Med Res* **7,** 7 (2020). https://doi.org/10.1186/s40779-020-00238-8

BEST EVIDENCE

The following 2 studies were identified as the 'best' evidence and selected for critical appraisal. Note: I have included both the original research article[1] and the article for the 3-year follow-up,[2] both by Vibe Fersum et al.
Rationale for selecting these studies were:

- Both Vibe et al[1,2] and Archer et al[3] were designed as randomized controlled trials, with levels of evidence being 2b and 1b on the evidence hierarchy proposed by Portney and Watkins. Both articles were of high quality, albeit Vibe Fersum et al did report a 48% attrition rate at 3-year follow up[2] and was unable to blind physical therapists or subjects,[1] which was a common difficulty found throughout the literature. Both studies were moderate-to-highly relevant with regard to my PICO question, albeit not the most relevant of the included studies. The most relevant studies with regard to psychologically informed practice were the narrative reviews/ perspective articles by O'Sullivan et al[4] and Keefe et al,[5] and a case series by Ferrari et al;[6] however, these studies remain low on the evidence hierarchy.

- Vibe Fersum K, O'Sullivan P, Skouen JS, Smith A, Kvåle A. 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(6):916-928. doi:10.1002/j.1532-2149.2012.00252.x
  - Vibe Fersum K, Smith A, Kvåle A, Skouen JS, O'Sullivan P. Cognitive functional therapy in patients with non-specific chronic low back pain-a randomized controlled trial 3-year follow-up. *Eur J Pain*. 2019;23(8):1416-1424. doi:10.1002/ejp.1399 //
- Archer KR, Devin CJ, Vanston SW, et al. Cognitive-Behavioral-Based Physical Therapy for Patients With Chronic Pain Undergoing Lumbar Spine Surgery: A Randomized Controlled Trial. *J Pain*. 2016;17(1):76-89. doi:10.1016/j.jpain.2015.09.013

SUMMARY OF BEST EVIDENCE

(1) Description and appraisal of *"Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: a randomized controlled trial"* by Vibe Fersum, Smith, Kvale, Skouen, and O'Sullivan (2013) with long-term data provided from the follow-up paper: *"Cognitive functional therapy in patients with non-specific low-back pain- a randomized controlled trial 3-year follow up"* by by Vibe Fersum, Smith, Kvale, Skouen, and O'Sullivan (2019)

Aim/Objective of the Study/Systematic Review:

This randomized controlled trial by Vibe Fersum et al aimed to investigate the efficacy of a behavioral approach to management by utilizing a multilevel, classification-based, person-centered clinical reasoning approach in patients with non-specific chronic low-back pain (NSCLBP) through an intervention called 'classification based cognitive functional therapy' (CB-CFT), compared with traditional manual therapy and exercise therapy (MT-EX). The 2019-published follow-up paper aimed to re-assess outcomes at 3-year follow up in the previous study participants.

Study Design

This 2013 study by Vibe Fersum et al[1] is of level 2b evidence is a randomized controlled trial (RCT) with moderately high quality and low risk of bias, evidence by a score of 9/11 on the PEDro scale. The PT and participants were unable to be blinded, as the nature of the treatments did not allow for it.

Participants were recruited from private outpatient physiotherapy practices, general practitioners, and the outpatient spine clinic based out of the Haukeland University Hospital in Bergen, Norway, as well as by local newspaper ads between March 2006 and June 2008, and were aware that two active treatment arms were used and that based on current evidence, one was not considered superior. Eligible participants were 18-65 years, experiencing diagnosed NSCLBP for at least 3 months at an intensity over the last 14 days of greater than 2/10 (NRS) and located primarily between T12 and gluteal folds, with reported change with posture, movement, and activity, and an Oswestry Disability Index (ODI) of greater than 14%. An extensive list of exclusion criteria were also noted (page 918). 121 eligible participants gave consent to participate and underwent baseline testing by a blinded examiner, then were randomly allocated by an independent person not involved in the study (opaque envelope). The initial interview focused on pain and psychosocial variables, with consideration of the Orebro Musculoskeletal Pain Questionnaire (OMPQ) for reporting anxiety, depression, fear of movement, and lack of pain coping strategies. The physical exam was systematic but tailored to the individual patient, and focused on primary functional impairments reported in the interview, body control and awareness, and aggravating and easing postures. An independent assessor, blinded to allocation, study aims, and past results was used for all assessments at all time points.

Interventions were carried out at 3 separate private clinics and lasted 12 weeks, at which point patients were followed up with immediately (3 months) and again at 12 months post-intervention, then finally at 3 years post-intervention, by Vibe Fersum et al (2019).[2] If patients were deemed no longer in need of treatment before the 12 weeks was complete, they were discharges, as is consistent with routine care. Patients were allowed to seek alternative care between the end of treatment and the subsequent follow-up sessions, and this was recorded and included in study results. All data were analyzed as intent-to treat, and linear regression models were used to account for any confounding variables and covariates.

Setting

This RCT was located out of the University of Bergen in western Norway. Participants were recruited from Bergen, Norway from March 2006 to June 2008 from private outpatient physiotherapy practices, general practitioners, the outpatient spine clinic based out of the Haukeland University Hospital, and local newspaper ads. Randomization took place at the University of Bergen. Initial comprehensive interviews and full physical exams were performed at the Department of Public Health Care. Interventions took place at 3 different private clinics in the "primary care" (outpatient orthopedic) setting.

Participants

Eligible participants were 18-65 years, experiencing diagnosed NSCLBP for at least 3 months at an intensity over the last 14 days of greater than 2/10 (NRS) and located primarily between T12 and gluteal folds, with reported change with posture, movement, and activity, and an Oswestry Disability Index (ODI) of greater than 14%. An extensive list of exclusion criteria were also noted (page 918). They were recruited from a single town in Bergen, Norway between March 2006 and June 2008, from private outpatient PT clinics, general practitioners, and a University-associated spine clinic, with advertisements also placed in the local newspaper. Of 169 eligible participants, 121 met inclusion criteria and were randomized to the CB-CFT group (n=62) or the MT-EX group (n=59). Of those randomized, 16 MT-EX patients (27.1%) and 11 CB-CFT patients (17.7%) either did not start treatment or were unbailable for follow up, all of which occurred prior to the intent-to-treat analysis. The remaining 94 participants (MT-EX n=43; CB-CFT n=51) underwent analysis, which showed that except for a small significant difference in HSCL (MT-EX 1.57; CB-CFT 1.4;) and FABQ-work (MT-EX 19.3; CB-CFT12.1) scores, study participants in both arms were comparable in baseline characteristics, including age (42.9 vs 41.0), female sex (48.8% vs 52.9%), duration of pain (> 5 years: 54.8% vs 60.8%), BMI (25.2 vs 25.6), and in other outcome measure scores. There were also no differences in medication intake before or after treatments in either group. Two subjects (one from each group), were missing data at 3 month follow up, but provided 12 month data, and 5 subjects (2 CB-CFT, 3 MT-EX) were missing 12 month data but provided 3 month data; all were included in the linear mixed model to control for this, which indicated no statistical difference between completers and non-completers on baseline scores, and confirmed the absence of confounders regarding major demographic characteristics. Linear mixed models adjusted for all baseline variables that were imbalanced across groups for the 3 year follow-up, where only 55.9% of MT-EX participants and 48.4% of CB-CFT participants remained, and a modified intention-to treat analysis was performed.

Intervention Investigated

Interventions were carried out at 3 different private clinics, lasted 12 weeks, and were followed up with immediately and again at 12 months post treatment, although patients were allowed to seek alternative care between the initial follow up at 3 months and the 12 month follow-up, though this was recorded and included in study results. Prior to start, all PTs in both groups experienced a half day of training with a clinical psychologist regarding best-practice cognitive approaches to manage back pain in an attempt to standardize this for both treatment arms. Treatment was discontinued prior to 12 weeks if the therapist deemed the participant had no further need of treatment to be consistent with standard practice.

Control- Manual Therapy + Exercise (MT-EX)

This group was treated with joint mobilization or manipulation techniques applied to the spine or pelvis, consistent with best practice guidelines, and carried out at the discretion of the providing PT, who was experienced physiotherapists (avg 25.7 year's experience) specializing in orthopedic manual therapy,who had not been trained in the experimental intervention. Initial sessions were an hour and follow up sessions were 30 minutes on average. 82.5% of participants were also given a home exercise program (HEP) that included general exercise and motor control exercises, defined as "isolated contractions of deep abdominals in different functional positions" (page 919). The mean number of treatments in this group was 8.0 (range 3-17, SD 2.9).

Experimental- Classification Based-Cognitive Functional Therapy (CB-CFT)

This was a behavioral management program based on the MDCS described by O'Sullivan et al (2005)[7] provided by 3 experienced physiotherapists, who underwent an average of 106 hours of CB-CFT training via workshops, patient exams, the pilot study, and creation of the clinical manual. 4 main components, tailored to the individual's level on the classification system were carried out weekly for the initial one hour session

and 1-2 30-45 minutes follow-up sessions, and then tapered to one follow-up session every 2-3 weeks for 12 total weeks. Instructions were all written and distributed to subjects, and they were asked to complete a diary outlining/tracking their compliance with each intervention.

1) Cognitive component- based on OMPQ scores and targeted to lifestyle factors relevant to that individual, including pain neuroscience education, decreasing sensitization, and addressing maladaptive beliefs

2) Functional Movement Exercise Component- specific exercises aimed at normalizing maladaptive behaviors based on movement classification levels, with no more than 3-4 exercises given at a time

3) Targeted Functional Integration Component- based on provocative and easing postures and movements to attempt to make these postures pain free and not avoidant

4) Physical Activity Component- a program tailored to the patient's movement classification level, dosed at 3-5 x/week beginning at 20-40 minutes each, if currently sedentary, with a focus on mindful, relaxed movements

The mean number of treatments in this group was 7.7 (range 4-16, SD 2.6)

Outcome Measures

Primary Outcomes:

The *Oswestry Disability Index (ODI)* was used to measure perceived functional status, and has well established psychometric properties, good construct validity, acceptable test-retest reliability and internal consistency, and high responsiveness. Clinically meaningful changes were established as a change of 10+ points.

The *Pain Intensity Numeric Rating Scale (PINS),* synonymous with the *Numeric Pain Rating Scale (NPRS),* was used to measure pain intensity in the previous 2 weeks, and has reportedly better reliability than the visual analogue scale, particularly in patients with lower education levels. Patients rate their intensity/severity from 0-10 (worst imaginable). Clinically meaningful changes were established as a change of 1.5+ points.

Secondary Outcomes:

The *Hopkins Symptoms Checklist (HSCL-25)* was used to measure anxiety and depressive symptom severity, and consists of 25 items (10 anxiety symptoms, 15 depressive symptoms). The optimal cut-off for meaningful change in women and men is 1.75 and 1.65 points, respectively.

The *Fear Avoidance Beliefs Questionnaire (FABQ)* was used to measure fear avoidance beliefs with physical activity and at work in participants, for which it is reliable and valid.

Other Measures and Information:

Total Lumbar Spine Range of Motion for flexion and extension was measured via the two-inclinometer method, with true lumbar motion obtained by subtracting pelvic motion from gross motion, and was expressed in angular degrees.

Patient satisfaction with their treatment was assessed with a simple 1-5 rating scale ranging from satisfied (1) to dissatisfied (5), and was administered at the 3 and 12 month follow-ups.

Care seeking and subsequent treatments between the 3 month intervention period and the 12 month follow up were also assessed at 12 months via 3 questions, inquiring if the patient had received other care, what type of care it was, and how many treatment sessions they attended for that care.

Sick -leave days via the question, "how many days of work have you missed because of pain in the last 18 months" were extracted from the Orebro Screening Questionnaire delivered at intake, with potential categorical answers of 0 days, 1-7 days, or > 7 days.

Main Findings

Mean Changes in Primary and Secondary Outcomes (3 months and 1 year follow-ups):

Table 2 Outcomes (unadjusted means and SDs).

	MT-EX		CB-CFT		CB-CFT vs MT-EX[a]
	Mean	SD	Mean	SD	Mean difference (95 % CI)
Primary outcome variables					
Oswestry Disability Index Questionnaire					
Baseline	24.0	8.0	21.3	7.5	
3 months	18.5	8.1	7.6	6.7	–9.7 (–12.7 to –6.7)***
12 months	19.7	11.7	9.9	9.8	–8.2 (–12.6 to –3.8)***
Pain intensity in last week					
Baseline	5.3	1.9	4.9	2.0	
3 months	3.8	1.9	1.7	1.7	–2.1 (–2.7 to –1.4)***
12 months	3.8	2.1	2.3	2.0	–1.3 (–2.1 to –0.5)***
Secondary outcome variables					
Hopkins Symptoms Checklist					
Baseline	1.56	0.39	1.40	0.33	
3 months	1.43	0.37	1.20	0.27	–0.12 (–0.19 to –0.04)**
12 months	1.51	0.47	1.22	0.32	–0.13 (–0.22 to –0.04)**
Fear-avoidance physical					
Baseline	11.8	5.0	11.1	3.9	
3 months	10.3	6.0	6.1	5.0	–3.6 (–5.3 to –1.9)***
12 months	10.9	5.5	5.8	5.5	–4.7 (–6.5 to –3.0)***
Fear-avoidance work					
Baseline	19.1	11.1	14.1	9.6	
3 months	17.4	10.8	8.3	8.4	–5.7 (–7.8 to –3.6)***
12 months	16.6	12.2	7.7	9.0	–5.6 (–8.7 to –2.5)***
Total lumbar spine range of motion					
Baseline (degrees)	46.2	13.0	50.2	14.9	
3 months	45.6	12.7	49.7	14.0	1.9 (–2.8 to 6.7)

	MT-EX			CB-CFT			
Sick-leave days [*n* (%)]	0	1–7	>7	0	1–7	>7	
Baseline	14 (31.8)	9 (20.5)	21 (47.7)	15 (29.4)	13 (25.5)	23 (45.1)	
12 months	16 (40.0)	7 (17.5)	17 (42.5)	32 (65.3)	7 (14.3)	10 (20.4)	$z = 2.95$**

	MT-EX					CB-CFT					
Patient satisfaction[b] [*n* (%)]	1	2	3	4	5	1	2	3	4	5	
3 months[3]	28 (68.3)	6 (14.6)	5 (12.2)	0	2 (5.9)	48 (94.1)	1 (2.0)	2 (3.9)	0	0	$z = 3.21$**
12 months[3]	18 (46.2)	8 (20.5)	9 (23.1)	3 (7.7)	1 (2.5)	46 (95.8)	1 (2.1)	1 (2.1)	0	0	$z = 5.18$***

Care-seeking after intervention [*n* (SD)]	MT-EX	CB-CFT	
12 months	10.6 (13.3)	2.1 (5.4)	$z = 4.79$***

Disability: Oswestry Disability Index (0–100), low scores indicate low disability.
Pain: intensity last week (pain intensity numerical rating scale 0–10), low scores indicate low pain intensity.
Anxiety/depression: Hopkins Symptoms Checklist – 25-item checklist – low scores indicate low anxiety and depression.
Fear of movement/(re) injury: The Fear-Avoidance Beliefs – Physical (0–24), low scores indicate low fear related to physical activities.
Fear of movement/(re) injury: The Fear-Avoidance Beliefs – Work (0–42), low scores indicate low fear related to work activities.
Range of motion: Lumbar motion was obtained from a subtraction of the pelvic motion from the gross motion expressed in angular degrees of flexion and extension.
CB-CFT, classification-based cognitive functional therapy; MT-EX, manual therapy and exercise; SD, standard deviation.
[a]Negative values favour CB-CFT.
[b]Patient satisfaction: (1–5), 1 = completely satisfied, 2 = a little bit satisfied, 3 = neither satisfied or dissatisfied, 4 = a little bit dissatisfied, 5 = completely dissatisfied.
**$p < 0.01$.
***$p < 0.001$.

Original mean changes in all outcomes were statistically different, with greater reductions noted across time at 3 and 12-month follow-ups for participants in the CB-CFT vs the MT-EX groups.

Mean Differences and Effect Sizes for Secondary Outcomes (3 months, 1 year, 3 years):

TABLE 4 Outcomes and treatment group comparisons for secondary outcomes

	MT-EX	CFT	CFT versus MT-EX	
	Estimated marginal mean[a] (SE)	Estimated marginal mean[a] (SE)	Mean difference (95% CI)	Effect Size as SMD[b]
Hopkins symptoms checklist				
3m	1.44 (0.03)	1.25 (0.03)	−0.20 (−0.28 to −0.11)***	0.82
1yr	1.50 (0.04)	1.27 (0.02)	−0.23 (−0.32 to −0.14)***	0.96
3yrs	1.47 (0.04)	1.28 (0.03)	−0.18 (−0.29 to −0.08)***	0.70
Fear-avoidance beliefs: Physical				
3m	9.8 (0.6)	6.7 (0.6)	−3.1 (−5.0 to −1.3)**	0.67
1yr	10.4 (0.6)	6.2 (0.6)	−4.1 (−5.8 to −2.7)***	0.91
3yrs	10.3 (0.9)	8.0 (0.8)	−2.3 (−4.9 to 0.2)*g	0.35
Fear-avoidance beliefs: Work				
3m	15.9 (1.0)	8.8 (0.9)	−7.2 (−9.6 to −4.7)***	0.97
1yr	15.4 (1.2)	8.4 (1.2)	−7.0 (−10.8 to −3.2)***	0.76
3yrs	15.1 (1.8)	7.1 (1.3)	−8.0 (−12.4 to −3.7)***	0.67

Abbreviations: CFT, Cognitive Functional Therapy; MT, Manual Therapy; SE, Standard error.
[a]Full Intention to Treat Analysis: Using mixed model, as randomized, including those with no follow-up measures, including baseline measure as dependent variable, and HSCL/FABQ as covariate) (*N* for analysis: MT = 59 CFT = 62).
[b]SMD: Standardized Mean Difference calculated from marginal estimates from primary analysis.
***$p<0.001$
**$p<0.01$
*$p<0.05$.

The CFT group demonstrated significantly different changes compared to the MT-EX group across outcomes, with greater overall improvements in anxiety and depressive symptoms, and in physical and work-related fear-avoidance beliefs across time points. The greatest effect sizes were noted at 1 year and were large for both anxiety and depressive symptoms, tapering to medium and low at the 3-year mark for mental health symptoms and physical fear-avoidance beliefs, respectively. The largest effect size was at 3 month follow-up for work-related fear-avoidance beliefs, and was large, and decreased over time after treatment had ended.

Clinically Important Changes for Primary Outcomes (3 months, 1 year, 3 years)

TABLE 3 Frequency of clinically important change for disability and pain, and with odds ratios for between-group comparisons

	No./total (%) achieving MCIC				
	MT-EX	CFT	Unadjusted risk ratio	Adjusted risk ratio[a] (95% CI)	*p*-value[a]
Oswestry disability index (10 point improvement or more)					
3m	14/42 (33.3%)	36/50 (72.0%)	2.16 (1.36–3.42)	2.26 (1.51–3.37)	<0.001
1yr	12/39 (30.8%)	31/49 (63.3%)	2.06 (1.23–3.45)	2.05 (1.25–3.35)	0.003
3yrs	12/33 (36.4%)	19/30 (63.3%)	1.74 (1.03–2.95)	2.09 (1.26–3.46)	0.008
Pain intensity in the last week (2 point improvement or more)					
3m	19/42 (45.2%)	38/50 (76.0%)	1.68 (1.16–2.43)	1.67 (1.23–2.27)	0.002
1yr	17/40 (42.5%)	36/49 (73.5%)	1.73 (1.16–2.57)	1.49 (1.07–2.08)	0.015
3yrs	22/33 (66.7%)	20/30 (66.7%)	1.00 (0.71–1.42)	0.95 (0.67–1.33)	0.756

[a]Estimated with logistic regression with post-estimation of adjusted risk ratio; Analysis as randomized using observed data, with baseline value of ODI, pain last week HSCL and FABQ as covariates.

Larger proportions of the CFT group reached clinically important changes for disability and pain, with most improvements in disability improving initially and staying the same between 1 and 3 year follows ups, and pain intensity improving significantly initially, staying relatively equal at 1-year follow up, but decreasing slightly at 3 year follow up.

Original Authors' Conclusions

The results of this study support that a behaviorally-oriented and targeted approach to manage non-specific chronic low back pain (NPCLBP) was more effective than traditional care consisting of manual therapy with or without adjunct exercise therapy in reducing pain, disability, fear avoidance beliefs, sick leave, and improving mood at long-term follow-up (12 months).[1] CB-CFT was also more effective than MT-EX in reducing disability, fear avoidance beliefs regarding work, and depressed mood and anxiety, but not pain intensity, at 3 year follow up. "These findings support the long term benefits of an individualized

behaviorally-oriented intervention that targets pain beliefs, functional restoration, and lifestyle factors." (Vibe Fersum 2019, page 7-1423)

Critical Appraisal

Validity

This 2013 study by Vibe Fersum et al[1] is of level 2b evidence is a randomized controlled trial (RCT) with moderately high quality and low risk of bias, evidence by a score of 9/11 on the PEDro scale. Points were lost because the study physical therapists and participants were unable to be blinded, as the physical therapists for the intervention group had to undergo extensive training of an average of 106 hours, and were to adhere to the CB-CFT protocol system. Participants were aware of the two treatment arms only with the details that they were different methods and that current evidence did not show one's superiority over the other. Group allocation was random and concealed via envelope and all assessors were blinded to allocation, previous results, and study aims and hypotheses. Of the 121 participants randomized, 16 MT-EX patients (27.1%) and 11 CB-CFT patients (17.7%) either did not start treatment or were unavailable for follow up, all of which occurred prior to the intent-to-treat analysis. The remaining 94 participants (MT-EX n=43; CB-CFT n=51) underwent analysis, which determined similar baseline characteristics, and missing data from 7 total participants was controlled for with a linear mixed model which indicated no statistical difference between completers and non-completers on baseline scores, and confirmed the absence of confounders regarding major demographic characteristics. Linear mixed models were adjusted for all baseline variables that were imbalanced across groups for the 3 year follow-up and a modified intention-to treat analysis was performed at 3 years to adjust for baseline covariates. Measures of at least one key outcome were obtained from over 85% of participants, and between group comparisons are reported for all primary and secondary outcomes at each time points. Still, loss to follow-up remained the main limitation of the study, especially at 3 year follow-up where only 55.9% of MT-EX participants and 48.4% of CB-CFT participants were available.

Major strengths of this study include its long-term follow-up at both 1 and at 3 years post-treatment, its strong evidence-base of its interventions, and its provision of details of its protocol in the appendix. Another major strength of this study was its individualized approach within a standardized plan of care, and its extensive training of physiotherapists, as well as its adherence to best practice guidelines; however, patients being discharged prior to 12 weeks if deemed no longer in need of PT may have skewed results, as the dosing of this cognitive component and of the accountability inherent to the program, as well as repetition and time being required for behavior change would then be inconsistently dosed, and patients experiencing positive short-term outcomes may have improved longer-term outcomes if they had completed the entire program. The comparison of the intervention group to a manual-therapy focused intervention, even with the majority of patients receiving exercises for a home program, is also less than ideal, as some drop-outs in the MT-EX group were due to poor experiences with manual therapy in the past, and this 'standard practice' is not what current practice guidelines indicate, as they have been updated since the time of this study. Also, due to the multidimensional nature and vast differences between the CB-CFT and MT-EX interventions, mechanistic conclusions cannot be made. Finally, extensive exclusion criteria excluding any adults with a variety of common comorbidities were used, including those with a history of lower extremity or spinal surgery, rheumatologic diseases, and diagnosed mental health disorders (including depression, anxiety), though, interestingly, some of the main outcomes were those related to anxiety and depressive symptoms.

Interpretation of Results

Relative effect sizes for primary and secondary outcomes were calculated as standardized mean differences from the primary adjusted analyses and classified via Cohens criteria for both the initial time points and 3-year follow up. Even so, primary analyses still indicated superior disability outcomes and a moderate effect size (d=0.70) at 3 year follow up for the CB-CFT group, with a significantly ($p< 0.001$) greater proportion of CB-CFT participants (63%) than MT-EX participants (34%) reaching a clinically meaningful change (10 pts) on the ODI from baseline. Although overall pain rating scores were higher in the CB-CFT vs MT-EX groups, with a significantly greater proportion of participants in the CB-CFT group reaching a clinically meaningful change of 2 points or more on the NPRS, this was not repeated at 3 years. The CB-CFT group maintained superior outcomes to the MT-EX group with moderate effect sizes noted across all time periods for anxiety and depression symptoms (HSCL), and for work-related fear avoidance beliefs (FABQ-work), but overall fear avoidance beliefs did not improve further between 1 and 3 year follow ups. The loss to follow-up and requirement for adjusted statistical analyses to estimate missing data, along with the fact that patients could be discharged prior to completion of the full 12 week programs, leading to a lack of standardization between dosing of various participants and between groups leads me to use caution when noting the reported effect sizes of each outcome by the CB-CFT protocol. Overall, however, the results indicate statistically and clinically significant findings over time, with overall maximal effects being seen at 1 year post-treatment, though positive effects continue up to three years in outcomes except for pain and reduction of general fear-avoidance beliefs not related to work, which is likely not a coincidence. Generalizability to other populations with other comorbidities is limited due to extensive exclusion criteria used in this study.

Applicability of Study Results

With regard to my PICO question, the study population did consist of adults experiencing chronic low back pain, and the intervention was based strongly in psychologically informed practice. The comparison group was not exactly "routine practice", as it was primarily focused on manual therapy with some exercise. Further, there was not a formal measure for "self-efficacy", although the focus of CB-CFT was strongly focused on the acquisition of self-management strategies, which was assumed to be evidenced by improvements in the chosen outcome measures. The mechanisms are likely multifactorial behind the CB-CFT approach, given the patient-centered, body-mind-behavioral approach. Overall, this ended up being moderate to highly-relevant to the clinical question of this CAT. This is a feasible approach to treatment of patients with NSCLBP by physiotherapists, but the practicality remains low to moderate at this time due to the extensive training required by the administering physiotherapists in order to be effective. This remains one of the largest strengths of this study, and the largest weakness, as further research will need to be done to determine *how much* training and of *what structure and modality* is necessary for these outcomes. Finally, generalizability is limited due to extensive exclusion criteria, including: continuous sick leave > 4 months, any lower limb or spinal surgery, pregnancy, diagnosed psychiatric disorders, widespread constant non-specific pain with no mechanical nature, active rheumatologic disease, history of cancer or cardiac events, and no present infection, acute trauma, or other major internal medical condition. Thus, only remarkably healthy adults with no other significant comorbidities besides NSCLBP were included, and potentially confounding variables surrounding those conditions cannot be assumed.

(2) Description and appraisal of "*Cognitive-Behavioral-Based Physical Therapy for Patients With Chronic Pain Undergoing Lumbar Spine Surgery: A Randomized Controlled Trial"* by Archer KR, Devin CJ, and Vanston SW, et al (2016)

Aim/Objective of the Study/Systematic Review:

The aim of this study by Archer et al was to determine the efficacy of a cognitive-behavioral based physical therapy program versus education for improving patient-reported pain, disability, and physical performance outcomes in adult patients at risk for developing chronic pain post-lumbar spine surgery. The program, Changing Behavior through Physical Therapy (CBPT), was delivered by a physical therapist, and aimed to decrease fear of movement and increase self-efficacy.

Study Design

This study is a randomized controlled trial (RCT), conducted with 86 adult participants recruited from a single academic medical center who were undergoing laminectomy with or without arthrodesis for a lumbar degenerative condition and who met eligibility criteria, provided informed consent, and attending a pre-operative clinic screening visit and pre-operative assessment. Participants were randomly allocated post-assessment at their routine 6-week post-op visit into one of two groups to participate in, in addition to routine care, both of which consisted of 6 weeks of 30-minute telephone-sessions with the study-PT. The groups included: the 1) *Changing Behavior through Physical Therapy (CBPT)* group, who received a protocol based in cognitive-behavioral based strategies, or 2) those undergoing an education program, who received general information about post-op rehabilitation.

Investigators, participating surgeons, research personnel who conducted the assessments, and patients/participants were all blinded to this group assignment, with patients/participants being told they would be assigned to one of two different educational treatments and asked to not discuss details of the study with any of their providers or research personnel. The study physical therapist could not be blinded to the treatment, since they had to carry it out, but was blinded to the aims and hypothesis of the study. Patients were overseen by study-assessors, who were blinded to group allocation, for completion of questionnaires and performance measures, including measures of psychosocial characteristics (fear of movement, pain self-efficacy), pain, disability, general health outcomes, use of other healthcare resources, lower extremity strength, functional mobility, and gait speed. Psychosocial measures included pain self-efficacy by the Pain Self-Efficacy Questionnaire (PESQ) and Fear of Movement by the Tampa Scale for Kinesiophobia (TSK). Primary outcomes included pain and disability, measured by the Brief Pain Inventory (BPI) and Oswestry Disability Index (ODI), respectively. Secondary outcomes included general health status via the 12-Item Short Form Health Survey (SF-12) and physical performance via the 5-Time Chair Stand (5xCS), Timed Up and Go (TUG), and the 10-meter Walk (10mW). Assessments of primary and secondary outcomes were performed at 3 time points: 1) pre-treatment, 2) post-treatment (3 months post-op), and 3) at 3-month follow up post-treatment (6 months post-op). Mean scores and standard deviations for each group were calculated at each time point, and mean change scores and 95% confidence intervals (95%CI) were calculated post treatment and at 3-month follow up within and between groups with a significance level of $p<0.05$. All analyses were intent-to treat. Multivariable linear regressions to control for a-priori variables and potential interactions between treatment, age, and surgery-type, and to compare preoperative baseline variables between groups to ensure similarity. Participants were reimbursed $25 for completing baseline assessments and $100 for each in person follow up assessment.

Setting

This study was performed with participants recruited from a single academic medical center, Vanderbilt University Medical Center, between March 2012 and April 2013. Treatments were provided at Vanderbilt Orthopaedic Institute, a hospital-based outpatient physical therapy clinic that is a part of Vanderbilt University Medical Center. These locations are urban, positioned in Nashville, Tennessee in the United States.

Participants

Participants were recruited from a single academic medical center between March 2012 and April 2013 where they were scheduled to undergo laminectomy with or without arthrodesis for a lumbar degenerative condition, including spinal stenosis, spondylosis with or without myelopathy, and degenerative spondylolisthesis. Researchers approached all patients meeting these criteria (n=499) pre-operatively to determine eligibility, including being 21 years or older, English speaking, had back and/or lower extremity (LE) pain for greater than 6 months, had no history of neurological movement disorder, and had no presence of psychotic disease in their medical record. Of 249 eligible participants, 132 consented to participate in the study and completed the Tampa Scale for Kinesiophobia (TSK) to screen for fear of movement beliefs. 102 participants scored 39 or greater on the TSK and were enrolled in the study and completed a battery of validated questionnaires to further assess pain, disability, general health, pain self-efficacy, depression, and physical function. At the routine 6-week post-op visit, 16 enrolled patients withdrew prior to randomization, and the 86 remaining participants received standard care, which could include removal of restrictions (e.g. driving, lifting) and/or referral to traditional physical therapy, completed a pre-treatment assessment, and were randomized immediately after to the CBPT (nC=43) or Education (nE=43) groups using computer-generated random assignment (REDCap) in a 1:1 ratio for blocks of assignments, and were frequency-matched to type of surgery (fusion vs no fusion) and screening score on the TSK (39-45, 46-49, 50-68) to help control for the impact of surgical type and fear of movement on patient-reported outcomes.

Student t- tests or Chi-squared tests were performed using group means and corresponding confidence intervals from baseline and preoperative demographic, clinical, and psychological characteristics and outcome measure scores to confirm balance between groups and were assessed with regard to the characteristics of patients who were vs were not lost to follow up. No significant differences were noted between the CBT and Education groups regarding demographic, clinical, or psychological factors or outcome measure scores, including average age (56.9 vs 58.4), female sex (nC=25 vs nE=23), fusion (nC=29 vs nE=31), average duration of pain prior to surgery (25.1 vs 23.1), or pre-operative fear of movement (TSK C43.5 vs E43.2). Across groups, 91% total participants received traditional PT during treatment and 47% total received PT between end of treatment and 3-month follow-up, with no significant difference noted. Average number of sessions during the treatment 8.6 (CBPT; SD 4.9) vs 8.0 (Education; SD 4.2) sessions, and average number of sessions between end of treatment and 3 month follow-up 6.5 (CBPT; SD 7.5) vs 6.6 (Education; SD 10.3) sessions with no significant difference across groups. The dropout rates for the CBPT and Education programs was 7% and 5%, respectively, with the follow-up rate for patient-reported and performance-based outcomes post treatment 98% and 95%, respectively, and at 3 month follow up 93% and 85%, respectively, and no significant difference in any measured variables between patients with and without complete data at follow up.

Intervention Investigated

One outpatient physical therapist completed formal training for both the CBPT and Education programs which included 8 hours of didactic work, 16 hours of experiential sessions with a clinical psychologist, 8 hours of experiential training with the PT that designed the programs. Competency was determined by a written test and skills test grade > 85% and a practice protocol with review of video and audiotaped sessions. All sessions were recorded and 30% were randomly chosen to be reviewed by the clinical psychologist and PT that provided the original training to determine adherence to the protocols via a checklist. The interventions below were completed in conjunction with other routine, post-op care, including routine physical therapy.

Control

The Education group was chosen with the aim of controlling for the time and attention of the physical therapist and to take into account normal healing that occurs from 6 weeks to 3 months post-op. The first session was an hour long and was in person, where participants were given a manual to follow along with for the remaining sessions, which were 30 minutes and delivered via telephone. The program focused on post-operative recovery, addressing the benefits of PT, proper biomechanics, importance of daily exercise, and promotion of healing, and information was provided on stress-reduction, sleep hygiene, communication with health care providers, prevention of future injury, and managing energy.

Experimental

Changing Behavior through Physical Therapy (CBPT) is a program integrating cognitive behavioral strategies within the physical therapy plan of care and is designed to be delivered by physical therapists. It was designed with the goals of decreasing pain and disability through decreasing fear of movement and increasing self-efficacy in participants. Patients participated in weekly sessions with their study-PT for 6 weeks. The first

session was an hour long and was in person, where participants were given a manual to follow along with for the remaining sessions, which were 30 minutes and delivered via telephone. The program focused on evidence-based and empirically supported behavioral self-management through various cognitive and behavioral strategies, with new strategies introduced each session and including: problem solving, cognitive restructuring, and relaxation training in order to help patients identify enjoyable activities, address dysfunctional pain beliefs, balance rest and activity, and help manage setbacks. The 3 main components of the program include: 1) education regarding the relationship between the mind, body, and activity, 2) a graded activity plan, and 3) weekly activity goals, rated by patients from 0-10 regarding their confidence on completing the goal (8 or greater considered realistic).

Outcome Measures

Prior to surgery, while in the hospital, eligible participants completed the *Tampa Scale for Kinesiophobia (TSK)* to determine fear of movement*,* and participants meeting the cutoff of 39, indicating a high probability of dysfunctional pain beliefs and poor post-surgical outcomes, maintained eligibility and completed the pre-op intake assessment to determine demographic and general health information, including baseline depressive symptoms via the *9-item Patient Health Questionnaire (PHQ-9).* Patients also completed all psychosocial and performance-based assessments (except repeating the PHQ-9) post-operatively, pre-treatment, immediately post-treatment, and at 3-month follow-up.

Psychosocial Outcome Measures:

The TSK is a 17-item test which has demonstrated good internal consistency and test-retest reliability, and an MCID set at 4 points for this population. Items were score on a 4-point Likert scale from 'strongly agree' to 'strongly disagree', with possible total scores ranging 17-68.

The *PHQ-9* (Sn 0.75; Sp 0.90) uses a 4-point Likert Scale from 'not at all' to 'almost every day' and with total scores ranging from 0-27, with higher scores indicating more severe depressive symptoms.

The Pain Self-Efficacy Questionnaire (PSEQ) was used to assess the strength of a participant's belief in their own ability to accomplish various activities despite pain, and has demonstrated excellent internal consistency, good test-retest reliability, and construct validity with correlations of depression, anxiety, coping strategies, pain ratings, and work-related task ability. The PSEQ has 10 items scored on a 7-point Likert Scale from 'not at all confident' to 'completely confident', with total scores ranging from 0-60 and scores greater than 40 indicating high self-efficacy.

Primary Outcome Measures: pain intensity, pain interference, & disability

The Brief Pain Inventory (BPI) was used to measure pain intensity and interference within daily life, and has demonstrated good reliability and validity in both surgical patients and in patients with chronic low back pain. The pain intensity subscale includes 4 items ranked from 0 (no pain at all) to 10 (as bad as you can imagine), and the pain interference scale includes 7 items ranked from 0 (no interference) to 10 (completely interferes). The MCID used for back and leg pain in participants post-surgery were 1.2 and 1.6 respectively, and the MCID for pain interference 1.6.

The Oswestry Disability Index (ODI) is a 10-point scale that has demonstrated excellent test-retest reliability, adequate internal consistency, and validity in measuring low back pain disability with regard 10 aspects of daily living. Each item is rated from 0 (high functioning) to 5 (low functioning), and totals are converted into percentages of disability, with categories of disability including minimal (0-20%), moderate (21-40%), severe (41-60%), crippled (61-80%) and bed bound or exaggerated (81-100%).The MCID used for patients post-op was 10 points (range: 10-12.8 pts).

Secondary Outcome Measures: general physical and mental health & physical performance

The *physical (PCS) and mental (MCS) component scales* of the *12-Item Short-Form Health Survey (SF-12)* were used for general physical and mental health measures, and have shown to demonstrate responsiveness, good test-retest reliability, good internal consistency, and validity in various populations. Each component scale measures 4 subdomains, with total sub-scores from 0-100 and higher scores representing better overall health status, and with an MCID for both of 4.9 post-op.

For physical performance, a variety of performance based measures were used, including the *5-Chair Stand (5xCS)* test to assess lower extremity strength (MCID -2.3 sec), the *Timed Up and Go (TUG)* test to assess functional mobility (MCID -1.2 to -1.4 sec), and the *10-meter Walk (10mW)* test to assess gait speed (MCID +0.10 to 0.16 m/s). All three of these tests have demonstrated good to excellent test-retest reliability, validity, and responsiveness.

Main Findings

Outcomes at 3 month follow-up	**MCIDs**	**Standardized Mean Effect Size** (Cohen's d)	**Magnitude of Effect Size**
Back & Leg Pain (BPI)	Back -1.2 Leg -1.6	0.62	Medium
Pain Interference (BPI)	-1.6	0.72	Large-medium
Disability (ODI)	-10	0.79	Large
General Physical Health (SF-12 PCS)	+4.9	0.75	Large-medium
General Mental Health (SF-12 MCS)	+4.9	1.35	Very Large
Physical Performance (5xCS, TUG, 10mW)	5xCS -2.3 Tug -1.4 10mW -0.16	0.41 to 0.49	Low-Medium
Fear of Movement (TSK)	-4	0.59	Medium
Pain Self-Efficacy (PSEQ)	>40, no MCID	0.85	Large

Standardized mean effect size differences between programs were assessed using Cohen's *d.* Separate multivariable linear regression models were then conducted for outcomes at 3 month follow-up controlling for a-priori variables.

Statistically Significant Changes ($p<0.05$)

Clinically Significant Change (MCID)

Psychosocial Outcomes: ***Fear of Movement, Dysfunctional Pain Beliefs & Pain Self-Efficacy***

Psychosocial Outcomes		**Pre-treatment**		**Post-treatment**		**3-month follow-up**	
		CBPT	***Education***	***CBPT***	***Education***	***CBPT***	***Education***
TSK Score MCID -4 pts	***Mean Score***	40.2 (SD 7.3)	38.7 (SD 6.5)	37.5 (SD 7.0)	36.3 (SD 7.2)	33.9 (SD 8.1)	36.2 (SD 8.4)
	Mean change from pre-treatment			-2.6 (SD -4 to -1.2)	-2.2 (SD -3.9 to -0.48)	-5.9 (SD -7.7 to -4.2)	-2.3 (SD -4.4 to -0.16)
	Mean between group difference			-0.4 (SD -2.6 to 1.8) p= 0.70		-3.6 (SD -6.3 to -0.93) p=0.009	
PSEQ Score Ideal >40	***Mean Score***	36.0 (SD 16.8)	41.5 (SD 15.2)	42.7 (SD 17.3)	44.1 (SD 16.5)	48.8 (SD 14.3)	43.5 (SD 16.3)
	Mean change from pre-treatment			6.6 (SD 3.8 to 9.3)	2.6 (SD -1.4 to 6.6)	11.9 (SD 8.7 to 15.1)	1.9 (SD -2.2 to 6)
	Mean between group difference			3.9 (-0.86 to 8.7) p=0.11		10.0 (SD 4.8 to 15.1) p<0.001	

Primary Outcomes: ***Pain Intensity, Pain Interference, & Disability***

Primary Outcomes			**Pre-treatment**		**Post-treatment**		**3 month follow-up**	
			CBPT	***Education***	***CBPT***	***Education***	***CBPT***	***Education***
BPI: Pain Intensity **Back** MCID -1.2 **Leg** MCID -1.6	***BACK***	***Mean Score***	3.0 (SD 2.2)	2.8 (SD 2.0)	2.9 (SD 2.6)	2.5 (SD 2.0)	1.9 (SD 2.0)	2.5 (SD 2.4)
		Mean change from pre-treatment (95% CI)			-0.08 (-0.65 to 0.49)	-0.3 (-0.68 to 0.08)	-1.1 (-1.5 to -0.74)	-0.26 (-0.76 to 0.23)
		Mean between group difference (95% CI)			0.22 (-0.46 to 0.9) p=0.52		-0.88 (-1.5 to -0.25) p= 0.007	
		Multivariable linear regression controlled accounting for 64% variance (95%CI)					-0.85 (-1.4 to -0.25) p=0006	
	LEG	***Mean Score***	2.5 (SD 2.6)	2.2 (SD 2.1)	2.1 (SD 2.2)	2.3 (SD 2.2)	1.3 (SD 2.1)	2.1 (SD 2.8
		Mean change from pre-treatment			-0.48 (-0.91 to -0.06)	0.05 (-0.34 to 0.44)	-1.3 (-1.9 to -0.72)	-0.1 (-0.74 to 0.55)
		Mean between group difference			-0.53 (-1.1 to 0.04) p=0.07		-1.2 (-2.1 to -0.34) p= 0.007	
		Multivariable linear regression controlled accounting for 44% variance (95%CI)					-1.1 (-1.9 to -0.27) p=0.005	
BPI: Pain Interference MCID -1.6		***Mean Score***	3.8 (SD 3.0)	3.1 (SD 2.6)	3.2 (SD 3.2)	2.8 (SD 2.9)	2.1 (SD 2.5)	2.8 (SD 2.8)
		Mean change from pre-treatment (95% CI)			-0.65 (-1.16 to -0.14)	-0.3 (-0.84 to 0.24)	-1.7 (-2.4 to -1.1)	-0.26 (-0.89 to 0.38)
		Mean between group difference			-0.35 (-1.1 to 0.38) p=0.34		-1.5 (-2.4 to -0.57) p= 0.002	
		Multivariable linear regression controlled accounting for 49% variance (95%CI)					-1.3 (-2.1 to -0.40) p=0.005	
ODI MCID -10		***Mean Score***	38.8 (SD 17.3)	34.0 (SD 16.7)	28.6 (SD 17.6)	27.9 (SD 19.4)	21.1 (SD 16.7)	26.5 (SD 20.5)
		Mean change from pre-treatment			-9.8 (-12.1 to -7.5)	-6.1 (-10.5 to -1.7)	-17.3 (-20.3 to -14.4)	-7.5 (-12.1 to -2.9)
		Mean between group difference			-3.7 (-8.6 to 1.2) p=0.14		-9.8 (-15.3 to -4.4) p<0.001	
		Multivariable linear regression controlled accounting for 59% variance (95%CI)					-9.4 (-14.9 to -4.0) p= 0.001	

Secondary Outcomes: ***General Physical and Mental Health & Physical Performance***

Secondary Outcomes			Pre-treatment		Post-treatment		3-month follow-up	
			CBPT	*Education*	*CBPT*	*Education*	*CBPT*	*Education*
SF-12 PCS & MCS MCID 4.9	*PHYSICAL*	***Mean Score***	29.8 (SD 0.5)	32.0 (SD 9.8)	36.5 (SD 10.8)	36.9 (SD 11.6)	43.0 (SD 10.9)	38.3 (SD 11.4)
		Mean change from pre-treatment			6.6 (4.2 to 8.9)	4.8 (2.1 to 7.6)	13.4 (10.4 to 16.4)	6.3 (3.3 to -9.3)
		Mean between group difference			1.7 (-1.9 to 5.3) p=0.34		7.1 (2.9 to 11.3) p= 0.001	
		Multivariable linear regression- controlled accounting for 59% variance (95%CI)					6.4 (2.3 to 10.6) p= 0.003	
	MENTAL	***Mean Score***	43.6 (SD 11.9)	53.9 (SD 10.1)	50.9 (SD 10.0)	53.7 (SD 12.2)	56.6 (SD 8.1)	53.4 (SD 12.0)
		Mean change from pre-treatment			7.4 (5.3 to 9.5)	-0.2 (-3.0 to 2.6)	12.5 (9.6 to 15.4)	-0.5 (-3.7 to 2.7)
		Mean between group difference			7.6 (4.2 to 11.1) p<0.001		13.0 (8.7 to 17.2) p< 0.001	
		Multivariable linear regression- controlled accounting for 35% variance (95%CI)					8.6 (4.5 to 12.7) p<0.001	
5 Chair Stand (sec) MCID = -2.3 sec		***Mean Score***	24.7 (SD 18.9)	20.3 (SD 15.4)	22.6 (SD 18.4)	21.0 (SD 16.2)	13.6 (SD 5.1)	16.7 (SD 11.7)
		Mean change from pre-treatment			-2.7 (-5.4 to 0.01)	0.4 (-3.2 to 4)	-11.6 (-17.3 to -5.9)	-4.6 (-8.2 to -0.91)
		Mean between group difference			-3.1 (-7.5 to 1.4) p=0.17		-7.0 (-13.7 to -0.37) p=0.04	
		Multivariable linear regression controlled accounting for 52% variance (95%CI)					-4.3 (-7.7 to -0.82) p=0.02	
TUG (sec) MCID -1.4 sec		***Mean Score***	11.5 (SD 5.0)	11.6 (SD 5.9)	10.0 (SD 2.7)	12.1 (SD 6.4)	9.6 (SD 4.2)	10.9 (SD 6.2)
		Mean change from pre-treatment			-1.7 (-2.8 to -0.55)	0.33 (-1.2 to 1.9)	-2.1 (-3.3 to -0.9)	-0.54 (-1.9 to 0.78)
		Mean between group difference			-2.0 (-3.9 to -0.11) p=0.04		-1.6 (-3.3 to 0.19) p= 0.08	
		Multivariable linear regression controlled accounting for 62% variance					-1.8 (-3.2 to -0.16) p=0.02	
10 Meter Walk (m/s) MCID 0.16 m/s		***Mean Score***	1.02 (SD 0.26)	1.07 (SD 0.29)	1.19 (SD 0.20)	1.08 (SD 0.30)	1.21 (SD 0.22)	1.17 (SD 0.26)
		Mean change from pre-treatment			0.10 (0.05 to 0.15)	0.01 (-0.08 to 0.09)	0.20 (1.3 to 0.26)	0.10 (0.004 to 0.19)
		Mean between group difference			0.09 (-0.01 to 0.19) p=0.07		0.10 (-0.14 to 0.21) p=0.08	
		Multivariable linear regression controlled accounting for 33% variance (95%CI)					0.09 (-0.008 to 0.18) p=0.07	

Original Authors' Conclusions

Screening patients scheduled for surgery for degenerative conditions pre-operatively for fear of movement using a validated scale, and enrolling these patients in a targeted cognitive-behavioral based program, such as *Changing Behavior through Physical Therapy (CBPT),* results in statistically significant and clinically meaningful improvements in pain, disability, general health, and physical performance compared with standard treatment or education alone. This program is effective when delivered by physical therapists, can be delivered over the phone, and could potentially be adapted into a recognized evidence-based program.

Critical Appraisal

Validity

This RCT study by Archer et al presents level 1b evidence and as an overall low risk of bias based on the PEDro scale, where it scored 10/11 possible points. The point lost was due to the inability of the physical therapist to be blinded, as they needed to complete significant training in both protocols to be able to effectively carry them out. The PT was, however, blinded to the aims and hypothesis of the study. Additionally, as all treatments were delivered by this single PT at a single-center, and because all patients were screened for high fear of movement as part of the inclusion criteria, the generalizability of these results to other populations is limited. Further, these results only extend to 6 months post-op and 3 months post-intervention of CBPT, so longer-term outcomes cannot be assumed.

All analyses were intent-to-treat and separate multivariable linear regression models were conducted for the 3-month follow-up outcomes controlling for a-priori variables including pre-treatment score of the outcome of interest, age, education, comorbidities, and number of PT visits. To ensure appropriate power of the study, authors had based sample size on pilot data simulations, and found that with at least 80 participants, they would be able to detect minimum clinically important differences (MCIDs) in participants with an 80% power and while controlling for Type I error rate at 5% in their chosen outcomes. Even so, the study is limited by a loss to follow up at 3 months post-treatment, as the sample size was underpowered at this point to detect smaller between-group difference in performance-based tests. Still, 85% of participants completed each outcome measure and statistical analyses indicated that the characteristics of patients lost to follow up were compared to those who completed the follow up assessments, with missing items calculated at less than 5% for the completed psychosocial and outcome scales.

Finally, a major strength of this study was the evaluation by participants. Participants rated the main strength of both programs as the telephone-delivery format, with CBPT participants noting that the sessions increased accountability, self-efficacy, and communication with health care providers. Participant-noted weaknesses were that the programs were too short and started too late post-surgery, and they did not provide enough information regarding healing processes and restrictions or guidelines for recovery.

Interpretation of Results

Overall, these study results indicate that psychologically-informed practice in the form of a targeted cognitive-behavioral based rehabilitation program as adjunct to routine care is effective in improving psychosocial, general health, and clinical outcomes in adult patients with chronic low back pain and high fear of movement beliefs post spinal surgery, and is more effective than an adjunct educational program. The education group experienced clinically meaningful changes via MCID, albeit at lower magnitudes for improving the 5 time Chair Stand and for improved subjective physical health via the SF-12 PCS at 3 months. Other MCID levels may have been met if authors had chosen the lower end of the suggested ranges, rather than the upper, but their choice to be more conservative allowed for the results and effect sizes to be much more meaningful when considering clinical relevance.

Based upon standardized mean effect sizes, this type of program resulted in a small improvement in physical performance, medium reductions in subjective pain intensity and fear of movement, medium to large improvements in subjective pain interference and physical health ratings, large improvements in disability ratings and pain self-efficacy, and very large improvements in subjective mental health ratings at 3 months post-treatment (6 months post-op). However, it is interesting that much of these improvements only met clinically meaningful or statistically significant changes at 3 month follow up *post- treatment,* and were not present immediately following intervention. Subjective physical and mental health ratings via the SF-12, and performance on the 5 time Chair Stand and the TUG were the only outcomes which met MCID levels immediately post-treatment, all of which only in the CBPT group, though disability via the ODI in the CBPT group was close (-9.8 vs MCID -10); however, even in these clinically meaningful improvements, only subjective mental health and performance on the TUG demonstrated statistically significant differences between groups. This begs the question as to whether these improvements were due to additional natural healing that occurs post-op during this time or to participants in the CBPT group actively practicing the cognitive-behavioral strategies they learned. Additionally, was it the cognitive-behavioral strategies or the inclusion of the graded activity list and structured walking program that the CBPT group received that resulted in improved outcomes, or was it the psychologically-informed method through which the program was delivered which made the difference, since many of the additional improvements at 3-month follow-up were psychosocially-focused?

These results nonetheless indicate that a cognitive-behavioral based approach to post-op care can make significant and clinically meaningful differences in outcomes in patients with conditions with notoriously poor prognoses long-term, and should be considered for further research with longer-term program protocols and follow-ups, and adoption into clinical practice pending feasibility. To be carried out effectively, however, the treating physical therapist should undergo extensive training with experiential learning with both psychologically-informed physical therapists and clinical psychologists.

Applicability of Study Results

This study was moderate-to-highly relevant and applicable to my PICO question. The major limitations were that it was in a post-op specific population who were screened and determined to have high fear of movement beliefs, and that it did not compare strictly to routine physical therapy, but instead compared to another educational treatment. Since both groups received physical therapy at comparable rates, however, these results remain relevant. The study findings indicate that cognitive-behavioral based physical therapy in the form of a structured program, such as CBPT, results in lower pain intensity and interference, lower disability, lower fear of movement beliefs, and higher physical and mental health and pain self-efficacy by validated patient reported measures, and better lower extremity strength and gait speed by validated performance-based measures at 6 months post-surgery for degenerative spinal conditions.

A major consideration regarding feasibility is that in this study, one physical therapist administered all treatments after undergoing extensive training. For this to be repeated, the PT or clinic in question would need to be able to afford to mimic this training for their clinicians, and would also need to pay for the manuals which are distributed to patients. Additionally, the clinician may not be reimbursed for the CBPT sessions, if delivered by telephone rather than within clinic as strategies implemented within the session itself. Finally, all patients were well-reimbursed for their time, so ensuring follow up and adherence without monetary incentive may skew outcomes. This program would likely be best repeated and most feasible as an evidence-based community program for patients post-op for degenerative musculoskeletal conditions, once more research on more generalized conditions and on long-term outcomes is performed, and once a standardized protocol and training manual is available for clinicians.

SYNTHESIS AND CLINICAL IMPLICATIONS

Overall, both studies in this CAT indicate that psychologically-informed practice, specifically, the integration of cognitive and behavioral focused strategies, as a methodology of delivery or as adjunct to routine physical therapy care, delivered by physical therapists, is effective in improving psychosocial and clinical outcomes related to pain interference, disability, and general mental and physical health, improving self-efficacy and reducing dysfunctional fear avoidance beliefs with moderate to large effect sizes.

Although both studies consisted of populations similar to the clinical question, as they were adults with chronic low back pain, the study by Vibe Fersum et al consisted of a population closer the clinical question, whereas the participants of the study by Archer et al consisted of a post-surgical population. Unfortunately, the Vibe Fersum et al population had a wide range of exclusion criteria which excluded participants with very common comorbidities, such as osteoarthritis and clinically diagnosed mental health disorders, regardless of the condition, which limited the generalizability of the study. Interestingly, both studies excluded patients with diagnosed mental health disorders, yet both also used outcomes measuring depressive and/or anxiety-related symptoms as primary or secondary outcomes. Vibe Fersum also excluded patients with a history of spinal surgery, whereas Archer et al focused exclusively on this population. Both studies also focused on populations with exaggerated fear avoidance beliefs, with large effect sizes and statistically and clinically significant changes noted in the Archer et al article via the TSK, but only no to limited changes in the Vibe Fersum article by the FABQ at all time points. Only the Archer et al article used explicit measures of self-efficacy via the PSEQ, with significant differences between groups noted at follow-up, but not immediately post-treatment. Both studies, however, noted that their program was aimed at improving self-efficacy by focusing on self-management strategies, and both studies indicated that improvements in their chosen patient-reported outcome measures were validated and associated with improvements in measures of self-efficacy.

Archer et al noted that the most clinically and statistically significant results in the intervention groups especially actually occurred 3 months post-treatment (6 months post-op), and were not present immediately post-treatment, hypothesizing that this may be due to continued practice of learned cognitive and behavioral strategies leading to more significant changes over time. Archer et al provided intervention sessions as adjunct to routine care, delivered via telephone over an overall shorter time period, half as long as the CB-CFT protocol used by Vibe Fersum et al, whereas the CB-CFT program was delivered as an entirely different methodology to PT care, which was delivered in person only. The largest effect sizes in both studies were noted at the first follow-ups post-treatment (3 months and 12 months post-treatment), and were noted primarily in psychosocial related outcomes, including PSEQ, depressive and anxiety or mental-health related symptoms, pain interference in daily life, and in self-rated disability. These cognitive and behavioral-type outcomes seemed to improve over time between treatment and follow-up, whereas in both studies, fear-avoidance beliefs and physical performance seemed to decline once treatment was no longer taking place and pain intensity was only minimally affected. Across studies, the most insignificant outcomes were physical function related.

Both studies demonstrated high levels and moderate to high quality of evidence and were moderately-to-highly relevant to the PICO question. Overall, this research indicates that cognitive and behavioral-based interventions are more effective than routine physical therapy or adjunct education alone for improving psychosocial outcomes in and improving self-efficacy in patients with chronic low back pain, if delivered by extensively trained physiotherapists in the established protocols, such as those provided in the above studies.

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