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EFETIVIDADE DA TERAPIA COGNITIVO-FUNCIONAL NAS DORES LOMBARES CRÔNICAS:

REVISÃO SISTEMÁTICA DA LITERATURA

RIO DE JANEIRO
2024

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Tese apresentada ao Programa de Pós-graduação em Ciências da Reabilitação, do Centro Universitário Augusto Motta, como parte dos requisitos para obtenção do título de **Doutor** em Ciências da Reabilitação.

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Orientador: Ney Armando de Mello Meziat Filho

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TERAPIA COGNITIVO-FUNCIONAL:

REVISÃO SISTEMÁTICA DA LITERATURA

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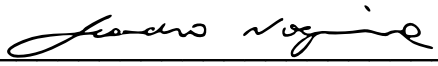

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“O sofrimento humano só é intolerável quando ninguém cuida”
Cicely Sounders.

Resumo

Introdução: A dor lombar é a condição de saúde mais prevalente e a condição que mais provoca incapacidade e com maior impacto socioeconômico em todo o mundo nas últimas três décadas. Em 90% dos casos, a dor lombar não está associada a causas anatômicas ou de doenças específicas, e por isso é classificada como inespecífica. Sabe-se que, fatores biopsicossociais, como aspectos emocionais, aspectos cognitivos, aspectos sociais, aspectos comportamentais e o estilo de vida estão relacionados, para cada indivíduo em diferentes proporções, no surgimento e persistência das dores. A Terapia Cognitivo Funcional (TCF) é uma abordagem que foca no manejo da dor e suas consequências. A TCF é uma intervenção comportamental que consiste em três componentes principais: um componente cognitivo (geralmente chamado de dar sentido à dor); exposição com controle; e mudança de estilo de vida. **Objetivo:** Investigar a efetividade da TCF para melhorar dor, incapacidade ou função específica em indivíduos com dor lombar crônica. **Metodologia:** Revisão sistemática de ensaios clínicos randomizados. A busca sistemática foi conduzida nas principais bases de dados PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro and Cochrane Central Register of Controlled Trials (CENTRAL). Foram incluídos estudos que investigaram a efetividade da TCF para dor lombar crônica comparada a intervenções ativas, intervenções passivas, intervenções mínimas ou sem intervenção. A ferramenta PEDro (Physiotherapy Evidence Database) foi utilizada para análise do risco de viés de cada estudo incluído e a escala GRADE (Grading, Assessment, Development and Evaluations) foi utilizada para interpretar o nível de certeza da evidência da meta-análise. **Resultados:** Foram incluídos oito ensaios clínicos envolvendo 1.322 participantes. Um nível de certeza moderado das evidências sugere que a TCF é superior às intervenções ativas para incapacidade em curto prazo (MD -8,58, IC 95% -10,67 a -6,49), baixo nível de certeza de evidência de que é superior em prazo moderado (MD -8,28, IC 95% -13,04 a -3,52) e alto nível de certeza de evidência que é ligeiramente superior em longo prazo (MD -4,00, IC 95% -7,42 a -0,58). Para dor, um nível de certeza de evidência muito baixo indica que a TCF é superior em curto prazo (MD -13,93, IC 95% -21,76 a -6,10) e uma baixa certeza que é superior em prazo moderado (MD -13,25, -19,44 a -7,05), e uma certeza moderada que TCF tem um pequeno efeito em longo prazo (MD -6,55, IC 95% -13,30 a 0,20). Baixo nível de certeza de evidências que a TCF é superior à intervenção mínima para incapacidade em curto prazo (MD -18,40, IC 95% -23,74 a -13,07). **Conclusão:** Em comparação com intervenções ativas, incluindo exercício, a TCF provavelmente reduz a incapacidade a curto prazo, pode reduzir a incapacidade a médio prazo e reduz ligeiramente a incapacidade a longo prazo. Para a intensidade da dor, a evidência é muito incerta sobre o efeito a curto prazo, mas a TCF pode reduzir a intensidade da dor a prazo moderado e provavelmente tem um pequeno efeito na redução da dor a longo prazo. Em comparação com intervenções mínimas, a TCF pode resultar numa grande redução da incapacidade e da intensidade da dor sustentada em longo prazo. As evidências atuais apoiam o uso da TCF em pacientes com dor lombar crônica.

Palavras-chave: Revisão sistemática; Dor lombar; Manejo da dor; Movimento. (http://decs.bvs.br/).

Abstract

Introduction: Low back pain is the most prevalent and the health condition that causes the most disability and has the greatest socioeconomic impact worldwide in the last three decades. In 90% of cases, low back pain is not associated with anatomical causes or specific diseases and is therefore classified as non-specific. It is known that biopsychosocial factors, such as emotional aspects, cognitive aspects, social aspects, behavioral aspects and lifestyle are related, for each individual in different proportions, to the emergence and persistence of pain. Functional Cognitive Therapy (FCT) is an approach that focuses on managing pain and its consequences. It is a behavioral intervention that consists of three main components: a cognitive component (generally called making sense of pain); controlled exposure; and lifestyle change. **Objective:** To investigate the effectiveness of Cognitive-Functional Therapy to improve pain, disability or specific function in individuals with chronic low back pain. **Methodology:** Systematic review of randomized clinical trials. The systematic search was conducted in the main databases PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro and Cochrane Central Register of Controlled Trials (CENTRAL), and were included studies that investigated the effectiveness of Cognitive-Functional Therapy for chronic low back pain compared to active interventions, passive interventions, minimal interventions or no intervention. The PEDro tool (Physiotherapy Evidence Database) was used to analyze the risk of bias of each included study and the GRADE (Grading, Assessment, Development and Evaluations) scale was used to interpret the level of certainty of the meta-analysis evidence. **Results:** Eight trials involving 1322 participants were included informing low to high certainty of evidence. When compared with active interventions including exercise, moderate certainty of evidence showed that CFT has a moderate effect in reducing disability in the short term *(*MD -8.58, 95% CI -10.67 to -6.49), low certainty evidence showed that CFT has a moderate effect in reducing disability in the moderate term (MD -8.28, 95% CI -13.04 to -3.52), and high certainty evidence showed that CFT has a small effect in the long term (MD -4.00, 95% CI -7.42 to -0.58). For pain intensity, very low certainty of evidence indicated CFT has a moderate effect in the short term (MD -13.93, 95% CI -21.76 to -6.10), low certainty of evidence indicated that CFT has a moderate effect in the moderate term (MD -13.25, -19.44 to -7.05), and moderate certainty of evidence that CFT has a small effect in the long-term (MD -6.55, 95% CI -13.30 to 0.20). Low certainty evidence suggests that CFT has a large effect compared with minimal intervention for disability in the short term (MD -18.40, 95% CI -23.74 to -13.07). **CONCLUSION:** Compared with active interventions including exercise, CFT probably reduces disability in the short term, may reduce disability in the moderate term and slightly reduces disability in the long term. For pain intensity, the evidence is very uncertain about the effect in the short term, but CFT may reduce pain intensity in the moderate term and probably has a small effect in pain reduction in the long term. Compared with minimal interventions, CFT may result in large reduction of disability and pain intensity sustained in the long term. Current evidence supports the use of CFT in patients with chronic low back pain.

Keywords: Systematic Review; Low Back Pain; Pain management; Movement.

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Lista de Abreviaturas e Siglas

CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CEP	Comitê de Ética em Pesquisa
CFT	Cognitive Functional Therapy
TCLE	Termo de Consentimento livre e esclarecido
TCF	Terapia Cognitivo-Funcional

Sumário

PARTE I – PROJETO DE PESQUISA

Capítulo 1 Revisão de Literatura

1.1 Dor, dor lombar e dor crônica

A definição de dor foi revisada pela Associação Internacional para o Estudo da Dor (IASP) no ano de 2020 e desde então passa a ser descrita como "uma experiência sensitiva e emocional desagradável associada, ou semelhante àquela associada, a uma lesão tecidual real ou potencial". A revisão da definição se fez necessária devido à mudança importante de conceitos com o avanço dos estudos, principalmente no campo da neurociência e comportamento, e consequentemente da compreensão do que é dor (RAJA et al., 2020).

A dor lombar é aquela localizada abaixo da margem costal (12ª costela) e acima das pregas glúteas inferiores (HOY et al., 2014). É a mais prevalente e a condição de saúde que mais provoca incapacidade e com maior impacto socioeconômico em todo o mundo nas últimas três décadas (VOS et al., 2020; WU et al., 2020). Assim como diversas condições crônicas de saúde, a dor lombar não está relacionada diretamente à mortalidade, mas com alto impacto na incapacidade. No Brasil, estima-se que 25 milhões indivíduos vivem com lombalgia, isso significa uma taxa de prevalência de 11.924,78 por 100.000 habitantes. Esses dados são de 2017 e representam um aumento de 26,83% comparada à taxa de prevalência observada em 1990. Isso significa que, apesar do crescimento exponencial de pesquisas que buscam formas de manejo, é crescente o aumento na quantidade de pessoas que sofrem dor lombar e seu impacto social e econômico, visto que é a condição que lidera o ranking anos vividos com incapacidade (DE DAVID et al., 2020).

A dor lombar é considerada crônica quando persiste por tempo superior ao que seria necessário para recuperação de possível comprometimento tecidual e/ou processo inflamatório ativo, e em geral, a literatura aponta esse tempo como superior a 3 meses. Em 90% dos casos, a dor lombar não está associada a causas anatômicas ou de doenças específicas, e por isso é classificada como inespecífica (MAHER; UNDERWOOD; BUCHBINDER, 2016).

1.2 Dor lombar e fatores multidimensionais

Sabe-se que, fatores psicossociais, como aspectos emocionais (ansiedade, depressão, medo), aspectos cognitivos (catastrofização da dor, crenças negativas sobre o que é a dor, percepção de vulnerabilidade do próprio corpo, baixa expectativa de melhora, baixa auto-eficácia), aspectos sociais (eventos de vida produtores de estresse, trabalho, baixa percepção de suporte no trabalho ou da família), aspectos comportamentais (hipervigilância, evitação de movimentos, posturas ou atividades, aumento de co-contração musculatura de tronco e membros inferiores, apnéia, respiração apical e superficial) e estilo de vida (sedentarismo, pobre qualidade de sono, falta ou ausência atividades prazerosas e/ou de lazer) estão relacionadas, para cada indivíduo em diferentes proporções, no surgimento e persistência das dores (MITCHELL et al., 2018).

1.3 Terapia Cognitivo-Funcional

A Terapia Cognitivo-Funcional (TCF) é uma abordagem que foca no manejo da dor e suas consequências e é dirigida aos diversos fatores envolvidos na dor lombar crônica. A intervenção é comportamental e consiste em três componentes principais: um componente cognitivo (geralmente chamado de dar sentido à dor); exposição com controle; e mudança de estilo de vida. Dentro do componente cognitivo, busca-se ressignificar algumas crenças e confrontar medos que os pacientes têm sobre a sua condição, educá-los sobre os mecanismos de dor, melhorar enfrentamento e percepção de controle do próprio corpo. O componente de exposição com controle consiste no treino de diferentes tarefas funcionais (posturas, movimentos e atividades provocativas), visando controlar o comportamento relacionado a dor (controle da atividade muscular de tronco, que normalmente é excessiva, recuperação da capacidade de realizar movimentos em algumas direções que estavam sendo evitadas, controle da respiração e outros sinais do sistema nervoso autônomo). Por fim, o componente que inclui a mudança no estilo de vida, inclui a discussão e planejamento de estratégias de mudanças de hábitos, como gerenciamento do sono,

estresse, rotina e retorno ou adequação de uma prática regular de atividade física (SULLIVAN et al., 2018).

1.3.1 Terapia Cognitivo-Funcional e evidências científicas disponíveis

O primeiro ensaio clínico que teve como objetivo investigar a efetividade da Terapia Cognitivo-Funcional em pacientes com dor lombar crônica foi conduzido na Austrália, por Fersum e seus colaboradores e publicado na revista *European Journal of Pain* em 2013 (VIBE FERSUM et al., 2013). O estudo comparou a intervenção com um grupo controle que consistiu em Terapia Manual e exercícios. A conclusão do estudo foi que a TCF foi mais efetiva para a redução de dor e incapacidade quando comparada a intervenção com Terapia Manual e exercícios. Apesar dos desfechos serem descritos como estatisticamente significativos e superiores (Melhora de 13,7 no nível de incapacidade comparada a 5,5 no grupo controle e melhora de 3,2 pontos na escala de dor comparada a 1,5 no grupo controle), existem falhas metodológicas importantes que não foram consideradas, dentre elas a não realização da análise por intenção de tratar e uma perda de *follow-up* superior a 15%. A análise por intenção de tratar consiste em incluir todos os dados que podem ser obtidos de cada participante e analisa os dados no grupo para o qual o participante foi randomizado, independente se recebeu a intervenção completa para qual foi alocado ou não (ELKINS; MOSELEY, 2015). Fersum et al., realizaram a exclusão de 27 dentre 121 pacientes antes do acompanhamento de 3 meses e a perda de *follow-up* foi de 26% no grupo controle e 18% para no grupo experimental (VIBE FERSUM et al., 2013).

Anos mais tarde, em 2019, o grupo publicou um novo artigo onde reportavam dados coletados com os mesmos pacientes, mas dessa vez 3 anos após a intervenção (VIBE FERSUM et al., 2019). Neste trabalho, os autores consideraram dor e incapacidade nos 3 anos como desfechos primários. Entretanto, o ensaio clínico original foi registrado com o desfecho primário sendo considerado 1 ano após intervenção, assim como descrito no artigo de 2013 (VIBE FERSUM et al., 2013). Sendo assim, dor e incapacidade no acompanhamento de 3 anos deveriam ser considerados desfechos secundários, mesmo que se trate de um novo artigo. Apesar da não realização da análise por intenção de tratar no artigo de 2013, eles afirmaram

que houve uma análise por intenção de tratar no acompanhamento de 3 anos. Isso mostra que os autores decidiram incluir de volta aqueles indivíduos excluídos, como se fossem parte de uma perda de acompanhamento. Isso significa que não conhecemos os resultados de quase metade da amostra (FERNANDEZ et al., 2019).

No ano de 2020, O'Keeffe e colaboradores publicaram os resultados de um novo ensaio clínico que teve como objetivo investigar a efetividade da TCF, mas dessa vez o estudo foi multicêntrico e grupo controle consistiu em exercícios e educação. Os desfechos principais foram dor e incapacidade 6 e 12 meses após a randomização e os resultados apontaram que a TCF reduziu mais a incapacidade, mas não a dor, comparada ao grupo controle (O'KEEFFE et al., 2020).

Esse estudo tem pontos fortes metodológicos em comparação aos anteriores de Fersum (VIBE FERSUM et al., 2013), como um tamanho de amostra maior, o que significa que é menos vulnerável ao erro tipo II e por se tratar de um estudo multicêntrico. Entretanto apresenta falhas que são importantes considerar. A primeira é a escolha de que os mesmos 3 fisioterapeutas foram responsáveis por ambos os grupos, experimental e controle. A justificativa dos autores foi que isso minimiza as diferenças de expertise clínica e habilidades de comunicação do terapeuta atuando dentro dos grupos. Entretanto, sabe-se que existe um alto risco de viés com essa escolha, visto que a pesquisa foi conduzida pelo grupo de pesquisa que desenvolveu a TCF e treina fisioterapeutas de todo o mundo para aplicar a abordagem. Por isso, entusiasmo e motivação ao conduzir o grupo de TCF pode ser considerado maior do que no grupo controle. Da mesma forma, se os fisioterapeutas que conduziram o grupo controle não estivessem envolvidos em nenhum tipo de treinamento TCF e tivessem uma forte crença em sua intervenção, pode-se argumentar que o desempenho do último grupo poderia ter sido melhor. Além disso, o grupo de TCF recebeu intervenção por 13,7 (10,9) semanas, e o grupo controle por apenas 4,4 (2,4). O mesmo profissional conduzindo ambos os grupos, combinado ao tempo maior de intervenção, pode ter gerado viés de desempenho (MEZIAT-FILHO et al., 2019).

Em 2015, foram publicados os resultados de um ensaio clínico investigando a efetividade da TCF em remadores adolescentes. Esse estudo incluiu um número de participantes pequeno, com apenas 36 indivíduos, e não descreveu como foi o grupo controle, apenas que foi um grupo ativo. A conclusão foi favorável para a TCF em comparação com grupo controle, para redução de dor, melhora na escala funcional específica e incapacidade após intervenção e nas 12 semanas de acompanhamento.

Além disso, foram observadas melhoras na resistência muscular e melhora do posicionamento da lombar quando sentados em postura estática. Não houve mudança da *endurance* e postura durante a atividade de remada (NG et al., 2015a).

O primeiro estudo conduzido pelo nosso grupo de pesquisa (CASTRO et al., 2022), teve como objetivo investigar a efetividade da Terapia Cognitivo-Funcional comparada ao treino de CORE e Terapia Manual em pacientes com dor lombar crônica inespecífica. O estudo apresenta diferenças em relação aos anteriores, como número menor de sessões, com até 5 atendimentos para ambos os grupos em 8 semanas, e a condução do grupo intervenção por uma fisioterapeuta recém-formada, mas que foi treinada previamente na abordagem. Além disso, apresenta melhores características metodológicas em relação aos anteriores, como perda mínima de acompanhamento dos indivíduos (*follow-up*) e análise por intenção de tratar conduzida de forma adequada. Como resultado, o estudo apresentou melhora dos desfechos de incapacidade em curto prazo (8 semanas), mas sem diferença para intensidade de dor. O efeito do tratamento não foi mantido nos desfechos de médio e longo prazo (CASTRO et al., 2022).

O estudo mais recente publicado foi nomeado RESTORE e foi conduzido pelo grupo de pesquisa liderado por Peter O'Sullivan e publicado na revista *The Lancet* no atual ano de 2023. O estudo teve como objetivo comparar a efetividade e eficiência econômica da intervenção através de um ensaio clínico randomizado comparando a TCF com e sem biofeedback aos cuidados usuais para pacientes com dor lombar crônica incapacitante. Os pacientes receberam até 7 sessões de tratamento em 12 semanas. Como resultados, o artigo descreveu uma melhora de ambas as intervenções com TCF comparada ao cuidado usual e esse efeito de tratamento se manteve em 52 semanas. Ambas as intervenções também foram efetivas para avaliação econômica com o questionário QALY's e menos dispendiosas em termos de custos sociais (diretos e indiretos e perda de produtividade) (KENT et al., 2023a)

O RESTORE é um trabalho importante na investigação das evidências da abordagem. É o maior ensaio clínico que investigou a efetividade clínica da TCF (492 participantes). O estudo foi multicêntrico, realizado em diversas clínicas e o tratamento foi conduzido por um grande número de fisioterapeutas treinados. O risco de viés de atrito em relação ao desfecho primário é menor do que os ensaios clínicos anteriores do mesmo grupo de pesquisa (KENT et al., 2023a)

Entretanto, é importante descrever algumas características do estudo que puderam gerar vieses importantes nos resultados. O grupo de cuidados usuais recebeu pouco tratamento, sendo assim o viés de desempenho pode explicar, pelo menos em parte, o grande tamanho de efeito dos grupos de TCF, que receberam mais atenção e cuidado, inclusive uma sessão de atendimento com 26 semanas. Além disso, os participantes foram informados que o estudo comparou cuidados usuais com duas intervenções baseadas em evidência e estavam cientes de sua alocação. Isso pode influenciar negativamente as expectativas dos pacientes de cuidados usuais (MEZIAT-FILHO; FERNANDEZ; CASTRO, 2023).

Uma dúvida que não pode ser resolvida pelo desenho de estudo, é se a TCF seria ainda mais benéfica sem a vigilância de um sensor de movimento preso na coluna ou se esse sensor poderia ser uma fonte de viés de desempenho e efeito placebo, explicando parte dos resultados (MEZIAT-FILHO; FERNANDEZ; CASTRO, 2023).

Além dos ensaios clínicos já publicados que foram citados anteriormente, existem pelo menos mais 3 em andamento, que já tiveram seus protocolos publicados e os resultados serão divulgados em breve.

Dentre eles está o trabalho de Belache e colaboradores, que reproduz o desenho do primeiro ensaio clínico randomizado de Fersum, comparando a TCF com Terapia Manual e exercícios de controle motor. Além da diferença da característica ambiental, social e da população, visto que foi conduzido em um país em desenvolvimento e o ambiente de atendimento com indivíduos em situações de extrema vulnerabilidade social, os autores propuseram corrigir as falhas metodológicas dos estudos anteriores, como cuidado para uma perda mínima de acompanhamento dos indivíduos (*follow-up*) e análise por intenção de tratar (BELACHE et al., 2018).

Outro trabalho que teve seu protocolo já publicado foi o de Avila e colaboradores, que tem como objetivo investigar a efetividade da TCF comparada ao treino de CORE e Terapia Manual em pacientes com síndrome da falha cirúrgica, que são um perfil de pacientes com dor lombar incapacitantes que já foram submetidos a uma ou mais cirurgias e sem resultados satisfatórios (AVILA et al., 2021).

Por fim, Lira e colaboradores publicaram o primeiro protocolo de estudo comparando a TCF com placebo. O grupo intervenção recebe sessões individualizadas de TCF (5 a 7 sessões) de forma pragmática baseada na progressão

de cada paciente e o grupo placebo consiste em 30 minutos de intervenção com fotobiomodulação usando um dispositivo descalibrado e 15 minutos de conversa sobre tópicos neutros. O trabalho pode ajudar a entender a influência de fatores não específicos nos resultados, como fatores contextuais (DE LIRA et al., 2022). Devido a grande repercussão da temática no cenário clínico e científico nos últimos anos, diversos grupos de estudos registraram no site PROSPERO protocolos para revisões sistemáticas sobre a abordagem.

A primeira revisão sistemática que se propôs a investigar a TCF comparada com outras intervenções para dor lombar crônica foi publicada em maio de 2022. Esse estudo investigou desfechos em relação a dor, incapacidade/estado funcional, qualidade de vida e fatores psicológicos. A revisão incluiu três estudos e, embora tenha encontrado diferenças estatisticamente significativas para dor, incapacidade/estado funcional e medo de atividade física, a qualidade das evidências foi baixa, indicando a importância de novos estudos para investigar a abordagem e futuramente uma nova revisão sistemática (MIKI et al., 2022).

Devonshire e colaboradores publicaram uma segunda revisão sistemática e concluíram que a TCF parece não ser mais efetiva que outras abordagens para dor e incapacidade em adultos com dor lombar. Entretanto, a revisão foi realizada antes da divulgação de resultados de ensaios clínicos importantes e conduziu a análise de dados através das médias pós-intervenção, sem levar em consideração as médias de dor e de incapacidade da linha de base, o que possivelmente mudaria os resultados (DEVONSHIRE et al., 2023).

1.3.2 Terapia Cognitivo-Funcional e possíveis modificadores de efeito

Melhorar os resultados das intervenções para dor lombar é o objetivo de diversos clínicos e pesquisadores, por isso, existem diversas intervenções sendo investigadas. Entretanto, apesar do número crescente de pesquisas na área, nenhuma das abordagens apresentou resultados expressivamente superiores em relação a outras.

Sabe-se que o perfil de indivíduos com dor lombar é heterogêneo em suas características, por isso, faz sentido investigar se existe um grupo de pacientes que

respondem melhor a determinadas abordagens, a fim de direcionar melhor os pacientes para intervenções que sejam possivelmente mais eficazes para eles. A análise de subgrupos aumenta a chance de adaptar melhor os tratamentos aos pacientes com base em características clínicas, indo contra a prática dos tratamentos "genéricos", em que uma intervenção única deve servir para todos, na busca por um cuidado individualizado (SARAGIOTTO et al., 2017).

São escassas as evidências de alta qualidade com subgrupos para pacientes com dor lombar, diversos estudos apresentam falhas metodológicas importantes e por isso, alguns autores defendem que ainda não é possível ser implementado na prática clínica (SARAGIOTTO et al., 2017).

A análise de modificação do presente estudo tem esse objetivo, identificar os pacientes que respondem melhor a Terapia Cognitivo-Funcional. Por se tratar de uma abordagem que considera e aborda fatores multidimensionais cognitivos e comportamentais, diferente de intervenções com exercícios e Terapia Manual, a hipótese é de que pacientes com níveis de aspectos psicossociais mais elevados (ansiedade, depressão, catastrofização, isolamento social, medo de movimento e estresse), pacientes com padrão de dor difusa e preencheram maior número de áreas de dor no mapa corporal e pacientes que tem alto risco para cronificação (classificados pelo STartBack e Orebro) respondem melhor a abordagem com a TCF.

1.4 Justificativas

1.4.1 Relevância para as Ciências da Reabilitação

A dor lombar crônica é uma condição com impacto socioeconômico importante no mundo inteiro. Dentre diversas abordagens propostas que visam melhorar a dor e incapacidade desses pacientes, está a Terapia Cognitivo-Funcional. Existem estudos já concluídos e outros em andamento que visam investigar sua efetividade e/ou eficácia em comparação a outras abordagens. É de extrema importância que os dados dos ensaios clínicos randomizados sejam analisados através de uma revisão sistemática, já que é a metodologia de estudo com maior poder de evidência científica e que vai colaborar com os próximos caminhos de clínicos e pesquisadores. Além disso, é válida também a análise de modificação de efeito da intervenção, visando

identificar se existem características que indivíduos que respondem melhor a abordagem, através de dados secundários de um ensaio clínico que os resultados já foram previamente publicados.

1.4.2 Relevância para as Prioridades Estratégicas da Organização Pan-Americana de Saúde[1]

O tema do projeto está dentro do eixo 5 da Agenda de Prioridades do Ministério da Saúde (APPMS), que corresponde às pesquisas relacionadas a doenças crônicas não transmissíveis.

1.4.3 Relevância para o Desenvolvimento Sustentável[2]

O projeto está alinhado com os Objetivos de Desenvolvimento Sustentável (ODS) do governo federal, que diz sobre Saúde e Bem-Estar: Assegurar uma vida saudável e promover o bem-estar para todos, em todas as idades (objetivo 3), assegurar o acesso a serviços essenciais de saúde de qualidade em todos os níveis de atenção através da cobertura universal de saúde (objetivo 3.8) e apoiar a pesquisa e o desenvolvimento de tecnologias e inovações em saúde para as doenças não-transmissíveis e proporcionar o acesso a essas inovações incorporadas ao Sistema Único de Saúde (Objetivo 3b).

1.5 Estratégia de apresentação dos estudos envolvidos no projeto

O presente projeto integra dois diferentes trabalhos científicos. O primeiro a ser apresentado (PROJETO A) é uma revisão sistemática da literatura e o segundo (PROJETO B) se trata de uma investigação de potenciais modificadores de efeitos da Terapia Cognitivo-Funcional, com dados secundários de um ensaio clínico randomizado.

[1] https://iris.paho.org/bitstream/handle/10665.2/57798/OPASBRA230009_por.pdf
[2] https://odsbrasil.gov.br/objetivo/objetivo?n=3

Capítulo 2 Projeto A: Revisão sistemática de ensaios clínicos da Terapia Cognitivo-Funcional

2.1 Objetivos

2.1.1 Objetivo Geral

Investigar a eficácia e efetividade da Terapia Cognitivo-Funcional para melhorar dor, incapacidade ou função específica em indivíduos com dor lombar crônica através de uma revisão sistemática da literatura.

2.1.2 Objetivos Específicos

1. Realizar uma revisão sistemática através de uma busca ampliada na literatura para seleção de ensaios clínicos randomizados que investigaram a eficácia ou efetividade da Terapia Cognitivo-Funcional em comparação com outras abordagens.
2. Extrair os dados dos estudos identificados e se os dados se apresentarem homogêneos suficiente, compilar para analise os resultados
3. Analisar a qualidade metodológica dos estudos inseridos e dos resultados obtidos com a revisão sistemática.

2.2 Hipóteses

A Terapia Cognitivo-Funcional é mais eficaz do que outras abordagens para redução de incapacidade em pacientes com dor lombar crônica.

2.3 Delineamento do estudo

Será realizada uma revisão sistemática da literatura com objetivo de identificar se a Terapia Cognitivo-Funcional é uma abordagem eficaz para melhorar dor, incapacidade e função em pacientes com dor lombar crônica.

2.4 Amostra

Essa revisão vai incluir participantes com dor lombar crônica (queixa principal de dor no espaço entre a altura da 12ª costela e as pregas glúteas, com ou sem dor irradiada para membros inferiores por pelo menos três meses de duração). Estudos que incluíram pacientes com doenças específicas (ex. fratura, síndrome da cauda equina, artrite inflamatória, malignidade ou estenose espinhal), doenças reumatológicas ou inflamatórias (artrite reumatoide, espondilite anquilosante, artrite psoriática, lúpus eritematosos, doença de *Scheuermann*), doenças neurológicas progressivas (ex. esclerose múltipla, doença de Parkinson, doença do neurônio motor) ou escoliose (se considerada causa primária de dor) serão excluídos.

2.4.1 Critérios de inclusão

Serão incluídos estudos que investigaram a eficácia ou efetividade da Terapia Cognitivo-Funcional para dor lombar comparada a intervenções ativas (intervenção com educação, exercícios gerais, exercícios de controle motor, exercícios de fortalecimento, entre outros), intervenções passivas (Terapia Manual, ultrassom, entre outros), intervenções mínimas (ex. cartilhas de orientações) ou sem intervenção (lista de espera). Os estudos devem descrever como é a abordagem da Terapia Cognitivo-Funcional, incluindo os componentes: cognitivo (comumente descrito como "*Making sense of pain*"), a exposição com controle ("*gradual exposure*" ou "*exposure with control*" e mudança de estilo de vida, para que seja confirmado que a intervenção realizada pode ser considerada como TCF.

2.4.2 Critérios de exclusão

Serão excluídos estudos sem grupo controle e estudos com randomização não padronizada. Os estudos não serão excluídos com base no ambiente em que foram conduzidos.

2.5 Procedimentos/Metodologia proposta

2.5.1 Estratégia de busca dos artigos

A busca será restrita para incluir estudos que envolvem humanos e não será limitado por idioma. Um revisor vai conduzir a busca sistemática para localizar estudos relevantes para responder à pergunta da pesquisa. A busca vai incluir as bases de dados PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro e Cochrane Central Register of Controlled Trials (CENTRAL).

2.5.2 Tipos de estudos

Serão incluídos apenas ensaios clínicos randomizados e que foram publicados em periódicos revisados por pares. Outros desenhos de estudos, anais de congressos, dissertações e pesquisas não originais serão excluídos.

2.5.3 Extração dos dados: seleção e codificação

Os artigos obtidos na busca sistemática serão exportados e salvos em um *software* de gerenciamento de referências (EndNote X9 Thomson Corporation) e as duplicadas serão removidas. Os títulos obtidos foram exportados para uma web *software* para gerenciamento de revisão sistemática (Covidance), onde dois revisores farão uma triagem independente dos títulos dos estudos obtidos na busca sistemática. Os títulos e resumos dos artigos serão avaliados quanto à relevância de acordo com critérios de inclusão. Serão obtidos textos completos de todos os artigos potencialmente elegíveis e selecionados para inclusão. Desentendimentos entre os dois revisores serão resolvidos por meio de discussão e um terceiro revisor será consultado para consenso se desacordo persistir.

Os autores dos estudos serão contatados por e-mail se necessário obter algum dado adicional. Serão enviados dois e-mails ao autor correspondente, se não obtiver resposta, a tentativa de contato será com outros autores dos estudos. Se não obtiver resposta, as tentativas de obter dados extras serão cessadas.

Os dois revisores irão extrair os seguintes dados: Autor, ano do estudo, local, tamanho da amostra, característica da amostra, grupo intervenção, grupo controle, desfechos, instrumentos de medida, média, desvio padrão, duração da intervenção e acompanhamentos/ *follow-ups.*

As informações que faltarem em relação ao desvio padrão serão calculadas com os intervalos de confiança extraídos do mesmo estudo, se possível e estiver disponível.

2.6 Desfechos

Desfechos serão intensidade de dor e incapacidade ou função específica em curto prazo (tempo menor ou igual a 3 meses após randomização), médio prazo (tempo de 4 a 11 meses após randomização) e longo prazo (tempo de 12 meses ou mais após randomização), com instrumentos devidamente acurados para avaliação de tais desfechos.

2.6.1 Medidas de efeitos

Diferença de médias ou diferença de médias padronizadas, quando diferentes medidas de resultados foram relatadas em cada estudo, levando em consideração os dados da linha de base.

2.7 Análise dos dados

2.7.1 Análise do risco de viés

A análise será feita através da ferramenta da Cochrane RoB 1, que é amplamente utilizada nas pesquisas de revisões de boa qualidade e considera os vieses que podem afetar os resultados nos ensaios clínicos randomizados. Esse instrumento contém 7 domínios, e de acordo com o julgamento dos revisores, o estudo é classificado como apresentando alto, médio ou baixo risco de viés. Os domínios são: Geração de sequência aleatória e ocultação de alocação para viés de seleção), cegamento de participantes e provedores para viés de desempenho, cegamento do

avaliador de resultados para viés de detecção, dados de resultados incompletos para viés de atrito, relato de resultados seletivos para viés de relato, entre outros tipos de vieses.

Quadro 1. Domínios da ferramenta Cochrane Risk of Bias (RoB 1).

DOMÍNIO	DESCRIÇÃO
Geração da sequência de randomização (viés de seleção)	Avalia os métodos utilizados para alocar os participantes nos grupos, como tabelas de números aleatórios, softwares, centrais de randomização, outros.
Sigilo de alocação (viés de seleção)	Avalia os métodos utilizados para garantir a implementação da sequência de randomização gerada, como centra telefônica, plataformas virtuais, envelopes selados e opacos numerados sequencialmente e outros.
Mascaramento dos participantes e equipe (viés de performance)	Avalia os métodos utilizados para garantir que os participantes e equipe não saibam para qual grupo foram alocados.
Mascaramento dos avaliadores dos desfechos (viés de detecção)	Avalia os métodos utilizados para garantir que os avaliadores dos desfechos não saibam para qual grupo os participantes foram alocados.
Dados incompletos dos desfechos (viés de atrito)	Avalia o impacto das perdas de participantes ao longo do estudo nos resultados.

Relato seletivo dos desfechos (viés de relato)	Avalia o alinhamento entre os desfechos planejados no protocolo do estudo e os desfechos avaliados e/ou relatados.
Outras fontes de viés	Avalia qualquer outra fonte de viés não considerada nos demais domínios, como desbalanço entre os grupos comparados no início do estudo, interrupção precoce do estudo e outros.

A ferramenta GRADE (*Grading of Recommendations Assessment, Development and Evaluation)* será utilizada para graduar a qualidade das evidências e a força das recomendações, baseada em 5 domínios: risco de viés, inconsistência, caráter indireto, imprecisão e viés de publicação. As recomendações serão graduadas em 4 níveis de certeza: alto, moderado, baixo e muito baixo.

2.7.2 Síntese dos dados

A medida da intensidade de dor será transformada em uma escala de 0 a 100, em seguida, será calculada a diferença média ponderada com intervalos de confiança de 95% e diferenças de riscos ponderadas.

Os outros desfechos serão combinados nas meta-análises usando modelos de efeitos aleatórios. Para resultados contínuos, as diferenças médias padronizadas serão calculadas a partir de médias extraídas e desvio padrão coletados considerando diferentes pontos do tempo.

A meta-análise será conduzida se houver intervenção (TCF), metodologia (ensaio clínico randomizado, população alvo, desfecho de dor e incapacidade) e estatística homogênea suficiente. Se houver homogeneidade suficiente, será conduzida meta-análise para acompanhamento de curto prazo (menos que três meses após randomização), médio prazo (pelo menos três meses e menos que doze meses após randomização) e longo prazo (doze meses ou mais após randomização). Decisões sobre heterogeneidade serão feitas via consenso dos autores quando a síntese de dados for concluída.

2.7.3 Análise de subgrupos

Se houver heterogeneidade clínica ou metodológica será considerada possibilidade de análise de subgrupo, de acordo com peculiaridades dos estudos e grupos, como duração, número e tipos de sessões das intervenções, características dos participantes, resultados (desfechos diferentes, tempo de acompanhamento diferente) e risco de viés. Será considerada a heterogeneidade de acordo com a estatística I2 e inspeção visual dos gráficos forest plots, recomendada pelo manual da Cochrane (Cochrane Handbook for Systematic Reviews of Interventions) (HIGGINS et al., 2022). Será declarada heterogeneidade substancial se I2>50%, se os valores de I2 forem ligeiramente superiores a 50%, mas não for identificado heterogeneidade clara por inspeção visual, os resultados serão combinados usando um modelo de efeito aleatório para calcular as estimativas agrupadas e suas variâncias, e será rebaixada a evidência por inconsistência na avaliação da qualidade da evidência (HIGGINS et al., 2022).

2.8 Apoio financeiro

Este estudo é financiado pela Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Código Financeiro 001.

Quadro 2: Apoio financeiro.

CNPJ	Nome	Tipo de Apoio financeiro	E-mail	Telefone
00889834/0001-08	CAPES	Bolsa	prosup@capes.gov.br	(061) 2022-6250

2.9 Cronograma

Quadro 3: Fase da revisão sistemática no momento da qualificação do projeto.

Estágio	**Iniciado**	**Concluído**
Buscas preliminares	SIM	SIM
Gerenciamento do processo de seleção dos estudos	SIM	SIM
Triagem formal dos resultados da pesquisa em relação aos critérios de elegibilidade	SIM	SIM
Extração de dados	SIM	NÃO
Análise risco de viés	NÃO	NÃO
Análise dos dados	NÃO	NÃO

Capítulo 3 Projeto B: Análise de modificação de efeito da Terapia Cognitivo-Funcional

3.1 Objetivos

3.1.1 Objetivo Geral

Analisar os potenciais modificadores de efeito nos desfechos de dor e incapacidade em pacientes com dor lombar crônica 3 meses após intervenção com Terapia Cognitivo-Funcional.

3.1.2 Objetivos Específicos

1. Identificar se características psicossociais dos indivíduos como sinais de ansiedade, de depressão, de catastrofização, de isolamento social, de medo de movimento, de estresse, são potenciais modificadores de efeito da Terapia Cognitivo-Funcional.

2. Identificar se o número de áreas do corpo que o paciente refere dor é um potencial modificador de efeito da Terapia Cognitivo-Funcional.

3. Identificar se pacientes classificados como alto risco de cronificação pelo questionário STartBack e questionário Örebro, são potenciais modificadores de efeito da Terapia Cognitivo-Funcional.

3.2 Hipóteses

Indivíduos com maiores níveis de ansiedade, medo, depressão, isolamento social, depressão, dor difusa e alto risco de cronificação respondem melhor a abordagem da Terapia Cognitivo-Funcional.

3.3 Aspectos éticos

Este protocolo de pesquisa foi submetido e aprovado pelo Comitê de Ética em Pesquisa (CEP) do Centro Universitário Augusto Motta (2.219.742) via Plataforma Brasil (https://plataformabrasil.saude.gov.br) antes da execução do estudo, em consonância com a resolução 466/20123[3].

Todos os participantes assinaram um termo de consentimento livre e esclarecido (TCLE; Apêndice 1) após serem informados sobre aa natureza do estudo e do protocolo a ser realizado.

Os resultados foram reportados seguindo declaração de CONSORT (ALTMAN et al., 2001) e o checklist TIDieR (HOFFMANN et al., 2014), e foi publicado na revista PAIN em 2022 (CASTRO et al., 2022).

3.4 Delineamento do estudo

Será realizada uma análise secundária com dados de um ensaio clínico randomizado e com avaliador cego, que investigou a efetividade da Terapia Cognitivo-Funcional comparada ao Treinamento de CORE e Terapia Manual em indivíduos com dor lombar crônica inespecífica.

3.4.1 Local de realização do estudo

O estudo foi conduzido em uma clínica de ortopedia com serviços de assistência particular ou suplementar, através de convênios e seguros de saúde, localizada na cidade de Campinas, São Paulo, Brasil (CASTRO et al., 2022).

3.4.2 Pré-registro do protocolo

O estudo foi registrado prospectivamente no site http://www.clinicaltrials.gov (NCT03273114).

[3] https://conselho.saude.gov.br/resolucoes/2012/Reso466.pdf

3.5 Amostra

3.5.1 Local de recrutamento do estudo

Os pacientes foram encaminhados pelos médicos ortopedistas que atuam na clínica em que o estudo se realizou, assim como também foram recrutados através de divulgação da pesquisa com cartazes pela clínica e na internet (Instagram, informativos enviados via *whatsaap*).

3.5.2 Critérios de inclusão

Os critérios de inclusão e exclusão estão descritos na tabela 1 (CASTRO et al., 2022).

Tabela 1. Critério de inclusão e exclusão para participação do estudo.

Critério de inclusão	**Critério de exclusão**
Idade entre 18 e 65 anos	Dor principal não é na região lombar (T12 até glúteo)
Dor lombar crônica há mais de 12 semanas	Dor na perna é o problema principal (ex. Compressão neural ou prolapso discal com dor radicular ou radiculopatia verdadeira, recesso lateral ou estenose central)
Mobilidade independente (com ou sem ajuda)	
Ser capaz de falar e entender português o suficiente para preencher os questionários de forma independente	Procedimentos para alívio da dor, como injeções (ex. epidurais) e rizotomia nos últimos 3 meses.
	Gestantes
	Doenças reumatológicas ou inflamatórias (ex. artrite reumatoide, espondilite anquilosante, artrite psoriática, lúpus eritematoso, e doença de Scheuermann.

	Doença neurológica progressiva (ex. Esclerose múltipla, doença de Parkinson, doença do neurônio motor). Escoliose (se considerada causa primaria de dor)
	Condições cardíacas instáveis
	Desordens de bandeiras vermelhas como malignidade/câncer, traumas agudos como fratura há menos de 6 meses ou infecção, e compressão da cauda equina.

3.6 Procedimentos/Metodologia proposta

3.6.1 Recrutamento, inclusão, randomização e acompanhamento dos participantes

Foram incluídos 148 indivíduos, de ambos os sexos, que procuravam por tratamento para dor lombar há mais de três meses e que foram avaliados por um fisioterapeuta para confirmar a elegibilidade. A avaliação envolveu validação de todos os critérios de inclusão e exclusão, incluindo a aplicação do questionário de incapacidade (*Oswestry*) que necessitava de uma pontuação mínima de 14% para preencher o critério de inclusão.

Após a confirmação de elegibilidade, os pacientes foram informados sobre os objetivos e procedimentos do estudo e foram informados que haveria dois grupos diferentes de intervenção e que não se sabia qual era superior. Os indivíduos puderam escolher se desejavam ou não fazer parte do estudo, e quando optaram por participar, um Termo de Consentimento livre e esclarecido (TCLE) era entregue para leitura e assinatura e em seguida acontecia a coleta dos dados da linha de base e o procedimento de randomização.

A randomização foi realizada através de um programa de computador, que gerou os números secretos e, que foram ordenados sequencialmente em envelopes opacos pelo pesquisador responsável, que não estava envolvido no recrutamento, avaliação ou tratamento dos participantes. Os envelopes só foram abertos sequencialmente pelos fisioterapeutas responsáveis pelas intervenções. Devido a

característica das intervenções, não foi possível cegar os participantes e fisioterapeutas.

Os participantes foram randomizados proporcionalmente nos dois diferentes grupos de intervenção e avaliados na linha de base, 2, 6 e 12 meses após randomização, por um profissional que não tinha acesso a informação sobre qual intervenção o participante foi submetido (Figura 1).

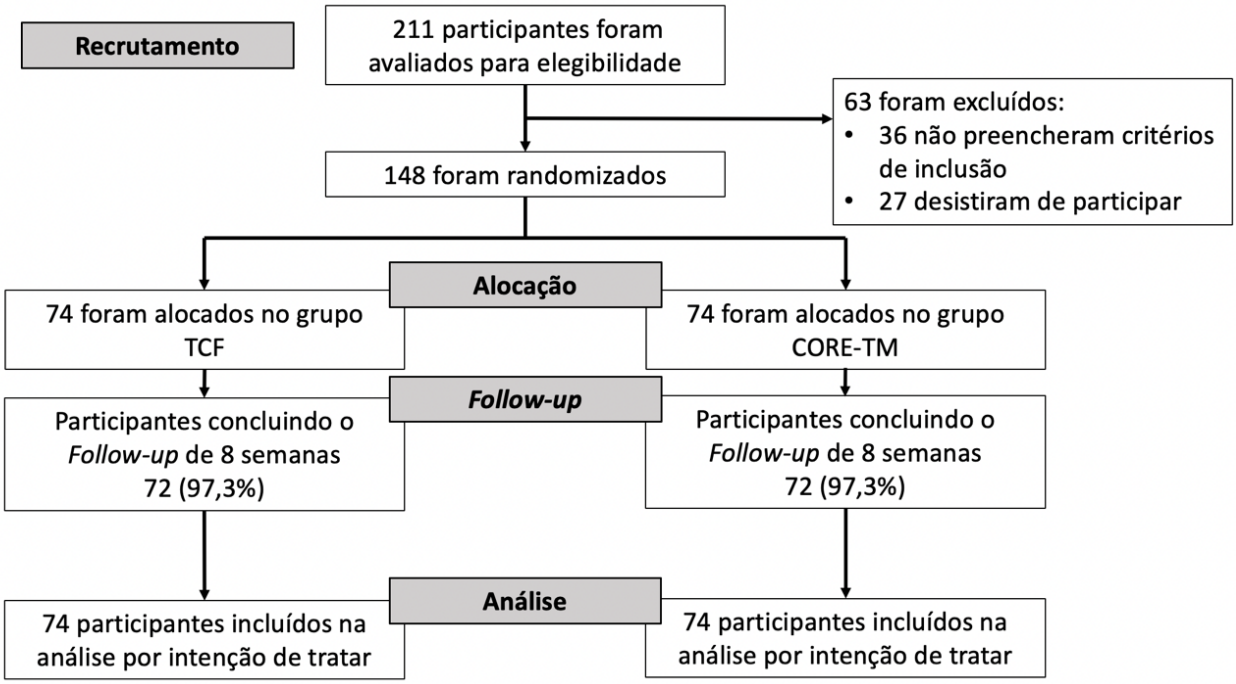

Figura 1. Fluxograma do estudo.

3.6.2 Intervenções

As intervenções de ambos os grupos foram presenciais, individuais e em um ambiente reservado para atendimento de apenas um paciente por vez. Os tratamentos consistiam em até 5 sessões, durante o período de 8 semanas, com frequência de 1 sessão semanal nas primeiras 2 semanas e depois 1 sessão a cada 2 ou 3 semanas. Os participantes foram atendidos sempre pelo mesmo profissional, que não foi envolvido nas reavaliações. Alguns exercícios foram filmados, descritos ou encaminhados através de cartilhas pelo fisioterapeuta, para que pudessem realizar em casa. Ambos os grupos foram monitorados e as intervenções foram conduzidas conforme planejadas.

3.6.2.1 Terapia Cognitivo-Funcional

A intervenção consiste em 3 componentes principais: Dar sentido a dor, exposição controlada e mudança de estilo de vida (O'KEEFFE et al., 2015).

O termo **"Dar sentido a dor"** foi traduzido do inglês *Making sense of pain*, e é um processo reflexivo que acontece principalmente durante a entrevista, mas que é também presente em todas as sessões de atendimento. Através de perguntas abertas e questões reflexivas, o paciente é encorajado a refletir e compartilhar a sua história, eventos de vida relevantes e experiências prévias, e através dessas informações é possível construir uma linha do tempo, que ajuda a compreender os fatores biopsicossociais que potencialmente influenciam o início e persistência dos sintomas dolorosos, facilitando a compreensão da sua condição de dor e incapacidade (CASTRO et al., 2022; SULLIVAN et al., 2018).

Uma escuta qualificada e ativa da história do paciente é a chave para identificar o contexto e características da dor, o nível de incapacidade, crenças, fatores físicos, estratégias de enfrentamento, objetivos e valores do indivíduo (CASTRO et al., 2022; SULLIVAN et al., 2018).

A aliança terapêutica é um elemento fundamental da abordagem e incluí elementos como empatia, espelhamento corporal, reflexões e reforço de comportamentos positivos (CASTRO et al., 2022; SULLIVAN et al., 2018).

Faz parte também desse componente, facilitar a compreensão sobre contexto em que as exacerbações dos sintomas acontecem, e assim, algumas estratégias podem ser discutidas e adotadas para manejar novos episódios (CASTRO et al., 2022; SULLIVAN et al., 2018).

A **Exposição controlada** é o nome dado ao processo de mudança de comportamento que permite com que o indivíduo retorne gradualmente as atividades funcionais que são importantes, sem que isso provoque mais dor ou estresse (CASTRO et al., 2022; SULLIVAN et al., 2018).

A exposição busca focar na experiência de dor de cada indivíduo. Identifica-se a postura, movimento ou atividade que está sendo dolorosa, temida ou evitada pelo paciente. Sabe-se que a experiência desagradável determinadas atividades cria um aprendizado associativo entre o que é considerado ameaçador e o aumento de dor ou lesão/dano (referência associação dor e ameaça). Sempre que possível uma nova

estratégia comportamental deve ser experienciada, para que assim a associação de que a tarefa é segura seja construída (CASTRO et al., 2022; SULLIVAN et al., 2018).

Expor o indivíduo de forma controlada, incluí buscar relaxamento antes da exposição e minimizar comportamentos de proteção, tais como contrações musculares excessivas e desnecessárias da musculatura, respiração apical ou apneia, sudorese e tremor. Além disso, é importante desenvolver a consciência e controle corporal, e permitir que o corpo, principalmente o segmento lombar, se movimente de forma natural novamente, com amplitudes de movimentos livres em todas as direções (flexão, extensão, inclinação) e que exista variabilidade dessas posições e direções de movimento, dependendo da tarefa alvo (CASTRO et al., 2022; SULLIVAN et al., 2018).

Se tarefa funcional que era ameaçadora para o indivíduo for experienciada de forma relaxada, sem comportamentos de proteção ou defesa, a experiência tem potencial de ser positiva, com menos dor e contribuir com o aprendizado associativo de que é uma tarefa segura. Essa estratégia parte do pressuposto de que a discrepância entre expectativa e experiência (expectativa violada) é útil para novos aprendizados. Para alguns indivíduos, o objetivo é sentir menos dor durante a execução da tarefa, enquanto para outros, pode ser envolver-se com as tarefas temidas e evitadas sem danos. Quando minimizamos respostas simpáticas e comportamentos de proteção, cria-se uma incompatibilidade entre as respostas de dor esperadas e reais do indivíduo (CASTRO et al., 2022; SULLIVAN et al., 2018).

O terceiro componente, descrito como **mudança no estilo de vida,** consiste em discutir comportamentos que são desfavoráveis e encontrar estratégias para um estilo de vida saudável. Dentre as estratégias está a prática regular de atividade física, considerando a preferência do paciente e que seja associada aos objetivos individuais de cada um. Considerar a acessibilidade, custo e engajamento social que a atividade promove, é fundamental para que o comportamento seja sustentável (CASTRO et al., 2022; SULLIVAN et al., 2018).

Problemas com a qualidade do sono também devem ser considerados e estratégias propostas, como estabelecimento de rotinas, diminuir uso de eletrônicos de noite e no ambiente em que se dorme e adesão a uso de medicamentos, caso houver prescrição médica. Por muitas vezes a dor é um dos fatores agravam qualidade de sono, para isso é importante treinamento específico de rolamento,

movimentos e posturas na cama, de maneira mais relaxada e menos dolorosa (CASTRO et al., 2022; SULLIVAN et al., 2018).

Algumas técnicas de relaxamento, como por exemplo a meditação guiada, ajudam no manejo de distúrbios de ansiedade e estresse, que são frequentemente presentes, assim como também pode ser uma ferramenta útil na melhora da qualidade do sono (CASTRO et al., 2022; SULLIVAN et al., 2018).

É importante ressaltar, que todas as estratégias atuam em conjunto, e que se complementam. Por exemplo, a prática regular de atividade física, além dos benefícios da modulação de intensidade de dor e de melhora da funcionalidade, facilita tanto a regulação do sono quanto com o manejo do estresse e ansiedade. O importante é considerar os diversos fatores que englobam o componente “estilo de vida” e que as estratégias e metas sejam realistas, pequenas e bem definidas, e principalmente, que sejam determinadas em conjunto do profissional com o paciente.

Dessa forma, facilita-se o engajamento do paciente com seu processo de recuperação e aumenta-se a chance de uma mudança comportamental e de hábitos que a abordagem almeja e preconiza (CASTRO et al., 2022; SULLIVAN et al., 2018).

3.6.2.2 Exercício de CORE e Terapia Manual

A intervenção do grupo controle foi de exercícios e Terapia Manual. O primeiro componente, o programa de exercícios, fez parte da abordagem de todos os pacientes do grupo controle. O programa consistia em melhorar resistência muscular de forma estática e estabilidade de forma dinâmica da região de CORE, baseado nos exercícios de McGill (MCGILL, 2001).

Antes de iniciar os exercícios de resistência, os indivíduos realizavam movimentos de mobilidade de flexão e extensão em posição de quatro apoios e foi ensinado como realizar a contração da musculatura abdominal e lombar (“contração do CORE”) em posição neutra (CASTRO et al., 2022; MCGILL, 2001).

O programa de exercícios envolve estímulo de contração e força em diferentes posições, da musculatura de tronco, abdominal e pélvica. Dentre os exercícios estavam a ponte em decúbito dorsal, ponte em posição de prono e ponte lateral, flexão de ombro e extensão quadril contralateral em posição de quatro apoios (“*Bird dog*”) e exercícios em posição supino, como flexão e extensão ombro e quadril contralateral com força de contração abdominal *(“dead bug”)* e abdominais.

Os participantes foram orientados a manter a musculatura de CORE ativas durante a execução dos movimentos multiplanares de membros superiores e inferiores, com objetivo de controlar os movimentos da coluna lombar e da cintura pélvica.

A prescrição de exercícios foi individualizada, e a dificuldade e intensidade dos exercícios aconteceram de acordo com a capacidade individual do participante. Materiais como faixas elásticas, halteres e/ou caneleiras foram utilizados para progressão de resistência e os exercícios também foram realizados em superfícies instáveis, de acordo com a evolução de cada indivíduo. O profissional fisioterapeuta do grupo controle ficou responsável por demonstrar e dar feebacks individuais sobre os exercícios (CASTRO et al., 2022).

O segundo componente do grupo controle foi a Terapia Manual. Diferente do primeiro componente, a Terapia Manual foi utilizada de forma pragmática, ou seja, quando e se o profissional julgasse necessário, com objetivo de restaurar movimentos, controlar a dor ou facilitar progressão dos exercícios de CORE(CASTRO et al., 2022)

Os pacientes foram instruídos e encorajados a realizar uma sessão de exercícios de 30 minutos em casa, 3 vezes por semana, incluindo 2 a 3 séries de 6 a 12 repetições (CASTRO et al., 2022).

3.7 Desfechos

3.7.1 Desfechos primários

Os desfechos primários foram intensidade de dor e incapacidade associados a dor lombar, medidos dois meses após a randomização.

1. Intensidade de dor: Medido pela versão brasileira da Escala Numérica de Dor (END) de 11 pontos (COSTA et al., 2008). A END varia de 0 a 10, onde 0 é “sem dor” e 10 é a “pior dor imaginável”. Participantes foram questionados sobre o nível de dor baseado nos últimos 7 dias.

2. Incapacidade: Medida pelo questionário Oswestry de incapacidade, que é uma ferramenta amplamente utilizada na pesquisa e na clínica para avaliar

incapacidade associada a dor lombar. O questionário tem 10 itens (0-5 pontos cada) relacionados a atividades de vida diária que os pacientes têm mais dificuldades. A pontuação é multiplicada por dois e a porcentagem de incapacidade varia de 0 a 100%. A ferramenta foi traduzida e adaptada para o português e as propriedades de medidas validadas em pacientes com dor lombar no Brasil (VIGATTO; ALEXANDRE; CORREA FILHO, 2007).

3.7.2 Variáveis potenciais modificação de efeito

Além dos desfechos primários de dor e incapacidade, o estudo contempla outros dados que são importantes de serem analisados, dentre eles estão os dados sobre potenciais modificadores de efeito do tratamento. Isto é, investigar se existe uma característica ou perfil dos participantes que favorece o resultado de uma determinada intervenção. As variáveis coletadas nesse estudo e que fazem sentido serem analisadas são: fatores psicossociais (sinais de ansiedade, depressão, medo de movimento, isolamento social, estresse e qualidade sono), risco de cronicidade e números de áreas de dor.

1. Fatores psicossociais: avaliados pelo questionário breve de triagem psicossocial (KENT et al., 2014), que parece ser comparável pelos questionários completos validados, através de perguntas ou afirmações direcionada a cada fator:
Sintomas de ansiedade: “Você se sente ansioso?” com as opções de respostas variando de “Não, e modo algum” a “Bastante ansioso”.
Isolamento: “Você se sente socialmente isolado?” com as opções de respostas variando de “Não, de modo algum” a “Bastante isolado”.
Catastrofização: “Quando sinto dor, é terrível e sinto que nunca vai melhorar” com as opções de respostas variando de “Sempre faço isso” a “Nunca faço isso”.
Sintomas depressivos: “Durante o mês passado você se sentiu triste, deprimido ou teve sensação de desesperança?” com as opções de respostas variando de “Nunca” a “O tempo todo”.
Medo de movimento: “A atividade física pode prejudicar minhas costas” com as opções de respostas variando de “Discordo completamente” a “Concordo completamente”.

Estresse: Você se sente estressado? com as opções de respostas variando de “Não estressado” a “Muito estressado”.
Sono: “Você teve problemas para dormir no último mês?”, baseado no inventário de queixas subjetivas de saúde (PINHEIRO et al., 2015), com as opções de respostas: “Nem um pouco”, “Um pouco”, “Algum” e “Sério”.

2. Risco de cronicidade: foi medido através do questionário Örebro (FAGUNDES et al., 2015) e a versão brasileira da ferramenta Start Back (PILZ et al., 2014).

3. Números de áreas de dor: foi obtido através do diagrama de áreas de dor (MARGOLIS; TAIT; KRAUSE, 1986).

3.8 Análise dos dados

3.8.1 Tamanho amostral

O cálculo do tamanho amostral do ensaio clínico foi 148 indivíduos, considerando os desfechos principais do estudo. Não será realizado novo cálculo amostral, visto que o estudo não foi delineado para estimar modificadores de efeito. A análise secundária proposta no presente projeto tem como proposta desenvolver hipóteses que poderão ser testadas em grandes ensaios, portanto os resultados serão considerados dados exploratórios.

3.8.2 Plano de análise estatística

Serão analisados os potenciais modificadores de efeito da intervenção com TCF e da intervenção com exercícios de CORE e Terapia Manual para os desfechos de intensidade de dor e incapacidade.

As 8 variáveis (6 psicossociais + risco de cronicidade + números de áreas de dor) serão analisadas como dicotômicas e separadas através de um modelo de regressão logística univariada, incluindo os fatores psicossociais, os quais serão utilizados pontos de corte propostos por Kent 2014 (KENT et al., 2014).

O modelo vai incluir o grupo, a variável possivelmente preditora e o fator de interação grupo x preditor. Os valores de intensidade de dor e incapacidade obtidos na linha de base serão incluídos na análise como fator de confusão. O termo de interação será usado para quantificar o tamanho da modificação do efeito.

As análises serão realizadas utilizando a versão 0.99.486 do R Studio.

3.9 Apoio financeiro

Este estudo é financiado pela Coordenação de Aperfeiçoamento de Pessoal de Nível Superior - Brasil (CAPES) - Código Financeiro 001.

Quadro 4: Apoio financeiro.

CNPJ	Nome	Tipo de Apoio financeiro	E-mail	Telefone
00889834/0001-08	CAPES	Bolsa	prosup@capes.gov.br	(061) 2022-6250

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Apêndice 1 – Termo de Consentimento Livre e Esclarecido

Termo de Consentimento Livre e Esclarecido

Você está sendo convidado a participar de uma pesquisa que vai comparar dois tipos de tratamento de fisioterapia. O título do estudo é: **Terapia Cognitivo-Funcional (TCF) comparada a Treinamento do Core e Terapia Manual em pacientes com Dor Lombar Crônica Inespecífica (DLCI): ensaio clínico controlado aleatorizado.**

Objetivos do estudo

Este trabalho tem como objetivo investigar a efetividade de um tipo de tratamento de fisioterapia chamado Terapia Cognitivo-Funcional comparada a um outro tipo de tratamento de fisioterapia chamado Exercícios e Terapia Manual para a melhora da dor e limitação funcional de pessoas com dor lombar persistente.

Como será feito o estudo

Se o(a) senhor(a) concordar em participar deste estudo, será realizada uma entrevista e preenchimento de questionário sobre sua dor lombar e sua saúde em geral. Após a entrevista o senhor(a) terá a opção de escolher se deseja fazer parte desse estudo. Caso o(a) senhor(a) concorde em participar desse estudo, será solicitado que o(a) senhor(a) responda a alguns questionários sobre a sua dor na lombar e em seguida será sorteado entre duas diferentes opções de tratamento que incluem entrevista e exercícios de fisioterapia para sua dor lombar. O tratamento fisioterápico será realizado semanalmente nas primeiros duas ou três sessões e depois progredirão para uma sessão a cada 2-3 semanas, durante aproximadamente 8 semanas de tratamento. Não haverá despesas pessoais ao participar do estudo, assim como também não haverá compensação financeira devido a sua participação.

Desconfortos e riscos

Os pesquisadores garantem que a participação no estudo não gerará riscos adicionais de qualquer natureza, em relação aos riscos que o tratamento fisioterapêutico convencional que o senhor(a) será submetido caso se recuse a participar do estudo.

Benefícios esperados

O senhor(a) receberá um tratamento de fisioterapia considerado efetivo para a sua dor lombar.

Liberdade de recusar

A participação no estudo é totalmente voluntária. A qualquer momento do estudo, o(a) senhor(a) pode se recusar a participar.

Confidencialidade

Todas as informações obtidas neste estudo são confidenciais, uma vez que seu nome não será associado às análises a serem realizadas. Os dados serão divulgados de forma a não possibilitar sua identificação. Os resultados serão divulgados apenas em apresentações ou publicações com fins científicos ou educativos.

Em caso de dúvida

Caso tenha qualquer dúvida sobre esta pesquisa, pergunte ao profissional de saúde que está lhe atendendo. Se o senhor(a) concordar em participar e desejar ter outras

informações poderá contactar os responsáveis. Este é um projeto de pesquisa realizado pelo Programa De Pós-Graduação Strictu Sensu Em Ciências Da Reabilitação - Centro Universitário Augusto Motta – UNISUAM, sob a responsabilidade dos pesquisadores Julia Castro e Ney Meziat Filho (contato com as pesquisadores responsáveis; Telefones: (19)994983034 e (21)99805-1386; E-mail: julia.d.castro@hotmail.com e neymeziat@gmail.com) e analisado pelo comitê de ética em pesquisa do centro universitário augusto motta – Unisuam (Endereço: Av. Paris, 84 - Bonsucesso, Rio de Janeiro - RJ, 21041-020).

Responda as perguntas a seguir, circulando a resposta SIM ou NÃO:
O senhor(a) leu o termo de consentimento?
Foram respondidas todas as suas perguntas sobre o estudo?
O senhor(a) se sente completamente esclarecido(a) sobre o estudo?

Se concorda em participar deste estudo, por favor assine o seu nome abaixo:

_____ _____

Sua assinatura Assinatura do profissional de saúde

Campinas, _____ de _____ de 201__.

PARTE II – PRODUÇÃO INTELECTUAL

Contextualização da Produção

Quadro 5: Declaração de desvios de projeto original.

Declaração dos Autores	**Sim**	**Não**
A produção intelectual contém desvios substantivos do <u>tema proposto</u> no projeto de pesquisa?		X
Justificativas e Modificações		
A produção intelectual contém desvios substantivos do <u>delineamento do projeto</u> de pesquisa?	X	
Justificativas e Modificações		
Inicialmente, estava prevista também uma análise de modificadores de efeito nos desfechos de dor e incapacidade em pacientes com dor lombar crônica 3 meses após intervenção com Terapia Cognitivo-Funcional. Essa parte, apresentada na parte I do presente documento (Capítulo 2 - Projeto B), não foi realizada em virtude da decisão dos autores em priorizar a condução adequada da Revisão Sistemática. Portanto, os resultados do Projeto B não estão descritos na Parte II – Produção intelectual.		
A produção intelectual contém desvios substantivos dos <u>procedimentos de coleta</u> e análise de dados do projeto de pesquisa?	X	
Justificativas e Modificações		
A ferramenta utilizada para análise do risco de viés dos estudos incluídos na revisão foi alterada. A previsão citava a ferramenta *Cochrane Risk of Bias* (RoB 1) (Projeto A, item 2.7.1), no entanto, por ser mais indicada para os estudos na área da fisioterapia, a ferramenta *Physiotherapy Evidence Database* (PEDro) foi utilizada.		

Disseminação da Produção

Artigos completos publicados em periódicos como primeira autora:

1. J. Castro, L.C. Lunkes, M. Menezes, N. Meziat-Filho, Letter to the editor concerning the article: Scapular exercise combined with cognitive functional therapy is more effective at reducing chronic neck pain and kinesiophobia than scapular exercise alone: A randomized controlled trial (2020), Clinical Rehabilitation. doi: 10.1177/0269215520967940.

2. Castro J, Correia L, Donato BS, Arruda B, Agulhari F, Pellegrini MJ, Belache FTC, de Souza CP, Fernandez J, Nogueira LAC, Reis FJJ, Ferreira AS, Meziat-Filho N. Cognitive functional therapy compared with core exercise and manual therapy in patients with chronic low back pain: randomised controlled trial. Pain. 2022 Dec 1;163(12):2430-2437. doi: 10.1097/j.pain.0000000000002644. Epub 2022 Apr 4. PMID: 35384931. (Observação: artigo oriundo do projeto de mestrado, com coleta de dados finalizada durante o doutorado)

Letter to the Editor

CLINICAL REHABILITATION

Clinical Rehabilitation
1–3

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Letter to the editor concerning the article: Scapular exercise combined with cognitive functional therapy is more effective at reducing chronic neck pain and kinesiophobia than scapular exercise alone: A randomized controlled trial

Julia Castro[1], Luciana C Lunkes[1,2], Michele Menezes[1] and Ney Meziat-Filho[1]

Dear editor,

We would like to thank the authors for publishing this article (Javdaneh et al.[1]). The researchers presented the results of a randomized controlled trial with the aim of investigating the effectiveness of scapular exercises alone and combined with cognitive functional therapy (CFT) in treating patients with chronic neck pain and scapular downward rotational impairment. The authors concluded that the multidisciplinary physiotherapy group, including a cognitive functional approach, was better than the scapular exercise alone group on the primary outcome pain intensity, and secondary outcomes kinesiophobia and muscle activity at 6 weeks. Also, that both rehabilitation programs were better than the control group (single session of instruction for home exercise program). We would like to comment on some relevant conceptual and methodological shortcomings.

First, the clinical trial protocol registered in the Iranian Clinical Trials Registry was modified several times since the first registration. The researchers defined multiple primary outcomes (pain intensity, disability, electromyography, alignment of the scapula, and kinesiophobia) which increase the likelihood of type I error (false positive). There were 11 secondary outcomes registered. Nevertheless, the published manuscript presented pain as the primary outcome, kinesiophobia and muscle activation as secondary outcomes. We wondered why disability was not included as a primary outcome, since this has been broadly used in chronic low back pain and CFT studies.[2–5] The recruitment period described by Javdaneh et al.[1] ended in March 2020. Since the intervention lasted 6 weeks and the article was submitted on March 13, 2020, it is very impressive how quickly the authors were able to analyze data and write the manuscript.

CFT is an intervention that requires trained physiotherapist since the demand of communication and clinical reasoning skills are not common for a great number of clinicians. The authors didn't

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make clear how many therapists were involved in the study and if there was any training and what it was. Although the authors mention that the patients were supervised by three different health professionals (physiotherapist, psychologist, and physical educator), it was not clear who delivered the combined scapular exercise plus CFT intervention. Because CFT is an individual and patient-centered approach, and that three components must be part of the treatment, it is difficult to understand how three health professionals treated the same patient and the reasons why they were from three distinct professions. It may have been a misunderstand of the differences between the terms multidisciplinary, multimodal, and multidimensional. The first involves different specialized professionals, the second means combined approaches, and the third is related to the different dimensions of pain (bio-psycho-social). CFT is a multidimensional biopsychosocial approach, but it is not a multidisciplinary nor a multimodal treatment.

There are three main components of CFT: making sense of pain, exposure with control, and lifestyle change. Javdaneh et al.[1] describe pain neuroscience education as a cognitive component, which consists of explaining to the patient about the processes associated with a pain experience, without maintaining the focus on anatomical structures.[6] However, it is not clear whether the volunteers received this intervention individually or in a group. Although pain neuroscience education is a possibly effective strategy, it is a way of addressing cognitive aspects that differs from those proposed by CFT intervention. The authors claim to follow the protocols for cognitive restructuring by Caneiro et al.[7] and O'Sullivan et al.,[3] who propose a reflective process within the biopsychosocial context, using analogies, metaphors, and associations between painful condition and relevant life events. Thus, the patient can better understand his condition and reframe his previous beliefs about pain. However, even though that Javdaneh et al.[1] have pointed out the relevance of biopsychosocial aspects in the management of painful conditions, the cognitive component was approached in a unidirectional way, with explanations coming from the clinician to the patient, instead of reflective questions as proposed by the intervention. Besides, exercises focused on specific muscle activation deviate from the intervention proposal. Patients are exposed to the activities and movements that are relevant and encouraged to perform them naturally again. Beyond explanations, the patient's history must be validated, giving meaning to their experiences, and as well as their goals and values.

In the present study, we found that the authors did not describe how the patient interview was conducted and did not make it clear whether the fundamental components of CFT were used. This gives health professionals the false impression that CFT addresses the constructs of cognitive aspects without necessarily providing a collaborative environment. Patient-centered interview process recommended by the CFT is based on sensitive and non-judgmental questions, carefully guided, facilitating the multidimensional understanding of pain and disability.

The participants performed scapular exercises intending to activate specific muscles to correct scapular position, based on the assumption that the scapular impairment was associated with neck pain. It would make sense if scapular downward rotation impairment was directly related to neck pain and that the correction of this position produced a clear reduction of symptoms in the neck. There is no evidence to support the idea that improvements in pain and disability are mediated by changes in muscle activation or position. In addition, general exercises seem to have the same effect when compared to specific muscle activation exercises.[8] CFT aims to identify maladaptive functional behaviors which are commonly the product of a persistent interaction between negative beliefs and fear of movement or pain. In the second component, exposure with control, the patient underwent an experiential learning process to abolish sympathetic responses and safety behaviors during painful, feared or avoided functional tasks. In the third component, lifestyle change, patients are encouraged to practice any regular exercise of their choice. It seems that the "CFT" intervention was just its first component, but with a focus on pain education, which is not the same as making sense of pain.[3]

We believe that the cognitive functional approach differs substantially to the idea of activation of specific muscles or positional changes as proposed by the study of Javdaneh et al.[1] Also, we think that

patients would have received conflicting information if they had to correct the muscle activation and the scapular position and at the same time relax and try to perform the movement in a more relaxed and natural way. The authors stated that the addition of CFT resulted in a better result because of the trapezius and serratus muscle activation and the decrease of the downward scapular rotation were able to diminish the compressive loads in the neck. This biomechanical explanation is contrary to CFT concepts.

Since there is no evidence that specific exercises for scapular muscles are better than general exercises for chronic neck pain, the control group should have included general exercises. It would be relevant if the authors performed a mediation analysis to investigate whether changes in scapular position explain the improvement in pain intensity.

We believe that CFT is a promising therapeutic approach and reinforce that investigating its effectiveness through clinical trials is essential. However, it is necessary that studies preserve the principles proposed by the intervention, in order to promote reliable information about its efficacy and collaborate with the knowledge of clinicians and researchers in the field of chronic pain.

Acknowledgements

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Author contributions

All the authors have contributed substantially to this work, and accept responsibility for the content of the manuscript.

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Research Paper

PAIN®

Cognitive functional therapy compared with core exercise and manual therapy in patients with chronic low back pain: randomised controlled trial

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Abstract

Cognitive functional therapy (CFT) is a physiotherapy-led intervention that has evolved from an integration of foundational behavioral psychology and neuroscience within the physiotherapist practice directed at the multidimensional nature of chronic low back pain (CLBP). The current evidence about the comparative effectiveness of CFT for CLBP is still scarce. We aimed to investigate whether CFT is more effective than core training exercise and manual therapy (CORE-MT) in pain and disability in patients with CLBP. A total of 148 adults with CLBP were randomly assigned to receive 5 one-hour individualized sessions of either CFT (n = 74) or CORE-MT (n = 74) within a period of 8 weeks. Primary outcomes were pain intensity (numeric pain rating scale, 0-10) and disability (Oswestry Disability Index, 0-100) at 8 weeks. Patients were assessed preintervention, at 8 weeks and 6 and 12 months after the first treatment session. Altogether, 97.3% (n = 72) of patients in each intervention group completed the 8 weeks of the trial. Cognitive functional therapy was more effective than CORE-MT in disability at 8 weeks (MD = −4.75; 95% CI −8.38 to −1.11; $P = 0.011$, effect size= 0.55) but not in pain intensity (MD = −0.04; 95% CI −0.79 to 0.71; $P = 0.916$). Treatment with CFT reduced disability, but the difference was not clinically important compared with CORE-MT postintervention (short term) in patients with CLBP. There was no difference in pain intensity between interventions, and the treatment effect was not maintained in the mid-term and long-term follow-ups.

Keywords: Low back pain, Cognitive therapy, Pain management, Behavioral interventions, Movement

1. Introduction

Low back pain is the leading cause of disability with a significant social and economic impact around the world.[13,18] There is strong evidence that chronic low back pain (CLBP) is associated with a complex interaction of biopsychosocial factors.[2,3,7,16,27] Although many of these factors are potentially modifiable, most existing interventions are based on a biomedical model focusing on the structure or disease, and they do not target a patient-centered approach for each case of chronic low back pain.[24]

Cognitive functional therapy (CFT) is a physiotherapy-led intervention that has evolved from an integration of foundational behavioral psychology and neuroscience within the physiotherapist practice directed at the multidimensional nature of low back pain.[22,25] The clinical journey is adapted to the individual's profile following 3 main components: (1) making sense of pain, (2) exposure with control, and (3) lifestyle changes.[25] Vibe Fersum et al.[30,31] found that CFT was significantly more effective than the combination of manual therapy and exercise for chronic low back pain and that the reduction in disability was maintained 3 years after the beginning of the study. This study had significant methodological shortcomings regarding the failure to carry out the intention to treat analysis, high risk of attrition bias, and random error.[9,11] O'Keeffe et al.[21] found that CFT was better than group-based exercise and education for disability. However, the high risk of attrition bias and performance bias precluded the confirmation of the CFT effectiveness for disability. Ussing et al.[29] found that CFT was feasible and displayed clinically important effects for chronic low back pain in a secondary care setting. However, the participants were not randomised. Therefore, it is important to conduct clinical trials to compare CFT with other interventions but overcoming these methodological shortcomings. The present study investigated whether CFT is more

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

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effective than CORE-MT in pain and disability over the 8 weeks of treatment in patients with CLBP.

2. Methods

2.1. Study design

This is a parallel-group, randomised, controlled trial conducted in the physiotherapy department of a private orthopedic clinic in Campinas, São Paulo, Brazil (**Fig. 1**). Individuals with CLBP were recruited by referral of physicians and social media from September 2017 to June 2019, with 12-month follow-up ending in June 2020. A total of 4 physiotherapists, one in the CFT group and 3 in the control group, delivered the interventions in this trial. The trial was prospectively registered and was first available on ClinicalTrials.gov on September 6, 2017. The last participant's data were collected on June 28, 2020 (Registration number: NCT03273114). The full protocol manuscript is available online (https://doi.org/10.21203/rs.3.rs-1438806/v1). The trial was reported following the CONSORT statement.[17]

2.2. Participants

Participants aged 18 to 65 years, were independently mobile (with or without aids), were seeking treatment for low back pain with at least 12 weeks of duration, and were able to speak and understand Portuguese. Following Vibe Fersum et al.[30] and O'Keeffe et al.[21] criteria, a score greater than 14% on Oswestry Disability Index (ODI) was required for inclusion. Participants were excluded if the primary pain area was not the lumbar spine (from T12 to buttocks); if leg pain was the primary problem (eg, nerve root compression or disc prolapse with true radicular pain/radiculopathy, lateral recess or central spinal stenosis); if the patient underwent invasive pain relieving procedures such as injection-based therapy (eg, epidurals) and day case procedures (eg, rhizotomy) in the past 3 months; if they were pregnant; if they had rheumatological/inflammatory disease (eg, rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, lupus erythematosus, Scheuermann disease) or progressive neurological disease (eg, multiple sclerosis, Parkinson's disease, motor neuron disease); if they had scoliosis (if considered the primary driver of pain); if they had unstable cardiac conditions; or if they had red flag disorders like malignancy/cancer, acute traumas like fracture (less than 6 months ago), infection, or spinal cord compression/equine tail.

A physiotherapist, who was unaware of the treatment allocation, screened the patients to confirm eligibility starting by the ODI. If the participants scored more than 14% on the ODI and consented to participate in the study, then they completed the remaining sections of the baseline questionnaire before randomisation. The first intervention session was within 1 week of randomisation. Eligible patients were informed about the study's objectives and procedures. All study assessors, both baseline and follow-up, were equally trained to apply the self-reported questionnaires.

2.3. Randomisation and blinding

A computer-generated allocation sequence was used to allocate participants to receive either CFT or CORE-MT. The allocation sequence was arranged using a block randomisation model (size of 4) by an independent investigator and concealed in 148 sequentially numbered, sealed, and opaque envelopes. Immediately before the assignment to the treatment group and after the patient signed the informed consent to participate in the study, the treating clinicians opened the envelope to reveal the group allocation. It was not possible to blind the participants and the treating clinicians. The assessors were not considered blinded because participants were not blinded and outcomes were self-reported. However, to guarantee that the treatment expectation was evenly balanced between the groups and decrease measurement bias, the participants did not know the study hypothesis, and the assessors did not know the participant's intervention group. The statistician was blinded to the group allocation.

2.4. Interventions

We have followed the template for intervention description and replication (TIDieR) checklist to describe the interventions.[12] Both interventions were face to face and individualized, in a room reserved for the session of only 1 patient at a time. The treatments

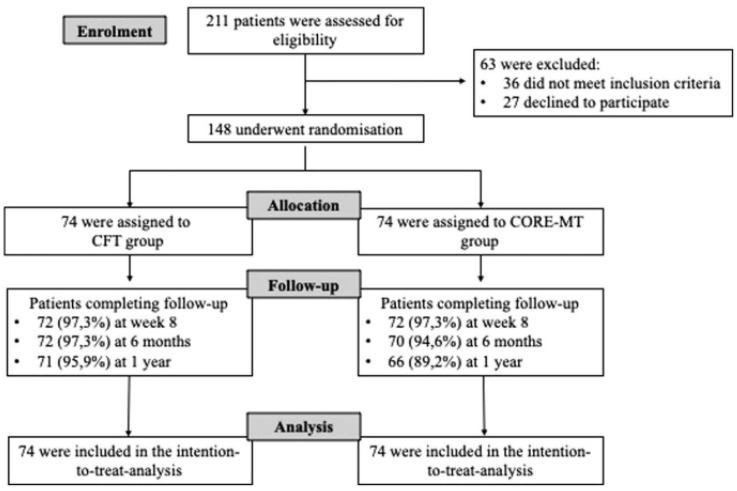

Figure 1. Recruitment of participants, exclusions, and randomisation of patients with chronic low back pain included in the study and follow-ups.

were 5 one-hour sessions for an 8-week intervention period, on a weekly basis for the first 2 weeks and then a session every 2 or 3 weeks. Participants were always treated by the same physical therapist who was not involved in the reassessments of participants. Prescribed exercises were filmed, written, or delivered via booklet by the physiotherapist so that participants could perform them at home regularly. The assessment of treatment fidelity was performed by in vivo observations as well as video recording during the pilot study and along the trial. Also, regular meetings to discuss these clinical cases were performed. Both groups were monitored and had adequate adherence to the treatment that was performed as planned.

2.4.1. Cognitive functional therapy

Cognitive functional therapy is an integrated and flexible behavioral approach developed to reduce pain and disability in people with chronic low back pain. There were 3 main components in the intervention, according to O'Sullivan et al.[25] and Caneiro et al.[4]: Making sense of pain, exposure with control, and lifestyle change.

Making sense of pain is a reflective process that uses a patient's own story and relevant life events, combined with their experiences during behavior exposure to not only achieve a new understanding of their pain but also increase self-efficacy to reach their goals. A timeline of the pain history recalling biopsychosocial factors that may have played a role in the rise and persistence of the symptoms can help patients make sense of their chronic low back pain and disability. Listening to the patient's history is key to identify the context, area and characteristics of pain, level of disability, beliefs, physical factors, coping strategies, lifestyle factors, goals, and values. Therapeutic alliance is enhanced with elements such as empathy, mirroring, reflective issues, and reinforcement of positive behaviors. The patients develop an understanding of the contexts in which pain flare-ups occur, and therefore, positive coping strategies could be determined and discussed. Afterward, a summary of what was discussed is reviewed with the patient.

Exposure with control is a process of behavior change that allows individuals to gradually return to their valued functional activities without pain escalation and associated distress. It aims at focusing the experience of pain as a hypothesis for testing behavioral experiments using the experience of pain where possible. For instance, "lifting with a flexed spine will increase my pain." An experience in which learned associations between threatening tasks and increased pain or harm may be corrected and new "safety" associations are formed. This strategy comes from the assumption that the discrepancy between expectancy and experience (expectancy violation) is helpful for new learning. For some individuals, the objective is to experience less pain during task performance, while for others, it may be getting involved with the feared and avoided tasks without damage. In this process, sympathetic responses and safety-seeking behaviors that happen during the performance of painful, feared, or avoided functional tasks are specifically targeted and controlled to create a mismatch between the individual's expected and actual pain responses. For instance, prior individual expectation: "I expect my pain will increase with repeated lifting. Individual experience": "When I relax, breathe and bend my back without protecting it, my pain does not get worse—it alleviates." Exposure with control includes promotion of body relaxation before exposure, reduction of protective behaviors, and encouragement of body awareness and control that enables the individual to experience functional activities in nonprotective ways. As an example, lifting in a relaxed manner and modifying how the individual physically performs the task without unhelpful protective responses (ie, bracing, breath holding, avoidance of spinal flexion) may result in a positive experience that promotes safety learning.

Lifestyle change is to help patients adopt a healthy lifestyle. Strategies for changing unfavorable lifestyle behaviors are discussed as part of making sense of pain. Physical activity is based on a person's preferences linked to individual goals considering costs, accessibility issues, and social engagement to stimulate enduring behavior change. Sleep deficits associated with by poor sleep hygiene are addressed establishing a daily routine and reducing the use of electronic in bed. Disturbances due to pain, worry, and stress may be managed with techniques of relaxation (ie, guided meditation) and engaging in regular physical activity. Specific training of rolling and posturing in bed in a relaxed way is explored when movement and postures in bed are an issue.

Participants randomised in the CFT group were treated by a newly graduated physiotherapist with 1 year of clinical experience in CFT. She attended 3 CFT workshops with 3 tutors of the method and completed 106 hours of training, including workshops, patient examinations, and a pilot study with the supervision of a physiotherapist with more than 4 years of clinical experience in CFT.

2.4.2. Core training exercise and manual therapy

The participants assigned to the comparison group were treated with a strengthening program to maximize static core muscle endurance and dynamic core stability, based on McGill core exercises.[20]The approach consisted of trunk, abdominal, and pelvic strengthening in different functional positions and was progressive in relation to difficulty and intensity. Before core endurance exercises, flexion-extension motion was performed by slowly cycling through full spine flexion to full extension in 4-point kneeling (cat–camel exercise) and the basic abdominal brace was taught in a relaxed neutral spine position. Core endurance exercises included bridge exercises (bridge, prone bridge, and side bridge), 4-point kneeling exercises (ie, bird–dog), and supine exercises (ie, dead bug, curl-up). Core muscles were maintained active to control the lumbar spine and pelvic girdle during multiplanar arm and leg movements (ie, lunges, hip abduction). A list including the detailed description of the main exercises is provided in the supplementary material (available at http://links.lww.com/PAIN/B612). The prescription of the exercises was individualized, and the exercises were performed with resistance (elastic bands, dumbbell, or ankle weights) and on unstable surfaces according to the progress of each patient. The physiotherapists of this group provided instruction, demonstration, and individual feedback for the exercises during the sessions. Patients were instructed and encouraged to perform a 30-minute exercise session at home including 2 to 3 sets of 6 to 12 repetitions holding the isometric contraction for 3 to 10 seconds of each prescribed exercise 3 times a week. The manual therapy interventions were joint mobilization or manipulation (thrust)[15] and mobilization with movement techniques[14] to the spine or pelvis. These interventions were used pragmatically whenever the therapist judged necessary, with the aim of restoring optimal motion, reducing pain, and facilitating core exercises progression. Participants in the CORE-MT group were treated by 3 physiotherapists with at least 5 years of clinical experience in manual therapy and core training exercises with no prior training in CFT.

2.5. Outcomes

The primary outcomes were pain intensity (on a numerical pain-rating scale from 0 to 10, with 0 indicating no pain and 10 the

worst possible pain) and disability associated with low back pain measured on the Oswestry Disability Index (scores ranged from 0 to 100) 8 weeks after first intervention session (postintervention).[6,32] Secondary outcomes were pain intensity and disability assessed 6 and 12 months after the first intervention session. Additional secondary outcomes were global perceived effect measured on Global Perceived Effect Scale (current symptoms as compared with baseline, on a scale from −5 [vastly worse] to 0 [unchanged], to +5 [completely recovered]), and patient satisfaction measured on the patient satisfaction questionnaire (1 = satisfied, 2 = just a little satisfied, 3 = neither satisfied nor dissatisfied, 4 = just a little dissatisfied, 5 = dissatisfied) at 8 weeks and 6 and 12 months after intervention.[10,33]

Other data that were collected included baseline sociodemographic information, symptoms duration, number of pain areas, family history of low back pain, MRI scans performed, back surgery, paid work, and chronicity risk (Örebro Musculoskeletal Pain Questionnaire [OMPQ] and and StarT back screening tool [SBST]).[8,26]

Outcomes were assessed at 8 weeks (primary end points), 6 months, and 12 months by means of telephone contact by 2 blinded assessors (1 physiotherapist and 1 physical educator) trained by the principal researcher during a pilot study. They did not treat any of the participants nor were aware of their group allocation or received any information regarding the treatment arm of the participants. Also, both assessors did not have access to the place where the treatment was administered or the waiting room.

2.6. Sample size calculation

We determined that a minimum sample size of 148 participants (74 per group) would be required to provide the trial with 80%

Table 1

Characteristics of the patients at baseline.

Characteristic	CFT group	CORE-MT group
Female sex—n (%)	44 (59.46)	47 (63.51)
Age—y; mean (±SD)	46.39 ± 10.62	40.43 ± 11.55
Height—m	1.69 ± 10.34	1.69 ± 9.75
Weight—kg	77.49 ± 12.02	78.06 ± 16.45
Paid work—n (%)	62 (83.78)	56 (75.68)
Disability (ODI)	30.66 ± 10.82	26.98 ± 9.44
Pain intensity (NPS)	5.78 ± 1.71	5.58 ± 1.84
Duration of LBP—months (median, IQR)	72 (120)	48 (72)
Low back surgery—n (%)	6 (8.22)	4 (5.56)
No of pain sites—(median, IQR)	5 (6.25)	5 (5)
Family history of LBP—n (%)	54 (73.97)	56 (77.77)
MRI scan performed—n (%)	60 (82.19)	60 (83.33)
Risk of chronicity, Örebro (0-100)	53.70 ± 11.21	53.36 ± 12.18
Risk of chronicity, StarTback—n (%)		
Low risk	17 (22.97)	21 (28.38)
Medium risk	34 (45.95)	35 (47.29)
High risk	23 (31.08)	18 (24.32)

Data of the variables family history, MRI scan performed and low back surgery of one participant in the CFT group and of 2 participants in the control group were missing.
CFT, cognitive functional therapy; CORE-MT, core training exercise and manual therapy; LBP, low back pain; NPS, numerical pain rating scale; ODI, Oswestry Disability Index.

Table 2

Unadjusted mean (SD) for each numeric outcome, including primary outcomes (pain intensity and disability at 8 weeks) and secondary outcomes (pain intensity and disability at 6 and 12 months, and global recovery), by treatment group and adjusted between-group mean differences for each follow-up time point.

	Baseline		8 wk				6 mo				12 mo			
	CFT (n = 74)	CORE-MT (n = 74)	CFT (n = 72)	CORE-MT (n = 72)	Adjusted between-group mean difference (95% CI)	Effect size as SMD*	CFT (n = 72)	CORE-MT (n = 70)	Adjusted between-group mean difference (95% CI)	Effect size as SMD*	CFT (n = 71)	CORE-MT (n = 66)	Adjusted between-group mean difference (95% CI)	Effect size as SMD*
Pain intensity (0-10)	5.78 (1.70)	5.58 (1.84)	3.57 (2.46)	3.51 (2.31)	−0.04 (−0.79 to 0.71)	0.07	3.82 (2.56)	4.16 (2.53)	−0.25 (−1.12 to 0.62)	0.14	3.92 (2.44)	3.52 (2.35)	0.29 (−0.54 to 1.11)	0.19
Disability (0-100)	30.66 (10.82)	26.98(9.44)	17.48 (13.43)	20.25 (11.43)	−4.75 (−8.38 to −1.11)†	0.55	17.35 (12.41)	18.90 (10.37)	−2.98 (−6.45 to 0.48)	0.43	18.21 (13.28)	17.67 (12.40)	−1.43 (−5.45 to 2.58)	0.22
Global recovery (−5 to +5)	—	—	2.76 (1.80)	2.42 (1.70)	0.34 (−0.33 to 1.01)	0.19	2.17 (2.32)	2.13 (2.28)	0.06 (−0.63 to 0.74)	0.02	2.07 (2.24)	2.35 (1.96)	−0.25 (−0.94 to 0.44)	0.13

* Standardized mean difference (SMD) calculated from marginal estimates (Cohen d).
† $P < 0.05$.
CFT, cognitive functional therapy; CORE-MT, core training exercise and manual therapy.

power to detect a between-group difference of 1.0 point for pain intensity and 5 points for disability (ODI) at 8 weeks. We performed the sample size calculation with lower values than what is considered clinical important changes to generate a larger statistical precision.[23] Assumptions for the pain intensity and disability included a 2-sided alpha level of 0.05 and a mean standard deviation of 2.0 for pain and 10% for disability. The estimated sample size also allowed a limit of 15% loss of follow-up.

2.7. Statistical analyses

Analyses were performed by a statistician who received the encoded data and were based on intention-to-treat principles. Missing data were assumed to be missing completely at random. Multiple imputation was used to account for these missing data.[28] Missing values in outcome variables were estimated using multiple imputation by chained equations after 50 replicated imputed data sets. Variables included in the multiple imputation process included (1) group factor, (2) time factor, and (3) the respective outcome variable. Descriptive statistics was used to describe the characteristics of the participants in both treatment groups. Two-sided *P* values of less than 0.05 were considered to indicate statistical evidence of significance. The outcomes pain intensity, disability, and global perceived effect were analyzed using repeated-measure linear mixed models (participants and time as random factors) that included all the scores that were reported after randomisation with the baseline scores as covariates. Adjusted mean differences were tested at week 8, 6 months, and 12 months. Multiple comparisons were performed using the Tukey test with *P* values adjusted using the Holm procedure. The variable patient satisfaction was compared by ridit analysis of the ordered categorical data. Effect sizes for primary and secondary outcomes (except patient satisfaction) were calculated as Cohen d from estimated marginal means and standard error estimates from the primary adjusted analysis. Effect sizes were interpreted according to Cohen criteria (small ≤ 0.2; moderate = 0.5; large ≥ 0.8).[5] All analyses were performed using the RStudio version 0.99.486 and packages "nlme," "emmeans," "mice," "miceadds," "mitml," "multicomp," "stddiff," and "ridittools" (supplementary material, available at http://links.lww.com/PAIN/B612).

3. Results

3.1. Recruitment and baseline data

A total of 148 participants from an orthopedic clinic underwent randomisation; 74 participants were randomly assigned to the CFT group and 74 to the CORE-MT group (**Fig. 1**). Altogether, 97.3% (n = 72) of participants in each intervention group completed the 8 weeks of the trial; 97.3% (n = 72) of participants in the CFT group and 94.6% (n = 70) of participants in the CORE-MT group completed the 6 months of the trial; 95.9% (n = 71) of participants in the CFT group and 89.2% (n = 66) completed the 1 year of the trial.

The characteristics of the participants at baseline are presented in **Table 1**. Participants were mainly middle aged, predominantly female, and had paid work. The median of low back pain duration was 60 months, and the median of the number of pain sites was 5. The majority of participants scored a high risk of chronicity on OMPQ (62.84%), which was the same for both groups, as well as family history of low back pain (75.86%) and MRI scan performed for low back pain (82.76%). The mean number of treatments (SD) was similar in both groups (CFT: 4.24 [1.17] vs CORE-MT: 4.23 [1.22]).

3.2. Primary outcomes

In the analysis of primary outcomes, CFT was more effective than CORE-MT in disability at 8 weeks (MD = −4.75; 95% CI −8.38 to −1.11; *P* = 0.011; effect size = 0.55). This study found no difference between groups in pain intensity (MD = −0.04; 95% CI −0.79 to 0.71; *P* = 0.916) (**Table 2** and **Fig. 2**).

3.3. Secondary outcomes

In the analysis of numeric secondary outcomes (**Table 2**), this study found no difference between groups in pain intensity at 6 months (MD = −0.25; 95% CI −1.12 to 0.62, *P* = 0.576) or in disability at 6 months (MD = −2.98; 95% CI −6.45 to 0.48, *P* = 0.091) (**Fig. 2**). There was no difference between groups in pain intensity (MD = 0.29: 95% CI −0.54 to 1.11, *P* = 0.494) or disability (MD = −1.43: 95% CI −5.45 to 2.58, *P* = 0.484) at 12 months (**Fig. 2**). No difference was found between groups in global perceived effect at 8 weeks (MD = 0.34; 95% CI −0.33 to 1.01, *P* = 0.32), at 6 months (MD = 0.06; 95% CI −0.63 to 0.74, *P* = 0.873), or 12 at months (MD = −0.25; 95% CI −0.94 to 0.44, *P* = 0.481). Also, no difference was found between group in patient satisfaction (**Table 3**). No serious adverse events related to the interventions were reported.

4. Discussion

4.1. Principal findings

This randomised clinical trial showed that CFT reduced disability, but the difference was not clinically important compared with CORE-MT post-intervention (short term) in patients with CLBP. There was no difference in pain intensity between interventions, and the treatment effect was not maintained in the mid-term and long-term follow-ups.

4.2. Comparison with other trials

O'Keeffe et al.[21] found a reduction in disability at 6 months and at 1-year follow-ups when CFT was compared with a group exercise and education but with a loss of follow-up of 30% of participants. It is difficult to compare O'Keeffe et al. trial findings to our findings because the authors did not present the results postintervention. However, the high risk of attrition bias of O'Keeffe et al. trial may explain why our trial failed to replicate the reduction in disability at 6 months and 1-year follow-ups. The same therapist applying both interventions combined with the longer period of the CFT group treatment may have generated performance bias and inflate the effect size.

Vibe Fersum et al.[30] also found a reduction in disability (MD = −9.7; 95% CI −12.7 to −6.7) with an effect size greater than in our trial, but contrary to our trial and the O'Keeffe et al. trial, they showed a reduction in pain intensity (MD = −2.1; 95% CI −2.7 to −1.4). The greater effect size and the reduction in pain intensity may be because the study of Vibe Fersum et al. was vulnerable not only because of the high risk of bias but also because of the high risk of random error due to the small sample size (n = 94). There was a substantial violation of intention-to-treat principles with the exclusion of 27 of 121 participants before the 3-month follow-up.

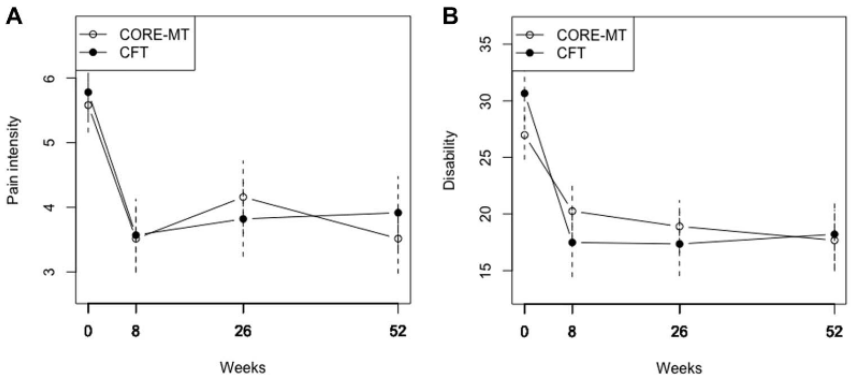

Figure 2. Mean pain intensity (left) and disability (right) for CFT and CORE-MT groups. CFT, cognitive functional therapy; CORE-MT, core training exercise and manual therapy.

Contrary to the O'Keeffe et al. and Vibe Fersum et al. trials, in our trial, the reduction in disability was not maintained at 6 and 12 months. In addition to the high risk of attrition bias as opposed to the low risk in our trial, there are other factors that may explain the difference in the results between studies. Besides, the newly graduated physiotherapist in the CFT group in our trial; the mean of treatments was 4.2 over 8 weeks, vs 7.7 over 12 weeks in the Vibe Fersum trial, and 5.0 over 13.7 weeks in the O'Keeffe trial. The higher number of treatments and weeks patients were receiving care could have prolonged the effect of treatment. Our results suggest that a booster session at 6 months may be necessary to prolong the treatment effect.[11]

Other biopsychosocial approaches that are in line with CFT presented promising results in recent clinical trials.[1,19] Ashar et al.[1] compared pain reprocessing therapy (PRT) with an open-label placebo and usual care for chronic low back pain and found large reduction in pain intensity that continued at 1-year follow-up. The aim of this approach was to promote patients' reconceptualization of primary (nociplastic) chronic pain as a brain-generated false alarm using cognitive, somatic, and exposure-based techniques. Malfiet et al.[19] showed that pain neuroscience education combined with cognition-targeted motor control training reduced pain intensity and disability with medium to large effect sizes compared with traditional back and neck education and general exercises for chronic spinal pain. Similarly, to the second component of CFT, cognition-targeted motor training was based on movements participants feared and avoided that were introduced using a graded approach with the progression toward physically, cognitively, and psychosocially demanding situations.

4.3. Clinical implications

Cognitive functional therapy reduced disability compared with core exercise and manual therapy for patients with chronic low back pain postintervention. However, this effect was not clinically important and was not maintained at mid- and long-term follow-up.

4.4. Strengths and limitations of the study

The present trial has several strengths and limitations. Our research group is independent of the group that developed CFT. Our trial was the first trial on CFT conducted outside Europe and in an upper-middle-income country. The study followed the prespecified protocol without substantial violations. The 3 physiotherapists of the comparison group were used to treating patients using core exercises and manual therapy and did not attend any CFT workshop. The primary outcomes were the ones prespecified in the registered protocol and our trial achieved a very low loss of follow-up of participants in the time point of the primary outcomes (2.7% vs 37% in the O'Keeffe et al.[21] trial and 22.5% in the Vibe Fersum et al.[30] trial) as well as at 6 months (4% vs 28% in the O'Keeffe et al. trial and 22.5% in the Vibe Fersum et al. trial) and at 12-month follow-ups (7.5% vs 31% in the O'Keeffe et al. trial and 22.5% in the Vibe Fersum et al. trial). Opposed to the Vibe Fersum et al. trial, our trial did not violate intention-to-treat principles.

There are some limitations. There was a slight random imbalance in the distribution of some variables in the characteristics of the sample (eg, disability). This was not a statistical issue because the primary outcome disability postintervention was adjusted by the baseline value of the same variable for the linear

Table 3

Secondary outcome patient satisfaction.

Patient satisfaction, n (%)	CFT group					CORE-MT group					
	1	2	3	4	5	1	2	3	4	5	
At 2 mo	63 (87.50%)	6 (8.33%)	1 (1.39%)	1 (1.39%)	1 (1.39%)	58 (81.69%)	8 (11.27%)	4 (5.63%)	1 (1.41%)	0 (0.00%)	$z = 0.597$, $P = 0.550$
At 6 mo	53 (73.61%)	10 (13.89%)	6 (8.33%)	3 (4.17%)	0 (0.00%)	47 (67.14%)	12 (17.14%)	7 (10.00%)	3 (4.29%)	1 (1.43%)	$z = 0.683$, $P = 0.494$
At 1 y	53 (74.65%)	10 (14.08%)	8 (11.27%)	0 (0.00%)	0 (0.00%)	45 (68.18%)	7 (10.61%)	11 (16.67%)	1 (1.52%)	2 (3.03%)	$z = 0.889$, $P = 0.374$

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.
CFT, cognitive functional therapy; CORE-MT, core training exercise and manual therapy.

mixed model. However, it seems that the block randomisation (size of 4) of 148 participants in 2 groups of 74 is still small to ensure balance of baseline characteristics and eliminates selection bias. It was not possible to blind assessors because the outcomes were self-reported and the participants were not blinded. The study was conducted in one clinic in Brazil, which may limit generalizability.

5. Conclusion

Treatment with CFT reduced disability, but the difference was not clinically important compared with CORE-MT postintervention (short term) in patients with CLBP. There was no difference in pain intensity between interventions, and the treatment effect was not maintained in the mid-term and long-term follow-ups.

Conflict of interest statement

The authors have no conflict of interest to declare.

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Authors contributions: All authors contributed to the concept and design of the study. J. Castro was the therapist of CFT group and was involved in setting the writing article assisted by N. Meziat-Filho, L. Correia, F.J.J. Reis, and L.C. Nogueira. N. Meziat-Filho also contributed in data interpretation and statistical analysis strategy. M.J. Pellegrini was one of the assessors. B.S. Donato, B. Arruda, and F. Agulhari were the therapists of the CORE-MT group. Statistical analysis was performed by A.S. Ferreira. F.T.C. Belache, C.P. Sousa, and J. Fernandez contributed to the critical revision of the article. All authors read and approved the final version of the article.

This study was approved by the Research Ethics Committee of Centro Universitário Augusto Motta Ethics Committee (approval number: 2219742). All patients signed the informed consent form prior to participation.

Appendix A. Supplemental digital content

Supplemental digital content associated with this article can be found online at http://links.lww.com/PAIN/B612.

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Manuscrito(s) para Submissão

NOTA SOBRE MANUSCRITOS PARA SUBMISSÃO

Este arquivo contém manuscrito(s) a ser(em) submetido(s) para publicação para revisão por pares interna. O conteúdo possui uma formatação preliminar considerando as instruções para os autores do periódico-alvo. A divulgação do(s) manuscrito(s) neste documento antes da revisão por pares permite a leitura e discussão sobre as descobertas imediatamente. Entretanto, o(s) manuscrito(s) deste documento não foram finalizados pelos autores; podem conter erros; relatar informações que ainda não foram aceitas ou endossadas de qualquer forma pela comunidade científica; e figuras e tabelas poderão ser revisadas antes da publicação do manuscrito em sua forma final. Qualquer menção ao conteúdo deste(s) manuscrito(s) deve considerar essas informações ao discutir os achados deste trabalho.

1.1 Effectiveness of Cognitive Functional Therapy for chronic low back pain: A systematic review with meta-analysis review #1

1.1.1 Contribuição dos autores do manuscrito para submissão #1

Iniciais dos autores, em ordem:	JC	RA	BS	LL	MP	NM
Concepção	X	X	X	X	X	X
Métodos	X	X	X	X	X	X
Programação	X		X			X
Validação	X		X			X
Análise formal	X		X	X		X
Investigação	X	X	X			X
Recursos	X	X	X			X
Manejo dos dados	X	X	X			X
Redação do rascunho	X		X	X	X	X
Revisão e edição	X		X	X	X	X
Visualização	X			X	X	X
Supervisão			X	X		
Administração do projeto	X					X
Obtenção de financiamento	-	-	-	-	-	-

Contributor Roles Taxonomy **(CRediT)**[4]

[4] Detalhes dos critérios em: https://doi.org/10.1087/20150211

EFFECTIVENESS OF COGNITIVE FUNCTIONAL THERAPY FOR CHRONIC LOW BACK PAIN: A SYSTEMATIC REVIEW AND META-ANALYSIS

ABSTRACT

Question: Is Cognitive Functional Therapy effective at improving pain and disability in people with chronic low back pain? **Design:** Systematic review of randomized controlled trials. PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro and Cochrane Central Register of Controlled Trials (CENTRAL) were searched from inception to November 2023. The Physiotherapy Evidence Database (PEDro) tool was used for assessing risk of bias and Grading, Assessment, Development and Evaluations (GRADE) was used to interpret certainty of evidence. **Participants:** People with chronic low back pain. **Intervention and Comparison:** Cognitive Functional Therapy (CFT) compared with active control, passive interventions, or minimal interventions. **Outcomes:** Pain intensity and disability (at short, intermediate, and long-term follow-up*)* by validated instruments to assess these outcomes. **Results:** Eight trials involving 1322 participants were included. When compared with active interventions including exercise, moderate certainty of evidence showed that CFT has a moderate effect in reducing disability in the short term *(*MD -8.58, 95% CI -10.67 to -6.49), low certainty evidence showed that CFT has a moderate effect in reducing disability in the moderate term (MD -8.28, 95% CI -13.04 to -3.52), and high certainty evidence showed that CFT has a small effect in the long term (MD -4.00, 95% CI -7.42 to -0.58). For pain intensity, very low certainty of evidence indicated CFT has a moderate effect in the short term (MD -13.93, 95% CI -21.76 to -6.10), low certainty of evidence indicated that CFT has a moderate effect in the intermediate term (MD -13.25, -19.44 to -7.05), and moderate certainty of evidence that CFT has a small effect in the long-term (MD -6.55, 95% CI -13.30 to 0.20). Low certainty evidence suggests that CFT has a large effect compared with minimal intervention for disability in the short term (MD -18.40, 95% CI -23.74 to -13.07). **Conclusion:** Current evidence supports the use of CFT for patients with chronic low back pain.

Registration: PROSPERO CRD42021230211.

BACKGROUND

Low back pain is the most prevalent health condition, responsible for the highest disability index and has the greatest socioeconomic impact across the world in the last three decades (DE DAVID et al., 2020; VOS et al., 2020; WU et al., 2020). In 90% of cases, low back pain is not associated with anatomical causes or specific diseases and is therefore classified as non-specific (MAHER; UNDERWOOD; BUCHBINDER, 2016).

It is known that psychosocial factors, such as emotional, cognitive, social, behavioral and lifestyle aspects are related, in different proportions between individuals, to the emergence and persistence of pain (MITCHELL et al., 2018). Cognitive Functional Therapy (CFT) is an intervention to manage pain and its consequences, considers multidimensional factors, and focuses on changing those that are modifiable. It is a behavioral approach and consists of three main components: a cognitive component (often called making sense of pain); controlled exposure; and lifestyle change (SULLIVAN et al., 2018).

There are previously published systematic reviews, with divergent results between them and a low level of certainty due to the limited number of published studies at that time (DEVONSHIRE et al., 2023; MIKI et al., 2022). There has been a growing number of randomized controlled trials regarding the approach in recent years (AHMAD et al., 2023; AVILA et al., 2024; BELACHE et al., 2018; KENT et al., 2023b). Therefore, this systematic review aims to estimate the effects of CFT on pain and disability in people with chronic low back pain, through a systematic review conducted with appropriate methodology and updated data.

METHODS:

The protocol for this systematic review was prospectively registered in PROSPERO (CRD42021230211) in February 2021. The design and reporting of this review followed the Preferred Reporting Items for Systematic Review and Meta-analyses (PRISMA) statement (LIBERATI et al., 2009).

Identification and selection of studies:

The search strategy was developed using Medical Subject Heading and keywords based on the Cochrane Handbook and included the following databases: PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro and Cochrane

Central Register of Controlled Trials (CENTRAL) from inception to November 2023 (search strategy can be found in Appendix).

The references obtained in the systematic search were exported and saved in reference management software (*EndNote X9 Thomson Corporation*) and duplicates were removed. The titles obtained were exported to web software for systematic review management (*Covidance*), where two reviewers (JC and RKA) independently screened the studies obtained in the systematic search.

The titles and abstracts were evaluated for relevance following our inclusion criteria. Full texts of potentially eligible articles were obtained. Disagreements between the two reviewers were resolved through discussion with a third reviewer (NM).

We included randomized controlled trials investigating Cognitive Functional Therapy compared with active control (education intervention, general exercises, motor control exercises, core training exercises, etc), passive interventions (manual therapy, ultrasound, etc.), minimal intervention (booklets) or no intervention (waiting-list) published in peer-reviewed journals. Other study designs, conference proceedings, dissertations, and non-original research were excluded (Figure 1).

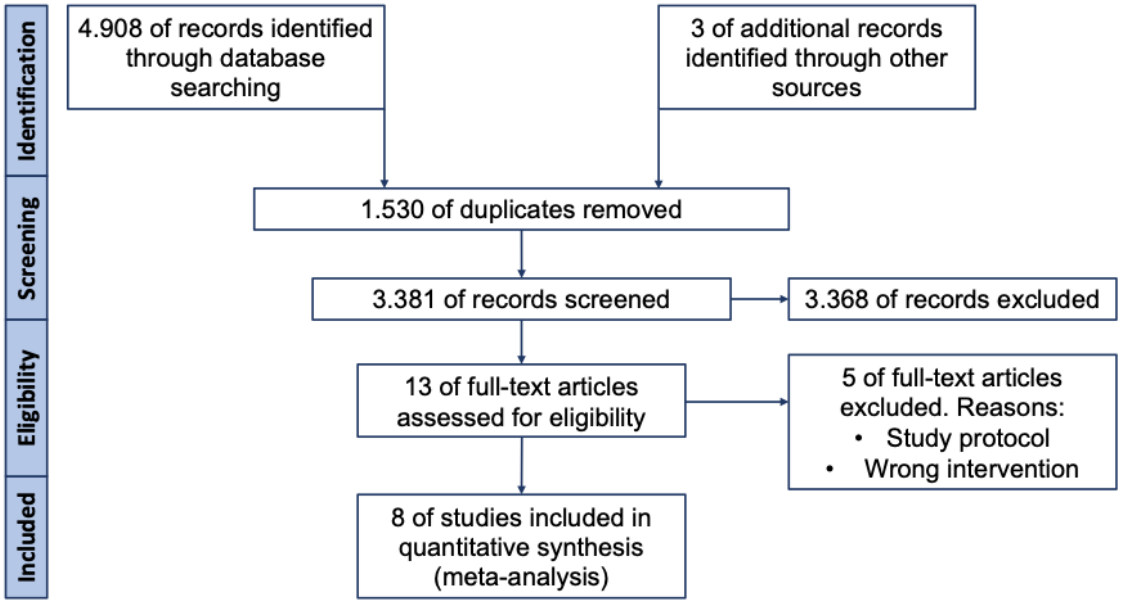

Figure 1. Flowchart of the different phases of the systematic review.

Assessment of characteristics of studies

The risk of bias of each study included in the review was assessed by two independent reviewers (JC and NM) using the PEDro scale, based on the following items: eligibility criteria, random allocation, concealed allocation, baseline comparability, blind subjects, blind therapist, blind assessor, adequate follow-up, intention-to-treat analysis, between-group statistical comparison, point estimates and measures of variability. The score is obtained by adding the number of items on the scale (0-10) that have been met. The first item, “eligibility criteria”, does not contribute to the total score and studies with a score lower than 6 are classified as high risk of bias. Although Cochrane (RoB) was registered in the PROSPERO, we chose PEDro tool because it is more suitable for physiotherapy studies (GAZZI et al., 2010; MAHER et al., 2003; OLIVO et al., 2008).

Data analysis

The studies’ characteristics, participants' characteristics and outcomes were extracted by two independent reviewers (JC and NM). The outcomes were pain intensity and disability at the following time points: short-term (less or equal than 3 months after randomization), intermediate term (4-11 months after randomization), and long-term (12 months or more) by validated instruments to assess these outcomes.

We calculated mean differences (MD) and 95% confidence intervals (CIs) for continuous outcomes using random-effect model meta-analyses. It was not necessary to contact any study author. All necessary information was obtained through the full text and supplementary materials from included studies.

Pain intensity data required a transformation from the 0 to 10 Numeric Rating Scale (CHILDS; PIVA; FRITZ, 2005) into a 0 to 100 scale for appropriate calculation and meta-analysis. It was also necessary to transform the Rolland Moris, 0 to 24 points scale, into a 0 to 100 scale, so that comparison with the Oswestry Disability Index (ODI) could be possible (ROLAND; FAIRBANK, 2000). These changes were made according to the Cochrane Handbook and previous research (CHIAROTTO et al., 2016).

Data analysis was completed using *RevMan,* the Cochrane tool for systematic review and meta-analysis. Data were pooled when trials investigated CFT with

similar control groups (active or minimal intervention). Data were presented using forest plots.

Subgroups and sensitivity analysis

We planned to perform subgroup and/or sensitivity analyses according to peculiarities of the studies and groups, such as duration, numbers and type of interventions sessions, characteristics of participants, outcomes (different outcomes and different follow up timing) and risk of bias whether there was enough data and homogeneous characteristics of participants.

The certainty of evidence

The certainty of evidence for pooled trials was assessed and interpreted using the GRADE (Grading of Recommendations Assessment, Development and Evaluation). All randomized clinical trials are initially classified as high level of certainty and can be downgraded by one or two levels for each of the follow five certainty evidence factors:

(i) Study design and risk of bias: downgrade if more than a quarter of participants sources are from high-risk bias studies. (ii) Inconsistency of results (downgrade one point if I^2 > 50% and two points if I^2 >75%) (GUYATT et al., 2011a). (iii) Indirectness (downgrade if results not generalizable to population context, intervention, outcome, and conclusion based on direct comparison) (GUYATT et al., 2011b). (iv) Imprecision (downgrade if there is imprecision in the effect estimates, insufficient and sparse data on the magnitude of the sample size and studies) (GUYATT et al., 2011c). (v) Publication bias (downgrade if confirmed by visual inspection of the forest plot) (GUYATT et al., 2011d). We planned to estimate the probability of publication bias using funnel plots when there were more than ten studies in the same comparison. However, this was not possible due the low number of included studies for each comparison. We considered imprecise those comparisons that included fewer than 400 participants for continuous outcomes which could be downgraded one level.

The recommendations will be graded into 4 levels of certainty: High (further research on the subject is very unlikely to change either the estimate or our

confidence in the results), moderate (further research on the subject is likely to have a significant impact on our confidence in the estimate of effect and may change the estimate), low (further research is very likely to have a significant impact on our confidence in the estimate of effect and is likely to change the estimate and very low (any estimate of effect is uncertain). Full details for all categories of GRADE, including heterogeneity, can be found in table 3. The communication of the findings was based on GRADE guidelines 26 (SANTESSO et al., 2020).

RESULTS:

Characteristics of trials

Eight trials involving 1322 participants were included (AHMAD et al., 2023; AVILA et al., 2024; BELACHE et al., 2018; CASTRO et al., 2022; KENT et al., 2023b; NG et al., 2015b; O'KEEFFE et al., 2020a; VIBE FERSUM et al., 2013). The mean age was 40.9 (SD=9.9) and 53.6% were female. The intervention duration varied between 8 to 12 weeks. Six trials compared CFT with an active control group and two trials compared with minimal intervention (table 1). Most studies (75%) were judged as "low risk of bias" by the PEDro Risk of bias tool (table 2) and lost points in the participants, therapists and evaluators blinding items. Two studies (25%) lost one point due to high loss of follow-up of participants and only one study (12.5%) lost one point for not adequately conducting intention-to-treat analysis.

Table 1. Characteristics of studies.

STUDY	PARTICIPANTS			INTERVENTION	
	Population	**CFT**	**Comparator**	**CFT**	**Comparator**
AMHAD ET AL., 2023	Adults with CLBP	Age 26 (3.17) Female 62.2%	Age 27.17 (5.10) Female 56.5%	Cognitive Functional Therapy (n=45)	Movement System Impairment (MSI)-based treatment (n=46)
AVILA ET AL., 2023	Adults with CLBP after spinal surgery	Age 49 (10.59) Female 60%	Age 50.45 (10) Female 50%	Cognitive Functional Therapy (n=40)	Core Training Exercise and Manual Therapy (n=40)
BELACHE ET AL., 2018	Adults with CLBP	Age 45.6 (11.7) Female 75.7%	Age 44.7 (12) Female 73.5%	Cognitive Functional Therapy (n=74)	Manual therapy and motor control exercise (n=74)
CASTRO ET AL., 2022	Adults with CLBP	Age 46.39 (10.62) Female 59.4%	Age 40.43 (11.55) Female 63.5%	Cognitive Functional Therapy (n=74)	Core Training Exercise and Manual Therapy (n=74)
O'KEFFE ET AL., 2020	Adults with CLBP	Age 47(13.2) Female 77.4%	Age 50.6 (14.9) Female 70%	Cognitive Functional Therapy (n=106)	Group-based exercise and education intervention (n=100)
FERSUM ET AL., 2013	Adults with CLBP	Age 41 (10.3) Female 52.9%	Age 42.9 (12.5) Female 48.8%	Cognitive Functional Therapy (n=51)	Manual therapy and exercise group (n=43)
NG ET AL., 2015	Adolescents rowers with CLBP	Age 16.3 (1.5) Female 0%	Age 15.2 (1.5) Female 0%	Cognitive Functional Therapy (n=19)	Usual care (rowing skills and conditioning exercise) (n=15)
KENT ET AL., 2023	Adults with CLBP with at least moderate pain-related physical activity limitation and pain > 4	Age 47.7 (16) Female 59%	Age 47.5 (15) Female 60%	Cognitive Functional Therapy (n=164)	Usual care (n=165) participant's health providers recommended or the participant chose eg, physiotherapy,massage, chiropractic care, medicines, injections, or surgical interventions.

Table 2. PEDro Risk of bias tool.

Study	Eligibility criteria	Random allocation	Concealed allocation	Baseline comparability	Blind subjects	Blind therapists	Blind assessor	Adequate follow-up	Intention-to-treat analysis	Between-group comparisons	Point estimates and variability	Total
AMHAD ET AL., 2023	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**
AVILA ET AL., 2023	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**
BELACHE ET AL., 2018	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**
CASTRO ET AL., 2022	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**
O'KEFFE ET AL., 2020	Y	Y	Y	Y	N	N	N	N	Y	Y	Y	**6**
FERSUM ET AL., 2013	Y	Y	Y	Y	N	N	N	N	N	Y	Y	**5**
NG ET AL., 2015	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**
KENT ET AL., 2023	Y	Y	Y	Y	N	N	N	Y	Y	Y	Y	**7**

Table 3. A summary of the quality of the evidence using the GRADE approach.

QUALITY ASSESSMENT						SUMMARY OF FINDINGS		
No of studies	**Risk of bias**	**Imprecision**	**Inconsistency**	**Indirectness**	**Publication bias**	**No of participants**	**Pooled mean difference (95% confidence intervals)**	**Quality of evidence**
Disability post intervention, CFT versus active intervention								
6	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	Low imprecision. The number of participants was higher than 400. Do not downgrade.	No inconsistency. I^2=0%. Do not downgrade	One study was performed with chronic low back pain after spinal surgery. Downgrade one point.	Undetected	674	-8.58 [-10.67, -6.49]	Moderate (●●●○)
Disability intermediate follow-up, CFT versus active intervention								
5	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	Low imprecision. The number of participants was higher than 400. Do not downgrade.	High inconsistency. I^2=71%. Downgrade one point	One study was performed with chronic low back pain after spinal surgery. Downgrade one point.	Undetected	582	-8.28 [-13.04, -3.52]	Low (●●○○)

Disability long-term follow-up, CFT versus active intervention								
4	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	Low imprecision. The number of participants was higher than 400. Do not downgrade.	Low inconsistency. I^2=26%. Do not downgrade.	Not serious Indirectness. Do not downgrade	Undetected	502	-4.00 [-7.42, -0.58]	High (●●●●)
Pain intensity post intervention, CFT versus active intervention								
6	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	Low imprecision. The number of participants was higher than 400. Do not downgrade.	High inconsistency. I^2=81%. Downgrade two points.	One study was performed with chronic low back pain after spinal surgery. Downgrade one point.	Undetected	673	-13.93 [-21.76, -6.10]	Very low (●○○○)
Pain intensity intermediate follow-up, CFT versus active intervention								
5	Low risk of bias. Less than 25% of studies with a score lower than 6 on PEDRO	Low imprecision. The number of participants were higher than 400.	Moderate inconsistency. I^2=51%.	One study was performed with chronic low back pain after spinal	Undetected	582	-13.25 [-19.44, -7.05]	Low (●●○○)

	scale. Do not downgrade.	Do not downgrade.	Downgrade one point.	surgery. Downgrade one point.				
Pain intensity long-term follow-up, CFT versus active intervention								
4	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	Low imprecision. The number of participants was higher than 400. Do not downgrade.	Moderate inconsistency. I^2=64%. Downgrade one point.	Not serious Indirectness. Do not downgrade	Undetected	504	-6.55 [-13.30, 0.20]	Moderate (●●●○)
Disability post intervention, CFT versus minimal intervention								
2	Low risk of bias. Less than 25% of participants in studies with a score lower than 6 on PEDRO scale. Do not downgrade.	High imprecision. The number of participants was lower than 400. Downgrade one point.	Low inconsistency. I^2=15%. Do not downgrade.	One study was performed with adolescents. Downgrade one point.	Undetected	315	-18.40 [-23.74, -13.07]	Low (●●○○)

Effects of intervention

Cognitive Functional Therapy compared with active interventions

Moderate certainty of evidence indicated that CFT has a moderate effect for disability at short term (MD -8.58, 95% CI -10.67, -6.49) (figure 2), low certainty evidence indicated a moderate effect at moderate term (MD -8.28, 95% CI -13.04, -3.52) (figure 3) and high certainty evidence indicated a small effect at long term (MD -4.00, 95% CI -7.42, -0.58) (figure 4).

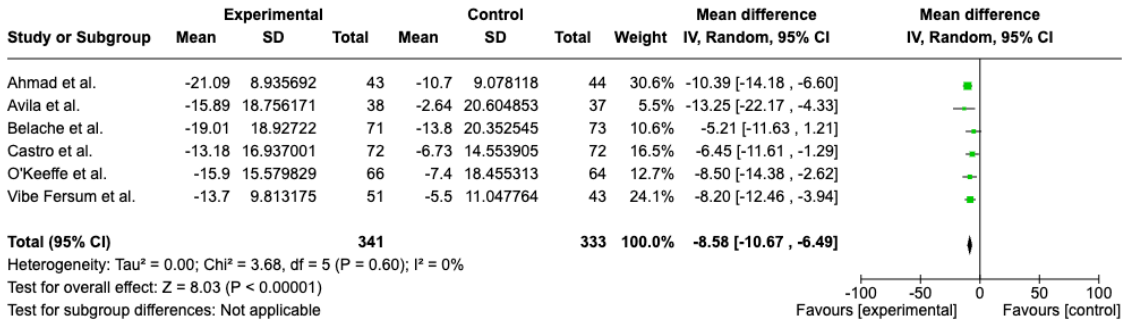

Figure 2. Cognitive Functional Therapy VS active interventions for disability at short term.

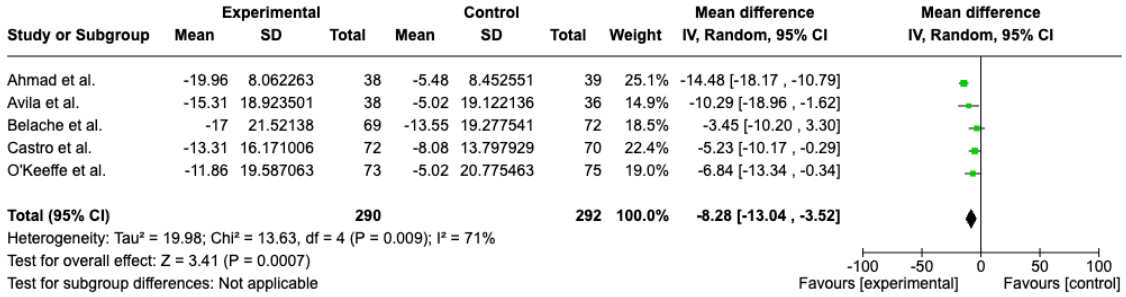

Figure 3. Cognitive Functional Therapy VS active interventions for disability at moderate term.

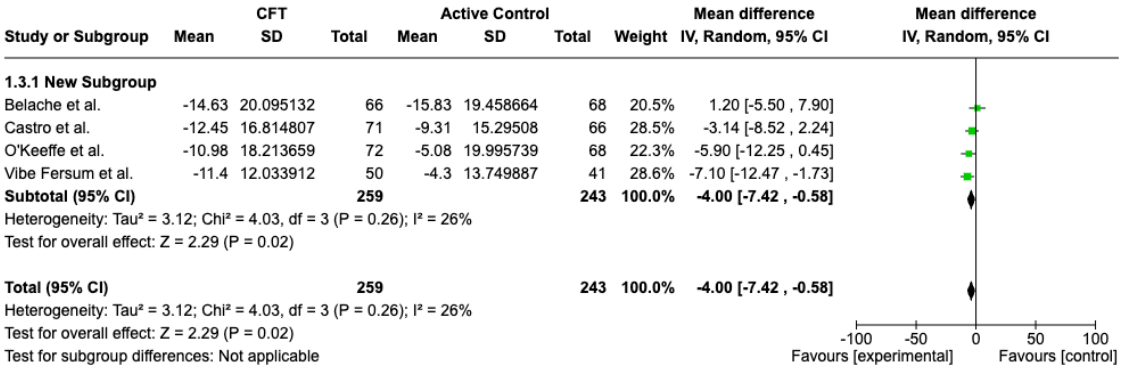

Figure 4. Cognitive Functional Therapy VS active interventions for disability at long term.

Very low certainty of evidence indicated that CFT has a moderate effect in pain intensity in the short term (MD -13.93, 95% CI -21.76, -6.10) (figure 5), low certainty evidence indicated a moderate effect in the moderate term (MD -13.25, 95% CI -19.44, -7.05) (figure 6), and a small effect in the long term (MD -6.55, 95% CI -13.30, 0.20) (figure 7).

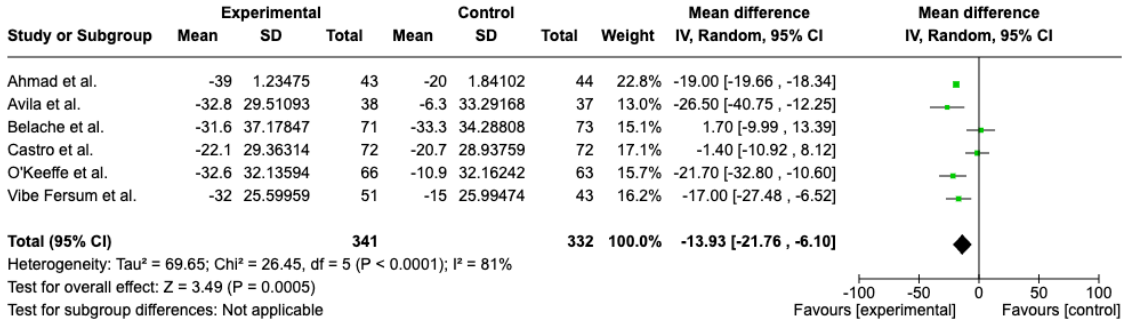

Figure 5. Cognitive Functional Therapy VS active interventions for pain at short term.

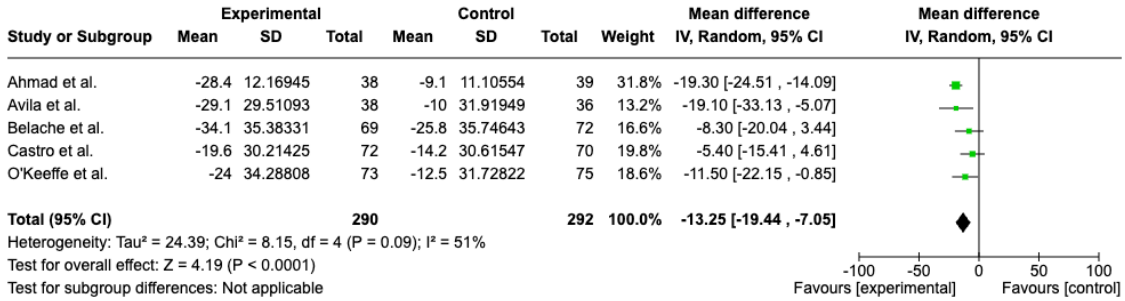

Figure 6. Cognitive Functional Therapy VS active interventions for pain at moderate term.

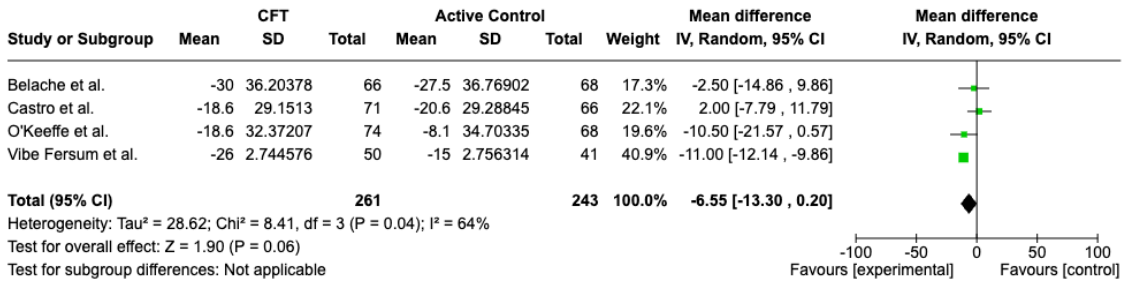

Figure 7. Cognitive Functional Therapy VS active interventions for pain at long term.

Cognitive Functional Therapy compared with minimal interventions.

Low certainty of evidence indicated that CFT has a large effect compared with minimal interventions in disability in the short term (MD -18.40, 95% CI -23.74 to -13.07). Only one study presented medium- and long-term disability data and short, moderate, and long-term pain data comparing CFT with minimal interventions (figure 8). Low certain evidence (data from RESTORE trial) shows that CFT has a large effect in disability in the moderate term (MD -20, 95% CI -20.68 to -19.32) and in the long term (MD -20, 95% CI -20.97 to -19.33); and that CFT has a large effect in pain intensity in the short term (MD -17, 95% CI 13.79 to 20.21), in the moderate term (MD -15, 95% CI 14.3 to 15.7), and in the long term (MD -16, 95% CI 15.3 to 16.7).

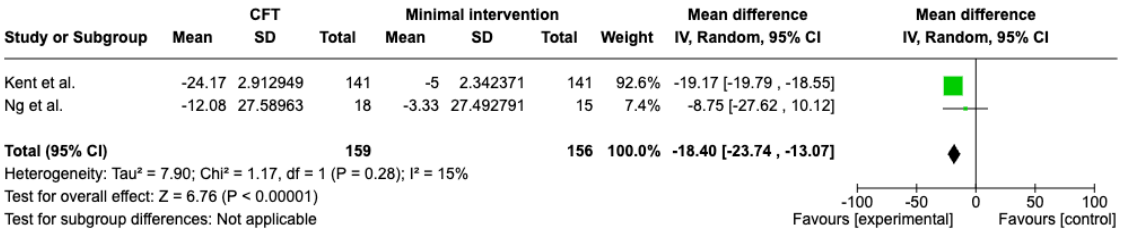

Figure 8. Cognitive Functional Therapy VS minimal interventions for pain at short term.

Subgroup and sensitivity analysis

We did not conduct subgroup analysis due to limited number of studies. A sensitivity analysis was conducted excluding the study that all the patients underwent spine surgery, because, although other studies did not exclude such individuals, this one was conducted only with this population. Therefore, it was considered as a specific population. With exclusion from the study, CFT remained superior for disability outcomes in the short (MD -8.31, CI -10.46 to -6.15) (figure 9) and moderate term (MD - 7.86, CI -13.49 to -2.22), with high and low certainty of evidence respectively (figure 10).

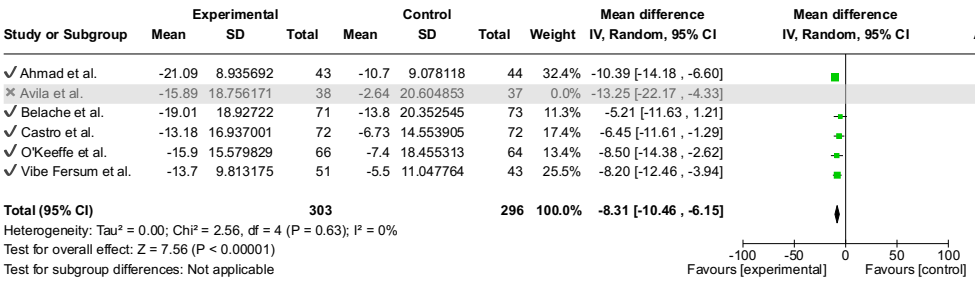

Figure 9. Sensitivity analysis of Cognitive Functional Therapy VS active interventions for disability at short term.

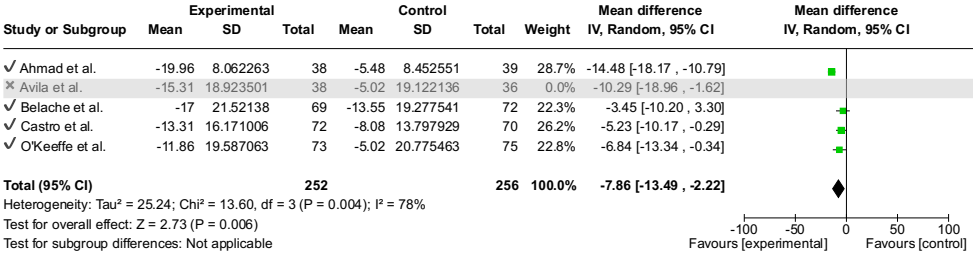

Figure 10. Sensitivity analysis of Cognitive Functional Therapy VS active interventions for disability at moderate term.

For pain, it also remained superior in the short (MD -11.99, CI -20.80 to -3.18) (figure 11) and moderate term (MD -12.12, CI -19.41 to -4.82) with low and moderate certainty level respectively (figure 12).

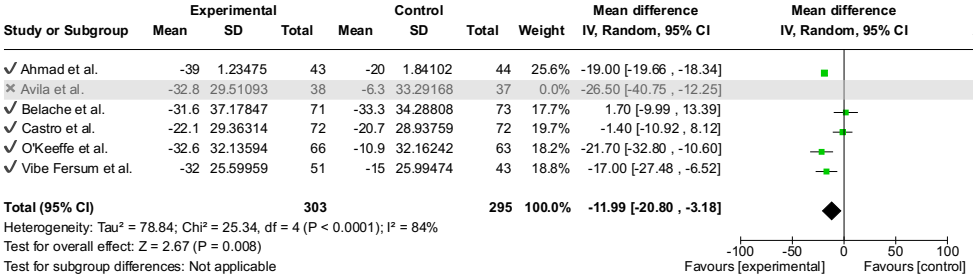

Figure 11. Sensitivity analysis of Cognitive Functional Therapy VS active interventions for pain at short term.

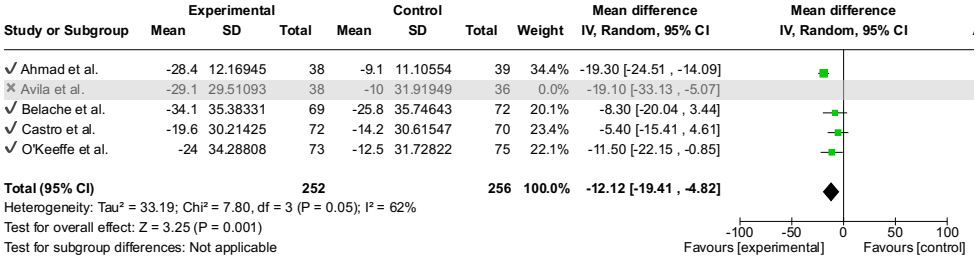

Figure 12. Sensitivity analysis of Cognitive Functional Therapy VS active interventions for pain at moderate term.

DISCUSSION:

Our review indicates that CFT is probably an effective approach compared with active interventions involving exercise for reducing disability in individuals with chronic low back pain but we are uncertain if it is effective for reducing pain intensity mainly due to heterogeneity of studies regarding this outcome. The differences in favor of CFT versus active interventions tend to decrease in the long term. CFT may result in large reduction of pain and disability when compared with minimal intervention. One study showed that the effect was sustained in long term.

There are two systematic reviews prior to this one with divergent results. The first review that presented data comparing CFT compared to other interventions was published in May 2022. The review included only three studies and, although it found statistically significant differences for pain, disability/functional status and fear of physical activity, the quality of the evidence was low, indicating the importance of new studies to investigate the approach and in the future a new systematic review (MIKI et al., 2022). The second systematic review, conducted by Devonshire and colleagues, concluded that TCF appears to be no more effective than other approaches for pain and disability in adults with low back pain. However, the data analysis was conducted using post-intervention means, without considering baseline pain and disability means, which might have changed the results (DEVONSHIRE et al., 2023). It is known that studies with a small number of participants, such as those included in the review, may present heterogeneity between groups, even with adequate randomization and it does not mean that higher baseline values regress more than lower baseline values. There are two main reasons why we chose to consider the “change in outcome from baseline” for calculating the mean difference as the most appropriate option for the analysis. First, using the delta the analysis is much more aligned with the results of individual studies and second, this strategy would clearly decrease heterogeneity between studies.

It is widely accepted that patients are heterogeneous and back pain is a multifactorial condition. So, that’s probably one of few reasons why most trials that have investigated unidimensional interventions presented modest effects.

Another reason may be the focus on pain and disability, assessed by unidimensional measures, whereas recovery is multidimensional (HANCOCK; HILL, 2016). Despite similar results in terms of effect size, approaches vary greatly in terms of costs, accessibility, complexity, potential risks, and patient satisfaction (ABDEL SHAHEED et al., 2023). CFT should be considered a good treatment option because is a multidimensional and low-risk intervention, that promotes greater patient satisfaction and lower socioeconomic costs (KENT et al., 2023b).

Numerous studies support the evidence that pain is multifactorial, and perhaps this can explain the superiority of CFT in comparison to other approaches identified by the present review. CFT is a patient centered complex approach, that targets multidimensional factors that are known to be predictors of outcomes, and considers the individual's pain function, activities, and work/daily routine. It addresses patients' pain-related concerns and understanding of their condition, encourages self-efficacy and confidence in self-management of pain. Helps patients to be more physically active and less worried about their pain, which improve the confidence in managing their back pain (SULLIVAN et al., 2018).
The results of the present review indicate that the effect size of CFT compared to active interventions is greater than the evidence for general exercise compared to other conservative treatments (MD -13.93, 95% CI -21.76, -6.10 against MD -9.1, 95% CI -12.6 to -5.6 for pain and MD -8.58, 95% CI 10.67, -6.49 against MD -4.1, 95% CI -6.0 to -2.2 for functional limitation outcomes) (HAYDEN et al., 2021).

We found evidence that CFT is superior to usual care or minimal interventions for disability. The effect size is also greater than the comparison with general exercise for functional limitations outcomes (MD -18.40, 95% CI -23.74 to -13.07 against MD -6.8 (95% CI -8.3 to -5.3) (HAYDEN et al., 2021). We did not conduct meta-analysis of the pain outcome as we obtained data from only one study.
Future research should consider the development of multidimensional measures and include particularly important and relevant domains for the patient's experience (HANCOCK; HILL, 2016). Also, subgroup analysis can increase the chance of better adapting treatments to patients based on clinical characteristics,

so it is relevant to investigate whether there is a group of patients who respond better to CFT approach, to better direct patients to interventions that are possibly more effective. It is the search for individualized care, going against the practice of "generic" treatments, in which a single intervention should serve everyone (SARAGIOTTO et al., 2017).

Strength and limitations: The present systematic review has limitations. The level of certainty of evidence is still quite variable between analyses and certainty of evidence was downgraded mainly due to heterogeneity and indirectness. Also, a minimum value was not established to be considered a clinically important difference. We know that this reference contributes to the interpretation of results and facilitates decision making for clinicians and patients. Besides the limitation, this review has strengths. To our knowledge the present study is the most updated systematic review about the effectiveness of CFT which is an approach of growing interest among clinicians and researchers. It was prospectively registered PROSPERO, extensive searches in the major electronic databases and clinical trials records were conducted, and there were no restrictions to language or date. Appropriate tools were used to assess the risk of bias and the level of certainty of evidence. All these strategies may facilitate the interpretation of the findings and support decision-making process.

CONCLUSION:

Compared with active interventions including exercise, CFT probably reduces disability in the short term, may reduce disability in the moderate term and slightly reduces disability in the long term. For pain intensity, the evidence is very uncertain about the effect in the short term, but CFT may reduce pain intensity in the moderate term and probably has a small effect in pain reduction in the long term. Compared with minimal interventions, CFT may result in large reduction of disability and pain intensity sustained in the long term. Current evidence supports the use of CFT in patients with chronic low back pain.

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SUPPLEMENTARY MATERIAL

Search Strategy for MEDLINE (OVID):

Part A: Generic search for randomized controlled trials and controlled clinical trials

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8
10. exp animals/ not humans.sh.
11. 9 not 10

*Cochrane Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity-maximizing version (2008 revision); Ovid format

Part B: Specific search for thoracic, low back, sacrum and coccyx problems

12. dorsalgia.ti,ab.
13. exp Back Pain/
14. backache.ti,ab.
15. exp Low Back Pain/
16. (lumbar adj pain).ti,ab.
17. coccyx.ti,ab.
18. coccydynia.ti,ab.
19. sciatica.ti,ab.
20. sciatic neuropathy/
21. spondylosis.ti,ab.
22. lumbago.ti,ab.
23. back disorder$.ti,ab.
24. or/12-23

Part C: Intervention

25. cognitive treatment.mp.
26. cognitive therapy.mp.
27. cognitive behavioral therapy.mp.
28. graded activity.mp.
29. graded exposure.mp.
30. exposure.mp.
31. behavioral graded activity.mp.
32. behavioural graded activity.mp.
33. graded exercises.mp.
34. cognitive functional therapy.mp.
35. CFT.mp.
36. cognitive functional therapy.ti.ab
37. CFT.ti.ab
38. or/ 22-34

Results

39. 11 and 24 and 38

Produção Colaborativa

1. Meziat-Filho N, Fernandez J, **Castro J.** Cognitive functional therapy for chronic disabling low back pain. Lancet. 2023 Jun 3;401(10391):1828-1829. doi: 10.1016/S0140-6736(23)00571-8. Epub 2023 May 2. PMID: 37146624.

2. Alaiti RK, Castro J, Lee H, Caneiro JP, Vlaeyen JWS, Kamper SJ, da Costa MF. What Are the Mechanisms of Action of Cognitive-Behavioral, Mind-Body, and Exercise-based Interventions for Pain and Disability in People With Chronic Primary Musculoskeletal Pain?: A Systematic Review of Mediation Studies From Randomized Controlled Trials. Clin J Pain. 2022 Jul 1;38(7):502-509. doi: 10.1097/AJP.0000000000001047. PMID: 35686580.

THE LANCET

COMMENT | VOLUME 401, ISSUE 10391, P1828-1829, JUNE 03, 2023 Download Full Issue

Cognitive functional therapy for chronic disabling low back pain

Ney Meziat-Filho • Jessica Fernandez • Julia Castro

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Cognitive functional therapy (CFT) is a physiotherapy-led intervention that is psychologically informed and directed at the multidimensional biopsychosocial nature of low back pain. [1] Peter Kent and colleagues [2] (RESTORE) aimed to compare the effectiveness and economic efficiency of CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic disabling low back pain in 20 primary care physiotherapy clinics in Perth, WA, and Sydney, NSW, Australia.

Doctopic: Analysis and Interpretation

Comment

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Cognitive functional therapy for chronic disabling low back pain

Cognitive functional therapy (CFT) is a physiotherapy-led intervention that is psychologically informed and directed at the multidimensional biopsychosocial nature of low back pain.[1] Peter Kent and colleagues[2] (RESTORE) aimed to compare the effectiveness and economic efficiency of CFT, delivered with or without movement sensor biofeedback, with usual care for patients with chronic disabling low back pain in 20 primary care physiotherapy clinics in Perth, WA, and Sydney, NSW, Australia.

Kent and colleagues randomly assigned 492 participants into three groups: usual care (n=165 [34%]), CFT plus biofeedback (n=163 [33%]), and CFT plus sham biofeedback (n=164 [33%]). The mean age of the participants was 47·3 years (SD 15·2), 292 (59%) were female, 200 (41%) were male, and 243 (49%) had university education. No ethnicity data were reported. At 13 weeks, 418 (85%) participants completed the primary outcome of disability assessed with the 0–24 Roland Morris Disability Questionnaire (141 [85%] in the usual care group, 141 [86%] in the CFT only group, and 136 (83%) in the CFT plus biofeedback group). 161 (33%) participants declined consent for their Medicare and Pharmaceutical Benefits Scheme data to be extracted.

The median number of consultations was seven (IQR 4–8) in both CFT groups. At the 13-week timepoint, 134 (82%) participants in the usual care group responded to a question about their care-seeking behaviour over the previous 3 months, with only 51 (38%) having sought care for their low back pain from a health-care practitioner. Their median number of consultations was three (IQR 2–7; range 1–22). This information is important when interpreting the effect size, since improvement in the usual care group was negligible. CFT only (mean difference −4·6 [95% CI −5·9 to −3·4]) and CFT plus biofeedback (−4·6 [−5·8 to −3·3]) treatments were both more effective than usual care, corresponding to large effect sizes (standardised mean difference 0·90 [−1·11 to −0·68] for CFT only and −0·87 [−1·08 to −0·66] for CFT plus biofeedback). These differences were maintained at 52 weeks. Both CFT groups received a booster session at 26 weeks.

Secondary outcomes—physical function, pain intensity, pain self-efficacy, catastrophising, and fear of movement—reflected the result of the primary outcome. For pain intensity (average of the past 14 days; 0–10 scale) that the mean difference between CFT only and usual care was −1·6 (95% CI −2·1 to −1·1) and between CFT plus biofeedback and usual care was −1·6 (−2·1 to −1·2). The difference between the CFT only and CFT plus biofeedback groups was not statistically significant (mean difference 0·0 [−0·5 to 0·5]). Furthermore, CFT only and CFT plus biofeedback were more cost-effective than usual care for quality-adjusted life-years, and much less costly in terms of societal costs (direct and indirect costs and productivity losses; AUS−$5276 [−10 529 to −24] for CFT only and −$8211 [−12 923 to −3500] for CFT plus biofeedback).

The strengths of the trial are that this was the largest clinical trial investigating the clinical effectiveness and efficiency of CFT. The study was done in multiple primary care clinics and the treatment was delivered by extensively trained physiotherapists. Notably, the risk of attrition bias regarding the primary outcome was much lower than in previous trials of CFT.[3,4]

In one extreme, efficacy is investigated in clear explanatory randomised trials to describe the expected effects under ideal study conditions. In the opposite extreme, effectiveness is investigated in observational, pragmatic, controlled trials to describe the observed effects under real-world conditions. Considering that RESTORE[2] seems to be somewhere between investigating efficacy and effectiveness and that the efficacy of CFT versus placebo is still unknown, some limitations are worth discussing. The usual care group received minimal treatment. Performance bias might explain at least partly the large effect size of CFT groups compared with the usual care group because the CFT groups received much more attention and care. Furthermore, participants were told that the trial compared usual care with two evidence-based interventions and were aware of their group allocation. This unmasking could have negatively influenced the expectations of participants in the usual care group. Also, the absence of a CFT group without movement sensors raised some questions: would CFT be even better without having a movement sensor attached with tape to the participant's lumbar spine? Could this movement

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sensor be a source of performance bias and placebo effect and partly explain the results?

That the biofeedback device was no more effective than the placebo device is good news for low-income and middle-income countries where health-care resources might be scarce. Our research group has been involved with some finished and ongoing randomised controlled trials comparing CFT with manual therapy and exercise.[5-7] To our knowledge, the first placebo-controlled trial addressing the efficacy of CFT is being done in Brazil.[8]

If the efficacy of CFT versus placebo is established, future studies should focus on investigating whether CFT is effective versus usual care in different contexts of health-care systems, not only in high-income countries but also in low-income and middle-income countries. Real-world, observational, pragmatic, controlled trials might be an option for implementing CFT in a scenario without randomisation, so that the decision between CFT or usual care depends on individual preferences and results of shared decision making.[9]

We declare no competing interests.

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REVIEW ARTICLE

What Are the Mechanisms of Action of Cognitive-Behavioral, Mind-body, and Exercise-based Interventions for Pain and Disability in People With Chronic Primary Musculoskeletal Pain?

A Systematic Review of Mediation Studies From Randomized Controlled Trials

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Steven J. Kamper, PhD,‡‡§§ and Marcelo F. da Costa, PhD‖‖*

Objectives: This systematic review examined studies that used mediation analysis to investigate the mechanisms of action of cognitive-behavioral, mind-body, and exercise-based interventions for pain and disability in people with chronic primary musculoskeletal pain.

Materials and Methods: We searched 5 electronic databases for articles that conducted mediation analyses of randomized controlled trials to either test or estimate indirect effects.

Results: We found 17 studies (n = 4423), including 90 mediation models examining the role of 22 putative mediators on pain or disability, of which 4 had partially mediated treatment effect; 8 had mixed results, and 10 did not mediate treatment effect. The conditions studied were chronic whiplash-associated pain, chronic low back pain, chronic knee pain, and mixed group of chronic primary musculoskeletal pain.

Discussion: We observed that several of the studies included in our systematic review identified similar mechanisms of action, even between different interventions and conditions. However, methodological limitations were common. In conclusion, there are still substantial gaps with respect to understanding how cognitive-behavioral, mind-body, and exercise-based interventions work to reduce pain and disability in people with chronic primary musculoskeletal pain.

Key Words: chronic pain, mediation, mechanisms of action, exercise, cognitive-behavioral

(*Clin J Pain* 2022;38:502–509)

Chronic primary musculoskeletal pain is among the most burdensome health conditions worldwide.[1–3] Since 1990, chronic low back pain (CLBP) and other chronic primary musculoskeletal painful conditions have been the leading causes of years lived with disability in most countries.[1,4] Although active treatment approaches, such as cognitive-behavioral, mind-body, and exercise-based interventions are effective in reducing pain and disability,[5–8] most interventions are not superior to each other and the effect sizes are often small.[9–11] A possible explanation is that most interventions do not sufficiently target relevant mediators, or may work through similar mechanisms despite their complex proposed mechanisms of action.[12]

The existence of evidence showing that complex interventions with very different proposed mechanisms of action are equally effective for chronic musculoskeletal pain (eg, cognitive-behavioral, mind-body, and exercise-based interventions) can be misleading and confusing for clinical researchers and clinicians. Therefore, better understanding of the underlying mechanisms of cognitive-behavioral, mind-body, and exercise-based treatment effects is important for the optimization and refinement of these complex interventions and may also assist clinicians in their clinical reasoning.[13]

Studying the role of mediators (ie, a variable by which one intervention affects an outcome[14]) in randomized clinical trials can generate evidence about the mechanisms of action for interventions.[14,15] Although systematic reviews of mediation studies exist for CLBP,[16,17] no review has tested the mechanisms of cognitive-behavioral, mind-body, and exercise-based interventions for chronic primary musculoskeletal pain in general. Understanding treatment mechanisms would save valuable research resources by identifying more promising

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Participação em eventos e Menções honrosas

UNISUAM UTS UNIVERSITY OF TECHNOLOGY SYDNEY

Effectiveness of Cognitive Functional Therapy for people with chronic low back pain: A Systematic Review with Meta-Analysis

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Introduction

Chronic low back pain is a public health issue associated with a complex interaction of biopsychosocial factors. Cognitive Functional Therapy (CFT) is a behavioral intervention directed at the multiple aspects of chronic low back pain.

The aim of this study was to investigate whether CFT is effective at improving pain and disability in people with chronic low back pain.

Methods

Systematic review with metanalysis of randomized controlled trials. The search included the following databases: PubMed, CINAHL (via EBSCOhost), EMBASE, PEDro and Cochrane Central Register of Controlled Trials (CENTRAL). Main outcomes were pain intensity and disability. The risk of bias of the studies included in this systematic review were assessed using the PEDro scale. The overall quality of the evidence and the strength of recommendations were evaluated using the GRADE approach.

Results

We included 7 randomised controlled trials involving 902 participants in this systematic review. The duration of the interventions ranged from 8 to 12 weeks. All studies were conducted with adults, with a mean age of 46.4 (SD=12.3), except for one that was conducted with adolescents with a mean age of 15.8 (SD=1.5) years. Of the participants, 61,6% were female.

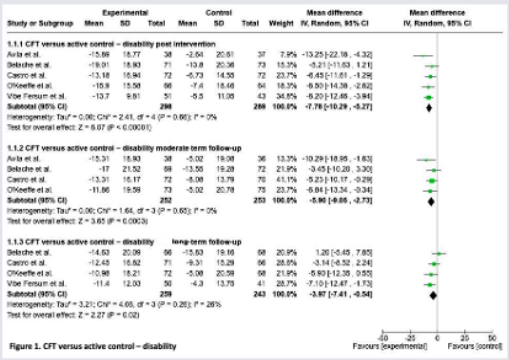

Figure 1. CFT versus active control – disability

CFT was compared with active control (manual therapy and exercise) in 5 trials, and compared to minimal intervention in 2 trials. **Regarding CFT versus active control, meta-analysis for disability at short term showed a mean difference of -7.78 (95% CI: -10.29 to -5.27); at moderate follow-up -5.90 (-9.06 to -2.73); and at long-term follow-up -3.97 (-7.41 to -0.54). The certainty of evidence was moderate for short-term and moderate follow-ups and high for long-term follow-up.**

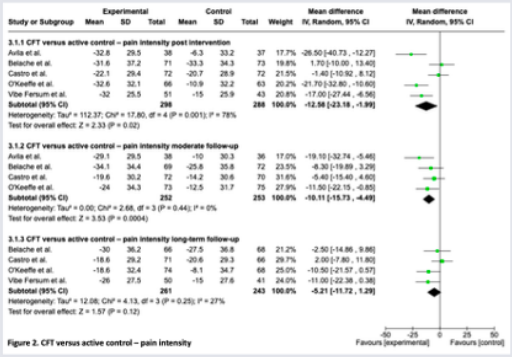

Figure 2. CFT versus active control – pain intensity

For pain intensity, meta-analysis showed a mean difference of -12.58 (95% CI:-23.18, -1.99) at short term; at moderate follow-up -10.11(-15.73 to -4.49); and at long-term follow-up -5.21 (-11.72 to 1.29). The certainty of evidence was very low for short-term, moderate for moderate follow-up and high for long-term follow-up.

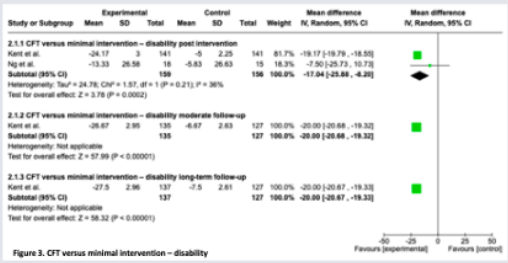

Figure 3. CFT versus minimal intervention – disability

Regarding CFT versus minimal intervention, meta-analysis for disability at short term showed a mean difference of -17.04 (95% CI: -25.88 to -8.20). One trial was included for disability at moderate and long term follow-up, and for pain intensity (Fig 3 and 4). **The certainty of evidence was low at all time points.**

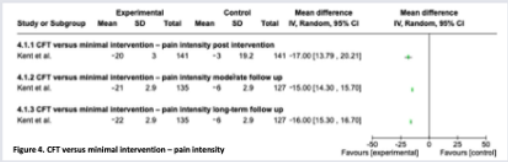

Figure 4. CFT versus minimal intervention – pain intensity

Discussion

Moderate to high certainty evidence shows that CFT was more effective than other active interventions in reducing disability with an effect size that decreases over the follow-ups. Very low to high certainty of evidence show that CFT was more effective than other active interventions in reducing pain intensity post intervention and in the moderate follow-up. Low certainty evidence shows that CFT was more effective than minimal intervention with large effect sizes.

Conclusion

This review provides the most updated evidence on the effectiveness of CFT for chronic low back pain. **The current evidence support the use of CFT for patients with chronic low back pain.**

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Acknowledgements

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Cognitive functional therapy compared with combined manual therapy and motor control exercise for patients with chronic low back pain: a randomised controlled trial

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Introduction

Cognitive functional therapy (CFT) is an intervention that deals with potentially modifiable multidimensional aspects of pain. Evidence about CFT effectiveness compared with active interventions is still scarce. **The aim of this study was to investigate the effectiveness of CFT compared with combined manual therapy and motor control exercise (MT-EX) on pain and disability after three months post randomisation in patients with chronic low back pain.**

Methods

A total of 148 adults with CLBP were randomly assigned to receive four to ten individualized sessions of either CFT (n=74) or MT-EX (n=74) within a period of 3 months. Primary outcomes were pain intensity (numeric pain rating scale, 0-10) and disability (Oswestry Disability Index, 0-100) at three months. Patients were reassessed at 6 and 12-months post randomisation.

Trial protocol

Results

In the CFT group, 95.9% (n=71) of participants completed the 3 months of the trial, while 98.6% (n=73) of the participants in the manual therapy and motor control exercise group completed the 3 months of the trial (figure 1). Table 1 shows the characteristics of the sample. **In the analysis of primary outcomes, the results suggest there is some effect of CFT on disability at three months but probably not clinically important when compared with MT-EX (MD= 4.15; 95% CI -0.91 to 9.22; p=0.11). This study found no difference between groups in pain intensity (MD=-0.17; 95% CI -1.14 to 0.81; p=0.73) at three months. There were no differences between groups at the 6-month and 12-month follow-ups** (table 2).

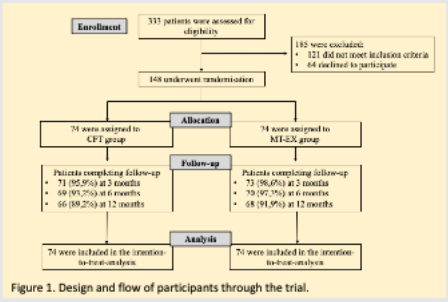

Figure 1. Design and flow of participants through the trial.

Table 1. Characteristics of the participants at baseline.

Characteristic	CFT-group (N=74)	MT-EX group (N=74)
Age – yr, mean (±SD)	45,6±11,7	44,7±12
Female sex – no. (%)	56(75,7)	47(63,5)
Body mass index (kg/m2), mean (±SD)	28,3±5,6	28,6±5,8
Levels of education, no. (%)		
Complete higher education	21(28,4)	10(13,5)
Incomplete higher education	22(29,7)	22(29,7)
High school complete	17(22,9)	24(32,4)
High school incomplete	7(9,5)	7(9,5)
Secondary school incomplete	3(4)	6(8,4)
Secondary school incomplete	2(2,7)	5(6,8)
Read and write	2(2,7)	0(0)
Paid work, no. (%)	47(63,5)	47(63,5)
Duration of LBP — months (median, IQR)	48(89,8)	48(96)
Family history of LBP –no.(%)	48(64,9)	51(68,9)
MRI scan performed – no. (%)	47(63,5)	47(63,5)
Low back surgery – no. (%)	3(4)	4(5,4)
Pain intensity (NPS), mean (±SD)	6,6(2,1)	6,6±2,1
Disability (ODI), mean (±SD)	33(12,4)	32,2(11,9)
Stressful life events , no. (%)	29(39,2)	33(44,6)
No of pain sites – (median, IQR)	7(5,75)	6,5(6,75)
Risk of chronicity, Örebro (0-100), mean (±SD)	67,3±9,9	65,9±11,7
High Risk on Örebro, n(%)	72(97,3)	66(89,2)
Risk of chronicity, STartBack score, mean (±SD)	5,7±2,2	5,6±2,5
StartBack, n (%)		
Low risk	11(14,9)	17(22,9)
Medium risk	33(44,6)	28(37,8)
High risk	30(40,5)	29(39,2)

Table 2. Unadjusted mean (SD) for each numeric outcome, including primary outcomes (pain intensity and disability at 3 months), by treatment group and adjusted between-group mean differences for each follow-up time point

	Baseline		3 months			6 months			12 months		
	CFT (n=74)	MT-EX (n=74)	CFT (n=71)	MT-EX (n=73)	Adjusted between-group mean difference (95% CI)	CFT (n=69)	MT-EX (n=72)	Adjusted between-group mean difference (95% CI)	CFT (n=66)	MT-EX (n=68)	Adjusted between-group mean difference (95% CI)
Pain intensity (0-10)	6.58 (2.21)	6.69 (1.94)	3.42 (3.06)	3.36 (2.88)	**-0.17 (-1.14 to 0.81)**	3.17 (2.87)	4.11 (3.07)	0.78 (-0.19 to 1.75)	3.58 (2.94)	3.94 (3.22)	0.34 (-0.73 to 1.41)
Disability (0-100)	32.95 (12.50)	32.20(11.93)	13.94 (14.64)	18.40 (16.95)	**4.15 (-0.91 to 9.22)**	15.95(18)	18.65 (15.59)	2.87 (-2.23 to 7.97)	18.32 (16.22)	16.37 (15.82)	-1.58 (-6.32 to 3.17)
Global recovery (-5 to 15)	-	-	3.55(1.35)	3.14(1.64)	-0.4 (-0.93 to 0.13)	3.35 (1.72)	2.90 (1.67)	-0.59 (-1.13 to -0.04)*	2.95 (1.72)	3.21 (1.67)	0.19 (-0.36 to 0.74)

*p<0.05

Discussion

This trial was conducted in a low socio-economic area of an upper-middle-income country. The study followed the prespecified protocol without substantial violations. The two physiotherapists of the CFT group attended three workshops with three different tutors of the method (POS, KOS, WD) and completed 106 hours of training, including workshops, patient examinations, and a pilot study with the supervision of a physiotherapist with more than 4 years of clinical experience in CFT.

Conclusion

There is a suggestion that CFT is more effective than manual therapy and motor control exercises in disability, but the difference is probably not clinically important and was not maintained at moderate and long term follow ups. There was no difference in pain intensity.

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Acknowledgements

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Identifying patients with chronic low back pain who respond better to cognitive functional therapy: a secondary analysis of a randomised controlled trial

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Introduction

Cognitive functional therapy (CFT) is a patient-centered behavioural intervention directed at the multidimensional biopsychosocial nature of low back pain (LBP). Although, people with chronic LBP present heterogeneous characteristics, still, no studies have identified subgroups of patients that respond better to CFT.

The aim of this study was to identify subgroups of patients with chronic LBP that respond better to CFT three months after randomisation in comparison to manual therapy and motor control exercise.

Methods

A secondary analysis of a randomised controlled trial was conducted to identify potential effect modifiers of CFT treatment in reducing pain intensity and disability three months after randomisation compared with manual therapy and motor control exercises in patients with chronic LBP. The potential effect modifiers included psychosocial factors (brief psychosocial questions [with a 0-10 score for each domain] for depression, social isolation, catastrophizing, fear of movement and stress) with the cut-points established in the validation study of Kent et al (2014); and high risk of chronicity on Örebro and STartBack questionnaires) and neurophysiological factors (number of pain areas).

Results

In the CFT group, 95.9% (n=71) of participants completed the three months of the trial, while 98.6% (n=73) of the participants in the manual therapy and motor control group completed the three months.

Most participants were female (69.6%, n=103) and the mean age was 45.2 (SD=11.8). The mean number of treatment sessions in CFT group was 4.98 (SD=1.89) versus 6.35 (SD=2.53) in the comparison group. **The variable anxiety modified the effect of CFT in reducing disability (BC [beta coefficient] = -19.25; 95% CI = -31.88 to -6.61; p=0.003) in patients with chronic LBP** (Table 1).

Table 1. Linear regression analysis for each potential moderator and the outcome disability

Variables	Beta coefficient	P	95% CI
Number of pain areas			
Treatment	-0,57	0,874	-7,71 to 6,57
Number of pain areas	6,39	0,077	-0,71 to 13,49
Interaction: treatment x Number of pain areas	-7,94	0,119	-17,07 to 2,09
Constant	3,95	0,340	-4,21 to 12,10
Anxiety			
Treatment	11,26	0,053	-0,13 to 22,65
Anxiety	5,14	0,218	-3,06 to 13,33
Interaction: treatment x anxiety	-19,25	0,003	-31,88 to -6,61
Constant	2,79	0,553	-6,5 to 12,09
Depression			
Treatment	-3,58	0,234	-9,5 to 2,34
Depression	8,71	0,027	-1,03 to 16,38
Interaction: treatment x depression	-3,19	0,563	-14,06 to 7,68
Constant	6,38	0,111	-1,48 to 14,23
Social isolation			
Treatment	-1,99	0,552	-8,56 to 4,59
Social isolation	12.21	0,001	5,08 to 19,34
Interaction: treatment x social isolation	-7,09	0,159	-16,99 to 2,82
Constant	5,98	0,143	-2,04 to 14,00
Catastrophization			
Treatment	0,65	0,898	-9,39 to 10,70
Catastrophization	3,81	0,413	-5,38 to 13,01
Interaction: treatment x catastrophization	-7,25	0,222	-18,94 to 4,44
Constant	3,37	0,500	-6,49 to 13,24

Cont. Table 1. Linear regression analysis for each potential moderator and the outcome disability

Fear of movement			
Treatment	-2,83	0,321	-8,45 to 2,79
Fear of movement	1,69	0,684	-6,52 to 9,91
Interaction: treatment x fear of movement	-10,51	0,108	-23,36 to 2,34
Constant	5,29	0,184	-2,54 to 13,14
Stress			
Treatment	-3,02	0,423	-10,45 to 4,41
Stress	2,93	0,422	-4,27 to 10,13
Interaction: treatment x stress	-2,88	0,576	-13,04 to 7,28
Constant	5,35	0,206	-2,97 to 13,67
High risk on StartBack			
Treatment	-4,33	0,192	-10,87 to 2,21
High risk on STartBack	0,85	0,822	-6,57 to 8,26
Interaction: treatment x high risk on STartBack	-0,68	0,898	-11,13 to 9,77
Constant	6,47	0,123	-1,77 to 14,71
High risk on Örebro			
Treatment	-7,6	0,533	-31,63 to 16,43
High risk on Örebro	4,18	0,477	-7,42 to 15,78
Interaction: treatment x high risk on Örebro	2,74	0,826	-21,86 to 27,35
Constant	3,47	0,562	-8,34 to 15,27

Disability on baseline was included in the linear regression models as a potential confounding factor

Discussion

Anxiety, using the question "Do you feel anxious?" and the cut-point of 5 on a 0-10 scale, was a modifier of the effect of CFT in reducing disability in patients with chronic LBP compared with manual therapy and motor control exercises three months after randomization. Clinical trials with stratification of subgroups of patients with and without high levels of anxiety randomised to receive CFT or manual therapy and motor control exercises are needed.

Conclusion

People with chronic low back pain and higher levels of anxiety may respond better to CFT in comparison with manual therapy and motor control exercise.

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IASP 2022 WORLD CONGRESS ON PAIN
Toronto, Canada • 19–23 September

CERTIFICATE OF PRESENTATION

The following poster was submitted and presented at the IASP World Congress on Pain, held from 19-23 September 2022

Aging is Inevitable, Disability can be Optional: Insights from a TeleRehabilitation Trial with Elderly People

Jessica Fernandez, PhD student – Centro Universitário Augusto Motta - UNISUAM
Marina J. Pellegrini, MSc Student – Centro Universitário Augusto Motta - UNISUAM
Ney Meziat-Filho, PhD – Centro Universitário Augusto Motta - UNISUAM
Julia Castro, PhD Student – PhD Student, Post Graduation Program, UNISUAM

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Ian Gilron, MD, MSc, FRCPC,
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2021 BACK & NECK PAIN FORUM

DOUTORADO EM CIÊNCIAS DA REABILITAÇÃO

Cognitive Functional Therapy (CFT) is slightly better than core exercises and manual therapy for disability, but not pain, post-treatment for chronic low back pain: a randomised controlled trial

Julia Castro[1], Luis Correia, Bruno de Sousa Donato, Bruno Arruda, Felipe Agulhari, Marina Jacobucci Pellegrini, Fabiana Terra Cunha Belache, Cíntia Pereira de Souza, Jessica Fernandez, Leandro Alberto Calazans Nogueira, Felipe José Jandre Reis, Arthur de Sá Ferreira, **Ney Meziat-Filho**[1]

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CERTIFICADO

CERTIFICADO

A Direção de Pesquisa, Inovação e Extensão tem a honra de certificar o artigo intitulado "**TRIAL PROTOCOL: COGNITIVE FUNCTIONAL THERAPY COMPARED WITH COMBINED MANUAL THERAPY AND MOTOR CONTROL EXERCISE FOR PEOPLE WITH NON-SPECIFIC CHRONIC LOW BACK PAIN: PROTOCOL FOR A RANDOMISED, CONTROLLED TRIAL**", com os autores *Fabiana Terra Cunha Belache, Cíntia Pereira de Souza, Jessica Fernandez, Julia Castro, Paula Dos Santos Ferreira, Elizana Rodrigues de Sousa Rosa, Nathalia Cristina Gimenez de Araújo, Felipe José Jandre Reis, Renato Santos de Almeida, Leandro Alberto Calazans Nogueira, Luís Cláudio Lemos Correia e Ney Armando de Mello Meziat Filho*, como vencedores do **Prêmio do Programa de Pós-graduação em Ciências da Reabilitação de Melhor Artigo** (período 2017-2020) na Linha de Pesquisa **Abordagem Terapêutica em Reabilitação**, sob a orientação do Prof. Dr. *Ney Armando de Mello Meziat Filho*, em 15/07/2021.

Rio de Janeiro, 24 de agosto de 2021

Claudia de Freitas Lopes Costa
Diretora de Pesquisa, Inovação e Extensão

CERTIFICADO DE MENÇÃO HONROSA para o trabalho: **STarTBack e Örebro como preditores de dor e incapacidade em indivíduos com dor lombar crônica inespecífica submetidos à fisioterapia** autoria de **JESSICA FERNANDEZ MOSQUEIRA GOMES,** Fabiana Terra Cunha Belache, Letícia Rangel Pinheiro, Cássia C. N. Rocha, Júlia Damasceno Castro, Cintia Pereira de Souza, Igor Macedo Tavares Correia, Ney A. Meziat-Filho foi classificado em **3º lugar** modalidade **ORAL área: Fisioterapia em Fisioterapia Traumato-Ortopédica, Esportiva e Osteopatia** no **XXIII Congresso Brasileiro de Fisioterapia** realizado de 29 a 31 de março de 2021 - Edição on-line.

Rio de Janeiro, 31 de março de 2021.


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