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Comparative effectiveness of cognitive behavioural therapy combined with exercise versus exercise in the management of non-specific chronic low back pain: A systematic review with meta-analysis

Paapa Kwesi Ampiah, Paul Hendrick, Erika Gonzalez Macias

ABSTRACT

Aims: To systematically review the evidence for the effectiveness of combining cognitive behavioural therapy (CBT) and exercise versus exercise alone in the management of patients with non-specific chronic low back pain (NSCLBP). Methods: Electronic search of CINAHL, PUBMED, Sports Discuss, SCOPUS, AMED, MEDLINE, Cochrane Central Register of Controlled Trials, and EMBASE, between 1990 – July 2017; complemented by hand searching of citation lists and citation tracking. Two independent reviewers screened titles and abstracts from the retrieved search results. Studies were considered based on PRISMA guidelines. Data was extracted based on Cochrane the Handbook of Systematic Reviews guidelines; the Cochrane Data Collection Form for Intervention Reviews (RCTs only), was customized and utilized. Risk of bias assessment was undertaken utilizing the Cochrane Back Review Group recommendations employing two independent reviewers. Meta-analysis was used to produce a weighted average for primary outcome measures, namely pain and disability. Results: Four studies were included (n = 406 participants); all studies provided post intervention results on pain and disability. Meta-analysis showed no significant difference between groups for both pain and disability, post intervention in the short term (pain; SMD -0.02, 95% CI -0.23 to 0.19; disability; SMD 0.06, 95% CI -0.15 to 0.27); medium term (pain; SMD -0.01, 95% CI -0.24 too.22; disability; SMD 0.00, 95% CI -0.23 to 0.23); and long term (pain; SMD 0.06, 95% CI -0.18 to 0.29; disability; SMD -0.06, 95% CI -0.39 to 0.27). Conclusion: The findings from this review reveal that there is no significant difference between groups; that is, there is moderate level evidence that the addition of CBT to exercise for patients with NSCLBP does not improve pain and disability outcomes in either the short, medium, or long term; however, both interventions (CBT plus exercise and exercise alone) produce favourable outcomes.

Keywords: Behavioural therapy, Chronic low back pain, Exercise therapy, Meta-analysis, Systematic review

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INTRODUCTION

Low back pain (LBP) is a leading cause of pain and disability, with an estimated lifetime prevalence of 84% [1]. The condition is classified into three broad categories: non-specific low back pain (NSLBP); severe spinal involvement; and neurological involvement [1, 2]. NSLBP, comprises approximately 90% of all LBP cases and is described as pain with no known alaetiology. Consequently, diverse prognostic and treatment protocols are utilized [3, 4].

Individuals go through rapid amelioration of pain and disability within twelve weeks of inception of LBP, with varying suggestions for percentages; however, a view amongst some authors is that most individuals recover within this period [4]. In spite of this, in a subgroup of individuals with LBP, there is persistence after twelve weeks; pain in this subgroup, is known as chronic LBP [5, 6].

Improvement in quality and safety of health delivery is very essential; to this end, various Clinical Practice Guidelines (CPGs) meant to improve evidence based practice (EBP) are published annually [7]. Psychological therapies are recommended in guidelines for assessment and management of patients with non-specific chronic low back pain (NSCLBP) [4].

Current reviews of CBGs recommend psychological therapies such as cognitive behavioural therapy (CBT) for the management of NSCLBP; exercise therapy also features in recommendations of both national and international guidelines [4]. Furthermore, recent National Institute for Health and Care Excellence (NICE) guidelines also recommends a multi-model approach (e.g., combination of exercise therapy with CBT) for managing NSCLBP [8].

The evidence for the effectiveness of either CBT or exercise in managing NSCLBP has been investigated in recent systematic reviews; a systematic review by Richmond et al., [9], concluded that CBT produces favourable outcomes (small to moderate) for NSCLBP patients. On the other hand, a systematic review by Gomes-Neto et al., [10], also reported beneficial outcomes for NSCLBP patients, with the utilization of exercise therapy interventions.

There is a substantial body of clinical research to support these two interventions [9, 11]; although there is a lack of consensus on the most effective form of exercise intervention [10]; however, the added benefits of combining CBT to exercise needs to be investigated.

Nonetheless, a key limitation to prevailing approaches to management is the possibility of addressing the pain and its consequences with multi-model treatment packages that do not address the needs of specific patient needs [4]. Systematic reviews have investigated the effectiveness of exercise therapy or CBT for the management of NSCLBP suggesting favourable outcomes [9,10]; however, to the best of our knowledge, the comparative effectiveness of CBT plus exercise versus exercise alone is yet to be reviewed. Therefore, this systematic review was to answer the question:

- What is the effectiveness of combining CBT plus exercise versus exercise alone in the management of NSCLBP patients?

METHODS

Types of studies included

This review included RCTs published in English with a clearly defined randomization process. Included RCTs investigated the comparative effectiveness of CBT plus exercise compared to exercise alone.

Types of participants included

Participants were considered for inclusion if they were classified as having NSCLBP; defined as pain that persists beyond twelve weeks with no associated pathoanatomical mechanism or specific condition [12, 13]. Adult, aged eighteen years and above were included. Participants with associated specific pathoanatomical conditions (e.g., fractures, ankylosing spondylitis, infection, spinal stenosis, radiculopathy), or an association with conditions such as pregnancy were excluded.

Interventions included

Studies defining CBT as a management approach involving a psychological intervention structured on utilizing cognitive and behavioural approaches established from evidenced based practice (EBP) were considered for inclusion in this review [14]. CBT approaches, encompassing models such as behaviour therapy (e.g., operant conditioning) and cognitive therapy, geared towards the promotion of good physical health in patients with NSCLBP were included [15].

RCTs utilizing exercise therapy interventions defined as, specific movements, supervised or recommended by a treating therapist through movement and activities aimed at relieving pain and promoting good physical health in patients with NSCLBP were considered; these included,

mobility, flexibility and stability exercises; strengthening and stretching exercises; and aerobic exercises [16].

Outcome measures utilized

Primary outcome measures considered for this review included disability and pain. Assessment tools with good validity and reliability were considered for both primary outcomes; back-specific disability assessment tools such as the Roland Morris Disability Questionnaire (RMDQ) and the Oswestry Disability Index (ODI) were considered. RMDQ, has a good test-retest reliability (r = 0.83 to 0.91) and internal consistency (Cronbach's α = 0.84 to 0.96) [17]. The ODI, has a good internal consistency (Cronbach's α = 0.71 to 0.87) and test-retest reliability (*r* = 0.83 to 0.99) [18].

Assessment tools with good validity and reliability, considered for measuring pain in LBP patients include the Numeric Rating Scale (NRS) and Visual Analogue Scale (VAS). The NRS, has good test-retest reliability (r = 0.96), and has excellent correlation with the VAS (r = 0.90); with VAS also having a good test-retest reliability (r = 0.94) [19,20].

Secondary outcome measures included; quality of life (QoL), depression, cost-effectiveness, kinesiophobia, and function. Measurement of secondary outcome measures was considered based on the utilization of assessment tools with good reliability and validity; secondary outcome measures included quality of life (QoL), depression, function, cost effectiveness and kinesiophobia.

Identification of studies

Based on relevant mapped terms to subject headings (MeSH) (e.g., Cognitive Behavioural Therapy), search expressions (e.g., behavior therapy, exercise therapy), and keywords (e.g., Exercise), the search was developed; including RCTs published in English between 1990 to July 2017. The search was computer-based, involving eight databases; CINAHL, PUBMED, Sports Discuss, SCOPUS, AMED, MEDLINE, Cochrane Central Register of Controlled Trials, and EMBASE.

Unpublished and grey literature were also considered using similar search terms in the listed databases: www.guidelines.gov, www.opengrey.eu, www.clinicaltrials.com, and www.controlled-trials.com. Finally, a thorough examination of reference lists from retrieved studies was performed per the criteria of inclusion.

Selection process

Two independent (PA and EM) reviewers screened titles and abstracts from the search results. Studies were removed if they did not meet criteria for inclusion. Full texts were assessed to ascertain whether they meet the inclusion criteria. Consensus was used to address any disparities; a third reviewer (PH) was utilized if necessary to address any disparities. Studies were considered based on guidelines from the, Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) group [21].

Data extraction

Data was extracted based on Cochrane Handbook of Systematic Reviews guidelines [22]. Extraction of data was based on major headings such as; Study type, Title of study, Methods, Population (criteria for inclusion and exclusion, mean age, gender), outcome (outcome measures), and notes. For the purpose of extraction, the Cochrane Data Collection Form for Intervention Reviews (RCTs only) was customized and utilized [22]. Extracted literature was critically appraised utilizing the critical appraisal skills program (CASP) checklist for RCTs [23].

Risk of bias assessment in included studies

Risk of bias assessment was undertaken to ascertain the quality of methodology of selected studies utilizing the Cochrane Back Review Group recommendations [24]. Two independent reviewers (PA and EM) conducted this to determine a consensus. The criteria for assessing risk of bias was as follows:

- Random generation of sequence.
- Treatment allocation concealment.
- Outcome reporting selectivity.
- Blinding of patients, outcome assessors, and therapists.
- Insufficiency of outcome data.

Possibility of other sources of bias [16].

Cochrane Back Review Group guidelines contains twelve (12) questions which address these criteria; attrition bias, performance bias, selection bias and detection bias; answers to enquiries were; 'yes', 'no', and 'unclear' [24]. A low risk of bias was assigned to assessed studies if a 'yes' answer was obtained for six out of twelve enquiries without major flaws, example being a 20% or higher rate of dropout in a specific study group [24].

Assessing bias in publication

Assessing publication bias was undertaken by two methods namely; publication bias between studies, assessed utilizing funnel plots; and publication bias within studies assessed by examining whether outcomes reported were as expected for each period of follow-up [25]. Attempts were made to contact authors of published studies to provide additional information or clarify, if information provided was not sufficient [26].

Synthesis of data

Summary of findings (SoF) was generated using the grade pro guideline tool for development (GRADEpro GDT) software to determine the quality of findings [22]. Forests plots and meta-analysis were conducted using the review manager (RevMan 5) [27]. Meta-analysis was used to produce a weighted average, increase the power over results of individual studies, and improve the effect size estimates [28]. Due to the inherent heterogeneity in LBP within available literature, the random effects model was used [11].

The measure of primary effect for measures of outcomes was the standardized mean difference (SMD) [28]. Assessment of statistical heterogeneity was undertaken with the use of the I^2 statistic [21]. Assessment of the I^2 statistic was on a percentage basis:

- High possibility of heterogeneity: 75–100%
- Substantial possibility of heterogeneity: 50–90%
- Moderate possibility of heterogeneity: 30–60%

Substantial heterogeneity not present: 0–40% [22].

RESULTS

Selection and description of studies for this review

Results from the initial search produced 1,458 results (n = 1,458); subsequent removal of duplicates (n = 631), and titles and abstracts screening removed 789 studies (Figure 1). Thirty-eight (n = 38) full-text articles of potential studies relevant to the review were subsequently retrieved. No extra articles were identified through reference lists of retrieved articles.

Thirteen (n = 13) articles were excluded because they were not RCTs [29–41]. Four articles (n = 4) were also excluded based on the fact that they were systematic reviews [42–45]. A further ten (n = 10) articles were excluded because the inclusion criteria did not include patients with NSCLBP [46–55]. Six (n = 6) RCTs were also excluded based on the fact that they did not answer the specific question under review [56–61].

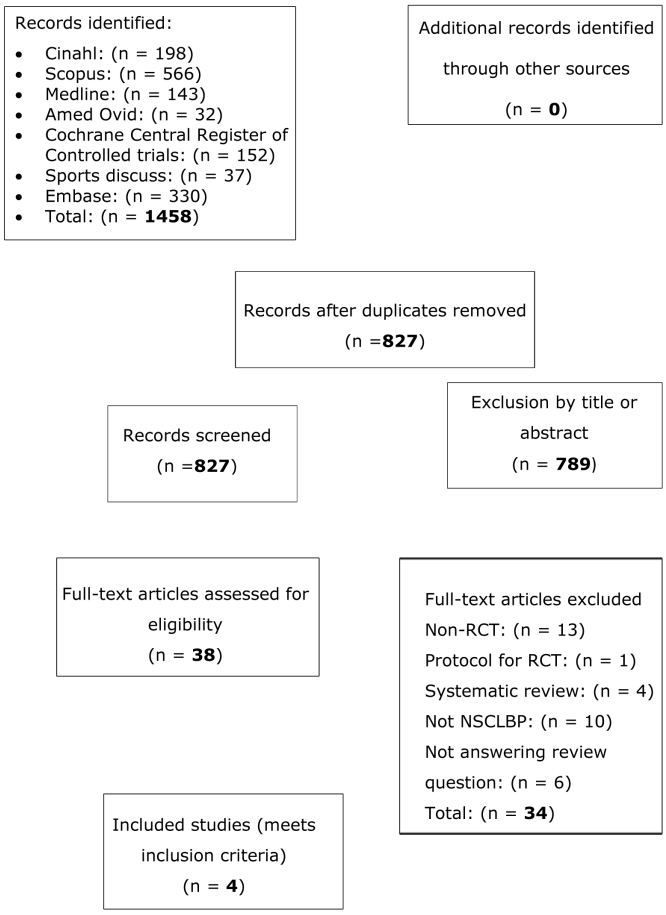

Figure 1: Flowchart detailing the study's selection process: adopted from; The PRISMA Group [21]

Included studies

Four studies met the inclusion criteria, thus were included for review [62–65]. The four studies included a total of four hundred and six participants (n = 406). Mean ages with standard deviations (SD) amongst other study characteristics are reported in Table 1. The studies employed the NRS (n = 2) [63, 65] and VAS (n = 2) [62, 64], were tools used to assess pain, while the RMDQ (n = 4); to assess disability in all four studies. Other outcome measures included the SF – 36 to measure QoL [63, 65], the Beck Depression Inventory to measure depression [62], the Tampa Scale for Kinesiophobia (TSK) to measure kinesiophobia [65], and the Pain Specific Function Scale [63] to measure function. Intervention periods ranged from six [65] to twelve weeks [64], with at least more than one session every week [62–65].

Risk of bias assessment in included studies

Table 2 illustrates information on the risk of bias in included studies; three out of the four studies had an overall low risk of bias as they had more than six 'yes' answers based on the Cochrane Back Review Group recommendations [62–65]. However, the overall risk of bias was high in one study, with three 'unclear' answers and four 'no' answers [64].

Description of interventions

All four studies incorporated CBT principles plus exercise therapy in one intervention group, and exercise alone in the other intervention group. Table 3 describes the interventions, with results for the treatment effects between groups, and their corresponding 95% CI at baseline, post intervention, and follow-up (6 months and

12 months).

SYNTHESIS OF DATA

Reporting bias

Due to similarities in outcome measures in included studies (n = 4), a meta-analysis was deemed appropriate. However, after the initial meta-analysis, Khan et al., [64], was excluded because it demonstrated a high risk of bias, publication bias, and also increased the statistical heterogeneity (Pain; I^2 =0–79%; Disability; I^2 =0–91%); thus the meta-analysis covered the three remaining included studies.A meta-analysis is recommended if both clinical and statistical heterogeneity are deemed to be at a minimal level [66–68].

Grading quality of studies for meta-analysis

Table 4 illustrates the summary of findings (SoF) generated from GRADEPro for studies included in meta-analysis; the quality grading revealed a high quality in all included studies (n = 3).

COMPARATIVE EFFECTIVENESS OF INTERVENTIONS

Pain

Three RCTs [62,63,65], with 346 participants included in meta-analysis, reported post intervention effect on pain (0 – 10 scale). A combination of these high quality RCTs revealed that there was no difference between CBT plus exercise and exercise alone post intervention (SMD = -0.02; 95% CI, -0.23 to 0.19) (Figure 2). Statistical heterogeneity between studies was low (I^2 = 0%; p-value = 0.92), indicative of a high homogeneity among included studies.

Medium (six months) and long term (twelve months) follow-up was only assessed by two studies; thus a meta-analysis was performed for two studies [62,63] (Figure 3). Medium term follow-up assessment for pain comprising 286 participants revealed, no difference between study

Table 1: Description of studies and characteristics

Study	Number of participants	Duration of pain in months, mean (± SD / range)	Mean age, (± SD), [range]	Frequency of delivery (CBT plus exercise)	Frequency of delivery (exercise alone)	Outcome measure(s)
Macedo et al., 2012	172 (Graded activity = 86, Motor control exercises = 86)	Graded activity: 100.7(109.2) Motor control exercises: 74.0(94.8)	49.6(16.3), [18-80]	12 initial sessions for 8 weeks, 2 booster sessions at 4 and 10 months, 1 hour per session	12 initial sessions for 8 weeks, 2 booster sessions at 4 and 10 months, 1 hour per session	NRS, RMDQ, SF-36, PS-FS
Khan et al., 2014	54 (CBT plus general exercise = 27, General exercise = 27)	Range: 3-24	39.61(5.3), [29-50]	3 sessions per week for 12 weeks	3 sessions per week for 12 weeks	VAS, RMDQ
Smeets at al., 2008	114 (CT = 61, APT = 53)	CT: 56.13(67.50) APT: 56.91(75.86)	41.91(9.65), [18-65]	19 sessions, 11 hours in total (about 30 minutes per session), for 10 weeks	3 sessions a week for 10 weeks, 1 hour 45 minutes per session	VAS, RMDQ, BDI
Magalhaes et al., 2015	66(Graded activity = 33, Physiotherapy exercise = 33)	Graded activity: 24(24-72) Physiotherapy exercise: 48(24-72)	46.6(9.5), [18-65]	2 sessions a week for six weeks, one hour per session	2 sessions a week for six weeks, one hour per session	NRS, RMDQ, SF-36, TSK

Abbreviations: NRS: Numeric Rating Scale; CBT: Cognitive Behavioural Therapy; TSK: Tampa Scale for Kinesiophobia; SF-36: Short Form Health Survey Questionnaire; CT: Combined Treatment (CBT plus APT); VAS: Visual Analogue Scale; RMDQ: Roland Morris Disability Questionnaire (0-24); APT: Active Physical Treatment; PS-FS: Pain Specific Functional Scale; BDI: Beck Disability Index

Table 2: Assessment of methodological quality (Based on Cochrane Back Review Group Guidelines)

	Selection bias			Performance bias				Attrition bias		Detection bias			
Included studies	**1**	**2**	**9**	**3**	**4**	**10**	**11**	**6**	**7**	**5**	**12**	**8**	**Overall risk of bias**
Macedo et al., 2012	+	+	+	-	-	-	+	+	+	+	+	+	Low
Smeets et al., 2008	+	+	+	-	-	+	+	+	+	+	+	+	Low
Khan et al., 2014	+	-	+	+	-	?	-	+	?	?	+	-	High
Magnalhaes et al., 2015	+	+	+	-	-	+	+	+	+	+	+	+	Low

Key: +: yes = criterion achieved; - : no = criterion not achieved;?: unclear = insufficient description to determine
1. Was the method of randomization adequate?
2. Was the treatment allocation concealed? Was knowledge of the allocated interventions adequately prevented during the study?
3. Was the patient blinded to the intervention?
4. Was the care provider blinded to the intervention?
5. Was the outcome assessor blinded to the intervention? Were incomplete outcome data adequately addressed?
6. was the drop-out rate described and acceptable?
7. Were all randomized participants analysed in the group to which they were allocated?
8. Are reports of the study free of suggestion of selective outcome reporting?
9. Were the groups similar at baseline regarding the most important prognostic indicators?
10. Were co-interventions avoided or similar?
11. Was the compliance acceptable in all groups?
12. Was the timing of the outcome assessment similar in all groups?

groups (SMD = -0.01; 95% CI, -0.24 to 0.22) (Figure 3). Statistical heterogeneity was low (I^2 = 0%; p-value = 0.91), signifying a high homogeneity among studies.

Long term follow-up assessment for pain comprising of 286 participants from two studies, demonstrated no difference between study groups (SMD = 0.06; 95% CI, -0.18 to 0.29) (Figure 4). Statistical heterogeneity was low (I^2 = 0%; p-value = 0.56), indicative of high homogeneity among included studies.

Khan et al.,[64]; reported a significant improvement in both the CBT plus exercise group (pain: 2.66;SD = 1.39; P-value < 0.0001), and the exercise alone group (pain: 5.25; SD = 1.19; P-value < 0.0001); however, between group analysis for treatment effects was not reported.

Disability

Three RCTs [62,63,65], with 346 participants included in the meta-analysis reported post intervention effect on disability. A combination of these high quality RCTs revealed no difference between study groups (SMD = 0.06; 95% CI, -0.15 to 0.27) (Figure 5). Statistical heterogeneity was low (I^2 = 0%; p-value = 0.94), signifying highly homogenous studies.

Medium term follow-up assessment for disability comprising 286 participants revealed no statistical difference between CBT plus exercise and exercise alone (SMD = 0.00; 95% CI, -0.23 to 0.23) (Figure 6). Statistical heterogeneity was low (I^2 = 0%; p-value = 0.36), signifying a high homogeneity among included studies.

Long term follow-up for disability comprising 286 participants, demonstrated no difference between study groups (SMD = -0.06;95% CI, -0.39 to 0.27) (Figure 7). Statistical heterogeneity was moderate (I^2 = 48%; p-value = 0.16), indicative of a possibility of a slight variation among included studies.

Furthermore, Khan et al.,[64], reported a significant improvement in both the CBT plus exercise group (disability: 5.33, SD = 2.67; P-value < 0.0001) and the exercise alone group (disability: 9.88, SD = 1.84; P-value < 0.0001) however, between group analysis for treatment effects was not reported.

SECONDARY OUTCOMES

Due to variations in reporting secondary outcomes for this review, a narrative synthesis was adopted aimed at describing the findings from included studies.

Quality of life (QoL)

Two studies assessed QoL as part of their outcome measures [63,65] (Table 1). QoL was assessed using the Short-Form Health Survey questionnaire (SF-36) in both studies. Macedo et al.,[63], found no difference between groups for the physical component score (PCS) for SF-36 post intervention, although there was an improvement in QoL in both CBT plus exercise group (51.6; SD, 13.4)

and exercise alone group (51.6; SD, 12.0), with the mean adjusted treatment effect showing a small effect ($\bar{x}$ = -0.2; 95% CI, -3.7 to 3.2; p-value = 0.89) [63].

Furthermore, the mental component score (MCS) post intervention also showed a similar increase in both CBT plus exercise group (55.8; SD, 13.0), and exercise alone group (56.0; SD, 10.9); with the mean adjusted treatment effect also showing a small effect ($\bar{x}$ = 2.3; 95% CI, -0.7 to 5.3; p-value = 0.14) [63]. Similar findings were observed at both medium and long term as illustrated in Table 3.

Magalhaes et al., [65], also reported that though improvements occurred in both CBT plus exercise (PCS: 75.3, SD 33.4, P<0.001; MSC: 84.4, SD = 31.2, P<0.001), and exercise alone groups (PCS: 68.1, SD = 41.1, P<0.001; MCS: 78.1, SD = 38.1, P<0.002), however, there was no

Table 3: Description and results of interventions

Study	CBT plus exercise group	Exercise alone group	Post intervention results; Mean difference between groups (95% CI, p-value)	Medium term results (6 months), Mean difference between groups (95% CI, p-value)	Long term results (12 months); Mean difference between groups (95% CI, p-value)
Smeets et al., 2008	CT: CBT; problem solving training and operant behavioural grading activity (biopsychosocial approach) APT: aerobic training, dynamic-static exercises	APT: aerobic training, dynamic-static exercises	VAS: -0.18(-9.34 to 8.99; p<0.05) RMDQ: -0.05(-1.71 to 1.62; p<0.05) BDI: 2.17(0.18 to 4.17; p<0.05)	VAS: 1.97(-1.71 to 5.65; p<0.05) RMDQ: 0.62(-1.06 to 2.30; p<0.05) BDI: 0.49(-1.54 to 2.51; p<0.05)	VAS: 8.04(-1.23 to 17.31; p<0.05) RMDQ: 1.16(-0.52 to 2.84; p<0.05) BDI: 1.05(-0.97 to 3.07; p<0.05)
Khan et al., 2014	CBT plus general exercise: CBT; operant behavioural grading activity and problem-solving training. General exercise; cycling, treadmill, bridging, rolling, hamstring stretch, knee to chest. Home exercise	General exercise; cycling (10 minutes), treadmill (10 minutes), bridging, rolling, hamstring stretch, knee to chest (20 repetitions). Home exercise program	Mean difference between groups not assessed. Post intervention results (mean ± SD) CBT plus general exercise: VAS: $\bar{x}$ = 2.66 ± 1.39 RMDQ: $\bar{x}$= 5.33 ± 2.67 General exercise: VAS: $\bar{x}$ = 5.25 ± 1.19 RMDQ: $\bar{x}$ = 9.88 ± 1.84	Not assessed	Not assessed
Macedo et al., 2012	Graded activity group: CBT principles with positive reinforcement plus activities deemed problematic to participants with time-contingent progression	Motor control exercises: Postural movement, muscle activation, breathing control, functional exercises. Home exercises	NRS: 0.0(-0.7 to 0.8; p=0.94) RMDQ: -0.8(-2.3 to 0.6; p=0.26) PS-FS: 0.2(-0.5 to 0.9; p=0.53) SF-36: mental: 2.3(-0.7 to 5.3; p=0.14) SF-36: physical; -0.2(-3.7 to 3.2; p=0.89)	NRS: 0.0(-0.8 to 0.8; p=0.99) RMDQ: -0.8(-2.3 to 0.6; p=0.26) PS-FS: -0.2(-0.9 to 0.5; p=0.53) SF-36: mental; 0.1;(-3.0 to 3.0; p=0.97) SF-36: physical; 1.1(-2.4 to 4.6; p=0.54)	NRS: 0.1(-0.7 to 0.9; p=0.83) RMDQ: -0.6(-2.0 to 0.9; p=0.45) PS-FS: -0.4(-1.1 to 0.3; p=0.25) SF-36: mental; 0.8(-2.2 to 3.9; p=0.62) SF-36: physical; -0.3(-3.8 to 3.3)
Magalhaes et al., 2015	Graded activity group: CBT principles stimulating behavioural change plus progressive submaximal exercises (aerobic and strengthening exercises). Educational book; the “Back book”.	Physiotherapy exercise group: Motor control exercises, strengthening exercises.	NRS: 0.1(-1.1 to 1.4; p=0.872) RMDQ: 0.8(-2.2 to 4.2; p=0.96) SF-36: physical; 6.0(-30.5 to 18.5; p=0.415) TSK: 4.0(-1.7 to 9.7; p=0.321)	Not assessed	Not assessed

Abbreviations: NRS: Numeric Rating Scale; CBT: Cognitive Behavioural Therapy; TSK: Tampa Scale for Kinesiophobia; SF-36: Short Form Health Survey Questionnaire; CT: Combined Treatment (CBT plus APT); VAS: Visual Analogue Scale; RMDQ: Roland Morris Disability Questionnaire (0-24); APT: Active Physical Treatment; PS-FS: Pain Specific Functional Scale; BDI: Beck Disability Index

Table 4: Summary of findings CBT plus Exercise compared to Exercise for Non-specific chronic low back pain

Outcomes	Number of participants (Studies) Follow-up	Quality of evidence (GRADE)	Measure of effect
Pain three studies assessed with: NRS Scale from: 0 to 10 follow up: mean 8 weeks	346 (3RCTs)	⨁⨁⨁⨁ High	SMD **0.02 SD lower** (0.23 lower to 0.19 higher)
Disability three studies assessed with: RMDQ Scale from: 0 to 24 follow up: mean 8 weeks	346 (3 RCTs)	⨁⨁⨁⨁ High	SMD **0.06 SD higher** (0.15 lower to 0.27 higher)

*__The risk in the intervention group__ (and its 95% confidence interval) is based on the assumed risk in the comparison group and the **relative effect** of the intervention (and its 95% CI).

CI: Confidence Interval; **SMD**: Standardised mean difference; **NRS**: Numeric Rating Scale; **RMDQ**: Roland Morris Disability Questionnaire; **RCT**: Randomised Controlled Trial

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect.

statistical difference between groups post intervention (PCS: 6.0; 95% CI, -30.5 to 18.5, p-value = 0.415; MCS: 4.5; 95% CI, -31.5 to 22.5, p-value = 0.388).

Function

Function was assessed by only one RCT [63] (Table 3). Function was assessed with the use of the Patient-Specific Functional Scale (PSFS); mean adjusted treatment effects were small post intervention ($\bar{x}$ = 0.2; 95% CI, -0.5

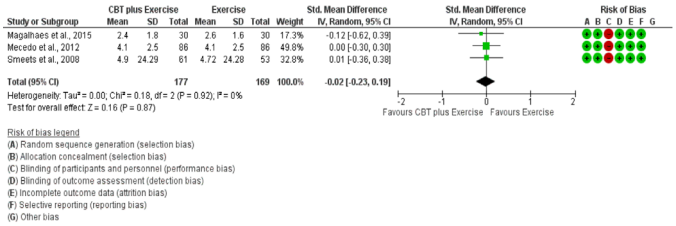

Figure 2: Forrest plot of CBT plus exercise versus exercise alone (3 RCTs) for pain post intervention.

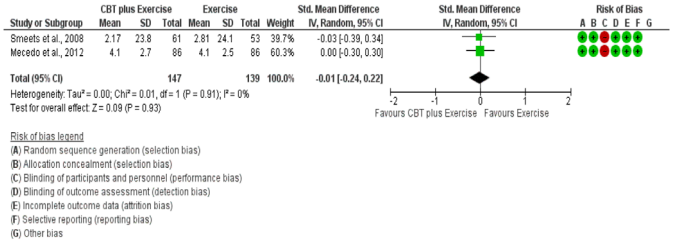

Figure 3: Forrest plot of CBT plus exercise versus exercise alone (2 RCTs) for pain at medium term (6 months).

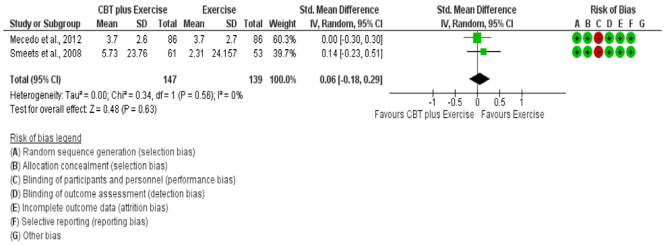

Figure 4: Forrest plot of CBT plus exercise versus exercise alone (2 RCTs) for pain at long term (12 months).

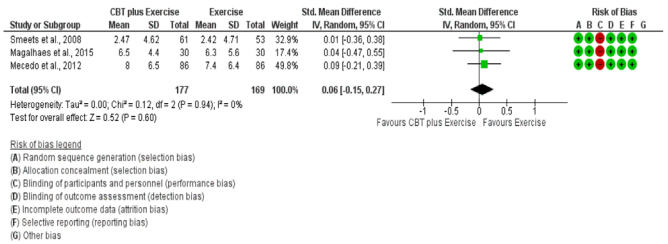

Figure 5: Forrest plot of CBT plus exercise versus exercise alone (3 RCTs) for disability post intervention.

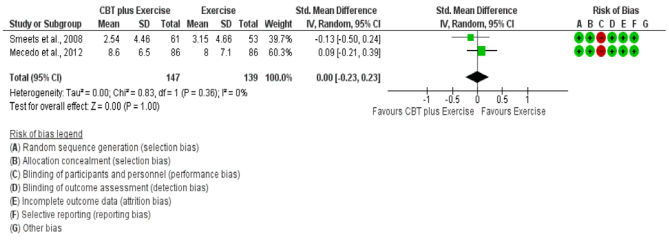

Figure 6: Forrest plot of CBT plus exercise versus exercise alone (2 RCTs) for disability at medium term (6 months).

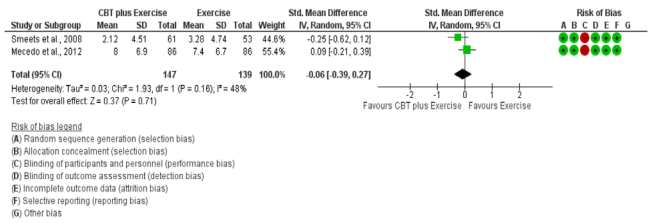

Figure 7: Forrest plot of CBT plus exercise versus exercise alone (2 RCTs) for disability at long term (12 months).

to 0.9, p-value = 0.53), with both interventions showing similarities (CBT plus exercise: 5.5; SD = 2.4; Exercise alone: 5.9; SD = 2.1) [63].

Medium term and long-term assessments demonstrated no difference between study groups, although both reported improvement in function (Medium term: CBT plus exercise; 5.7; SD = 2.4; Exercise alone; 5.7; SD = 2.3; Long term: CBT plus exercise; 6.1; SD = 2.3; Exercise alone; 5.9; SD = 2.2), with small mean adjusted treatment effect (Medium term: $\bar{x}$ = -0.2; 95% CI, -0.9 to 0.5, p-value = 0.53 Long-term: $\bar{x}$ = -0.4; 95% CI, -1.1 to 0.3, p-value = 0.25) [63].

Depression

Assessment of depression was undertaken by only one study [62] (Table 1). The Beck Depression Inventory (BDI) was utilized in assessing depression; between group (CBT plus exercise and exercise alone) mean difference post intervention revealed a statistically significant but not clinically meaningful difference ($\bar{x}$ = 2.17; 95% CI, 0.18 to 4.17, p<0.05), post intervention [62]. The minimal clinically important difference (MCID) recommended by NICE and developed by the National Collaborating Centre for Mental Health (NCCMH) is a difference greater than or equal to 3.0 BDI points [69].

Furthermore, medium, and long-term assessment results also revealed statistically significant but not clinically meaningful mean differences (medium term: $\bar{x}$ = 0.49; 95% CI, -1.54 to 2.51, p<0.05; long-term: $\bar{x}$ = 1.05; 95% CI, -0.97 to 3.07, p<0.05) between CBT plus exercise and exercise alone groups [62].

Kinesiophobia

Kinesiophobia was assessed by only one study [65]. The Tampa Scale for Kinesiophobia was the outcome tool utilized for measurement. Post intervention mean difference between groups was not significant ($\bar{x}$ = 4.0; 95% CI, -1.7 to 9.7; p-value = 0.321), although there was significant improvement in individual groups (CBT plus exercise: $\bar{x}$ = 36.6, SD = 8.1, p-value < 0.007; Exercise: $\bar{x}$ = 35.6, SD = 9.5, p-value< 0.001).

DISCUSSION

Summary of findings

The aim of this review was to ascertain the comparative effectiveness of CBT plus exercise versus exercise alone in the management of patients with NSCLBP. Overall, the meta-analysis showed no significant difference between the CBT plus exercise group in comparison to the group receiving exercise alone, for primary outcomes (pain and disability) and secondary outcomes (QoL, kinesiophobia, function). However, although there was a significant difference between groups for depression in one study [62], favouring CBT plus exercise, this was not clinically meaningful; mean difference in BDI values was below 3.0 which is considered as not clinically meaningful according to NICE recommendations [69].

Statistical heterogeneity post intervention, medium term, and long term was predominantly low (I^2 = 0%) (except for disability at long term: I^2 = 48%), for pain and disability; therefore, our findings, suggesting that combining CBT with exercise is no better than exercise alone for the management of NSCLBP post intervention, medium term, and long term, can be considered to be robust. Furthermore, Khan et al.,[64], also reported no significant difference between groups although between group analysis was not reported; however, a high risk of bias was ascertained from the evidence.

Strengths and weaknesses of included studies

Khan et al., [64], was excluded from the meta-analysis due to possible high risk of bias, low methodological quality, high heterogeneity, and potential reporting bias. The three studies included in the meta-analysis, overall showed a low risk of bias, with a high quality in the overall grading, and a predominantly low heterogeneity (I^2 = 0% for all except long term outcome for disability; I^2 = 48%); this signifies a strong internal validity and reliability [70].

Treating therapists, and participants were not blinded in all three studies, thus possibly increasing the performance bias; however, it is difficult to achieve this blinding in active physiotherapy studies [11]. Macedo et al.,[63], and Smeets et al.,[62], performed their trial analysis based on intention to treat; however, Magalhaes et al.,[65], did not perform trial analysis based on intention to treat as there were drop-outs in both groups (CBT plus exercise = 3; Exercise alone = 3), thus possiblyweakening the internal validity of the study [71].

Again, study characteristics were varied based on treatment delivery (format, content, dosage), participants employment status, economic status, duration of pain, and associated symptoms such as leg pain; patients whose characteristics indicated psychopathology were also excluded in two studies [62, 65].

Furthermore, none of the included studies incorporated a patient subgrouping process (e.g., risk assessment tool; STarT Back); to stratify patients based on the risk of chronicity potentially enabling a more targeted intervention process. Guidelines such as NICE recommend stratification as part of comprehensive management approach for NSCLBP [8]; consequently, systematic stratification and identification of high risk groups who are potentially likely to respond to a multimodal approach (including exercise and CBT) is an area for future research.

Studies did not include a range of psychological measures including, kinesiophobia, self-efficacy, and depression, which are highlighted as measures in CBT interventions [72]. Also, none of the included studies assessed cost effectiveness of combining CBT with exercise; although, systematic reviews by Lin et al., [73], and Kamper et al., [74], have concluded that management utilizing either CBT or exercise for pain and disability is cost-effective, its inclusion would help better inform clinical decisions.

Implications for clinical practice

The results of a research have the potential to determine the direction of clinical practice, allocation of funding, and the determination of areas that may necessitate quality improvement. The results confirm the favorable outcomes of guideline recommended therapies (CBT and exercise) for the management of NSCLBP. Importantly, the results showed no significant difference between groups receiving CBT plus exercise and exercise alone for measures of pain and disability (short or long term).

These results have important implications in relation to service delivery planning for patients with NSCLBP and clinicians managing patients with NSCLBP. The addition of CBT in this review to exercise-based therapy did not improve outcomes of pain and disability suggesting that focus for the interventions should be based around exercise primarily although certainly a multimodal approach may need to be considered for some patients. The studies did not (for example) look at subgrouping of patients based on psychological profiling and it may be that specific subgroups of patients with higher levels of psychological distress do better with a multimodal approach combining exercise and CBT therapies.

The other important fact to highlight is that this review focused on pain and disability as outcome measures and few of the included studies incorporated psychological outcome measures such as depression and kinesiophobia. It might be argued that the added value of CBT to exercise therapy would be reflected in these outcomes and further research is required in this area.The need to situate the evidence in a contextual framework while taking into consideration individual patients needs is essential. Consequently, the results of this review; a confirmation of guideline recommended approaches, and an outcome revealing no significant difference between groups; will serve as a valuable resource in clinical practice. Furthermore, relevant questions and recommendations from this review will serve as an opportunity for further research to update existing evidence.

The results of this review are relevant to the physiotherapy community. The fact that all included studies confirm guideline-recommended therapies as having a favorable outcome for NSCLBP is an affirmation of the relevance of practicing in an EBP framework. Furthermore, the results from this review have the potential to draw the attention of physiotherapists to institutionalizing stratified care interventions, geared towards specific patient needs.

Limitations of this review

This review was conducted with a comprehensive literature search, with two independent reviewers undertaking a full text screening for including and extracting data, thus minimizing bias; however only studies published in English were included in this review possibly introducing a language bias.

How these results add to the literature base

A systematic review with meta-analysis by Kamper et al., [74], investigated combined treatments in a multidisciplinary biopsychosocial framework, compared to usual care (which entailed health professional prescribed treatment), reported that the combined biopsychosocial framework had favourable outcomes; however, effect sizes were small.

Furthermore, a systematic review with narrative synthesis by George, [75], comparing a biopsychosocial framework (entailing neurobiological conditioning, graded exposure, and empowerment of the patient), to CBT, usual care or no treatment, also concluded favourable outcomes for the multimodal biopsychosocial framework.

CONCLUSION

This systematic review is to the best of our knowledge, the first to investigate the comparative effectiveness of CBT plus exercise versus exercise alone in the management of NSCLBP. Results from this review suggest that although combining CBT with exercise or exercise alone are effective management approaches for managing NSCLBP patients, combining CBT plus exercise is not more effective than exercise alone on patient outcomes.

RECOMMENDATIONS

Although we are confident our findings are robust, the following recommendations are based on observations made from the study;

- Firstly, future RCTs that seek to answer this question should have a clear stratification procedure based on validated tools such as the STarT Back to clearly ascertain patients risk levels to be able to make conclusions on effectiveness within the subgroups.
- Secondly, therapists should consider patients preferences within available resources when deciding on which approach to adopt to management.
- Finally, although guidelines recommend a CBT approach combined with exercise for NSCLBP, perhaps more clarity in necessary to ascertain which subgroup of NSCLBP patients would benefit from a combined therapy.

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Author Contributions

Paapa Kwesi Ampiah – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Paul Hendrick – Substantial contributions to conception and design, Acquisition of data, Analysis and interpretation of data, Drafting the article, Revising it critically for important intellectual content, Final approval of the version to be published

Erika Gonzalez Macias – Acquisition of data, Analysis and interpretation of data, Revising it critically for important intellectual content, Final approval of the version to be published

Guarantor of Submission
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Authors declare no conflict of interest.

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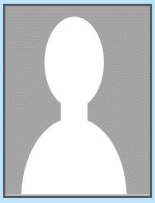

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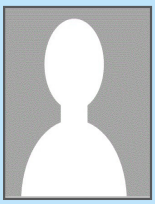

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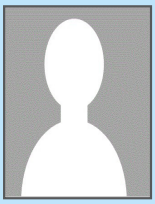

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