C.4 Cognitive behavioural therapy (CBT)

Overview of the PICO structure

Definition of the intervention

Cognitive behavioural therapy (CBT), is based on a multidimensional model of pain and focuses on reducing pain and distress by modifying physical sensation, catastrophic thinking and unhelpful behaviour(s). Treatment may include education about a multi-dimensional view of pain, identifying pain-eliciting and pain-aggravating situations, thoughts and behaviours, and using coping strategies and applied relaxation; in sum, integrating components of operant, respondent and cognitive therapies. Goal-setting and activity increases are encouraged as the basis of CBT to reduce feelings of helplessness and help the person gain control over their pain experience.

PICO question								
Population and subgroups	Community-dwelling adults (aged 20 years and over) experiencing chronic primary low back pain, with or without leg pain, including older people (aged 60 years and older).							
	 Subgroups: Age (all adults and those aged 60 years and over) Gender and/or sex Presence of leg pain (radicular, non-radicular, mixed) Race/ethnicity - studies of populations who were historically marginalized compared with studies of those who were not Regional economic development - studies carried out in high-income countries compared with studies in low- to middle-income countries 							
Comparators	a) Placebo/shamb) No or minimal intervention, or where the effect of the intervention can be isolatedc) Usual care (described as usual care in the trial)							

Outcomes	Critical outcomes constructs (all adults)
	• Pain
	Back-specific function/disability
	General function/disability
	Health-related quality of life
	Psychosocial function
	Social participation
	Self-efficacy
	Adverse events (as reported in trials) Pain
	Back-specific function/disability
	General function/disability
	Health-related quality of life
	Psychosocial function
	Adverse events (as reported in trials)

Other Evidence-to-Decision (EtD) considerations

Summary of values and preferences					
All adults	Older people				
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified				

Summary of resource considerations	
All adults	Older people

No evidence synthesis commissioned for all adults. Judgements made	No evidence identified
based on experience of GDG members	

Summary of equity and human rights considerations				
All adults	Older people			
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified			

Summary of acceptability considerations					
All adults	Older people				
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified				

Summary of feasibility considerations					
All adults	Older people				
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified				

Summary of judgements

Domain All adults Ol		Older people
Benefits	Small; trivial; uncertain	Small; trivial; uncertain
Harms	Trivial; uncertain	Trivial; uncertain
Balance benefits to harms	Probably favours CBT; uncertain	Probably favours CBT; uncertain

Overall certainty	Very low	Very low			
Values and preferences	Important uncertainty or variability; possibly important uncertainty or variability	Important uncertainty or variability; possibly important uncertainty or variability			
Resource considerations	Moderate; large; varies	Moderate; large; varies			
Equity and human rights	Possibly reduced; no impact; uncertain; varies	Possibly reduced; no impact; uncertain; varies			
Acceptability	Probably yes; probably no; varies	Probably yes; probably no; varies			
Feasibility	Varies	Varies			

GRADE Table 1. What are the benefits and harms of cognitive behavioural therapy (CBT) in the management of community-dwelling adults (including older adults aged 60 years and over) with chronic primary low back pain (with or without leg pain) compared with <u>placebo</u>?

No trials.

GRADE Table 2. What are the benefits and harms of cognitive behavioural therapy (CBT) in the management of community-dwelling adults (including older adults aged 60 years and over) with chronic primary low back pain (with or without leg pain) compared with <u>no intervention</u>?

	Certainty assessment				№ of patients		Effect				
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Pain - short	t term										
22	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	1265	1075	-	SMD 0.49 lower (0.75 lower to 0.24 lower)	⊕○○○ Very low
Population	subgroups 1 ar	nd 2 - not rep	orted (no subgroup	analysis was perf	formed)	'					
Population	subgroup 3: pr	esence of rad	licular leg pain								
Excluded radicular leg pain 3	randomized trials	very serious ^a	serious ^b	not serious	seriouse	none	98	99	-	SMD 0.71 lower (1.85 lower to 0.43 higher)	⊕⊖⊖⊖ Very low
Not specified whether radicular leg pain included 19	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	1167	976	-	SMD 0.47 lower (0.73 lower to 0.2 lower)	⊕○○○ Very low
Population	subgroup 4: re	gional econo	mic development	!	!	-		!	!	!	
Low/ middle income 2	randomized trials	very serious ^a	serious ^b	not serious	seriouse	none	46	45	-	MD 1.42 lower (3.74 lower to 0.9 higher)	⊕○○○ Very low

Pain - intermediate term	Effect		Effect	
Pain - intermediate term				
Fopulation subgroups 1 and 2 - not reported (no subgroup analysis was performed) Excluded radicular leg pain 1 not serious 2 not serious 3 not serious 3 not serious 3 not serious 3 not serious 4 not serious 4 not serious 5 not serious 5 not serious 6 not serious 7 not serious 7 not serious 8 none 8 none 9 not serious 9 none 9 not serious 9 not serious 9 not serious 9 none 9 none 9 not serious 9 none 9 none 9 not serious 9 none 9 not serious 9 none 9 not serious 9 none 9 none 9 none 9 not serious 9 none 9 not serious 9 none 9 none 9 none 9 none 9 none 9 none 9 not serious 9 none 9 no	SMD 0.44 lower (0.7 lower to 0.19 lower)	-	(0.7 lower to	_
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed) Population subgroup 3: presence of radicular leg pain Excluded radicular deg pain 1 randomized serious 1 randomized trials serious 1 randomized wery serious 1 randomized wery serious 1 randomized whether radicular leg pain 1 randomized whether radicular leg pain included 4 radicular leg pain included 4 regional economic development (no subgroup analysis was performed) Population subgroup 4: regional economic development (no subgroup analysis was performed)				
Population subgroup 3: presence of radicular leg pain Excluded randomized very serious not serious not serious none 51 52 - Not randomized very serious not serious not serious none 519 316 - 52 Not randomized very serious not serious not serious none 519 316 - 52 Population subgroup 4: regional economic development (no subgroup analysis was performed) Pain - long term	SMD 0.08 lower (0.32 lower to 0.16 higher)	-	(0.32 lower to	
Excluded radicular leg pain 1				
radicular leg pain 1 Not randomized very serious not serious none 519 316 - Serious radicular leg pain included 4 Population subgroup 4: regional economic development (no subgroup analysis was performed) Pain - long term				
specified trials serious ^a whether radicular leg pain included 4 Population subgroup 4: regional economic development (no subgroup analysis was performed) Pain - long term	MD 0.00 lower (0.85 lower to 0.85 higher)	-	(0.85 lower to)
Pain - long term	SMD 0.08 lower (0.39 lower to 0.22 higher)	-	(0.39 lower to	
7 randomized very serious ^d not serious serious ^e none 799 593 - S				
trials serious ^a	SMD 1.06 lower (1.66 lower to 0.47 lower)	-	(1.66 lower to	5
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed)				
Population subgroup 3: presence of radicular leg pain				

			Certainty assess	sment			Nº of p	patients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	seriouse	none	49	49	-	MD 1.00 lower (1.83 lower to 0.17 lower)	⊕○○○ Very low
Not specified whether radicular leg pain included 6	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	none	750	544	-	SMD 1.18 lower (1.86 lower to 0.49 lower)	⊕⊖⊖⊖ Very low
Population	subgroup 4: reç	gional econo	mic development (no subgroup anal	ysis was performe	ed)					
Back-specif	fic functional st	atus – short t	term								
21	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	1219	1025	-	SMD 0.46 lower (0.75 lower to 0.18 lower)	⊕○○○ Very low
Population	subgroups 1 an	d 2 - not rep	orted (no subgroup	analysis was perf	ormed)						
Population	subgroup 3: pre	esence of rad	licular leg pain								
Excluded radicular leg pain 3	randomized trials	very serious ^a	serious ^b	not serious	seriouse	none	98	99	-	SMD 0.76 lower (1.86 lower to 0.35 higher)	⊕○○○ Very low
Not specified whether radicular leg pain included 18	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	none	1121	926	-	SMD 0.42 lower (0.72 lower to 0.11 lower)	⊕○○○ Very low

			Certainty assess	sment			Nº of p	oatients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Low/ middle income 2	randomized trials	very serious ^a	serious ^b	not serious	seriouse	none	46	45	-	SMD 1.12 lower (2.76 lower to 0.52 higher)	⊕⊖⊖⊖ Very low
High income 19	randomized trials	very serious ^a	serious ^b	not serious	seriouse	none	1173	980	-	SMD 0.4 lower (0.68 lower to 0.11 lower)	⊕○○○ Very low
Back-speci	fic functional st	atus - interme	ediate term								
5	randomized trials	very serious ^a	not serious	not serious	not serious	none	538	361	-	SMD 0.15 lower (0.3 lower to 0)	⊕⊕○○ Low
Population	subgroups 1 an	id 2 - not repo	orted (no subgroup	analysis was perf	ormed)						
Population	subgroup 3: pre	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	54	54	-	MD 0.1 lower (1.53 lower to 1.73 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 4	randomized trials	very seriousª	not serious	not serious	not serious	none	484	307	-	SMD 0.18 lower (0.35 lower to 0.02 lower)	⊕⊕○○ Low
Population	subgroup 4 - no	ot reported (n	o subgroup analysi	s was performed)		-			!	!	
Back-speci	fic functional st	atus - long te	rm								
7	randomized trials	very serious ^a	serious ^d	not serious	seriouse	none	745	557	-	SMD 1.16 lower (2.01 lower to 0.32 lower)	⊕○○○ Very low

						142 01 }	patients		Effect		
Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty	
ubgroups 1 an	d 2 - not repo	orted (no subgroup	analysis was perf	ormed)						,	
ubgroup 3: pre	esence of rad	icular leg pain									
randomized trials	very serious ^a	not serious ^f	not serious	seriouse	none	49	49	-	MD 1.1 lower (2.86 lower to 0.66 higher)	⊕○○○ Very low	
randomized trials	very serious ^a	serious ^d	not serious	serious ^e	none	696	508	-	SMD 1.33 lower (2.31 lower to 0.34 lower)	⊕⊖⊖⊖ Very low	
subgroup 4: reg	jional econor	nic development (no subgroup anal	ysis was performe	:d)		-				
ctional status –	short term, i	ntermediate term	or long term: no	studies identifie	d that reported o	n this outcome					
-	-	-	-	-	-	-	-	-	-	-	
ed quality of life	e - short term				1		-				
randomized trials	very serious ^a	serious ^d	not serious	seriouse	none	504	519	-	SMD 0.61 higher (0.11 higher to 1.1 higher)	⊕○○○ Very low	
subgroup 1, 2, 3	3 and 4 - not i	reported (no subgre	oup analysis was	performed)						-	
ed quality of life	e - intermedia	te term									
randomized trials	very serious ^a	not serious	not serious	seriouse	none	207	233	-	SMD 0.25 higher (0.07 higher to 0.44 higher)	⊕○○○ Very low	
il	ubgroups 1 and ubgroup 3: pre randomized trials randomized trials ubgroup 4: reg tional status — d quality of life randomized trials d quality of life randomized	ubgroups 1 and 2 - not report ubgroup 3: presence of rad randomized very seriousa randomized trials very seriousa ubgroup 4: regional econor tional status – short term, i	ubgroups 1 and 2 - not reported (no subgroup ubgroup 3: presence of radicular leg pain randomized trials very seriousa seriousa seriousa very seriousa trials very seriousa seriousa trials very seriousa seriousa seriousa seriousa very seriousa very seriousa seriousa trials very seriousa seriousa seriousa seriousa seriousa very seriousa seriousa seriousa very seriousa seriousa very seriousa development (no subgroup 1, 2, 3 and 4 - not reported (no	ubgroup 3: presence of radicular leg pain randomized trials very seriousa not serious randomized trials very seriousa seriousa not serious randomized trials very seriousa seriousa not serious ubgroup 4: regional economic development (no subgroup analytional status – short term, intermediate term or long term: no	ubgroup 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very seriousa serious not serious seriouse randomized trials very seriousa not serious seriouse ubgroup 4: regional economic development (no subgroup analysis was performent ional status – short term, intermediate term or long term: no studies identified trials very seriousa not serious seriouse ad quality of life - short term randomized very seriousa not serious seriouse ubgroup 1, 2, 3 and 4 - not reported (no subgroup analysis was performed) d quality of life - intermediate term randomized very not serious not serious seriouse	ubgroups 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very serious³ not serious¹ not serious serious³ none randomized trials very serious³ serious⁴ not serious serious³ none ubgroup 4: regional economic development (no subgroup analysis was performed) tional status - short term, intermediate term or long term: no studies identified that reported or conditional status - short term randomized trials very serious³ not serious serious³ none ubgroup 1, 2, 3 and 4 - not reported (no subgroup analysis was performed) d quality of life - intermediate term randomized very not serious not serious serious³ none	design bias ubgroups 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very serious³ not serious¹ not serious serious³ none 49 randomized trials very serious³ serious³ not serious serious³ none 696 ubgroup 4: regional economic development (no subgroup analysis was performed) tional status - short term, intermediate term or long term: no studies identified that reported on this outcome - - - - d quality of life - short term randomized trials very serious³ serious serious serious serious none none 504 d quality of life - intermediate term randomized very not serious not serious serious serious none none 207	ubgroups 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very serious³ not serious serious³ none 49 49 randomized trials very serious³ not serious serious³ none 696 508 ubgroup 4: regional economic development (no subgroup analysis was performed) tional status - short term, intermediate term or long term: no studies identified that reported on this outcome - - - - - d quality of life - short term trials very serious³ serious serious° none 504 519 ubgroup 1, 2, 3 and 4 - not reported (no subgroup analysis was performed) d quality of life - intermediate term randomized very not serious serious° none 207 233	ubgroup 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized very serious³ not serious not serious serious° none 49 49 - randomized very serious³ not serious serious° none 696 508 - randomized very serious³ not serious serious° none 696 508 - ubgroup 4: regional economic development (no subgroup analysis was performed) tional status – short term, intermediate term or long term: no studies identified that reported on this outcome	ubgroup 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very serious serious not serious serious none 49 49 49 - MD 1.1 lower (2.86 lower to 0.66 higher) randomized very serious serious not serious serious none 696 508 - SMD 1.33 lower (2.31 lower to 0.34 lower) ubgroup 4: regional economic development (no subgroup analysis was performed) titinal status - short term, intermediate term or long term: no studies identified that reported on this outcome	ubgroup 1 and 2 - not reported (no subgroup analysis was performed) ubgroup 3: presence of radicular leg pain randomized trials very serious³ not serious serious° none 49 49 - MD 1.1 lower (2.86 lower to 0.66 higher) very low of trials serious³ serious³ not serious serious° none 696 508 - SMD 1.33 lower (2.31 lower to 0.34 lower) ubgroup 4: regional economic development (no subgroup analysis was performed) titional status – short term, intermediate term or long term: no studies identified that reported on this outcome

			Certainty assess	sment			№ of	patients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Health-rela	ted quality of life	e - long term									
4	randomized trials	very serious ^a	serious ^d	not serious	seriouse	none	311	301	-	SMD 1.06 higher (0.03 higher to 2.1 higher)	⊕○○○ Very low
Population	subgroup 1, 2,	3 and 4 - not	reported (no subgr	oup analysis was	performed)						
Adverse ev	ents – narrative	results only	(see text)								
-	-	-	-	-	-	-	-	-	-	-	-
Serious ad	verse events: no	studies ider	ntified that reporte	d on this outcom	ne						
-	-	-	-	-	-	-	-	-	-	-	-
Psychologi	ical functioning	(depression)	- short term								
8	randomized trials	very serious ^a	not serious	not serious	not serious	none	335	312	-	SMD 0.14 lower (0.3 lower to 0.01 higher)	⊕⊕○○ Low
Population	subgroups 1 ar	nd 2 - not repo	orted (no subgroup	analysis was perf	formed)	-!					
Population	subgroup 3: pro	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	52	54	-	MD 0 lower (1.73 lower to 1.73 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 7	randomized trials	very serious ^a	not serious	not serious	not serious	none	283	258	-	SMD 0.18 lower (0.36 lower to 0)	⊕⊕○○ Low

			Certainty assess	sment			№ of _l	patients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Population	subgroup 4: re	gional econor	mic development (no subgroup anal	ysis was performe	ed)					
Psychologi	cal functioning	(depression)	- intermediate terr	n							
3	randomized trials	very serious ^a	not serious	not serious	not serious	none	165	162	-	SMD 0.06 lower (0.38 lower to 0.26 higher)	⊕⊕○○ Low
Population	subgroups 1 ar	nd 2 - not repo	orted (no subgroup	analysis was perf	ormed)						
Population	subgroup 3: pro	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	54	54	-	MD 0.7 higher (0.59 lower to 1.99 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 2	randomized trials	very seriousª	not serious	not serious	not serious	none	111	108	-	SMD 0.2 lower (0.47 lower to 0.07 higher)	⊕⊕○○ Low
Population	subgroup 4 - no	t reported (n	o subgroup analysis	s was performed)							
Psychologi	cal functioning	(depression)	- long term								
2	randomized trials	very serious ^a	not serious	not serious	not serious	none	151	149	-	SMD 0.1 lower (0.33 lower to 0.13 higher)	⊕⊕○○ Low
Population	subgroups 1 ar	nd 2 - not repo	orted (no subgroup	analysis was perf	formed)						
Population	subgroup 3: pro	esence of rad	licular leg pain								

			Certainty assess	sment			Nº of p	oatients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	49	49	-	MD 0.3 lower (1.69 lower to 1.09 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	102	100	-	MD 0.46 lower (1.63 lower to 0.71 higher)	⊕⊕○○ Low
Population	subgroup 4 - no	ot reported (n	o subgroup analysi	s was performed)				1			'
Psychologic	cal functioning	(anxiety) - sh	ort term								
4	randomized trials	very serious ^a	not serious	not serious	not serious	none	196	194	-	SMD 0.08 lower (0.28 lower to 0.11 higher)	⊕⊕○○ Low
Population	subgroups 1 an	nd 2 - not repo	orted (no subgroup	analysis was perf	formed)						'
Population	subgroup 3: pre	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	52	54	-	MD 0.6 lower (1.75 lower to 0.55 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 3	randomized trials	very serious ^a	not serious	not serious	not serious	none	144	140	-	SMD 0.04 lower (0.28 lower to 0.19 higher)	⊕⊕○○ Low

			Certainty assess	sment		Nº of p	patients		Effect		
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Psychologi	cal functioning	(anxiety) - int	termediate term								
2	randomized trials	very serious ^a	not serious	not serious	not serious	none	153	152	-	SMD 0.14 lower (0.37 lower to 0.08 higher)	⊕⊕○○ Low
Population	subgroups 1 ar	nd 2 - not repo	orted (no subgroup	analysis was perf	formed)						
Population	subgroup 3: pr	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	51	52	-	MD 0.6 lower (1.6 lower to 0.4 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	102	100	-	MD 0.56 lower (2.1 lower to 0.98 higher)	⊕⊕○○ Low
Population	subgroup 4 - no	ot reported (n	o subgroup analysi	s was performed)		-					
Psychologi	cal functioning	(anxiety) - lo	ng term								
2	randomized trials	very serious ^a	not serious	not serious	not serious	none	151	149	-	SMD 0.2 lower (0.43 lower to 0.03 higher)	⊕⊕○○ Low
Population	subgroups 1 ar	nd 2 - not rep	orted (no subgroup	analysis was perf	formed)			·		,	'
Population	subgroup 3: pr	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	49	49	-	MD 0.6 lower (1.76 lower to 0.56 higher)	⊕⊕○○ Low

			Certainty assess	sment			Nº of p	atients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Not specified whether radicular leg pain included 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	102	100	-	MD 0.98 lower (2.35 lower to 0.39 higher)	⊕⊕○○ Low
Population	subgroup 4 - no	ot reported (n	o subgroup analysi	s was performed)							
Psycholog	ical functioning	(coping) - sh	ort term								
4	randomized trials	very serious ^a	not serious	not serious	seriouse	none	126	112	-	SMD 0.49 higher (0.23 higher to 0.75 higher)	⊕○○○ Very low
Population	subgroups 1, 2	, 3 and 4 - not	t reported (no subg	roup analysis was	s performed)						-
Social part	icipation - short	term: no stud	dies identified that	reported on this	outcome						
Social part	icipation - short	term: no stud	dies identified that	reported on this	s outcome -	-	-	-	-	-	-
-		-		t reported on this		-	-	-	-	-	-
-	-	-		reported on this		- none	- 44/64 (68.8%)	35/62 (56.5%)	RR 1.08 (0.51 to 2.30)	45 more per 1.000 (from 277 fewer to 734 more)	- Very low
Social part	randomized trials	rediate term very seriousa	-	not serious	very serious ⁹				RR 1.08 (0.51 to	45 more per 1.000 (from 277 fewer	
Social part 2 Population	randomized trials	rediate term very seriousa 3 and 4 - not	- serious ^b	not serious	very serious ⁹				RR 1.08 (0.51 to	45 more per 1.000 (from 277 fewer	

			Certainty assess	sment			№ of	patients		Effect	
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty
Self-efficacy	y - short term										
4	randomized trials	very serious ^a	not serious	not serious	not serious	none	148	139	-	SMD 0.04 higher (0.19 lower to 0.28 higher)	⊕⊕○○ Low
Population :	subgroups 1 ar	nd 2 - not rep	orted (no subgroup	analysis was perf	formed)						
Population :	subgroup 3: pr	esence of rad	licular leg pain								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	52	54	-	MD 0.9 higher (4.02 lower to 5.82 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 6	randomized trials	very serious ^a	not serious	not serious	not serious	none	96	85	-	SMD 0.03 higher (0.26 lower to 0.32 higher)	⊕⊕○○ Low
Population :	subgroup 4 - no	ot reported (n	o subgroup analysis	s was performed)		-				-	
Self-efficacy	y - intermediate	term									
1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	51	52	-	MD 0.2 higher (4.28 lower to 4.68 higher)	⊕⊕○○ Low
Population :	subgroups 1, 2	, 3 and 4 - no	t reported (no subg	roup analysis was	s performed)					!	
Self-efficacy	y - long term										
1	randomized trials	very serious ^a	not serious	not serious	not serious	none	49	49	-	MD 2.6 higher (1.71 lower to 6.91 higher)	⊕⊕○○ Low

			Certainty asses	sment			Nº of ∣	patients		Effect		
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other consideratio ns	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	Certainty	
Population s	subgroups 1, 2,	, 3 and 4 - not	t reported (no subg	roup analysis was	s performed)							

CI: confidence interval; MD: mean difference; SMD: standardized mean difference

Explanations

aRisk of bias downgraded by 2 levels: due to unclear or high risk of bias across all studies regarding random sequence generation, allocation concealment, blinding of participants, blinding of care providers, blinding of outcome assessment, incomplete outcome data, selective reporting, similarity of groups at baseline, co-interventions, and compliance with the intervention.

blnconsistency downgraded by 1 level: unexplained considerable heterogeneity I² > 80%

clnconsistency downgraded by 1 level: unexplained substantial heterogeneity I² = 50% - 75%

dInconsistency downgraded by 1 level: unexplained considerable heterogeneity I² > 90%

elmprecision downgraded by 1 level: due to wide confidence interval consistent with the possibility for benefit and the possibility for no effect.

fluconsistency not assessed, only one study reported on this outcome.

Imprecision downgraded by 2 levels: due to wide confidence interval consistent with the possibility for benefit and the possibility for harm.

GRADE Table 3. What are the benefits and harms of combined behavioural therapy in the management of community-dwelling adults (including older adults aged 60 years and over) with chronic primary low back pain (with or without leg pain) compared with <u>usual care</u>?

			Certainty as	sessment			Nº of pa	atients		Effect		
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Pain - sho	rt term											
4	randomized trials	very serious ^a	not serious	not serious	not serious	none	484	485	-	MD 0.24 lower (0.35 lower to 0.12 lower)	⊕⊕○○ Low	
Population	subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	is was performe	d)	!	!	!			
Pain - inte	rmediate term											
5	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	552	553	-	MD 0.13 lower (0.35 lower to 0.09 higher)	⊕○○○ Very low	
Population	subgroups 1	and 2 - not	reported (no sub	group analysis wa	s performed)		!					-
Population	n subgroup 3: p	resence of	radicular leg pa	in								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not seriouse	not serious	not serious	none	68	68	-	MD 0.5 higher (0.14 lower to 1.14 higher)	⊕⊕○○ Low	
Not specified whether radicular leg pain included 4	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	484	485	-	MD 0.18 higher (0.38 lower to 0.03 higher)	⊕○○○ Very low	
Population	n subgroup 4 - I	not reporte	d (no subgroup a	nalysis was perfor	med)							
Pain - long	ı term				·							

			Certainty as	sessment			Nº of pa	atients		Effect		
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
4	randomized trials	very serious ^a	not serious	not serious	not serious	none	448	448	-	MD 0.24 lower (0.48 lower to 0.01 higher)	⊕⊕○○ Low	
Population	subgroups 1	and 2 - not	reported (no sub	group analysis was	s performed)							
Population	subgroup 3: p	resence of	radicular leg pa	in								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not seriouse	not serious	not serious	none	68	68	-	MD 0.1 higher (0.66 lower to 0.86 higher)	⊕⊕○○ Low	
Not specified whether radicular leg pain included 3	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	380	380	-	MD 0.29 lower (0.58 lower to 0.0)	⊕○○○ Very low	
Population	subgroup 4 -	not reporte	d (no subgroup ar	nalysis was perfori	med)		1		-	-		
Back-spec	ific functional	status – sh	ort term									
2	randomized trials	very serious ^a	not serious	not serious	serious ^c	none	231	234	-	MD 1.46 lower (2.34 lower to 0.58 lower)	⊕○○○ Very low	
Population	subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	s was performe	d)	!				,	
Back-spec	ific functional	status - inte	ermediate term									
3	randomized trials	very serious ^a	not serious	not serious	not serious	none	299	302	-	MD 1.01 lower (1.87 lower to 0.14 lower)	⊕⊕○○ Low	
Population	subgroups 1	and 2 - not	reported (no sub	group analysis was	s performed)		1					
Population	n subgroup 3: p	resence of	f radicular leg pa	in								

			Certainty as	sessment		№ of patients		Effect				
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
Excluded radicular leg pain 1	randomized trials	very serious ^a	not seriouse	not serious	serious ^c	none	68	68	-	MD 0.2 lower (2.05 lower to 1.65 higher)	⊕⊖⊖⊖ Very low	
Not specified whether radicular leg pain included 2	randomized trials	very serious ^a	not serious	not serious	serious	none	231	234	-	MD 1.24 lower (2.22 lower to 0.26 lower)	⊕○○○ Very low	
Population	Population subgroup 4 - not reported (no subgroup analysis was performed)											
No subgrou	No subgroup analysis was performed; all studies performed in high income settings.											
Back-spec	ific functional	status - Ion	g term									
3	randomized trials	very serious ^a	not serious	not serious	not serious	none	299	302	-	MD 0.94 lower (1.85 lower to 0.03 lower)	⊕⊕○○ Low	
Population	subgroups 1	and 2 - not	reported (no sub	group analysis was	s performed)							
Population	subgroup 3: p	resence of	radicular leg pa	n								
Excluded radicular leg pain 1	randomized trials	very serious ^a	not seriouse	not serious	serious	none	68	68	-	MD 0.2 higher (1.82 lower to 2.22 higher)	⊕⊖⊖⊖ Very low	
Not specified whether radicular leg pain included 2	randomized trials	very serious ^a	not serious	not serious	serious	none	231	234	-	MD 1.23 lower (2.25 lower to 0.21 lower)	⊕⊖⊖⊖ Very low	
Population	subgroup 4 -	not reporte	d (no subgroup ar	nalysis was perforr	ned)							

Certainty assessment								№ of patients		Effect		
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
General functional status - short term, intermediate term or long term: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Health-related quality of life - short term												
2	randomized trials	very serious ^d	not serious	not serious	not serious	none	253	251	-	MD 2.25 lower (3.85 lower to 0.66 lower)	⊕⊕○○ Low	
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	s was performe	d)						
Health-rela	ated quality of I	ife - interm	ediate term									
2	randomized trials	very serious ^d	not serious	not serious	not serious	none	253	251	-	MD 1.89 lower (3.5 lower to 0.28 lower)	⊕⊕○○ Low	
Population	n subarouns 1	2 3 and 4.	not reported (no	subgroup analysi	s was nerforme	'd)				0.20 1011017		
-	ated quality of I		<u> </u>	- January and Janu	o wao ponomia	<u> </u>						
						None	004	050		MD 0 00 lever		Matazalad
2	randomized trials	very serious ^d	not serious	not serious	not serious	None	261	259	-	MD 0.86 lower (2.59 lower to 0.87 higher) MD 3.43 lower (5.28 lower to	⊕⊕○○ Low	Not pooled
										1.58 lower)		
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	s was performe	d)				-		
Adverse e	vents – narrativ	ve results o	only (see text)									
-	-	-	-	-	-	-	-	-	-	-	-	
Serious ac	dverse events:	no studies	identified that re	ported on this ou	tcome							
-	-	-	-	-	-	-	-	-	-	-	-	
Psycholog	jical functionin	g (depressi	ion) - short term							<u> </u>		

Certainty assessment								№ of patients		Effect		
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
2	randomized trials	very serious ^d	not serious	not serious	not serious	None	216	218	-	MD 1.47 lower (3.33 lower to 0.39 higher)	⊕⊕○○ Low	Not pooled
										MD 2.17 lower (2.88 lower to 1.46 lower)		
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysis	s was performe	d)						
Psycholog	jical functionin	g (depressi	on) - intermediat	e term								
2	randomized trials	very serious ^d	not serious	not serious	not serious	None	216	218	-	MD 0.98 lower (2.82 lower to 0.86 higher)	⊕⊕○○ Low	Not pooled
										MD 1.16 lower (1.95 lower to 0.37 lower)		
Population	subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysis	s was performe	d)						
Psycholog	jical functionin	g (depressi	on) - long term									
2	randomized trials	very serious ^d	not serious	not serious	not serious	None	261	159	-	MD 0.84 lower (1.66 lower to 0.02 lower)	⊕⊕○○ Low	Not pooled
										MD 1.61 lower (2.68 lower to 0.54 lower)		
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysis	s was performe	d)						
Psycholog	ical functionin	g (anxiety)	- short term									
1	randomized trials	very serious ^d	not seriouse	not serious	not serious	none	112	113	-	MD 0.42 lower (0.71 lower to 0.13 lower)	⊕⊕○○ Low	
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysis	s was performe	d)						

Certainty assessment								№ of patients		Effect			
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance	
Psycholog	Psychological functioning (anxiety) - intermediate term												
1	randomized trials	very serious ^d	not seriouse	not serious	not serious	none	112	113	-	MD 0.51 lower (0.86 lower to 0.16 lower)	⊕⊕○○ Low		
Population	າ subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	s was performe	d)	1						
Psycholog	gical functionin	g (anxiety)	- long term										
1	randomized trials	very serious ^d	not seriouse	not serious	not serious	none	112	113	-	MD 0.25 lower (0.58 lower to 0.08 higher)	⊕⊕○○ Low		
Population	Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Social par	ticipation - sho	rt term, inte	ermediate term or	long term: no st	tudies identifie	d that reported on t	his outcome						
-	-	-	-	-	-	-	-	-	-	-	-		
Self-effica	cy - short term												
2	randomized trials	very serious ^d	not serious	not serious	not serious	none	253	251	-	MD 2 higher (0.01 lower to 4.01 higher)	⊕⊕○ ○ Low		
Population	n subgroups 1,	2, 3 and 4 -	not reported (no	subgroup analysi	s was performe	d)							
Self-effica	cy - intermedia	te term											
2	randomized trials	very serious ^d	not serious	not serious	not serious	none	253	251	-	MD 1.65 higher (0.61 lower to 3.9 higher)	⊕⊕○ ○ Low		
Population	ı subgroups 1,	2, 3 and 4 -	· not reported (no	subgroup analysi	s was performe	d)	1						
-	cy - long term			•	·								
	-												

		Certainty as	sessment		№ of patients			Effect				
№ of studies	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecisio n	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)	Certainty	Importance
1	randomized trials	very serious ^d	not seriouse	not serious	serious ^c	none	149	146	-	MD 4.23 higher (1.84 higher to 6.62 higher)	⊕○○ ○	
Population	n subgroups 1,	2, 3 and 4 -	· not reported (no	subgroup analysi	s was performe	d)					Very low	

Topalation outsgroups 1, 2, outside 1 not reported (no outsgroup analysis nas ponom

CI: confidence interval; MD: mean difference

Explanations

a Risk of bias downgraded by 2 levels: due to unclear or high risk of bias across all studies regarding random sequence generation, allocation concealment, blinding of participants, blinding of care providers, blinding of outcome assessment, selective reporting, co-interventions, and compliance with the intervention.

blnconsistency downgraded by 1 level: unexplained substantial heterogeneity I²=59%

clmprecision downgraded by 1 level: due to wide confidence interval consistent with the possibility for benefit and the possibility for no effect.

dRisk of bias downgraded by 2 levels: due to high risk of bias across all studies regarding blinding of participants, blinding of care providers, blinding of outcome assessment, and compliance with the intervention. elnconsistency not assessed, only one study reported on this outcome.