

C.4 Cognitive behavioural therapy (CBT)

Overview of the PICO structure

Definition of the intervention	
<p>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.</p>	
PICO question	
Population and subgroups	<p>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).</p> <p>Subgroups:</p> <ul style="list-style-type: none"> • 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	<p>a) Placebo/sham</p> <p>b) No or minimal intervention, or where the effect of the intervention can be isolated</p> <p>c) Usual care (described as usual care in the trial)</p>

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Outcomes	Critical outcomes constructs (all adults)	Critical outcomes constructs (older adults, aged ≥ 60 years)
	<ul style="list-style-type: none"> • 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) 	<ul style="list-style-type: none"> • 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

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

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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

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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 placebo?*

No trials.

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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 no intervention?

Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Pain - short 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											
Excluded radicular leg pain 3	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	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: regional economic development											
Low/middle income 2	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	none	46	45	-	MD 1.42 lower (3.74 lower to 0.9 higher)	⊕○○○ Very low

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Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
High income 20	randomized trials	very serious ^a	serious ^b	not serious	not serious	none	1219	1030	-	SMD 0.44 lower (0.7 lower to 0.19 lower)	⊕○○○ Very low
Pain - intermediate term											
5	randomized trials	very serious ^a	serious ^c	not serious	not serious	none	570	368	-	SMD 0.08 lower (0.32 lower to 0.16 higher)	⊕○○○ Very low
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	not serious	none	51	52	-	MD 0.00 lower (0.85 lower to 0.85 higher)	⊕⊕○○ Low
Not specified whether radicular leg pain included 4	randomized trials	very serious ^a	serious ^c	not serious	not serious	none	519	316	-	SMD 0.08 lower (0.39 lower to 0.22 higher)	⊕○○○ Very low
Population subgroup 4: regional economic development (no subgroup analysis was performed)											
Pain - long term											
7	randomized trials	very serious ^a	serious ^d	not serious	serious ^e	none	799	593	-	SMD 1.06 lower (1.66 lower to 0.47 lower)	⊕○○○ Very low
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	serious ^e	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: regional economic development (no subgroup analysis was performed)											
Back-specific functional status – short 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											
Excluded radicular leg pain 3	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	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
Population subgroup 4: regional economic development											

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Low/middle income 2	randomized trials	very serious ^a	serious ^b	not serious	serious ^e	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	serious ^e	none	1173	980	-	SMD 0.4 lower (0.68 lower to 0.11 lower)	⊕○○○ Very low
Back-specific functional status - intermediate 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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 serious ^a	not serious	not serious	not serious	none	484	307	-	SMD 0.18 lower (0.35 lower to 0.02 lower)	⊕⊕○○ Low
Population subgroup 4 - not reported (no subgroup analysis was performed)											
Back-specific functional status - long term											
7	randomized trials	very serious ^a	serious ^d	not serious	serious ^e	none	745	557	-	SMD 1.16 lower (2.01 lower to 0.32 lower)	⊕○○○ Very low

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^f	not serious	serious ^e	none	49	49	-	MD 1.1 lower (2.86 lower to 0.66 higher)	⊕○○○ Very low
Not specified whether radicular leg pain included 6	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
Population subgroup 4: regional economic development (no subgroup analysis was performed)											
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											
6	randomized trials	very serious ^a	serious ^d	not serious	serious ^e	none	504	519	-	SMD 0.61 higher (0.11 higher to 1.1 higher)	⊕○○○ Very low
Population subgroup 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)											
Health-related quality of life - intermediate term											
2	randomized trials	very serious ^a	not serious	not serious	serious ^e	none	207	233	-	SMD 0.25 higher (0.07 higher to 0.44 higher)	⊕○○○ Very low
Population subgroup 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)											

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Health-related quality of life - long term											
4	randomized trials	very serious ^a	serious ^d	not serious	serious ^e	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 subgroup analysis was performed)											
Adverse events – narrative results only (see text)											
-	-	-	-	-	-	-	-	-	-	-	-
Serious adverse events: no studies identified that reported on this outcome											
-	-	-	-	-	-	-	-	-	-	-	-
Psychological 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Population subgroup 4: regional economic development (no subgroup analysis was performed)											
Psychological functioning (depression) - intermediate term											
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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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 serious ^a	not serious	not serious	not serious	none	111	108	-	SMD 0.2 lower (0.47 lower to 0.07 higher)	⊕⊕○○ Low
Population subgroup 4 - not reported (no subgroup analysis was performed)											
Psychological 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular leg pain											

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Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
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 - not reported (no subgroup analysis was performed)											
Psychological functioning (anxiety) - short 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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
Population subgroup 4 - not reported (no subgroup analysis was performed)											

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Certainty assessment							№ of patients		Effect		Certainty
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Psychological functioning (anxiety) - intermediate 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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 - not reported (no subgroup analysis was performed)											
Psychological functioning (anxiety) - long 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
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 - not reported (no subgroup analysis was performed)											
Psychological functioning (coping) - short term											
4	randomized trials	very serious ^a	not serious	not serious	serious ^e	none	126	112	-	SMD 0.49 higher (0.23 higher to 0.75 higher)	⊕○○○ Very low
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)											
Social participation - short term: no studies identified that reported on this outcome											
-	-	-	-	-	-	-	-	-	-	-	-
Social participation - intermediate term											
2	randomized trials	very serious ^a	serious ^b	not serious	very serious ^g	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
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)											
Social participation - long term											
2	randomized trials	very serious ^a	serious ^c	not serious	very serious ^g	none	73/137 (53.3%)	76/135 (56.3%)	RR 1.02 (0.66 to 1.57)	11 more per 1.000 (from 191 fewer to 321 more)	⊕○○○ Very low
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)											

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Self-efficacy - 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 and 2 - not reported (no subgroup analysis was performed)											
Population subgroup 3: presence of radicular 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 - not reported (no subgroup analysis was performed)											
Self-efficacy - 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 - not reported (no subgroup analysis was performed)											
Self-efficacy - 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

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Certainty assessment							No of patients		Effect		Certainty
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	No intervention	Relative (95% CI)	Absolute (95% CI)	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was 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.

^bInconsistency downgraded by 1 level: unexplained considerable heterogeneity $I^2 > 80\%$

^cInconsistency downgraded by 1 level: unexplained substantial heterogeneity $I^2 = 50\% - 75\%$

^dInconsistency downgraded by 1 level: unexplained considerable heterogeneity $I^2 > 90\%$

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

^fInconsistency not assessed, only one study reported on this outcome.

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

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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 usual care?

Certainty assessment							N ^o of patients		Effect		Certainty	Importance
N ^o of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
Pain - short 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 analysis was performed)												
Pain - intermediate 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 subgroup analysis was performed)												
Population subgroup 3: presence of radicular leg pain												
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^e	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 subgroup 4 - not reported (no subgroup analysis was performed)												
Pain - long term												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
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 subgroup analysis was performed)												
Population subgroup 3: presence of radicular leg pain												
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^e	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 reported (no subgroup analysis was performed)												
Back-specific functional status – short 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 analysis was performed)												
Back-specific functional status - intermediate 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 subgroup analysis was performed)												
Population subgroup 3: presence of radicular leg pain												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^e	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 ^c	none	231	234	-	MD 1.24 lower (2.22 lower to 0.26 lower)	⊕○○○ Very low	
Population subgroup 4 - not reported (no subgroup analysis was performed)												
No subgroup analysis was performed; all studies performed in high income settings.												
Back-specific functional status - long 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 subgroup analysis was performed)												
Population subgroup 3: presence of radicular leg pain												
Excluded radicular leg pain 1	randomized trials	very serious ^a	not serious ^e	not serious	serious ^c	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 ^c	none	231	234	-	MD 1.23 lower (2.25 lower to 0.21 lower)	⊕○○○ Very low	
Population subgroup 4 - not reported (no subgroup analysis was performed)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
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 subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Health-related quality of life - intermediate 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 subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Health-related quality of life - long term												
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 1.58 lower)	⊕⊕○○ Low	Not pooled
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Adverse events – narrative results only (see text)												
-	-	-	-	-	-	-	-	-	-	-	-	-
Serious adverse events: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	-
Psychological functioning (depression) - short term												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
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) MD 2.17 lower (2.88 lower to 1.46 lower)	⊕⊕○○ Low	Not pooled
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (depression) - intermediate 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) MD 1.16 lower (1.95 lower to 0.37 lower)	⊕⊕○○ Low	Not pooled
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (depression) - 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) MD 1.61 lower (2.68 lower to 0.54 lower)	⊕⊕○○ Low	Not pooled
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (anxiety) - short term												
1	randomized trials	very serious ^d	not serious ^e	not serious	not serious	none	112	113	-	MD 0.42 lower (0.71 lower to 0.13 lower)	⊕⊕○○ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
Psychological functioning (anxiety) - intermediate term												
1	randomized trials	very serious ^d	not serious ^e	not serious	not serious	none	112	113	-	MD 0.51 lower (0.86 lower to 0.16 lower)	⊕⊕○○ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (anxiety) - long term												
1	randomized trials	very serious ^d	not serious ^e	not serious	not serious	none	112	113	-	MD 0.25 lower (0.58 lower to 0.08 higher)	⊕⊕○○ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Social participation - short term, intermediate term or long term: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficacy - 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 subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Self-efficacy - intermediate 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 subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Self-efficacy - long term												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Combined behavioural	Usual care	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials	very serious ^d	not serious ^e	not serious	serious ^c	none	149	146	-	MD 4.23 higher (1.84 higher to 6.62 higher)	⊕○○○ ○ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												

CI: confidence interval; MD: 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, selective reporting, co-interventions, and compliance with the intervention.

^bInconsistency downgraded by 1 level: unexplained substantial heterogeneity $I^2=59\%$

^cImprecision 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.

^eInconsistency not assessed, only one study reported on this outcome.