E.2 Multicomponent biopsychosocial care

Overview of the PICO structure

Definition of the intervention	
Multicomponent biopsychosocial care involves delivery of at least two of the three components of care from the biopsychosocial model: physical, psychological or social, delivered by a single provider or a multidisciplinary team. These components align with the biopsychosocial model of chronic pain and its applicability to older people. Multicomponent biopsychosocial care adopts a rehabilitation approach that aims to optimize function and reduce disability in individuals with health conditions in interaction with their environment. For the purpose of the guideline, trials of all types of interventions for multicomponent biopsychosocial care were included where they satisfied the criterion of a multicomponent intervention that targets *functioning* (body structures and functions, activities and participation). The intervention should target at least two domains of the biopsychosocial model: either the biological component targeting physical aspects of functioning such as body structures or functions (e.g. an exercise programme targeting an increase in muscle strength), psychological component (e.g. addressing coping with pain) or social and occupational component (e.g. addressing involvement in meaningful life roles including work).	
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/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/sham b) No or minimal intervention or comparators, or where the effect of the intervention can be isolated c) Usual care (described as usual care in the trial) including care where the intervention can be isolated
Outcomes	Critical outcomes constructs (all adults) Critical outcomes constructs (older adults, aged ≥ 60 years) • 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) • Change in the use of medications • Falls

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

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Summary of *resource 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 *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

Multicomponent biopsychosocial care (single provider)

Domain	**All adults**	**Older people**

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Benefits	Small; uncertain	Small; uncertain
Harms	Uncertain	Uncertain
Balance benefits to harms	Probably favours single-provider multicomponent biopsychosocial care (single provider); uncertain	Probably favours single-provider multicomponent biopsychosocial care (single provider); uncertain
Overall certainty	Very low	Very low
Values and preferences	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty
Resource considerations	Large costs; moderate costs; varies	Large costs; moderate costs; varies
Equity and human rights	Increased; probably increased; probably reduced; reduced; varies	Increased; probably increased; probably reduced; reduced; varies
Acceptability	Yes; probably yes; varies	Yes; probably yes; varies
Feasibility	Yes; probably yes; probably no; varies	Yes; probably yes; probably no; varies

Multicomponent biopsychosocial care (MDT provider)

Benefits	Moderate; small; uncertain	Small; uncertain
Harms	Uncertain	Uncertain
Balance benefits to harms	Probably favours multicomponent biopsychosocial care (MDT provider); uncertain	Probably favours multicomponent biopsychosocial care (MDT provider); uncertain
Overall certainty	Low; very low	Low; very low
Values and preferences	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty
Resource considerations	Large costs; moderate costs; varies	Large costs; moderate costs; varies

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Equity and human rights	Increased; probably increased; probably reduced; reduced; varies	Increased, probably increased; probably reduced; reduced; varies
Acceptability	Yes; probably yes; varies	Yes; probably yes; varies
Feasibility	Yes; probably yes; probably no; varies	Yes; probably yes; probably no; varies

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GRADE Table 1. ***What are the benefits and harms of multicomponent biopsychosocial care 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 to placebo?***

No trials

GRADE Table 2. ***What are the benefits and harms of multicomponent biopsychosocial care delivered by a multidisciplinary team 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 to no intervention?***

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	No intervention	Relative (95% CI)	Absolute (95% CI)		
Pain - short term												
3[a]	randomized trials	very serious[b]	Not serious[c]	not serious	serious[d]	none	106	107	-	SMD **0.73 SD lower** (1.22 lower to 0.24 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Pain - intermediate term or long term – no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Back-specific functional status – short term												
3[a]	randomized trials	very serious[b]	not serious	not serious	serious[e]	none	106	107	-	SMD **0.49 SD lower** (0.76 lower to 0.22 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Back-specific functional status - intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
General functional status - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Health-related quality of life - short term, intermediate term or long term: no studies were identified that reported on this outcome												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	No intervention	Relative (95% CI)	Absolute (95% CI)		
-	-	-	-	-	-	-	-	-	-	-	-	
Adverse events or serious adverse events: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning (depression) - short term (lower score means less depression)												
3[a]	randomized trials	very serious[b]	not serious	not serious	serious[f]	none	106	107	-	SMD **0.21 SD lower** (0.59 lower to 0.18 higher)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning - intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Social participation - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficacy - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	

CI: confidence interval; SMD: standardized mean difference

Explanations

a. Jäckel 1990, Smeets 2006, Turner 1990

b. Risk of bias downgraded by 2 levels for unclear or serious risk of bias in all studies for random sequence generation, allocation concealment, blinding of participants, clinicians, and outcome assessors, incomplete outcome data, selective reporting, compliance, and co-interventions.

c. Despite some heterogeneity (I-sq = 64%), not downgraded for inconsistency because direction of effect was same from all studies.

d. Imprecision downgraded by 1 level for wide confidence intervals that encompass a potential benefit and little to no effect. We re-expressed the SMD as mean difference on a 0 to 100 pain scale using an SD of 22.6 (i.e. control group SD from Smeets 2006) which gave MD -16.5 (-27.6 to -5.4). The minimal important difference on the 0 to 100 pain scale is approximately 15.

e. Imprecision downgraded by 1 level for wide confidence intervals that encompass a potential benefit and little to no effect. We re-expressed the SMD as mean difference on a 0 to 24 RDQ scale using an SD of 4.78 (i.e. control group SD from Smeets 2006) which gave MD -2.3 (-3.6 to -1.1). The minimal important difference on the 0 to 24 RDQ pain scale is approximately 10%.

f. Imprecision downgraded by 1 level for small sample size.

GRADE Table 3. ***What are the benefits and harms of multicomponent biopsychosocial care delivered by a single provider 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 to usual care?***

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Rehabilitation	Usual care	Relative (95% CI)	Absolute (95% CI)		
Pain - short term – no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Pain - intermediate term – no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Pain - long term (two-point reduction of pain intensity from 11-point scale)												
1[a]	randomized trials	very serious[b]	not serious[c]	not serious	serious[d]	none	29/60 (48.3%)	20/54 (37.0%)	**RR 1.30** (0.84 to 2.02)	**111 more per 1000** (from 59 fewer to 378 more)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one included study on this outcome)												
Back-specific functional status – short term or intermediate term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Back-specific functional status - long term (30% improvement)												
1[a]	randomized trials	very serious[b]	not serious[c]	not serious	serious[d]	none	34/60 (56.7%)	26/54 (48.1%)	**RR 1.18** (0.83 to 1.68)	**87 more per 1000** (from 82 fewer to 327 more)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one included study on this outcome)												
General functional status – short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Rehabilitation	Usual care	Relative (95% CI)	Absolute (95% CI)		
Health-related quality of life - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Adverse events												
1[a]	randomized trials	very serious[b]	not serious[c]	not serious	very serious[e]	none	0/60	0/54	RR not estimable	-	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one included study on this outcome)												
Serious adverse events: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Social participation - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficacy - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	

CI: confidence interval; RR: risk ratio

Explanations

a. van der Roer 2008

b. Risk of bias downgraded by 2 levels due to unclear or high risk of bias in blinding of participants, clinicians, and outcome assessors, selective reporting, compliance, and co-interventions.

c. Inconsistency not assessed, only one study included on this outcome

d. Imprecision downgraded by 1 level due to wide confidence intervals that encompass a potential benefit and no effect with intervention.

e. Imprecision downgraded by 2 levels due to no events reported.

GRADE Table 4. ***What are the benefits and harms of multicomponent biopsychosocial care delivered by a multidisciplinary team 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 to usual care?***

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
Pain - short term												
10[a]	randomized trials	very serious[b]	serious[c]	not serious	serious[d]	none	478	495	-	SMD **0.52 SD lower** (0.77 lower to 0.27 lower)	⨁◯◯◯ Very low	
Population subgroup 1: gender/sex												
Female only 1	randomized trials	very serious[b]	not serious[o]	not serious	serious[l]	none	44	47	-	SMD **0.61 SD lower** (1.03 lower to 0.19 lower)	⨁◯◯◯ Very low	
Mixed 9	randomized trials	very serious[b]	serious[c]	not serious	serious[dl]	none	434	448	-	SMD **0.51 SD lower** (0.79 lower to 0.23 lower)	⨁◯◯◯ Very low	
Population subgroup 2: race/ethnicity - not reported (no subgroup analysis was performed; no study included marginalized populations)												
Population subgroup 3: presence of radicular leg pain												
Excluded leg pain 1	randomized trials	very serious[b]	not serious[o]	not serious	serious[l]	none	12	11	-	SMD **0.32 SD lower** (1.14 lower to 0.51 higher)	⨁◯◯◯ Very low	

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
Mixed 9	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	466	484	-	SMD **0.53 SD lower** (0.8 lower to 0.27 lower)	⨁◯◯◯ Very low	
Population subgroup 4: regional economic development												
Low/middle income 3	randomized trials	very serious[b]	not serious	not serious	serious[p]	none	148	155	-	SMD **0.46 SD lower** (0.69 lower to 0.23 lower)	⨁◯◯◯ Very low	
High income 7	randomized trials	very serious[b]	serious[c]	not serious	serious[d]	none	330	340	-	SMD **0.56 SD lower** (0.92 lower to 0.19 lower)	⨁◯◯◯ Very low	
Pain - intermediate term												
5[e]	randomized trials	very serious[b]	serious[c]	not serious	serious[f]	none	326	320	-	SMD **0.62 SD lower** (0.93 lower to 0.31 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2 and 3 - not reported (no subgroup analysis was performed)												
Population subgroup 4: regional economic development												
Low/middle income 1	randomized trials	very serious[b]	not serious[o]	not serious	serious[l]	none	92	96	-	SMD **0.49 SD lower** (0.78 lower to 0.2 lower)	⨁◯◯◯ Very low	
High income 4	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	234	224	-	SMD **0.68 SD lower** (1.12 lower to 0.25 lower)	⨁◯◯◯ Very low	

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
Pain - long term												
8[f]	randomized trials	very serious[b]	not serious	not serious	not serious	none	517	446	-	SMD **0.25 SD lower** (0.41 lower to 0.09 lower)	⨁⨁◯◯ Low	
Population subgroups 1 and 2 - not reported (no subgroup analysis was performed)												
Population subgroup 3: presence of radicular leg pain												
Excluded leg pain 1	randomized trials	very serious[b]	not serious[o]	not serious	Serious[l]	none	12	11	-	SMD **0.28 SD lower** (-1.1 lower to 0.54 higher)	⨁◯◯◯ Very low	
Mixed 7	randomized trials	very serious[b]	not serious	not serious	not serious	none	505	435	-	SMD **0.25 SD lower** (0.43 lower to 0.08 lower)	⨁⨁◯◯ Low	
Population subgroup 4: regional economic development												
Low/middle income 2	randomized trials	very serious[b]	not serious	not serious	serious[l]	none	81	88	-	SMD **0.47 SD lower** (0.77 lower to 0.16 lower)	⨁◯◯◯ Very low	
High income 6	randomized trials	very serious[b]	not serious	not serious	not serious	none	436	358	-	SMD **0.21 SD lower** (0.39 lower to 0.03 lower)	⨁⨁◯◯ Low	
Back-specific functional status – 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	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
10[g]	randomized trials	very serious[b]	serious[c]	not serious	Not serious	none	506	527	-	SMD **0.47 SD lower** (0.69 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 leg pain 2	randomized trials	very serious[b]	serious[c]	not serious	Very serious[s]	none	84	90	-	SMD **0.1 SD higher** (1.01 lower to 1.22 higher)	⨁◯◯◯ Very low	
Mixed 8	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	422	437	-	SMD **0.55 SD lower** (0.78 lower to 0.31 lower)	⨁◯◯◯ Very low	
Population subgroup 4: regional economic development												
Low/middle income 2	randomized trials	very serious[b]	serious[c]	not serious	Very serious[s]	none	104	108	-	SMD **0.16 SD higher** (0.83 lower to 1.14 higher)	⨁◯◯◯ Very low	
High income 8	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	402	419	-	SMD **0.57 SD lower** (0.79 lower to 0.34 lower)	⨁◯◯◯ Very low	
Back-specific functional status - intermediate term												
6[h]	randomized trials	very serious[b]	serious[c]	not serious	Not serious	none	394	392	-	SMD **0.43 SD lower** (0.66 lower to 0.19 lower)	⨁◯◯◯ Very low	

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	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 leg pain 1	randomized trials	very serious[b]	Not serious[o]	not serious	serious[p]	none	68	72	-	SMD **0.2 SD lower** (0.53 lower to 0.13 lower)	⨁◯◯◯ Very low	
Mixed 5	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	326	320	-	SMD **0.49 SD lower** (0.77 lower to 0.21 lower)	⨁◯◯◯ Very low	
Population subgroup 4: regional economic development												
Low/middle income 1	randomized trials	very serious[b]	Not serious[o]	not serious	serious[p]	none	92	96	-	SMD **0.32 SD lower** (0.6 lower to 0.03 lower)	⨁◯◯◯ Very low	
High income 5	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	302	296	-	SMD **0.47 SD lower** (0.77 lower to 0.17 lower)	⨁◯◯◯ Very low	
Back-specific functional status - long term												
7[i]	randomized trials	very serious[b]	not serious	not serious	not serious	none	467	397	-	SMD **0.25 SD lower** (0.4 lower to 0.11 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	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
Excluded leg pain 1	randomized trials	very serious[b]	not serious[o]	not serious	Very serious[s]	none	12	11	-	SMD **0.26 SD lower** (1.08 lower to 0.57 higher)	⨁◯◯◯ Very low	
Mixed 6	randomized trials	very serious[b]	not serious	not serious	not serious	none	455	386	-	SMD **0.26 SD lower** (0.42 lower to 0.09 lower)	⨁⨁◯◯ Low	
Population subgroup 4: regional economic development												
Low/middle income 2	randomized trials	very serious[b]	not serious	not serious	Serious[p]	none	81	88	-	SMD **0.34 SD lower** (0.65 lower to 0.04 lower)	⨁◯◯◯ Very low	
High income 5	randomized trials	very serious[b]	not serious	not serious	not serious	none	386	309	-	SMD **0.24 SD lower** (0.43 lower to 0.05 lower)	⨁⨁◯◯ Low	
General functional status - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Health-related quality of life - short term												
3[j]	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	151	143	-	SMD **0.4 SD lower** (1.11 lower to 0.31 higher)	⨁◯◯◯ Very low	
Population subgroup 1: gender/sex												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
Female 1	randomized trials	very serious[b]	Not serious[o]	not serious	serious[p]	none	37	37	-	SMD **1.08 SD lower** (1.57 lower to 0.59 lower)	⨁◯◯ ◯ Very low	
Mixed 2	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	114	106	-	SMD **0.05 SD lower** (0.49 lower to 0.38 higher)	⨁◯◯ ◯ Very low	
Population subgroup 2: race/ethnicity - not reported (no subgroup analysis was performed; no study included marginalized populations)												
Population subgroup 3: presence of radicular leg pain												
Excluded leg pain 1	randomized trials	very serious[b]	Not serious[o]	not serious	serious[l]	none	73	77	-	SMD **0.14 SD higher** (0.18 lower to 0.46 higher)	⨁◯◯ ◯ Very low	
Mixed 2	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	78	66	-	SMD **0.7 SD lower** (1.45 lower to 0.05 higher)	⨁◯◯ ◯ Very low	
Population subgroup 4: regional economic development												
Low/middle income 1	randomized trials	very serious[b]	Not serious[o]	not serious	serious[p]	none	37	37	-	SMD **1.08 SD lower** (1.57 lower to 0.59 lower)	⨁◯◯ ◯ Very low	
High income 2	randomized trials	very serious[b]	serious[c]	not serious	serious[l]	none	114	106	-	SMD **0.05 SD lower** (0.49 lower to 0.38 higher)	⨁◯◯ ◯ Very low	
Health-related quality of life - intermediate term												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
3[j]	randomized trials	very serious[b]	not serious[k]	not serious	not serious	none	147	137	-	SMD **0.23 SD lower** (0.58 lower to 0.12 higher)	⨁⨁◯◯ Low	
Population subgroup 1: gender/sex												
Female 1	randomized trials	very serious[b]	not serious[o]	not serious	Serious[p]	none	37	37	-	SMD **0.54 SD lower** (1.01 lower to 0.08 lower)	⨁◯◯◯ Very low	
Mixed 2	randomized trials	very serious[b]	not serious	not serious	Serious[l]	none	110	100	-	SMD **0.08 SD lower** (0.38 lower to 0.23 higher)	⨁◯◯◯ Very low	
Population subgroup 2: race/ethnicity - not reported (no subgroup analysis was performed; no study included marginalized populations)												
Population subgroup 3: presence of radicular leg pain												
Excluded leg pain 1	randomized trials	very serious[b]	not serious[o]	not serious	Serious[l]	none	69	71	-	SMD **0.04 SD higher** (0.29 lower to 0.37 higher)	⨁◯◯◯ Very low	
Mixed 2	randomized trials	very serious[b]	not serious	not serious	Serious[p]	none	78	66	-	SMD **0.42 SD lower** (0.75 lower to 0.08 lower)	⨁◯◯◯ Very low	
Population subgroup 4: regional economic development												
Low/middle income 1	randomized trials	very serious[b]	not serious[o]	not serious	Serious[p]	none	37	37	-	SMD **0.54 SD lower** (1.01 lower to 0.08 lower)	⨁◯◯◯ Very low	

Web Annex D.E2: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
High income 2	randomized trials	very serious[b]	not serious	not serious	Serious[l]	none	110	100	-	SMD **0.08 SD lower** (0.38 lower to 0.23 higher)	⨁◯◯◯ Very low	
Health-related quality of life - long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Adverse events or serious adverse events: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning (depression) - short term												
1[l]	randomized trials	very serious[b]	not serious[o]	not serious	Serious[p]	none	13	15	-	MD **4.4 lower** (9.99 lower to 1.19 higher)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one study included on this outcome)												
Psychological functioning - intermediate term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning (depression) - long term												
1[n]	randomized trials	very serious[b]	not serious[o]	not serious	Serious[p]	none	61	43	-	MD **0.7 lower** (2.27 lower to 0.87 higher)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one study included on this outcome)												
Psychological functioning (anxiety) - short term												

Web Annex D.E2: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
1[l]	randomized trials	very serious[b]	not serious[o]	not serious	serious[p]	none	13	15	-	MD **12.3 lower** (20.52 lower to 4.08 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one study included on this outcome)												
Psychological functioning (anxiety) - intermediate term – no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning (anxiety) - long term												
1[n]	randomized trials	very serious[b]	not serious[o]	not serious	serious[p]	none	61	43	-	MD **1.9 lower** (3.65 lower to 0.15 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed; only one study included on this outcome)												
Social participation (work) - short term												
3[p]	randomized trials	very serious[b]	serious[c]	not serious	very serious[s]	none	157/212 (74.1%)	162/255 (63.5%)	**RR 1.30** (0.73 to 2.34)	**191 more per 1000** (from 172 fewer to 851 more)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Social participation (work) - intermediate term												
2[r]	randomized trials	very serious[b]	serious[c]	not serious	very serious[s]	none	133/167 (79.6%)	144/196 (73.5%)	**RR 1.08** (0.73 to 1.60)	**59 more per 1000** (from 198 fewer to 441 more)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Social participation - long term												

Web Annex D.E2: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	MBR	Usual care	Relative (95% CI)	Absolute (95% CI)		
7[s]	randomized trials	very serious[b]	not serious	not serious	not serious	none	526/701 (75.0%)	483/648 (74.5%)	**RR 1.00** (0.93 to 1.08)	**0 fewer per 1000** (from 52 fewer to 60 more)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Self-efficacy - short term, intermediate term or long term: no studies were identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	

CI: confidence interval; MD: mean difference; RR: risk ratio; SMD: standardized mean difference

Explanations

a. Abbasi 2012, Basler 1997, Bendix 1996, Lambeek 2010, Moix 2003, Morone 2011, Morone 2012, Tavafian 2007, Tavafian 2011, Von Korff 2005
b. Risk of bias downgraded by 2 levels for unclear or high risk of bias in all studies for random sequence generation, allocation concealment, blinding of participants, clinicians, and outcome assessors, incomplete outcome data, selective reporting, compliance, and co-interventions.
c. Inconsistency downgraded by 1 level for substantial statistical heterogeneity not explained by subgroup analyses (I-sq > 60%)
d. Imprecision downgraded by 1 level for wide confidence intervals that encompass a potential benefit and little to no effect. We re-expressed the SMD as mean difference on a 0 to 100 pain scale using an SD of 20 (i.e. average SD from control groups that used this scale) which gave MD -10.4 (-15.4 to -5.4). The minimal important difference on the 0 to 100 pain scale is approximately 15.
e. Lambeek 2010, Morone 2011, Morone 2012, Tavafian 2011, Von Korff 2005
f. Imprecision downgraded by 1 level for wide confidence intervals that encompass a potential benefit and little to no effect. We re-expressed the SMD as mean difference on a 0 to 100 pain scale using an SD of 20 (i.e. average SD from control groups that used this scale) which gave MD -12.4 (-18.6 to -6.2). The minimal important difference on the 0 to 100 pain scale is approximately 15.
g. Abbasi 2012, Bendix 1996, Lambeek 2010, Linton 2005, Lukinmaa 1989, Strand 2001, Tavafian 2011, Von Korff 2005
h. Abbasi 2012, Basler 1997, Bendix 1996, Lambeek 2010, Moix 2003, Morone 2011, Morone 2012, Tavafian 2011, Vollenbroek-Hutten 2004, Von Korff 2005
i. Lambeek 2010, Morone 2011, Morone 2012, Tavafian 2011, Vollenbroek-Hutten 2004, Von Korff 2005
j. Abbasi 2012, Lambeek 2010, Linton 2005, Lukinmaa 1989, Strand 2001, Tavafian 2011, Von Korff 2005
k. Morone 2011, Tavafian 2007, Vollenbroek-Hutten 2004
l. Imprecision downgraded by 1 level for wide confidence intervals that encompass a potential benefit and little to no effect.
m. Despite some statistical heterogeneity, this was largely explained by the subgroup analyses.
n. Moix 2003
o. Inconsistency not assessed, only one study included on this outcome
p. Imprecision downgraded by 1 level due to small sample size.
q. Linton 2005
r. Bendix 1996, Skouen 2002, Von Korff 2005
s. Imprecision downgraded by 2 levels for very wide confidence intervals that encompass a potential harm, no effect, and a potential benefit.
t. Skouen 2002, Von Korff 2005
u. Bendix 1996, Linton 2005, Lukinmaa 1989, Mitchell 1994, Skouen 2002, Strand 2001, Von Korff 2005.