C.5 Mindfulness-based stress reduction (MBSR) therapy

Overview of the PICO structure

Definition of the intervention	
Mindfulness-based stress reduction (MBSR) therapy aims to reduce stress by developing mindfulness: a non-judgemental, moment-by-moment acceptance of awareness. The intervention is free of any cultural, religious and ideological factors, but it is associated with the Buddhist origins of mindfulness.	
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/sham b) No or minimal intervention, or where the effect of the intervention can be isolated c) Usual care (described as usual care in the trial)

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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)

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	From the qualitative studies it appears that mindfulness and meditation therapies are an accepted treatment to adults aged 60 and over, although the certainty of the evidence was low or very low. **# Review findings GRADE-CERQual Assessment of confidence** 18 Mindfulness and meditation allowed some participants to increase their body awareness in relation to, for example, breathing, posture, cognition and pain. In some cases, this allowed for early recognition of pain. VERY LOW 19 Mindfulness and meditation encouraged participants to examine, assess, understand and accept their pain rather than avoid it. In some cases, this decreased the significance or power of the pain in the participants' lives, allowing some participants to take control and push pain into the background. In turn, participants were more aware of their bodies, increasing their ability to relax and handle stress in relation to their pain and in other day to day situations such as better sleep, attention, wellbeing, and general quality of life. LOW 20 Some participants were able to use mindfulness and meditation for pain management and coping to varying degrees. Some participants experienced no relief, while others had some or short-term relief and a few were able to eliminate feelings of pain. LOW

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

Domain	**All adults**	**Older people**
Benefits	Uncertain	Uncertain
Harms	Trivial; uncertain	Trivial; uncertain
Balance benefits to harms	Uncertain	Uncertain

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Overall certainty	Low; very low	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 mindfulness-based stress reduction 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 placebo?***

No trials.

GRADE Table 2. ***What are the benefits and harms of mindfulness-based stress reduction 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 no intervention***?

No trials.

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GRADE Table 3. ***What are the benefits and harms of mindfulness-based stress reduction 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							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mindfulness-based stress reduction	Usual care	Relative (95% CI)	Absolute (95% CI)		
Pain - short term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.63 lower** (1 lower to 0.26 lower)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Pain - intermediate term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.45 lower** (0.89 lower to 0.01 lower)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Pain - long term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.63 lower** (1.06 lower to 0.2 lower)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
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	Mindfulness-based stress reduction	Usual care	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials	very serious[a]	not serious[b]	not serious	serious[c]	none	116	113	-	MD **1.57 lower** (2.67 lower to 0.47 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Back-specific functional status - intermediate term												
1	randomized trials	very serious[a]	not serious[b]	not serious	serious[c]	none	116	113	-	MD **1.37 lower** (2.52 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 - long term												
1	randomized trials	very serious[a]	not serious[b]	not serious	serious[c]	none	116	113	-	MD **1.87 lower** (3.11 lower to 0.63 lower)	⨁◯◯◯ Very low	
Population subgroups 1, 2, 3 and 4 - not reported (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												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **1.48 higher** (0.04 lower to 3 higher)	⨁⨁◯◯ 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	Mindfulness-based stress reduction	Usual care	Relative (95% CI)	Absolute (95% CI)		
Health-related quality of life - intermediate term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.31 higher** (1.52 lower to 2.14 higher)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Health-related quality of life - long term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.94 higher** (0.85 lower to 2.73 higher)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Adverse events or serious adverse events: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Psychological functioning (depression) - short term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **1.48 lower** (2.3 lower to 0.66 lower)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (depression) - intermediate term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.68 lower** (1.43 lower to 0.07 higher)	⨁⨁◯◯ Low	

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Mindfulness-based stress reduction	Usual care	Relative (95% CI)	Absolute (95% CI)		
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (depression) - long term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.63 lower** (1.47 lower to 0.21 higher)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (anxiety) - short term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.24 lower** (0.56 lower to 0.08 higher)	⨁⨁◯◯ Low	
Population subgroups 1, 2, 3 and 4 - not reported (no subgroup analysis was performed)												
Psychological functioning (anxiety) - intermediate term												
1	randomized trials	very serious[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.02 lower** (0.4 lower to 0.36 higher)	⨁⨁◯◯ 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[a]	not serious[b]	not serious	not serious	none	116	113	-	MD **0.01 lower** (0.37 lower to 0.35 higher)	⨁⨁◯◯ 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	Mindfulness-based stress reduction	Usual care	Relative (95% CI)	Absolute (95% CI)		
Social participation – short term, intermediate term or long term: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficacy – short term, intermediate term or long term: no studies identified that reported on this outcome												
-	-	-	-	-	-	-	-	-	-	-	-	

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 blinding of participants, blinding of care providers, blinding of outcome assessment, co-interventions, and compliance with the intervention.

[b]Inconsistency not assessed, only one study reported on this outcome.

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