

B.8 Assistive products: lumbar braces, belts and/or supports and mobility assistive products

Overview of the PICO structure

Definition of the intervention	
<p>The WHO defines assistive products as any external product (including devices, equipment, instruments or software), specially produced or generally available, the primary purpose of which is to maintain or improve an individual’s functioning and independence, and thereby promote well-being.</p> <p>Non-rigid and rigid lumbar braces, belts and/or supports include plastic (rigid) or flexible (elastic or non-elastic) material with or without rigid inserts wrapping the lumbar/thoracolumbar trunk to block/limit mobility and/or reduce strains and physical demands on the lower back. These products are commonly used for CPLBP either as a treatment or to reduce recurrences of pain. They are accessible in most countries, with limitations due to costs (they are usually out of pocket expense) and climate (they are difficult to wear in high temperatures).</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</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 • 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) • 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

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	Moderate; trivial; uncertain: no evidence	Trivial; uncertain: no evidence
Harms	Moderate; trivial; uncertain: no evidence	Moderate; uncertain: no evidence

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Balance benefits to harms	Probably favours lumbar braces, belts and/or supports; probably does not favour lumbar braces, belts and/or supports; uncertain: no evidence	Probably favours lumbar braces, belts and/or supports; probably does not favour lumbar braces, belts and/or supports; uncertain: no evidence
Overall certainty	Very low: no evidence	Very low: no evidence
Values and preferences	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty; no important uncertainty or variability	Important uncertainty; possibly important uncertainty or variability; probably no important uncertainty; no important uncertainty or variability
Resource considerations	Moderate; moderate costs; negligible; varies	Moderate; moderate costs; negligible; varies
Equity and human rights	No impact; reduced; uncertain	No impact; reduced; uncertain
Acceptability	Yes, probably yes; probably no	Yes; probably yes; probably no
Feasibility	Yes; probably yes; uncertain	Yes; probably yes; uncertain

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GRADE Table 1. *What are the benefits and harms of lumbar braces, belts and/or supports 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/sham?*

No trials

GRADE Table 2. *What are the benefits and harms of lumbar braces, belts and/or supports 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 or minimal intervention?*

No trials

GRADE Table 3. *What are the benefits and harms of lumbar braces, belts and/or supports 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 or where the effect of the intervention could be isolated?*

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Lumbar support plus usual care	usual care	Relative (95% CI)	Absolute (95% CI)		
Pain (follow-up: 4 weeks; assessed with: VAS and NRS) - better outcomes indicated by lower SMD												
2	randomized trials	serious ^a	not serious	not serious	serious ^b	none	98	51	-	SMD 1.19 lower (2.38 lower to 0.01 lower)	⊕⊕○○ Low	
Disability (follow-up: 4 weeks; assessed with: RMDQ and ODI) - better outcomes indicated by lower SMD												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Lumbar support plus usual care	usual care	Relative (95% CI)	Absolute (95% CI)		
2	randomized trials	serious ^a	serious ^c	not serious	serious ^b	none	98	51	-	SMD 0.63 lower (1.43 lower to 0.17 higher)	⊕○○○ Very low	

Explanations

- a. Risk of Bias: Downgraded one level for high risk of performance and detection bias in all RCTs
- b. Imprecision: Downgraded one level for imprecision (less than 400 participants)
- c. Inconsistency: Downgraded one level for inconsistency ($I^2 > 75\%$)

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Narrative synthesis

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Lumbar support plus usual care	usual care	Relative (95% CI)	Absolute (95% CI)		
Pain narrative												
2	randomized trials	serious ^a	not serious	not serious	very serious ^b	none	No significant differences in pain changes over the study period in all four studies		⊕○○○		Very low	
Disability narrative												
3	randomized trials	serious ^a	not serious	not serious	very serious ^b	none	No significant differences in disability in two studies and significant changes (p<0.01) in one study over the study period		⊕○○○		Very low	
Quality of life narrative												
1	randomized trials	serious ^a	not serious ^c	not serious	very serious ^b	none	Significant differences in quality of life changes (p<0.05)		⊕○○○		Very low	

Explanations

a. Risk of bias: Downgraded one level for high of performance, detection and attrition biases for all RCTs.

b. Imprecision: Downgraded two levels for imprecision (less than 100 participants)

c. Inconsistency: It could not be judged due to a single trial.