

## Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

### C.3 Cognitive therapy

#### Overview of the PICO structure

Definition of the intervention	
Cognitive therapy aims to identify and modify cognition regarding pain and disability. It is proposed that beliefs about the meaning of pain and expectations regarding control over pain can be directly modified using cognitive restructuring techniques such as imagery and attention diversion.	
PICO question	
<b>Population and subgroups</b>	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: <ul style="list-style-type: none"><li>• Age (all adults and those aged 60 years and over)</li><li>• Gender and/or sex</li><li>• Presence of leg pain (radicular, non-radicular, mixed)</li><li>• Race/ethnicity - studies of populations who were historically marginalized compared with studies of those who were not</li><li>• Regional economic development - studies carried out in high-income countries compared with studies in low- to middle-income countries</li></ul>
<b>Comparators</b>	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)

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

<b>Outcomes</b>	<p>Critical outcomes constructs (all adults)</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Back-specific function/disability</li> <li>• General function/disability</li> <li>• Health-related quality of life</li> <li>• Psychosocial function</li> <li>• Social participation</li> <li>• Self-efficacy</li> <li>• Adverse events (as reported in trials)</li> </ul>	<p>Critical outcomes constructs (older adults, aged ≥ 60 years)</p> <ul style="list-style-type: none"> <li>• Pain</li> <li>• Back-specific function/disability</li> <li>• General function/disability</li> <li>• Health-related quality of life</li> <li>• Psychosocial function</li> <li>• Adverse events (as reported in trials)</li> </ul>
-----------------	---	---

*Other Evidence-to-Decision (EtD) considerations*

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

<b>Summary of resource considerations</b>	
<b>All adults</b>	<b>Older people</b>

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

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**

<b>All adults</b>	<b>Older people</b>
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified

**Summary of acceptability considerations**

<b>All adults</b>	<b>Older people</b>
No evidence synthesis commissioned for all adults. Judgements made based on experience of GDG members	No evidence identified

**Summary of feasibility considerations**

<b>All adults</b>	<b>Older people</b>
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
<b>Benefits</b>	Trivial; uncertain	Uncertain
<b>Harms</b>	Trivial; uncertain	Trivial; uncertain
<b>Balance benefits to harms</b>	Uncertain	Uncertain

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

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

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

GRADE Table 1. *What are the benefits and harms of cognitive 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.

Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

**GRADE Table 2. What are the benefits and harms of cognitive 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?**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Pain - short term</b>												
3	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	37	46	-	MD 2.74 lower (8.58 lower to 3.1 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Pain - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	5	6	-	MD 0.02 higher (0.98 lower to 1.02 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Pain - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	4	5	-	MD 0.08 higher (0.93 lower to 1.09 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Back-specific functional status – short term</b>												
4	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	133	93	-	SMD 0.1 lower (0.37 lower to 0.17 higher)	⊕○○○ ○ Very low	

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Back-specific functional status - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	7	6	-	MD 4.09 lower (13.51 lower to 5.33 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Back-specific functional status - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	6	5	-	MD 4.41 lower (14.11 lower to 5.29 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>General functional status – short term, intermediate term or long term: no studies identified that reported on this outcome</b>												
-	-	-	-	-	-	-	-	-	-	-	-	
<b>Health-related quality of life – short term, intermediate term or long term: no studies identified that reported on this outcome</b>												
-	-	-	-	-	-	-	-	-	-	-	-	
<b>Adverse events and serious adverse events: no studies identified that reported on this outcome</b>												
-	-	-	-	-	-	-	-	-	-	-	-	
<b>Psychological functioning (anxiety) - short term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	8	7	-	MD 4.56 higher (7.66 lower to 16.78 higher)	⊕○○○ ○ Very low	

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (anxiety) - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	7	6	-	MD 1.71 higher (10.65 lower to 14.07 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (anxiety) - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	6	5	-	MD 6.23 lower (27.59 lower to 15.13 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (depression) - short term</b>												
2	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>b</sup>	none	24	25	-	MD 1.97 higher (1.41 lower to 5.34 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Psychological functioning (depression) - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	7	6	-	MD 3.03 lower (10.6 lower to 4.54 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (depression) - long term</b>												



**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	6	5	-	MD <b>4.77 lower</b> (12.33 lower to 2.79 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (coping) - short term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	8	7	-	MD <b>29.46 higher</b> (5.42 lower to 64.34 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (coping) - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	7	6	-	MD <b>27.26 higher</b> (4.82 lower to 59.34 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Psychological functioning (coping) - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>c</sup>	not serious	serious <sup>b</sup>	none	6	5	-	MD <b>20.33 higher</b> (8.31 lower to 48.97 higher)	⊕○○○ ○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed, only one included study on this outcome)												
<b>Social participation – short term, intermediate term or long term: no studies identified that reported on this outcome</b>												
-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Self-efficacy – short term, intermediate term or long term: no studies identified that reported on this outcome</b>												

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

Certainty assessment							No of patients		Effect		Certainty	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Cognitive therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
-	-	-	-	-	-	-	-	-	-	-	-	

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

**Explanations**

<sup>a</sup>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, incomplete outcome data, selective reporting, similarity of groups at baseline, co-interventions, and compliance with the intervention.

<sup>b</sup>Imprecision downgraded by 1 level: low number of participants.

<sup>c</sup>Inconsistency not assessed because only one study included in this analysis.

**Web Annex D.C3: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults**

GRADE Table 3. *What are the benefits and harms of cognitive 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?*

No trials.