

## Web Annex D.C1: ETD summary for WHO Guideline on non-surgical management of chronic primary low back pain in adults

### C.1 Operant therapy

#### Overview of the PICO structure

Definition of the intervention	
Operant therapy aims to replace pain-related behaviours with helpful, healthy behaviours (e.g. exercise, work). Time-contingent exercises (i.e. quotas) and encouraging people with CPLBP to increase their activity levels are its main principles. This type of therapy is aligned with behavioural activation therapy.	
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)

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<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>
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*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>

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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**

<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>	Moderate; uncertain	Moderate; uncertain
<b>Harms</b>	Trivial; uncertain	Trivial; uncertain
<b>Balance benefits to harms</b>	Probably favours operant therapy; uncertain	Probably favours operant therapy; uncertain

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<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

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

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**GRADE Table 2. What are the benefits and harms of operant 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							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operant therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Pain - short term</b>												
4	randomized trials	very serious <sup>a</sup>	Not serious <sup>b</sup>	not serious	serious <sup>c</sup>	none	89	77	-	SMD <b>0.66 lower</b> (1.14 lower to 0.17 lower)	⊕○○○	Very low
<b>Population subgroup 1: gender and/or sex</b>												
Females 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	36	30	-	SMD <b>1.04 lower</b> (1.55 lower to 0.52 lower)	⊕○○○	Very low
Mixed 3	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	53	47	-	SMD <b>0.45 lower</b> (0.94 lower to 0.04 higher)	⊕○○○	Very low
<b>Population subgroups 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Pain - intermediate term</b>												
2	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>d</sup>	none	40	36	-	SMD <b>0.76 lower</b> (1.24 lower to 0.29 lower)	⊕○○○	Very low
<b>Population subgroup 1: gender and/or sex</b>												
Females 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	36	30	-	SMD <b>0.69 lower</b> (1.19 lower to 0.19 lower)	⊕○○○	Very low
Mixed 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>g</sup>	none	4	6	-	SMD <b>1.37 lower</b> (2.85 lower to 0.11 higher)	⊕○○○	Very low

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№ of studies	Study design	Certainty assessment					№ of patients		Effect		Certainty	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operant therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Population subgroups 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Pain - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	5	5	-	MD <b>0.66 lower</b> (1.7 lower to 0.38 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>												
3	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	55	47	-	MD <b>1.38 lower</b> (3.65 lower to 0.9 higher)	⊕○○○ Very low	
<b>Population subgroups 1, 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Back-specific functional status - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	6	6	-	MD <b>5.36 lower</b> (17.11 lower to 6.39 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>e</sup>	not serious	very serious <sup>g</sup>	none	6	5	-	MD <b>1.33 lower</b> (13.59 lower to 10.93 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>												

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No of studies	Study design	Certainty assessment					No of patients		Effect		Certainty	Importance
		Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operant therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
-	-	-	-	-	-	-	-	-	-	-	-	
<b>Adverse events or serious adverse events: no studies identified that reported on this outcome</b>												
-	-	-	-	-	-	-	-	-	-	-	-	
<b>Psychological functioning (depression) - short term</b>												
3	randomized trials	very serious <sup>a</sup>	serious <sup>f</sup>	not serious	very serious <sup>d</sup>	none	62	56	-	SMD <b>0.29 lower</b> (1.27 lower to 0.69 higher)	⊕○○○	Very low
<b>Population subgroup 1: gender and/or sex</b>												
Females 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	36	30	-	SMD <b>1.13 lower</b> (1.65 lower to 0.60 lower)	⊕○○○	Very low
Mixed 2	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>g</sup>	none	4	6	-	SMD <b>0.2 higher</b> (0.35 lower to 0.74 higher)	⊕○○○	Very low
<b>Population subgroups 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Psychological functioning (depression) - intermediate term</b>												
2	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	42	36	-	MD <b>3.05 lower</b> (5.41 lower to 0.7 lower)	⊕○○○	Very low
<b>Population subgroup 1: gender and/or sex</b>												
Females 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	serious <sup>c</sup>	none	36	30	-	MD <b>3.2 lower</b> (5.62 lower to 0.78 lower)	⊕○○○	Very low
Mixed 1	randomized trials	very serious <sup>a</sup>	not serious	not serious	very serious <sup>g</sup>	none	6	6	-	MD <b>0.5 lower</b> (10.57 lower to 9.57 higher)	⊕○○○	Very low



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№ of studies	Certainty assessment						№ of patients		Effect		Certainty	Importance
	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operant therapy	No intervention	Relative (95% CI)	Absolute (95% CI)		
<b>Population subgroups 2, 3 and 4 - not reported</b> (no subgroup analysis was performed)												
<b>Psychological functioning (depression) - long term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	6	5	-	MD <b>1.07 higher</b> (8.58 lower to 10.72 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) - short term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	8	7	-	MD <b>3.81 higher</b> (8.08 lower to 15.7 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) - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	6	6	-	MD <b>3.17 higher</b> (9.5 lower to 15.84 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>e</sup>	not serious	very serious <sup>g</sup>	none	6	5	-	MD <b>10.57 lower</b> (28.67 lower to 7.53 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>e</sup>	not serious	very serious <sup>g</sup>	none	8	7	-	MD <b>1.59 higher</b> (33.19 lower to 36.37 higher)	⊕○○○ Very low	

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№ of studies	Certainty assessment						№ of patients		Effect		Certainty	Importance
	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Operant 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 (coping) - intermediate term</b>												
1	randomized trials	very serious <sup>a</sup>	not serious <sup>e</sup>	not serious	very serious <sup>g</sup>	none	6	6	-	MD 13 lower (46.9 lower to 20.9 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>e</sup>	not serious	very serious <sup>g</sup>	none	6	5	-	MD 4.5 lower (32.34 lower to 23.34 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>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>												
-	-	-	-	-	-	-	-	-	-	-	-	-

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 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>Inconsistency not downgraded despite I<sup>2</sup> = 52%; heterogeneity may be explained by gender subgroups.

<sup>c</sup>Imprecision downgraded by 1 level: due to low number of participants

<sup>d</sup>Imprecision downgraded by 2 levels: due to wide confidence interval consistent with the possibility for benefit and the possibility for no effect and low number of participants.

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

<sup>f</sup>Inconsistency downgraded by 1 level: unexplained considerable heterogeneity (I-sq = 83%)

<sup>g</sup>Imprecision downgraded by 2 levels: due to very low number of participants

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