C.2 Respondent therapy

Overview of the PICO structure

Definition of the	intervention
•	apy aims to modify the physiological response system to pain through the reduction of muscular tension through gressive relaxation and applied relaxation. This type of therapy is aligned with relaxation therapy.
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)

Outcomes	 Critical outcomes constructs (all adults) Pain Critical outcomes constructs (older adults, aged ≥ 60 years)
	 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	No evidence identified							

Summary of resource considerations						
All adults	Older people					

No evidence synthesis commissioned for all adults. Judgements made	No evidence identified
based on experience of GDG members	

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 <i>feasibility considerations</i>							
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	Small; trivial; uncertain	Uncertain			
Harms	Trivial; uncertain	Uncertain			
Balance benefits to harms	Uncertain	Uncertain			

Overall certainty	Very 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			

<u>GRADE Table 1</u>. What are the benefits and harms of respondent 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 <u>placebo</u>?

			Certainty a	ssessment			Nº of	patients		Effect	Certainty I	Importance
№ of studi es	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecision	Other considerations	Responde nt therapy	Placebo	Relative (95% Cl)	Absolute (95% Cl)		
Pain - s	Pain - short term											
2	randomized trials	seriousª	not serious	not serious	serious ^b	none	29	29	-	MD 6.21 lower (14.94 lower to 2.52 higher)	⊕⊕⊖ ⊖ Low	
Popula	tion subgroups ′	l, 2, 3 and 4	- not reported (r	no subgroup anal	ysis was perform	ed)						
-	ntermediate term			• •								
-	-	-	-	-	-	-	-	-	-	-	-	
Back-s	pecific functiona	l status – s	hort term	<u></u>	<u> </u>	<u> </u>	1	<u></u>	<u></u>			1
2	randomized trials	serious ^a	not serious	not serious	serious ^b	none	29	29	-	SMD 0.07 higher (0.45 lower to 0.58 higher)	⊕⊕○ ○ Low	
Popula	tion subgroups ′	l, 2, 3 and 4	- not reported (no subgroup anal	ysis was perform	ed)	1	<u></u>	<u></u>	I		1
Back-s	pecific functiona	l status - in	termediate term	or long term: no	studies identifi	ied that reported on t	this outcome					
-	-	-	-	-	-	-	-	-	-	-	-	
Genera	I functional statu	ıs - short te	rm, intermediate	e term or long te	rm: no studies i	dentified that reporte	ed on this outo	come	·			·
-	-	-	-	-	-	-	-	-	-	-	-	
Health-	related quality o	f life - short	term, intermedia	ate term or long	term: no studie	s identified that repo	orted on this o	utcome				
-	-	-	-	-	-	-	-	-	-	-	-	

Certainty assessment							№ of patients		Effect			
№ of studi es	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecision	Other considerations	Responde nt therapy	Placebo	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Advers	Adverse events or serious adverse events: no studies identified that reported on this outcome											
-	-	-	-	-	-	-	-	-	-	-	-	
Psycho	logical functioni	ng - short t	erm, intermediat	e term or long te	erm: no studies	identified that report	ted on this out	come		1		1
-	-	-	-	-	-	-	-	-	-	-	-	
Social p	participation - sh	ort term, in	termediate term	or long term: no	studies identifi	ed that reported on	this outcome					
-	-	-	-	-	-	-	-	-	-	-	-	
Self-eff	Self-efficacy - short term, intermediate term or long term: no studies identified that reported on this outcome											
-	-	-	-	-	-	-	-	-	-	-	-	

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

Explanations

^aRisk of bias downgraded by 1 level: due to unclear or high risk of bias in one study regarding random sequence generation, allocation concealment, 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. ^bImprecision downgraded by 1 level: low number of participants

<u>GRADE Table 2.1</u>. What are the benefits and harms of respondent therapy (biofeedback) 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 <u>no</u> <u>intervention</u>?

			Certainty asses	sment			Nº of p	atients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Pain - short t	erm											
3	randomize d trials	very serious ^a	not serious	not serious	serious ^b	none	53	47	-	SMD 0.66 lower (1.1 lower to 0.22 lower)	⊕OO ○	
										,	Very low	
Population s	ubgroups 1, 2	and 3 - not r	eported (no subgro	oup analysis wa	s performed)	1	<u> </u>	-			1	<u> </u>
Population s	ubgroup 4: reg	gional econo	mic development									
Low/middle income	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	27	25	-	SMD 0.53 lower (1.08 lower to	⊕00	
1										0.03 higher)	Very low	
High income 2	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	26	22	-	SMD 0.79 lower (1.6 lower to 0.01 higher)	⊕OO ○	
											Very low	
Pain - interm	ediate term or	long term: r	o studies identifie	ed that reported	d on this outcon	ne						
-	-	-	-	-	-	-	-	-	-	-	-	
Back-specific	c functional st	atus – short	term		·							
2	randomize d trials	very seriousª	not serious	not serious	serious ^b	none	43	37	-	SMD 0.62 lower (1.07 lower to 0.17 lower)	⊕OO ○	
											Very low	

			Certainty asses	sment			Nº of p	atients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Population su	ıbgroups 1, 2	and 3 - not r	eported (no subgro	oup analysis was	s performed)			·	·			
Population su	ıbgroup 4: reg	gional econo	mic development									
Low/middle income 1	randomize d trials	very serious ^a	not serious	not serious	serious ^b	None	27	25	-	SMD 0.51 lower (1.06 lower to 0.04 higher)	⊕⊖⊖ ⊖ Very low	
High income 1	randomize d trials	very serious ^a	not serious	not serious	serious ^b	None	16	12	-	SMD 0.85 lower (1.64 lower to 0.06 lower)	⊕OO ○	
											Very low	
											,	
Back-specific	functional st	atus - interm	ediate term or lon	ıg term: no stud	dies identified th	hat reported on this	outcome					
Back-specific -	functional st	atus - interm -	ediate term or lon -	ig term: no stud -	dies identified th -	hat reported on this -	outcome -	-	-	-	-	
-	-	-	-	-	-	hat reported on this - ified that reported o	-	-	-	-	-	
-	-	-	-	-	-	-	-	-	-	-	-	
General funct	- ional status - -	- short term, i -	- intermediate term -	or long term: n	- no studies identi -	ified that reported c	- on this outcome -	-	-	-	-	
General funct	- ional status - -	- short term, i -	- intermediate term -	or long term: n	- no studies identi -	ified that reported c	- on this outcome -	-	- -	- -	-	
General funct - Health-related -	ional status - - I quality of life -	- short term, i - e - short tern -	- intermediate term - n, intermediate ter	or long term: n - m or long term -	- io studies identi - : no studies ide -	ified that reported o	on this outcome - d on this outcome	- e	- -	- -	-	
General funct - Health-related -	ional status - - I quality of life -	- short term, i - e - short tern -	- intermediate term - n, intermediate ter -	or long term: n - m or long term -	- io studies identi - : no studies ide -	ified that reported o	on this outcome - d on this outcome	- e	- -	- -	- - -	
General funct - lealth-related - Adverse ever -	ional status - - I quality of life - ts or serious	- short term, i - e - short tern - adverse eve -	ntermediate term - n, intermediate ter - nts: no studies ide	or long term: n - m or long term - entified that rep	- o studies identi - : no studies ide - ported on this o	ified that reported of the second sec	on this outcome - d on this outcome -	- e -	- -	- -	- -	
General funct - Health-related - Adverse even -	ional status - - I quality of lif - ts or serious -	- short term, i - e - short tern - adverse eve -	ntermediate term - n, intermediate ter - nts: no studies ide	or long term: n - m or long term - entified that rep	- o studies identi - : no studies ide - ported on this o	ified that reported of the second sec	on this outcome - d on this outcome -	- e -	- -	- - - MD 5.15 lower (8.74 lower to 1.57 lower)	- -	

			Certainty asses	sment			Nº of p	atients		Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Population su	ıbgroup 4: reg	gional econo	mic development					,	ļ			
Low/middle income 1	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	27	25	-	MD 5.3 lower (9.32 lower to 1.28 lower)	⊕⊖⊖ ⊖ Very low	
High income 1	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	16	12	-	MD 4.58 lower (12.46 lower to 3.3 higher)	⊕⊖⊖ ⊖ Very low	
Psychologica	I functioning	(depression)) - short term									
2	randomize d trials	very seriousª	not serious	not serious	serious ^b	none	43	37	-	MD 3.78 lower (8.06 lower to 0.5 higher)	⊕⊖⊖ ⊖ Very low	
Population su	ıbaroups 1. 2	and 3 - not r	eported (no subgro	bup analysis wa	s performed)						,	
•	•••		mic development									
Low/middle income 1	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	27	25	-	MD 0.52 lower (7.37 lower to 6.33 higher)	⊕⊖⊖ ⊖ Very low	
High income 1	randomize d trials	very seriousª	not serious	not serious	serious ^b	None	16	12	-	MD 5.24 lower (9.03 lower to 1.45 lower)	⊕⊖⊖ ⊖ Very low	

			Certainty asses	sment			Nº of p	atients		Effect		
№ of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
1	randomize d trials	very serious ^a	not serious ^c	not serious	serious ^b	none	16	12	-	MD 6.92 higher (10.83 lower to	$\oplus \bigcirc \bigcirc$	
	u unais	Serious								24.67 higher)	\bigcirc	
											Very low	
Population su	ubgroups 1, 2	3 and 4 - no	t reported (no sub	group analysis v	vas performed; o	nly one included stud	y on this outcome	e)				
Psychologica	al functioning	- intermediat	te term or long ter	m: no studies i	dentified that re	eported on this outc	ome					
-	-	-	-	-	-	-	-	-	-	-	-	
Social partici	pation - short	term, interm	ediate term or lon	g term: no stud	lies identified th	nat reported on this	outcome	1				1
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficacy	- short term, i	ntermediate	term or long term:	no studies ide	ntified that repo	orted on this outcon	ne	1	1			1
-	-	-	-	-	-	-	-	-	-	-	-	

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

Explanations

^aRisk 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. ^bImprecision downgraded by 1 level: low number of participants. ^cInconsistency not assessed because only one study included in this analysis.

<u>GRADE Table 2.2</u>. What are the benefits and harms of respondent therapy (relaxation) 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 <u>no</u> <u>intervention</u>?

			Certainty assess	sment			Nº of	patients	E	Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Pain - short	term											
2	randomized trials	very serious ^a	serious ^b	not serious	very serious ^c	none	31	27	-	MD 21.8 lower (45.78 lower to 2.17 higher)	⊕⊖⊖ ⊖ Very low	
Population	subgroups 1, 2,	3 and 4 - not	reported (no subgr	oup analysis wa	as performed)							
Pain - interr	nediate term or I	ong term – n	o studies identifie	d that reported	on this outcom	e	_		_		_	
-	-	-	-	-	-	-	-	-	-	-	-	
Back-specif	fic functional sta	tus – short te	rm									
2	randomized trials	very serious ^a	not serious	not serious	serious ^d	none	31	27	-	SMD 0.97 lower (1.52 lower to 0.41 lower)	⊕⊖⊖ ⊖ Very low	
Population	subgroups 1, 2,	3 and 4 - not	reported (no subgr	oup analysis wa	as performed)	1					1	
Back-specif	fic functional sta	tus - interme	diate term or long	term: no studi	es identified tha	t reported on this o	outcome					
-	-	-	-	-	-	-	-	-	-	-	-	
General fun	ctional status - s	short term, in	termediate term o	r long term: no	studies identifi	ed that reported on	this outcome					
-	-	-	-	-	-	-	-	-	-	-	-	
Health-relat	ed quality of life	- short term,	intermediate term	or long term:	no studies ident	tified that reported	on this outcome	9				

			Certainty assess	ment			Nº of	patients	E	Effect		
Nº of studies	Study design	Risk of bias	Inconsistency	Indirectnes s	Imprecision	Other considerations	Respondent therapy	No intervention	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
-	-	-	-	-	-	-	-	-	-	-	-	
Adverse ev	ents or serious a	dverse event	s: no studies iden	tified that repo	rted on this out	come						
-	-	-	-	-	-	-	-	-	-	-	-	
Psychologi	cal functioning (depression) -	short term					·		•		
2	randomized trials	very serious ^a	serious⁰	not serious	very serious	none	31	27	-	MD 6.8 lower (19.73 lower to 6.12 higher)	⊕⊖⊖ ⊖ Very low	
-			reported (no subgr		. ,			•	•			
Psychologi	cal functioning -	intermediate	term or long term	: no studies ide	entified that rep	orted on this outco	me					
-	-	-	-	-	-	-	-	-	-	-	-	
Social parti	cipation - short	term, interme	diate term or long	term: no studie	es identified that	t reported on this o	outcome					
-	-	-	-	-	-	-	-	-	-	-	-	
Self-efficac	y - short term, in	termediate te	rm or long term: n	o studies iden	tified that report	ted on this outcom	e	•		*		
-	-	-	-	-	-	-	-	-	-	-	-	

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

Explanations

^aRisk 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.

^bInconsistency downgraded by 1 level: unexplained substantial heterogeneity I²=57%

cImprecision 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.

^dImprecision downgraded by 1 level: low number of participants.

eInconsistency downgraded by 1 level: unexplained considerable heterogeneity I2=85%

<u>GRADE Table 3</u>. What are the benefits and harms of respondent therapy (relaxation) 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 <u>usual care</u>?

			Certainty a	ssessment			Nº of p	atients		Effect		
№ of studi es	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecision	Other considerations	Respondent therapy	Usual care	Relative (95% CI)	Absolute (95% Cl)	Certainty	Importance
Pain - s	hort term											
1	randomized trials	very serious ^a	not serious ^b	not serious	very serious ^c	none	57	43	-	MD 11 lower (22.22 lower to 0.22 higher)	⊕⊖⊖ ⊖ Very low	
Popula	tion subgroups 1	l, 2 and 3 - r	not reported (no s	subgroup analysis	was performed)		!			<u> </u>	!	1
Populat	tion subgroup 4:	regional ec	onomic develop	ment (no subgrou	up analysis was p	erformed; all studies p	performed in high	income settings))			
Pain - i	ntermediate term	I										
1	randomized trials	very seriousª	not serious ^b	not serious	serious ^d	none	54	45	-	MD 1.4 lower (12.65 lower to 9.85 higher)	⊕⊖⊖ ⊖ Very low	
Populat	tion subgroups 1	, 2, 3 and 4	- not reported (n	o subgroup analy	sis was performe	d; only one included s	tudy on this outco	ome)	<u> </u>			
Pain - Io	ong term: no stu	dies identifi	ed that reported	on this outcome)							
-	-	-	-	-	-	-	-	-	-	-	-	
Back-s	pecific functiona	l status - sh	ort term				!			<u> </u>		1
1	randomized trials	very seriousª	not serious ^ь	not serious	serious ^d	none	57	43	-	MD 3.3 lower (11.6 lower to 5 higher)	⊕⊖⊖ ⊖ Very low	
Populat	tion subgroups 1	, 2, 3 and 4	- not reported (n	o subgroup analy	sis was performe	d; only one included s	tudy on this outco	ome)	1	1	1	ļ

			Certainty a	issessment			Nº of pa	atients		Effect		
№ of studi es	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecision	Other considerations	Respondent therapy	Usual care	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Back-s	pecific functiona	l status - in	termediate term									
1	randomized trials	very serious ^a	not serious ^ь	not serious	serious ^d	none	54	45	-	MD 1.6 lower (9.22 lower to 6.02 higher)	⊕⊖⊖ ⊖ Very low	
Popula	tion subgroups 1	, 2, 3 and 4	- not reported (n	o subgroup analy	sis was performe	ed; only one included st	udy on this outco	ome)	1			1
Back-s	pecific functiona	l status - lo	ng term: no stud	ies identified that	at reported on th	iis outcome						
-	-	-	-	-	-	-	-	-	-	-	-	
Genera	I functional statu	is - short te	rm, intermediate	term or long ter	m: no studies id	lentified that reported	on this outcom	e				
-	-	-	-	-	-	-	-	-	-	-	-	
Health-	related quality of	f life - short	term	1	1	l		1		1		
1	randomized trials	very serious ^a	not serious ^ь	not serious	serious ^d	none	57	43	-	MD 6.9 higher (2.51 lower to 16.31 higher)	⊕⊖⊖ ⊖ Very low	
Popula	tion subgroups 1	l, 2, 3 and 4	- not reported (n	o subgroup analy	sis was performe	ed; only one included st	udy on this outco	ome)				
Health-	related quality of	i life - intern	nediate term									
1	randomized trials	very seriousª	not serious ^ь	not serious	serious ^d	none	54	45	-	MD 2.6 lower (11.9 lower to 6.7 higher)	⊕⊖⊖ ⊖ Very low	
Populat	tion subgroups 1	l, 2, 3 and 4	- not reported (n	o subgroup analy	vsis was performe	ed; only one included st	udy on this outco	ome)	<u> </u>	!	<u> </u>	1
Health-	related quality of	f life - long t	term: no studies	identified that re	eported on this o	outcome						
-	-	-	-	-	-	-	-	-	-	-	-	

			Certainty a	assessment			Nº of p	atients		Effect		
№ of studi es	Study design	Risk of bias	Inconsistenc y	Indirectness	Imprecision	Other considerations	Respondent therapy	Usual care	Relative (95% Cl)	Absolute (95% Cl)	Certainty	Importance
Advers	e events or serio	ous adverse	events: no stud	ies identified tha	t reported on th	is outcome						
-	-	-	-	-	-	-	-	-	-	-	-	
Psycho	logical functioni	ng (depress	sion) - short term	1			1					
1	randomized	very	not serious ^b	not serious	serious ^d	none	57	43	-	MD 1.5 lower	$\oplus \bigcirc \bigcirc$	
	trials	serious ^a								(5.87 lower to 2.87 higher)	\bigcirc	
											Very low	
Psycho	logical functioni	ng (depress	sion) - intermedia	ate term								
1	randomized trials	very seriousª	not serious ^b	not serious	serious ^d	none	54	45	-	MD 0.2 lower (4.16 lower to 3.76	$\oplus \bigcirc \bigcirc$	
	lilais	Serious								higher)	\bigcirc	
											Very low	
Psycho	logical functioni	ng - long te	rm: no studies io	dentified that rep	orted on this ou	itcome						
-	-	-	-	-	-	-	-	-	-	-	-	
Social	participation – sł	nort term, in	termediate term	or long term: no	studies identifi	ed that reported on th	nis outcome			·		
-	-	-	-	-	-	-	-	-	-	-	-	
Self-eff	icacy – short ter	m, intermed	liate term or long	g term: no studie	s identified that	reported on this outo	come			<u>.</u>		
-	-	-	-	-	-	-	-	-	-	-	-	

CI: confidence interval; MD: mean difference

Explanations

aRisk 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.

^bInconsistency not assessed because only one study included in this analysis.

clmprecision 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. dlmprecision downgraded by 1 level: low number of participants.