B.7 Transcutaneous electrical nerve stimulation (TENS)

Overview of the PICO structure

Definition of the intervention	
TENS is a non-invasive peripheral electrical stimulation modality applied to the skin using surface electrodes. TENS uses low-voltage electrical currents between the electrodes to modify the perception of pain, acting through segmental inhibition or activation of descending nociceptive-inhibitory systems. TENS devices may be used in health facilities or may be portable for use at home. A range of stimulation parameters may be selected, based on clinical indication, including pulse intensity, frequency, duration and type (burst or continuous). Among the included trials used to inform the guideline, TENS interventions involved electrode placement over the paravertebral lumbosacral area and sometimes the affected leg in the case of associated leg pain, using conventional continuous or burst pulse parameters.	
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

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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 • 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) • 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**
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	Small; uncertain	Small; uncertain
Harms	Small; uncertain	Small; 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 costs; high costs; varies (according to country and health system)	Moderate costs; high costs; varies (according to country and health system)
Equity and human rights	No impact; probably reduced; varies	No impact; probably reduced; varies
Acceptability	Probably yes; uncertain; varies	Probably yes; uncertain; varies
Feasibility	Probably yes	Probably yes

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GRADE Table 1. ***What are the benefits and harms of TENS 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 sham?***

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
ALL ADULTS												
Pain (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
9[a]	randomized trials	very serious[1,2,3,4,5,6,7,8,b]	serious[c]	not serious[d]	serious[e]	none	280	187	-	MD **0.9 lower** (1.54 lower to 0.26 lower)	⨁◯◯◯ Very low	CRITICAL
Pain in females (follow-up: closest to 2 weeks; assessed with: Borg scale; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	very serious[5,b]	not serious[g]	serious[h]	serious[i]	none	23	21	-	MD **0.1 higher** (0.2 lower to 0.4 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in females and males (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
8	randomized trials	very serious[b]	serious[k]	not serious[d]	serious[l]	none	257	187	-	MD **1.03 lower** (1.69 lower to 0.36 lower)	⨁◯◯◯ Very low	CRITICAL
Pain in people without leg pain (follow-up: closest to 2 weeks weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
5	randomized trials	very serious[1,2,4,5,8,b]	serious[m]	not serious[d]	serious[n]	none	129	102	-	MD **0.64 lower** (1.83 lower to 0.54 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in people with unclassified presence of leg pain (follow-up: closest to 2 weeks; assessed with: VAS, NRS; benefit indicated by lower values; scale: 0 to 10)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
2[o]	randomized trials	very serious[3,7,b]	not serious[p]	not serious[q]	serious[l]	none	100	47	-	MD **1.34 lower** (2.44 lower to 0.25 lower)	⨁◯◯◯ Very low	CRITICAL
Pain in people with mixed radicular and non-radicular leg pain (follow-up: closest to 2 weeks; assessed with: NRS; benefit indicated by lower values; scale: 0 to 10)												
2[r]	randomized trials	very serious[6,10,b]	very serious[s]	not serious[q]	very serious[t]	none	51	38	-	MD **0.96 lower** (4.59 lower to 2.67 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials undertaken in high to upper-middle income countries (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
8[u]	randomized trials	very serious[1,2,3,5,6,7,8,10,b]	serious[v]	not serious[d]	serious[l]	none	219	125	-	MD **1.01 lower** (1.69 lower to 0.34 lower)	⨁◯◯◯ Very low	CRITICAL
Pain in trials undertaken in low- or lower middle-income countries (follow-up: closest to 2 weeks; assessed with: NRS; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	serious[4,w]	not serious[g]	serious[x]	serious[j]	none	30	32	-	MD **0** (0.4 lower to 0.4 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials using a single TENS treatment session (follow-up: closest to 2 weeks; assessed with: VAS, NRS; benefit indicated by lower values; scale: 0 to 10)												
4[y]	randomized trials	very serious[1,3,4,6,b]	very serious[z]	not serious[d]	serious[n]	none	135	90	-	MD **0.68 lower** (2 lower to 0.65 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials using 10-20 TENS treatment sessions (follow-up: closest to 2 weeks; assessed with: VAS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
5[aa]	randomized trials	very serious[2,5,7,8,10,b]	serious[ab]	not serious[q]	serious[l]	none	145	97	-	MD **1.06 lower** (1.94 lower to 0.18 lower)	⨁◯◯◯ Very low	CRITICAL
Pain (after removing high risk of bias trials) (follow-up: closest to 2 weeks; assessed with: VAS, NRS; benefit indicated by lower values; scale: 0 to 10)												
2	randomized trials	serious[4,8,ac]	serious[ad]	not serious[d]	very serious[t]	none	80	55	-	MD **0.63 lower** (2.78 lower to 1.53 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (follow-up: closest to 3 months; assessed with: VAS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
2[ae]	randomized trials	very serious[5,8,af]	serious[ag]	not serious[q]	very serious[t]	none	73	44	-	MD **0.4 lower** (2.21 lower to 1.41 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in females (follow-up: closest to 3 months; assessed with: Borg scale; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	very serious[5,af]	not serious[g]	serious[h]	serious[i]	none	23	21	-	MD **0.1 higher** (0.23 lower to 0.43 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in females and males (follow-up: closest to 3 months; assessed with: VAS; benefit indicated by lower values; scale: 0 to 10)												
1[ae]	randomized trials	serious[8,w]	not serious[g]	serious[h]	very serious[ah]	none	50	23	-	MD **1.06 lower** (4.23 lower to 2.12 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (after removing high risk of bias trials) (follow-up: closest to 3 months; assessed with: VAS; benefit indicated by lower values; scale: 0 to 10)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
1[ae]	randomized trials	serious[8,w]	not serious[g]	serious[h]	very serious[ah]	none	50	23	-	MD **1.06 lower** (4.23 lower to 2.12 higher)	⨁◯◯◯ Very low	CRITICAL
Pain stratified by race/ethnicity												
0												
Function (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
4[ai]	randomized trials	very serious[2,5,7,10,b]	very serious[aj]	not serious[q]	very serious[ak]	none	95	74	-	SMD **0.96 SD lower** (3.2 lower to 1.28 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females and males (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
3	randomized trials	very serious[2,7,10,b]	very serious[aj]	not serious[q]	very serious[ak]	none	72	53	-	SMD **1.3 lower** (4.38 lower to 1.78 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females (follow-up: closest to 2 weeks; assessed with: ODI; benefit indicated by lower values)												
1	randomized trials	very serious[5,af]	not serious[g]	serious[h]	very serious[ah]	none	23	21	-	SMD **0.27 higher** (0.33 lower to 0.86 higher)	⨁◯◯◯ Very low	CRITICAL
Function in people with no leg pain (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
2	randomized trials	very serious[2,5,b]	not serious[p]	not serious[q]	very serious[al]	none	34	32	-	SMD **0.16 higher** (1.19 lower to 1.51 higher)	⨁◯◯◯ Very low	CRITICAL

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
Function in people either with or without radicular leg pain (follow-up: closest to 2 weeks; assessed with: RMDQ; benefit indicated by lower values)												
1	randomized trials	very serious[10,b]	not serious[g]	serious[h]	serious[am]	none	31	30	-	SMD **1.97 lower** (2.59 lower to 1.36 lower)	⨁◯◯◯ Very low	CRITICAL
Function in people with unclassified presence of leg pain (follow-up: closest to 2 weeks; assessed with: ODI; benefit indicated by lower values)												
1[ai]	randomized trials	very serious[7,b]	not serious[g]	serious[h]	very serious[al]	none	30	12	-	SMD **1.67 higher** (28.66 lower to 25.33 higher)	⨁◯◯◯ Very low	CRITICAL
Function (follow-up: closest to 3 months; assessed with: ODI; benefit indicated by lower values; scale: 0 to 50)												
2[ae]	randomized trials	very serious[5,8,af]	serious[an]	not serious[q]	serious[ao]	none	73	44	-	MD **0.24 lower** (4.3 lower to 3.81 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females (follow-up: closest to 3 months; assessed with: ODI; benefit indicated by lower values; scale: 0 to 50)												
1	randomized trials	very serious[5,b]	not serious[g]	serious[h]	serious[ao]	none	23	21	-	MD **0.5 higher** (1.22 lower to 2.22 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females and males (follow-up: closest to 3 months; assessed with: ODI; benefit indicated by lower values; scale: 0 to 50)												
1[ae]	randomized trials	serious[8,w]	not serious[g]	serious[h]	serious[ap]	none	50	23	-	MD **2.61 lower** (6.42 lower to 1.2 higher)	⨁◯◯◯ Very low	CRITICAL
Function (after removing high risk of bias trials) (follow-up: closest to 3 months; assessed with: ODI; scale: 0 to 50)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
1[ae]	randomized trials	serious[8,w]	not serious[g]	serious[h]	serious[ao]	none	50	23	-	MD **2.61 lower** (6.42 lower to 1.2 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on function stratified by race/ethnicity, number of treatment sessions or in adults in low- or lower middle-income countries not identified												
Health-related quality of life (follow-up: closest to 2 weeks; assessed with: SF-36 (PCS); benefit indicated by higher values; scale: 0 to 100)												
2[ai]	randomized trials	very serious[2,7,b]	serious[an]	not serious[q]	very serious[aq]	none	41	23	-	MD **3.21 higher** (21.17 lower to 27.59 higher)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life in people with no radicular leg pain (follow-up: closest to 2 weeks; assessed with: SF-36 (PCS); benefit indicated by higher values; scale: 0 to 100)												
1	randomized trials	very serious[2,b]	not serious[g]	serious[h]	very serious[ar]	none	11	11	-	MD **20.45 lower** (56.67 lower to 15.77 higher)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life in people with unclassified presence of leg pain (follow-up: closest to 2 weeks; assessed with: SF-36 (PCS); benefit indicated by higher values; scale: 0 to 100)												
1[ai]	randomized trials	very serious[7,b]	not serious[g]	serious[h]	serious[as]	none	30	12	-	MD **5.91 higher** (0.44 lower to 12.26 higher)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life (follow-up: closest to 2 weeks; assessed with: SF-36 (MCS); benefit indicated by higher values; scale: 0 to 100)												
2[ai]	randomized trials	very serious[2,7,b]	very serious[at]	serious[h]	serious[as]	none	41	23	-	MD **3.57 higher** (30.06 lower to 37.2 higher)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life in people with no radicular leg pain (follow-up: closest to 2 weeks; assessed with: SF-36 (MCS); benefit indicated by higher values; scale: 0 to 100)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials	very serious[2,b]	not serious[g]	serious[h]	serious[au]	none	11	11	-	MD **11.63 lower** (20.59 lower to 2.67 lower)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life in people with unclassified presence of leg pain (follow-up: closest to 2 weeks; assessed with: SF-36 (MCS); benefit indicated by higher values; scale: 0 to 100)												
1[ai]	randomized trials	very serious[7,b]	not serious[g]	serious[h]	serious[l]	none	30	12	-	MD **11.63 higher** (9.96 higher to 13.31 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on health-related quality of life stratified by gender, race/ethnicity, number of treatment sessions or in adults in low- or lower middle-income countries not identified												
Depression (follow-up: closest to 3 months; assessed with: BDI; benefit indicated by lower values; scale: 0 to 63)												
1[ae]	randomized trials	serious[8,w]	not serious[g]	serious[h]	very serious[av]	none	50	23	-	MD **3.04 higher** (19.15 lower to 25.22 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on depression stratified by gender, race/ethnicity, number of treatment sessions, national economic development or presence of leg pain not identified												
Trials on fear avoidance, catastrophizing, anxiety or self-efficacy not identified												
Adverse events/harms (high-income country, no leg pain)												
1	randomized trials	serious[8,w]	not serious[g]	serious[h]	serious[aw]	none	Authors reported that no TENS-associated adverse events developed in any participants.				⨁◯◯◯ Very low	CRITICAL
Trials on adverse events/harms stratified by gender, race/ethnicity, number of treatment sessions, presence of leg pain or in adults in low- or lower middle-income countries not identified												
Trials on social participation not identified												
0												

<u>OLDER ADULTS (aged 60 years or more)</u>

Pain (follow-up: closest to 2 weeks; assessed with: NRS; benefit indicated by lower values; scale: 0 to 10)

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	Sham	Relative (95% CI)	Absolute (95% CI)		
1[r]	randomized trials	very serious[6,b]	not serious[g]	serious[h]	very serious[t]	none	20	8	-	MD **0.13 higher** (9.8 lower to 10.06 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on pain stratified by gender, race/ethnicity, number of treatment sessions, national economic development or presence of leg pain not identified												
0												
Trials on function, health-related quality of life, depression, fear avoidance, catastrophizing, anxiety, self-efficacy, social participation, change in use of medications, falls or adverse events/harms not identified												
0												

BDI: Beck Disabiltiy Index; **CI:** confidence interval; **MCS:** Mental Component Summary; **MD:** mean difference; **MPQ:** McGill Pain Questionnaire; **NRS:** numeric rating scale; **ODI:** Oswestry Disability Index; **OIS:** Optimal Information Size; **PCS:** Physical Component Summary; **RMDQ:** Roland-Morris Disability Questionnaire; **SMD:** standardized mean difference; **VAS:** visual analogue scale

The following was used to guide the ratings:
Risk of bias: *Not serious:* all or most of the weight (>50%) comes from overall low risk of bias trial(s). *Serious:* some of the weight (<50%) comes from overall low risk of bias trial(s). *Very serious:* all or most of the weight (>50%) comes from overall high or unclear risk of bias trial(s).
Inconsistency: *Not serious:* high extent of similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 0% and 40%, which might not be important. *Serious:* some extent of similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 30% and 60%, which could not be explained due to small subgroups and may represent moderate heterogeneity. *Very serious:* little or no similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 50% and 90% or 75% and 100%, which could not be explained due to small subgroups and may represent substantial or considerable heterogeneity, respectively.
Indirectness: *Not serious:* trial(s) were conducted in different countries or settings. *Serious:* trial(s) were conducted from a single country/setting. *Very serious:* evidence is not directly related to PICO question.
Imprecision: *Not serious:* Optimal Information Size (OIS) was reached (i.e., sample sizes with at least 200 participants per group may provide prognostic balance); and the entire confidence interval lies on one side of the threshold that may be considered clinically important (≥10% scale range or SMD ≥0.2 for continuous variables, ≥10% for binary variables), such that the clinical course of action would not differ if the upper versus the lower boundary of the confidence interval represented the truth. *Serious:* OIS would not have been reached (sample sizes with less than 200 participants per group); if the OIS was reached, the clinical course of action might differ if the upper versus the lower boundary of the confidence interval represented the truth. *Very serious:* similar to 'serious' but to a greater extent (e.g., very small sample sizes and confidence intervals crossing appreciable benefit and harm).
Other considerations: *Not serious:* Publication bias is undetected. *Serious/very serious:* Publication bias is strongly suspected.

Explanations
a. Four trials had 2 arms: Dias 2021 (TENS (GT100Hz) vs. sham, TENS (GT2Hz) vs. sham), Topuz 2004 (conventional TENS vs. sham, low-frequency TENS vs. sham), Yaksi 2021 (burst TENS vs. sham, conventional TENS vs. sham) and Shimoji 2007 (TENS bidirectional modulated sine wave vs. sham, TENS conventional bidirectional pulsed wave vs. sham). For each of these 4 trials we included both arms in meta-analysis and split the comparison groups in half. One trial reporting only p-values was not included in meta-analysis (Bloodworth 2004); results were reported narratively and graded. In this cross-over design, 11 participants with radiculopathy received 4 different TENS interventions and 2 placebo TENS interventions in random order in a single day. Only p-values were provided. Trial authors reported no significant differences between groups (stochastic resonance TENS on back/leg vs. sham, p=0.096; conventional TENS on back/leg vs. sham, p=0.519).
b. Risk of bias: We downgraded twice. Most or all of the trials were rated as overall high risk of bias.
c. Inconsistency: We downgraded once. There is similarity in some of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 77%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
d. Indirectness: We did not downgrade. Multiple trials are included from different countries both high- and lower-middle income.
e. Imprecision: We downgraded once due to small sample size (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -1); the confidence interval does not cross the null but the lower boundary crosses the threshold for what may be considered appreciable benefit (MD = -1).
f. Risk of bias: We downgraded twice due to unclear items related to selection and reporting bias.
g. Inconsistency: We did not downgrade; however, there are no additional trials with which to compare these findings.
h. Indirectness: We downgraded once. This is a single trial from a single centre (high or upper-middle income country).

i. Imprecision: We downgraded twice due to low sample size (the OIS would not have been reached).
j. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -1); the confidence interval crossed the null but not the thresholds for what may be considered appreciable benefit (-1) or harm (+1).
k. Inconsistency: We downgraded once. There is similarity in some of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 73%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
l. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached). The point estimate reached the pre-specified threshold for what may be considered appreciable benefit (MD = -1). The confidence interval did not cross the null.
m. Inconsistency: We downgraded once. There is similarity in the majority of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 74%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
n. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -1). The confidence interval crossed the null and the lower boundary crossed the threshold for what may be considered appreciable benefit (MD = -1).
o. These trials had 2 arms each: Dias 2021 (TENS (GT100Hz) vs. sham, TENS (GT2Hz) vs. sham), Topuz 2004 (conventional TENS vs. sham, low-frequency TENS vs. sham).
p. Inconsistency: We did not downgrade. The point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 0%).
q. Indirectness: We did not downgrade because the trials were conducted in different countries (high or upper-middle income).
r. Shimoji 2007 included 2 arms (TENS bidirectional modulated sine wave vs. sham, TENS conventional bidirectional pulsed wave vs. sham). Both were included in meta-analysis and the comparison group was split in half.
s. Inconsistency: We downgraded twice. The point estimates differ with some overlap in confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 72%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
t. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (MD = -1); the confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds of appreciable benefit (MD = -1) and harm (MD = +1).
u. Four trials had 2 arms: Dias 2021 (TENS (GT100Hz) vs. sham, TENS (GT2Hz) vs. sham), Topuz 2004 (conventional TENS vs. sham, low-frequency TENS vs. sham), Yaksi 2021 (burst TENS vs. sham, conventional TENS vs. sham), and Shimoji 2007. For each of these 4 trials we included both arms in meta-analysis and split the comparison groups in half.
v. Inconsistency: We downgraded once. There is similarity in some of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 78%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
w. Risk of bias: We downgraded once due to the potential for selection and performance bias.
x. Indirectness: We downgraded once. This is a single trial from a single centre (low or lower-middle income country).
y. Two trials included 2 arms (Dias 2021: (TENS (GT100Hz) vs. sham, TENS (GT2Hz) vs. sham); and Shimoji 2007. All arms were included in the meta-analyses by splitting the comparison groups in half.
z. Inconsistency: We downgraded twice. Some estimates differ in direction. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 64%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
aa. Two trials had 2 arms each (Topuz 2004: conventional TENS vs. sham, low-frequency TENS vs. sham; Yaksi 2021: burst TENS vs. sham, conventional TENS vs. sham). For each of these 2 trials we included both arms in meta-analysis and split the comparison groups in half.
ab. Inconsistency: We downgraded once. There is similarity in some of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 84%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
ac. Risk of bias: We downgraded once. Items were rated as unclear in the selection, performance and reporting domains.
ad. Inconsistency: We downgraded once. There is similarity in some of the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 70%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
ae. Yaksi 2021 had 2 arms (burst TENS vs. sham, conventional TENS vs. sham); both arms were included in the meta-analysis with the comparison group split in half.
af. Risk of bias: We downgraded twice due to the potential for selection, performance and reporting biases.
ag. Inconsistency: We downgraded once. There is similarity in the point estimates with overlapping confidence intervals. Statistical heterogeneity is between 30% and 60% (i.e., I2 = 50%); this could not be explained due to small subgroups and may represent moderate heterogeneity.
ah. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate reached the pre-specified threshold for what may be considered clinically important (MD = -1); the confidence interval crosses the null.
ai. Topuz 2004 had 2 arms(conventional TENS vs. sham, low-frequency TENS vs. sham); both were included in the meta-analysis and the comparison group was split in half.
aj. Inconsistency: We downgraded twice. The results are in different directions with some non-overlapping confidence intervals. Statistical heterogeneity is between 75% and 100% (i.e., I2 = 92%); this could not be explained due to small subgroups and may represent considerable heterogeneity.
ak. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate reached the pre-specified threshold for what may be considered clinically important (MD = -0.2); the confidence interval crosses the null.
al. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (SMD = -0.2); the confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds of appreciable benefit (MD = -0.2) and harm (MD = +0.2).
am. Imprecision: We downgraded once due to low sample size (the OIS would not have been reached).
an. Inconsistency: We downgraded once. The point estimates are in different directions with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 0%).

ao. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -5); the confidence interval crossed the null but not the thresholds for what may be considered appreciable benefit (-5) or harm (+5).
ap. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -5). The confidence interval crossed the null; the lower boundary crossed the threshold for what may be considered appreciable benefit (-5).
aq. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (MD = +10); the confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds of appreciable benefit (MD = +10) and harm (MD = -10).
ar. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate reached the pre-specified threshold for what may be considered clinically important favouring the comparison (MD = -10); the confidence interval crossed the null.
as. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = +10); the confidence interval crossed the null.
at. Inconsistency: We downgraded twice. The point estimates differ in direction and the confidence intervals do not overlap. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 87%); this could not be explained due to small subgroups and may represent substantial heterogeneity.
au. Imprecision: We downgraded once. The sample size was small (OIS would not have been reached). The pointe estimate reached the threshold for what may be considered clinically important favouring the comparison (MD = -10); the confidence interval did not cross the null.
av. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (MD = -6.3). The confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds of appreciable benefit (MD = -6.3) and harm (MD = +6.3).
aw. Imprecision: We downgraded once due to low sample size (the OIS would not have been reached).

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GRADE Table 2. ***What are the benefits and harms of TENS 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 treatment or treatments where the effect of TENS could be isolated?***

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
ALL ADULTS												
Pain (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
8	randomized trials	very serious[1,2,3,4,5,6,7,8,a,b]	not serious[c]	not serious[d]	serious[e]	none	192	146	-	MD **0.19 lower** (0.51 lower to 0.14 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in females and males (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
7	randomized trials	very serious[1,2,3,4,5,7,8,b]	not serious[c]	not serious[d]	serious[f]	none	171	123	-	MD **0.35 lower** (0.66 lower to 0.03 lower)	⨁◯◯◯ Very low	CRITICAL
Pain in females (follow-up: closest to 2 weeks; assessed with: Borg scale; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	very serious[6,b]	not serious[g]	serious[h]	serious[e]	none	21	23	-	MD **0.2 higher** (0.07 lower to 0.47 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in people without leg pain (follow-up: closest to 2 weeks; assessed with: VAS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
4	randomized trials	very serious[2,6,7,8,a,b]	not serious[i]	not serious[d]	serious[e]	none	122	79	-	MD **0** (0.42 lower to 0.41 higher)	⨁◯◯◯ Very low	CRITICAL

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
Pain in people with unclassified presence of leg pain (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
2	randomized trials	very serious[1,3,b]	not serious[i]	not serious[d]	serious[j]	none	27	27	-	MD **0.18 higher** (0.12 higher to 0.24 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in people with and without leg pain (radicular or non-radicular) (follow-up: closest to 2 weeks; assessed with: VAS, NRS; benefit indicated by lower values; scale: 0 to 10)												
2	randomized trials	very serious[4,5,b]	serious[k]	not serious[l]	very serious[m]	none	43	40	-	MD **0.48 lower** (5.31 lower to 4.35 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials undertaken in high to upper-middle income countries (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
6	randomized trials	very serious[1,4,5,6,7,8,b]	not serious[n]	not serious[l]	serious[e]	none	151	120	-	MD **0.15 lower** (0.49 lower to 0.19 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials undertaken in low- or lower middle-income countries (follow-up: closest to 2 weeks; assessed with: VAS, NRS; benefit indicated by lower values; scale: 0 to 10)												
2	randomized trials	very serious[2,3,b,o]	not serious[p]	not serious[q]	very serious[m]	none	41	26	-	MD **0.53 lower** (3 lower to 1.95 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials using 10-20 TENS treatment sessions (follow-up: closest to 2 weeks; assessed with: VAS, NRS, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
6	randomized trials	very serious[2,3,4,5,6,7,b,o]	not serious[r]	not serious[d]	serious[e]	none	116	100	-	MD **0.21 lower** (0.72 lower to 0.29 higher)	⨁◯◯◯ Very low	CRITICAL
Pain in trials using <10 TENS treatment sessions (follow-up: closest to 2 weeks; assessed with: VAS; benefit indicated by lower values; scale: 0 to 10)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
2[s]	randomized trials	very serious[1,8,b]	not serious[i]	not serious[l]	serious[e]	none	76	46	-	MD **0.04 higher** (0.3 lower to 0.38 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (high-income country) (follow-up: closest to 3 months; assessed with: Brief Pain Inventory, Borg scale; benefit indicated by lower values; scale: 0 to 10)												
2	randomized trials	very serious[6,9,t,u]	very serious[v]	not serious[l]	very serious[m]	none	50	54	-	MD **0.98 lower** (16.83 lower to 14.88 higher)	⨁◯◯◯ Very low	CRITICAL
Pain (females and males, either with or without radicular or non-radicular leg pain) (follow-up: closest to 3 months; assessed with: Brief Pain Inventory; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	serious[9,t]	not serious[g]	serious[h]	serious[w]	none	29	31	-	MD **2.3 SD lower** (3.51 lower to 1.09 lower)	⨁◯◯◯ Very low	CRITICAL
Pain (females, no leg pain) (follow-up: closest to 3 months; assessed with: Borg Scale; benefit indicated by lower values; scale: 0 to 10)												
1	randomized trials	very serious[6,b]	not serious[g]	serious[h]	serious[f]	none	21	23	-	MD **0.2 higher** (0.01 lower to 0.41 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on pain stratified by race/ethnicity, number of treatment sessions or in adults in low- or lower middle-income countries not identified												
0												
Function (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
6	randomized trials	very serious[1,2,3,4,7,10,b,o]	not serious[x]	not serious[d]	serious[y]	none	108	91	-	SMD **0.32 lower** (0.71 lower to 0.07 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females (follow-up: closest to 2 weeks; assessed with: modified ODI; benefit indicated by lower values)												
1	randomized trials	very serious[10,b]	not serious[g]	serious[z]	very serious[aa]	none	8	8	-	SMD **0.29 lower** (1.28 lower to 0.69 higher)	⨁◯◯◯ Very low	CRITICAL
Function in females and males (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
5	randomized trials	very serious[1,2,3,4,7,b]	not serious[ab]	not serious[d]	serious[y]	none	100	83	-	SMD **0.32 lower** (0.78 lower to 0.15 higher)	⨁◯◯◯ Very low	CRITICAL
Function in people without leg pain (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
3	randomized trials	very serious[2,7,10,b,o]	not serious[i]	not serious[d]	serious[ac]	none	49	34	-	SMD **0.15 lower** (0.37 lower to 0.08 higher)	⨁◯◯◯ Very low	CRITICAL
Function in people with unclassified presence of leg pain (follow-up: closest to2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
2	randomized trials	very serious[b,o]	not serious[i]	not serious[d]	very serious[ad]	none	27	27	-	SMD **0.08 lower** (0.74 lower to 0.58 higher)	⨁◯◯◯ Very low	CRITICAL
Function in people either with or without radicular leg pain (follow-up: closest to 2 weeks; assessed with: RMDQ; benefit indicated by lower values)												
1	randomized trials	very serious[4,b]	not serious[g]	serious[h]	serious[w]	none	32	30	-	SMD **1.03 lower** (1.56 lower to 0.49 lower)	⨁◯◯◯ Very low	CRITICAL
Function in trials undertaken in low- or lower middle-income countries (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												
3	randomized trials	very serious[2,3,10,b,o]	not serious[i]	not serious[q]	serious[ae]	none	49	34	-	SMD **0.16 lower** (0.36 lower to 0.03 higher)	⨁◯◯◯ Very low	CRITICAL
Function in trials undertaken in high to upper-middle income countries (follow-up: closest to 2 weeks; assessed with: RMDQ; benefit indicated by lower values)												
3	randomized trials	very serious[1,4,7,b]	serious[af]	not serious[ag]	very serious[aa]	none	59	57	-	SMD **0.47 lower** (1.94 lower to 1 higher)	⨁◯◯◯ Very low	CRITICAL
Function in trials using 10-20 TENS treatment sessions (follow-up: closest to 2 weeks; assessed with: ODI, RMDQ; benefit indicated by lower values)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
5	randomized trials	very serious[2,3,4,7,10,b,o]	not serious[ah]	not serious[d]	serious[ai]	none	92	75	-	SMD **0.35 lower** (0.82 lower to 0.12 higher)	⨁◯◯◯ Very low	CRITICAL
Function in trials using <10 treatment sessions (follow-up: closest to 2 weeks; assessed with: RMDQ; benefit indicated by lower values; scale: 0 to 24)												
1	randomized trials	very serious[1,aj,b]	not serious[g]	serious[h]	very serious[ad]	none	16	16	-	SMD **0.12 lower** (0.82 lower to 0.57 higher)	⨁◯◯◯ Very low	CRITICAL
Function (high-income country) (follow-up: closest to 3 months; assessed with: ODI, PDI; benefit indicated by lower values)												
2	randomized trials	very serious[6,9,b]	very serious[ak]	serious[h]	very serious[aa]	none	50	54	-	SMD **1.05 higher** (18.51 lower to 20.61 higher)	⨁◯◯◯ Very low	CRITICAL
Function (females, no leg pain) (follow-up: closest to 3 months; assessed with: ODI; benefit indicated by lower values)												
1	randomized trials	very serious[6,b]	not serious[g]	serious[h]	serious[w]	none	21	23	-	SMD **2.6 higher** (1.78 higher to 3.42 higher)	⨁◯◯◯ Very low	CRITICAL
Function (females and males, either with or without radicular or non-radicular leg pain) (follow-up: closest to 3 months; assessed with: PDI; benefit indicated by lower values)												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
1	randomized trials	serious[9,t]	not serious[g]	serious[h]	serious[y]	none	29	31	-	SMD **0.48 lower** (0.99 lower to 0.04 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on function stratified by race/ethnicity not identified												
0												
Health-related quality of life (no leg pain, high-income country) (follow-up: closest to 2 weeks; assessed with: SF-36 (PCS); benefit indicated by higher values; scale: 0 to 100)												
1	randomized trials	very serious[7,b]	not serious[g]	serious[h]	very serious[al]	none	11	11	-	MD **6.82 lower** (27.06 lower to 13.42 higher)	⨁◯◯◯ Very low	CRITICAL
Health-related quality of life (no leg pain, high-income country) (follow-up: closest to 2 weeks; assessed with: SF-36 (MCS); benefit indicated by higher values; scale: 0 to 100)												
1	randomized trials	very serious[7,b]	not serious[g]	serious[h]	serious[am]	none	11	11	-	MD **2.91 lower** (10.25 lower to 4.43 higher)	⨁◯◯◯ Very low	CRITICAL
Trials on health-related quality of life stratified by gender, race/ethnicity, presence of leg pain or in adults in low- or lower middle-income countries not identified												
0												
Depression (either with or without radicular or non-radicular leg pain, high-income country) (follow-up: closest to 3 months; assessed with: HADS; benefit indicated by lower values; scale: 0 to 21)												
1	randomized trials	serious[9,t]	not serious[g]	serious[h]	very serious[an]		29	31	-	MD **1.4 lower** (5.57 lower to 2.77 higher)	-	CRITICAL
Trials on depression stratified by gender, race/ethnicity, presence of leg pain or in adults in low- or lower middle-income countries not identified												

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Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of trials	Trial design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	TENS	No treatment	Relative (95% CI)	Absolute (95% CI)		
0												
Catastrophizing (either with or without radicular or non-radicular leg pain, high-income country) (follow-up: closest to 3 months; assessed with: Pain Catastrophizing Scale; benefit indicated by lower values; scale: 0 to 52)												
1	randomized trials	serious[9,t]	not serious[g]	serious[h]	serious[w]	none	29	31	-	MD **11.2 lower** (17.88 lower to 4.52 lower)	⨁◯◯◯ Very low	CRITICAL
Trials on catastrophizing stratified by gender, race/ethnicity, presence of leg pain or in adults in low- or lower middle-income countries not identified												
0												
Trials on fear avoidance, anxiety, self-efficacy or social participation not identified												
0												
Adverse events/harms (high-income country, either with or without leg pain (radicular or non-radicular)												
1	randomized trials	serious[t]	not serious[g]	serious[h]	serious[w]	none	Authors reported that none of the participants reported experiencing any long-term adverse events from using high-frequency TENS.				⨁◯◯◯ Very low	CRITICAL
Trials on adverse events/harms stratified by gender, race/ethnicity or in adults in low- or lower middle-income countries not identified												
0												
OLDER ADULTS (aged 60 years or more)												
Trials in older adults on pain, function, health-related quality of life, depression, fear avoidance, catastrophizing, anxiety, self-efficacy, social participation, adverse events, change in use of medications or falls not identified												
0												

BDI: Beck Disabiltiy Index; **CI:** confidence interval; **MCS:** Mental Component Summary; **MD:** mean difference; **MPQ:** McGill Pain Questionnaire; **NRS:** numeric rating scale; **ODI:** Oswestry Disability Index; **OIS:** Optimal Information Size; **PCS:** Physical Component Summary; **PDI:** Pain Disability Index; **RMDQ:** Roland-Morris Disability Questionnaire; **SMD:** standardized mean difference; **VAS:** visual analogue scale

The following was used to guide the ratings:
Risk of bias: *Not serious:* all or most of the weight (>50%) comes from overall low risk of bias trial(s). *Serious:* some of the weight (<50%) comes from overall low risk of bias trial(s). *Very serious:* all or most of the weight (>50%) comes from overall high or unclear risk of bias trial(s).
Inconsistency: *Not serious:* high extent of similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 0% and 40%, which might not be important. *Serious:* some extent of similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 30% and 60%, which could not be explained due to small subgroups and may represent moderate

heterogeneity. *Very serious:* little or no similarity of point estimates and overlap of confidence intervals; statistical heterogeneity (I^2) is between 50% and 90% or 75% and 100%, which could not be explained due to small subgroups and may represent substantial or considerable heterogeneity, respectively.

Indirectness: *Not serious:* trial(s) were conducted in different countries or settings. *Serious:* trial(s) were conducted from a single country/setting. *Very serious:* evidence is not directly related to PICO question.

Imprecision: *Not serious:* Optimal Information Size (OIS) was reached (i.e., sample sizes with at least 200 participants per group may provide prognostic balance); and the entire confidence interval lies on one side of the threshold that may be considered clinically important (≥10% scale range or SMD ≥0.2 for continuous variables, ≥10% for binary variables), such that the clinical course of action would not differ if the upper versus the lower boundary of the confidence interval represented the truth. *Serious:* OIS would not have been reached (sample sizes with less than 200 participants per group); if the OIS was reached, the clinical course of action might differ if the upper versus the lower boundary of the confidence interval represented the truth. *Very serious:* similar to 'serious' but to a greater extent (e.g., very small sample sizes and confidence intervals crossing appreciable benefit and harm).

Other considerations: *Not serious:* Publication bias is undetected. *Serious/very serious:* Publication bias is strongly suspected.

Explanations

a. Elserty 2016 included 2 arms (fixed pulse TENS + exercise vs. exercise; adjusted pulse TENS + exercise vs. exercise). Both were included in meta-analysis by splitting the comparison group number in half. Petrofsky 2020 included 4 arms (Continuous TENS + spent sham heat vs. spent sham heat; continuous TENS + LLCH (low-level continuous heat) vs. LLCH; TENS last 15 min + LLCH vs. LLCH; TENS last 15 min + spent sham heat vs. spent sham heat). All were included in meta-analysis by splitting the comparison group numbers accordingly.
b. Risk of bias: We downgraded twice. Most or all of the trials were rated as overall high risk of bias.
c. Inconsistency: We did not downgrade. The point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 6%).
d. Indirectness: We did not downgrade. Trials are included from different countries both high- and lower-middle income.
e. Imprecision: We downgraded once. The sample size is small (OIS would not have been achieved). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -1). The confidence interval crossed the null but not the thresholds for what may be considered appreciable benefit (-1) or harm (+1).
f. Imprecision: We downgraded once. The sample size was small (OIS would not have been reached). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (MD = -1); the confidence interval did not cross the null.
g. Inconsistency: We did not downgrade; however, there are no additional trials with which to compare these findings.
h. Indirectness: We downgraded once. This is a single trial from a single centre (high or upper-middle income country).
i. Inconsistency: We did not downgrade. The point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 0%).
j. Imprecision: We downgraded once. The sample size was small (OIS would not have been reached). The point estimate did not reach the threshold for what may be considered clinically important (MD = -1); the confidence interval did not cross the null.
k. Inconsistency: We downgraded once. The point estimates are close with some overlap in the confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 65%). This could not be explained due to small subgroups and may represent substantial heterogeneity.
l. Indirectness: We did not downgrade because the trials were conducted in different countries (high or upper-middle income).
m. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (MD = -1); the confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds of appreciable benefit (MD = -1) and harm (MD = +1).
n. Inconsistency: We did not downgrade. The point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 10%).
o. Elserty 2016 included 2 arms (fixed pulse TENS + exercise vs. exercise; adjusted pulse TENS + exercise vs. exercise). Both were included in meta-analysis by splitting the comparison group number in half.
p. Inconsistency: We did not downgrade. The point estimates differ in direction but the confidence intervals overlap; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 4%).
q. Indirectness: We did not downgrade because the trials were conducted in different countries (low or lower-middle income).
r. Inconsistency: We did not downgrade. The point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 30% and 60%, which may represent moderate heterogeneity (i.e., I2 = 48%).
s. Depaoli Lemos 2021 used 4 TENS sessions; Petrofsky 2020 used a single TENS session.
t. Risk of bias: We downgraded once due to the potential for selection, performance and other biases.
u. Kofotolis and Jamison: Participants had 20-90 treatment sessions.
v. Inconsistency: We downgraded twice. The point estimates were in different directions with little to no overlap in confidence intervals. Statistical heterogeneity is between 75% and 100% (i.e., I2 = 94%). This could not be explained due to small subgroups and may represent considerable heterogeneity.
w. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached).
x. Inconsistency: We did not downgrade. Most of the point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 28%).
y. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached). The point estimate reached the pre-specified threshold for what may be considered appreciable benefit (SMD = -0.2). The confidence interval crossed the null.
z. Indirectness: We downgraded once. This is a single trial from (low or lower-middle income country).
aa. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate reached the pre-specified threshold for what may be considered clinically important (SMD = -0.2); the confidence interval crosses the null.
ab. Inconsistency: We did not downgrade. Most of the point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 39%).

ac. Imprecision: We downgraded once. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (SMD = -0.2). The confidence interval crossed the null but the upper boundary did not cross the pre-specified threshold for what may be considered appreciable harm (SMD = +0.2).
ad. Imprecision: We downgraded twice. The sample size is small (OIS would have not been achieved). The point estimate did not reach the pre-specified threshold for what may be considered clinically important (SMD = -0.2); the confidence interval crosses the null with the lower and upper boundaries crossing the pre-specified thresholds for what may be considered appreciable benefit (SMD = -0.2) and harm (SMD = +0.2).
ae. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (SMD = -0.2). The confidence interval crossed the null.
af. Inconsistency: We downgraded once. There was some difference in magnitude and direction of the point estimates, but there was some overlap in confidence intervals. Statistical heterogeneity is between 50% and 90% (i.e., I2 = 69%). This could not be explained due to small subgroups and may represent substantial heterogeneity.
ag. We did not downgrade because the trials were conducted in different countries.
ah. Inconsistency: We did not downgrade. Most of the point estimates are similar with overlapping confidence intervals; statistical heterogeneity is between 0% and 40%, which might not be important (i.e., I2 = 39%).
ai. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached). The point estimate reached the pre-specified threshold for what may be considered appreciable benefit (SMD = -0.2). The confidence interval crossed the null but the upper boundary did not cross the pre-specified threshold for what may be considered appreciable harm (SMD = +0.2).
aj. Depaoli Lemos 2021 used 4 TENS sessions.
ak. Inconsistency: We downgraded twice. The point estimates were in different directions with little to no overlap in confidence intervals. Statistical heterogeneity is between 75% and 100% (i.e., I2 = 97%). This could not be explained due to small subgroups and may represent considerable heterogeneity.
al. Imprecision: We downgraded twice due to small sample size (the OIS would not have been reached). The point estimate did not reach the pre-specified threshold for what may be considered appreciable harm (-10). The confidence interval crossed the null with the boundaries crossing the pre-specified thresholds for what may be considered appreciable harm (-10) and benefit (+10).
am. Imprecision: We downgraded once due to small sample size (the OIS would not have been reached). The point estimate did not reach the pre-specified threshold for what may be considered appreciable harm (MD = -10). The confidence interval crossed the null.
an. Imprecision: We downgraded twice due to small sample size (the OIS would not have been reached). The point estimate did not reach the pre-specified threshold for what may be considered appreciable benefit (MD = -2.1). The confidence interval crossed the null with the boundaries crossing the pre-specified thresholds for what may be considered appreciable benefit (-2.1) or harm (+2.1).

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