

Table 21: Clinical evidence profile: bilateral pallidal deep brain stimulation versus pre-operative

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bilateral pallidal deep brain stimulation	preoperative	Relative (95% CI)	Absolute (95% CI)		
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 General Health; Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 3.30 higher to 10.54 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Physical Functioning; Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	serious b	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 3.46 higher to 30.00 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Role (Physical); Scale from: 0 to 100; Higher better)</b>												

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No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bilateral pallidal deep brain stimulation	preoperative	Relative (95% CI)	Absolute (95% CI)		
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 4.62 higher to 43.40 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Role (Emotional); Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 23.09 higher to 29.10 higher)	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Social Functioning; Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 0.96 higher to 23.40 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Body pain; Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 18.54 higher to 36.80 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Vitality; Scale from: 0 to 100; Higher better)</b>												

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No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bilateral pallidal deep brain stimulation	preoperative	Relative (95% CI)	Absolute (95% CI)		
2	observational studies	not serious	not serious	not serious	serious <sup>3</sup>	none	28	28	-	HRQoL after DBS ranged from 2.31 higher to 15.70 higher	VERY LOW	CRITICAL
<b>HRQoL (follow up: range 1 years to 4 years; assessed with: SF-36 Mental health; Scale from: 0 to 100; Higher better)</b>												
2	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	28	28	-	HRQoL after DBS ranged from 8.92 higher to 15.70 higher	VERY LOW	CRITICAL
<b>Dystonia (follow up: range 6 months to 4 years; assessed with: Burke-Fahn-Marsden movement scale; Scale from: 0 to 120; Lower better)</b>												
4	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	42	42	-	Dystonia after DBS ranged from 7.60 lower to 35.40 lower	VERY LOW	CRITICAL
<b>Dystonia (follow up: range 6 months to 4 years; assessed with: Burke-Fahn-Marsden disability scale ; Scale from: 0 to 30; Lower better)</b>												
4	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	42	42	-	Dystonia after DBS ranged from 0.40 lower to 6.60 lower	VERY LOW	CRITICAL
<b>Satisfaction - not reported</b>												
-	-	-	-	-	-	-	-	-	-	-	-	CRITICAL
<b>Motor function - not reported</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bilateral pallidal deep brain stimulation	preoperative	Relative (95% CI)	Absolute (95% CI)		
-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
<b>Adverse events - Hypophonia (follow up: 4 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 2/15 (13%)				VERY LOW	IMPORTANT
<b>Adverse events - Dysarthria (follow up: 4 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 4/15 (27%)				VERY LOW	IMPORTANT
<b>Adverse events - Local pain (follow up: range 1 years to 4 years)</b>												
2	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate ranged from 1/13 (8%) to 2/15 (13%)				VERY LOW	IMPORTANT
<b>Adverse events - Paraesthesia (follow up: 4 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 2/15 (13%)				VERY LOW	IMPORTANT
<b>Adverse events - Anxiety (follow up: 1 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 5/13 (38%)				VERY LOW	IMPORTANT
<b>Adverse events - Stimulation adjusted due to insufficient benefit (follow up: 1 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 4/13 (31%)				VERY LOW	IMPORTANT
<b>Adverse events - Stimulator failure (exposure to magnetic field) (follow up: 1 years)</b>												
1	observational studies	serious <sup>4</sup>	not serious	not serious	serious <sup>2</sup>	none	Rate was 1/13 (8%)				VERY LOW	IMPORTANT
<b>Goal attainment scores - not reported</b>												
-	-	-	-	-	-	-	-	-	-	-	-	IMPORTANT
<b>Pain (follow up: 1 years)</b>												

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Bilateral pallidal deep brain stimulation	preoperative	Relative (95% CI)	Absolute (95% CI)		
1	observational studies	not serious	not serious	not serious	serious <sup>2</sup>	none	13	13	-	MD 0.93 lower (2.79 lower to 0.93 higher)	VERY LOW	IMPORTANT