

(from Gadot & Najera et al., 2021)

Supplementary File A. Detailed overview of all complications and adverse events from systematic review.

Serious Adverse Events (SAEs) – transient/permanent	n	%
Surgery-related		
Infection (surgically treated) – transient	5	2.0
Infection (antibiotics only) – transient	5	2.0
Intracranial hemorrhage (asymptomatic) – transient	2	0.8
Intracranial hemorrhage (w/ sequelae) ¹ – permanent	2	0.8
Device-related ²		
Mispositioned electrodes – transient	8	3.2
Allergy to device – transient	5	2.0
Mispositioned pulse generator – transient	2	0.8
Lead breakage – transient	1	0.4
Tension in cables – transient	1	0.4
Pulse generator erosion through skin – transient	1	0.4
Unexpected battery depletion – transient	1	0.4
High impedance – transient	1	0.4
Stimulation-induced		
Pain associated with leads or pulse generator – permanent	15	6.0
Increased libido – permanent	6	2.4
Seizures (generalized tonic-clonic) – transient	5	2.4
Seizures (absences or partial) – transient	3	1.2
Forgetfulness – permanent	3	1.2
Micturition, enuresis, polyuria – permanent	2	0.8
<i>De novo</i> obsession associated with DBS therapy/device – permanent	2	0.8
Word-finding difficulties – permanent	1	0.4
Increased irritability, anger, impulsivity – permanent	1	0.4
Sleep disorder – permanent	1	0.4
Compulsive gambling – permanent	1	0.4
Other ³		
Suicide attempts	6	2.4
Suicide	1	0.4
¹ Sequelae include permanent finger palsy (1) & permanent dysarthria (1)		
² Excludes expected battery depletion and subsequent pulse generator replacement; includes only those SAEs where unexpected surgical revision, removal, or replacement of leads/pulse generator were required		
³ In 1 patient the following occurred (not included in previously listed SAEs): generalized tonic-clonic seizure, bronchopneumonia, intracranial infection, pleural effusion, pneumothorax, shock, axillary vein thrombosis, pharmacologically induced coma		

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Transient, Non-Serious, Stimulation-Induced Adverse Events	n	%
Hypomania	30	25.2
Gastrointestinal upset (nausea, vomiting/emesis, diarrhea, stomachaches)	7	5.9
Worse anxiety	6	5.0
Sleep disorder	6	5.0
Headaches	5	4.2
Dysgeusia/ageusia	4	3.4
Worse depression	3	2.5
Tiredness	3	2.5
Paresthesias in hands or feet	3	2.5
Disinhibition	3	2.5
Jaw sensations	2	1.7
Facial asymmetry	2	1.7
Aggression	2	1.7
Difficulty with concentration	2	1.7
Significant weight gain (> 20%)	2	1.7
Dysphagia	1	0.8
Walking difficulties	1	0.8
Dyskinesias	1	0.8
Worse obsessions	1	0.8
Dyspnea	1	0.8
Sexual intrusions	1	0.8
Dizziness	1	0.8
Forgetfulness	1	0.8
Dysarthria	1	0.8
Visual disturbance	1	0.8
Vertigo	1	0.8
Olfactory hallucinations	1	0.8
Déjà vu	1	0.8
Tingling or other sensation in chest wall	1	0.8
Reduced libido	1	0.8
Sympathetic signs (flushing, tachycardia, hypertension)	1	0.8

Supplementary File B. Thompson & Sharp Test for Funnel Plot Asymmetry. Standardized treatment effect plotted as a predictor weighted by the inverse variance. Non-significant effect seen suggesting random dispersion of treatment effect irrespective of study size. Additive residual heterogeneity variance by the DerSimonian-Laird method for $\tau^2 = 14.5481$.

