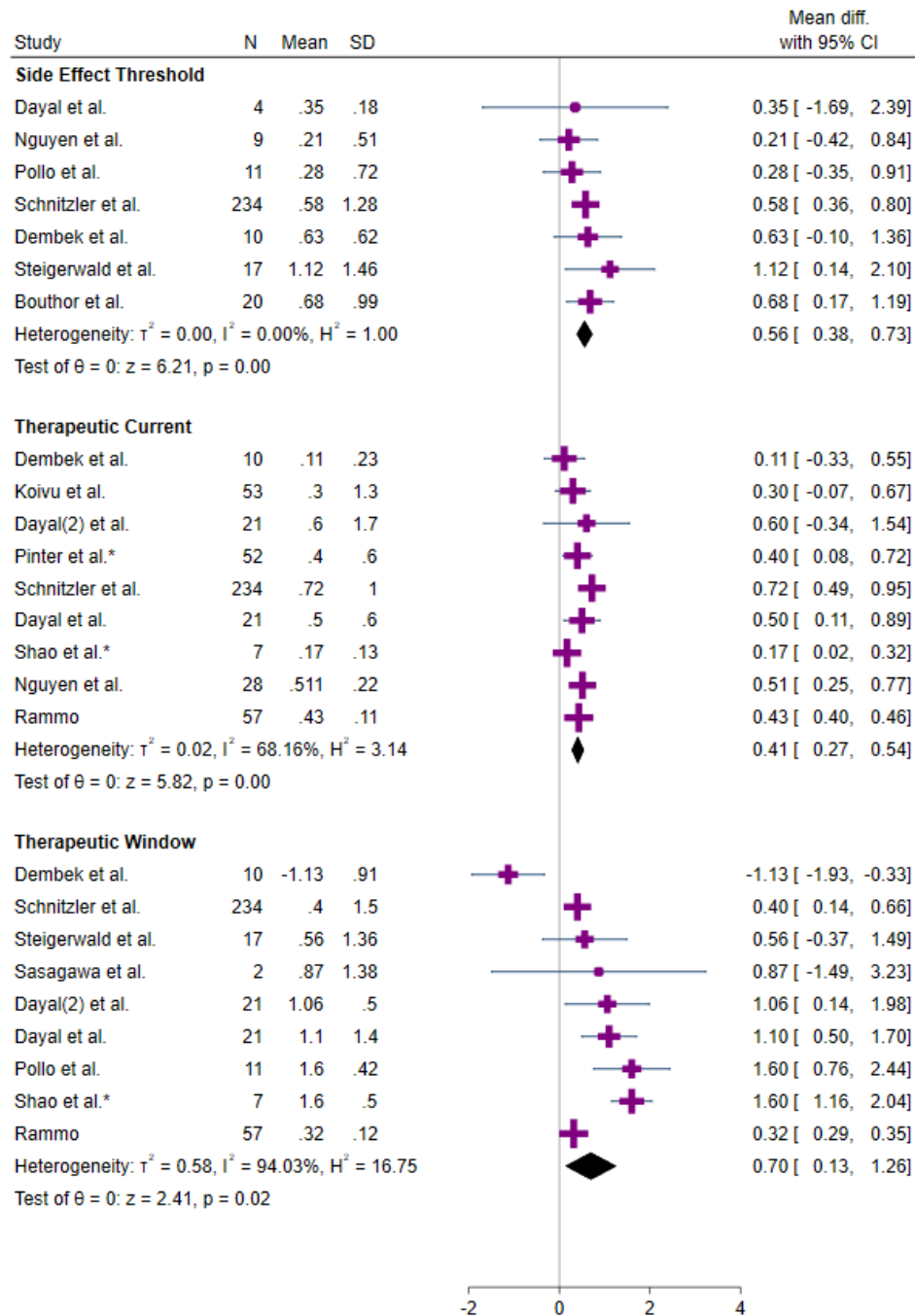
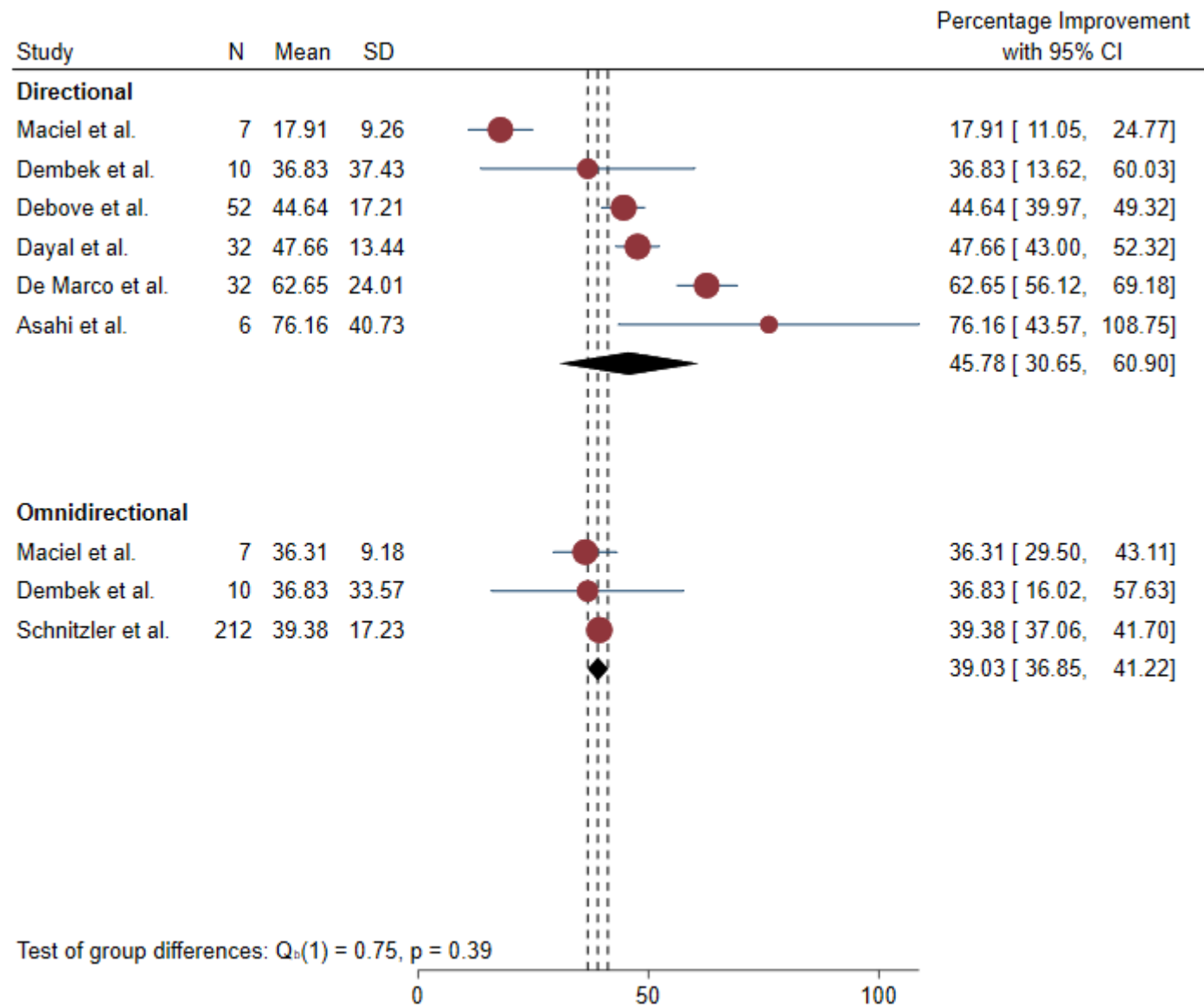


**Figure 1:** Flowchart detailing study selection. dDBS = Directional Deep Brain Stimulation, PD = Parkinson’s Disease. Made with BioRender

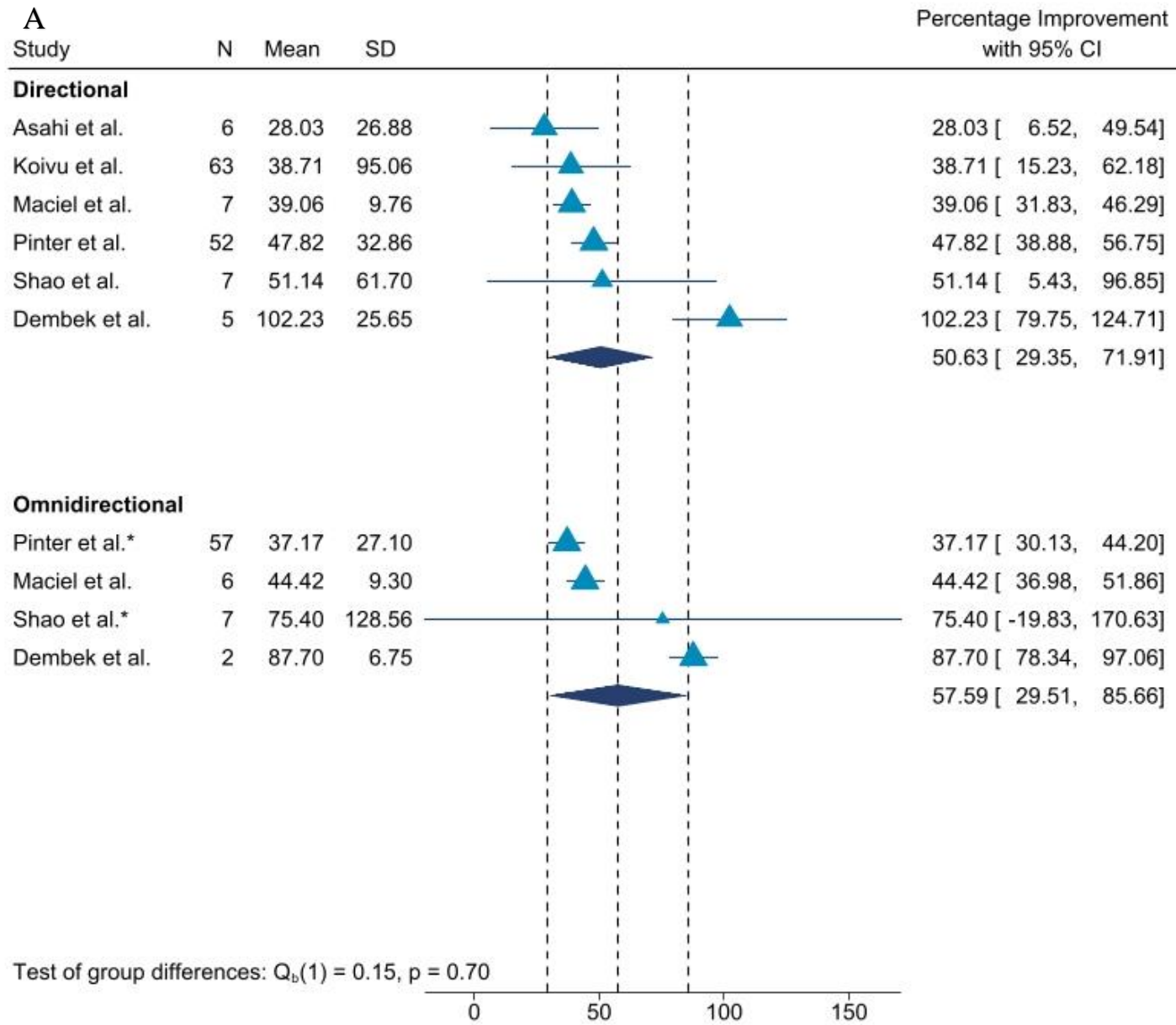


**Figure 2:** Overall comparison of stimulation parameters such as side effect threshold, therapeutic current and therapeutic window in dDBS compared to conventional. Positive indicates in favor of dDBS. . \*Studies include data on conventional omnidirectional electrodes.



Random-effects REML model

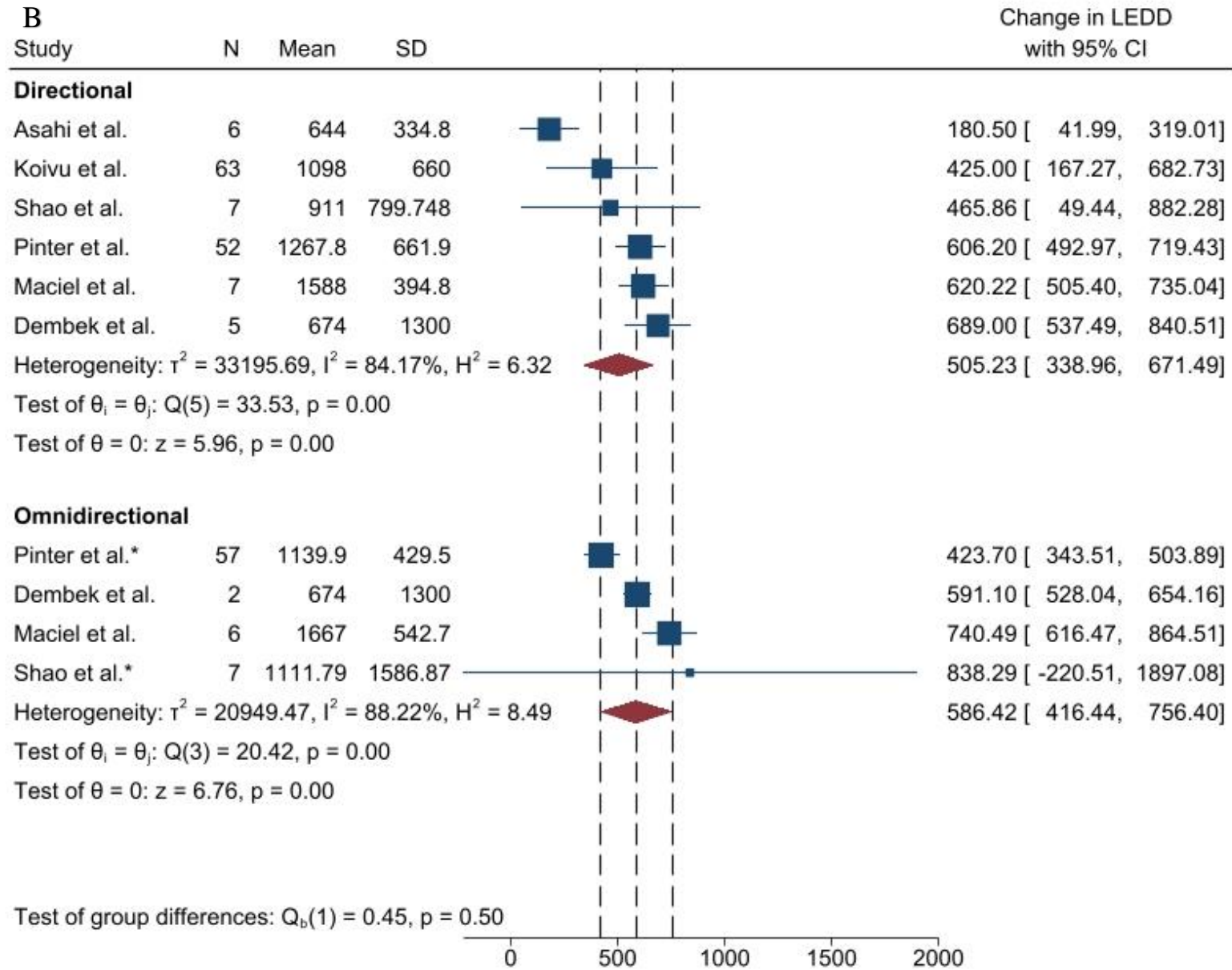
**Figure 3.** Percentage change in UPDRS III in directional DBS compared to omnidirectional in the medication OFF condition. Dashed lines indicate mean and 95 % confidence interval for conventional DBS. When computed comparing raw changes in UPDRS III, there were significant differences, favoring dDBS ( $p < 0.001$ ). However, when taking baseline UPDRS III score into account, these differences disappeared ( $p = 0.39$ )



Random-effects REML model



**B**



Random-effects REML model



**Figure 4:** Comparison of changes in LEDD in dDBS compared to oDBS in percentage (A) and in absolute values converted to LEDD in mg (B). LEDD = Levodopa equivalent daily dosage. \*Studies comparing dDBS to conventional omnidirectional electrodes.

| <b>Table 1:</b> Summary of all studies included. |  |                     |               |           |             |            |           |                              |                          |  |
|--|--|---------------------|---------------|-----------|-------------|------------|-----------|------------------------------|--------------------------|--|
| <b>Study</b>                                     | <b>dLeads/patients<br/>(conventional<br/>leads/patients)</b> | <b>Mean<br/>F/U</b> | <b>Target</b> | <b>TW</b> | <b>TEED</b> | <b>SET</b> | <b>TC</b> | <b>Clinical<br/>outcomes</b> | <b>Other<br/>aspects</b> | <b>Summary</b>   |
| Asahi, T et al. 2019[1]                          | 12/6   | 1 y                 | STN           | N/A       | N/A         | N/A        | N/A       | UPDRS-III,<br>LEDD           | Side effects             | The mean UPDRS-III score improved significantly ( $p = 0.03$ ) with directional stimulation. There was an insignificant reduction in the LEDD ( $p=0.1$ ). |

|                             |        |       |     |     |     |     |     |                    |                           |   |
|-----------------------------|--------|-------|-----|-----|-----|-----|-----|--------------------|---------------------------|---|
| Bouthour, W et al. 2019 [2] | 20/10  | 12 m  | STN | N/A | N/A | N/A | N/A | LEDD<br>UPDRS-III  | Side effects              | There was a greater improvement in stimulation-induced dyskinesia with directional stimulation with anti-bradykinetic effects and alleviation of dyskinesia maintained at 1-year follow up.   |
| Dayal, V et al. 2020[3]     | 64/32  | 6 m   | STN | +   | N/A | +   | N/A | UPDRS-III          | Side effects, utilisation | Directional steering combined with shorter pulse width significantly improved stimulation-induced dyskinesia ( $p < 0.001$ ), dysarthria ( $p = 0.005$ ) and pyramidal adverse effects ( $p = 0.015$ ) acutely and at follow up compared to omnidirectional steering and at larger pulse width. |
| De-Marco, R et al. 2020[4]  | 64/32  | 6 m   | STN | N/A | N/A | N/A | N/A | UPDRS-III          | N/A                       | At follow-up, there was a 62.65% improvement in the UPDRS-III   |
| Debove, I et al. 2023[5]    | 104/52 | 5-9 m | STN | N/A | N/A | N/A | N/A | UPDRS III,<br>LEDD | N/A                       | At follow-up, there was a 74% improvement in the LEDD and 45% in UPDRS-III  |
| Dembek, TA et al. 2017[6]   | 20/10  | 3-6 m | STN | +   | N/A | +   | +   | UPDRS III,<br>LEDD | N/A                       | Directional steering led to significantly larger TWs ( $p = 0.09$ ) and higher SET ( $p = 0.01$ ) compared to omnidirectional stimulation. At follow-up, there was a 56% improvement in UPDRS III and a 48% reduction in LEDD.  |
| Hurt, C et al. 2023[7]      | 31/31  | 1 m   | STN | N/A | N/A | +   | N/A | N/A                | Side effect               | Directional stimulation yielded better side effect thresholds than ring stimulation ( $P = 0.001$ ). This mildly correlated with motor improvement.   |

|                           |        |                 |             |     |     |     |     |                 |   |   |
|---------------------------|--------|-----------------|-------------|-----|-----|-----|-----|-----------------|---|---|
| Karl, J et al. 2022[8]    | 104/56 | 3, 12, 24, 36 m | STN/GPi/ViM | N/A | N/A | N/A | N/A | N/A             | Side effects, battery life, utilisation | The number of patients on a directional mode increased during the course of the study. Reasons were better symptom control, reduction of side-effects or both.  |
| Koivu, M et al. 2022[9]   | 106/53 | 6, 12, 18 m     | STN         | N/A | N/A | N/A | +   | LEDD            | Battery life, utilisation               | There was significant reduction in the therapeutic current with single contact stimulation ( $p=0.001-0.05$ ) compared to two segment activation and ring mode. And reduction in the LEDD at follow-up ( $p=0.013$ ). Battery consumption was not significant between dDBS and oDBS at 6, 12 and 18 months. |
| Maciel, R et al. 2021[10] | 25/14  | 3 m             | STN         | N/A | N/A | N/A | N/A | UPDRS-III, LEDD | Side-effects, battery life, utilisation | 69.2% of the patients initially on ring mode required directionality due to stimulation-induced side-effects. All side-effects improved with steering. Battery consumption was comparable.  |
| Mishra, A et al. 2022[11] | 45/28  | 12m             | STN, GPi    | N/A | N/A | N/A | N/A | LEDD            | Adverse events, utilisation             | There was a 4% increase in the number of patients on a directional mode throughout the follow-up period. DBS led to a significant reduction in the LEDD, although there was no difference between oDBS and dDBS.  |
| Nguyen, TA et al 2019[12] | 56/28  | 4-6 m           | STN         | N/A | N/A | -   | +   | N/A             | N/A                                     | There was significant reduction in therapeutic current with directional stimulation compared to omnidirectional stimulation ( $p=0.004$ ) with no significant difference in side-effect threshold.  |

|                               |                 |           |     |     |     |     |     |                 |   |   |
|-------------------------------|-----------------|-----------|-----|-----|-----|-----|-----|-----------------|---|---|
| Pinter, D et al. 2023[13]     | 104/52 (114/57) | 12 m      | STN | N/A | N/A | N/A | N/A | UPDRS-III, LEDD | Adverse events                          | Directional stimulation led to a comparable symptomatic improvement as conventional stimulation but greater improvement in HR-QoL and greater reduction in the LEDD and total dose of antiparkinson medication. TEED was comparable.  |
| Rammo, R et al. 2022[14]      | 105/57          | 4w, 12m   | STN | +   | +   | N/A | N/A | UPDRS-III       | Utilisation                             | Directional stimulation led to a significant reduction in TEED (P=<0.05) and therapeutic current (p=0.0001) and an insignificant improvement in the TW.   |
| Sabourin, S et al. 2020[15]   | 17/9            | 2-19 m    | STN | N/A | N/A | N/A | N/A | UPDRS III       | N/A                                     | No significant difference in the UPDRS III was seen between directional or ring mode.   |
| Sasagawa, A. et al 2020[16]   | 2/4             | 1 m       | STN | +   | N/A | N/A | N/A | UPDRS-III       | N/A                                     | Directional stimulation of structures adjacent to the STN led to reduction of some parkinsonian symptoms.   |
| Schnitzler, A et al. 2016[17] | 468/234         | 3 and 6 m | STN | +   | N/A | +   | +   | UPDRS-III       | Utilisation, side effects, battery life | Directional stimulation led to a significantly higher TW, SET and lower TC compared to omnidirectional. Clinical outcomes were comparable. More adverse events and stimulation-induced side effects occurred during the first three months when oDBS was used. More subjects and clinicians preferred the directional period. |
| Shao, M et al. 2020[18]       | 14/7 (14/7)     | 6m        | STN | +   | N/A | N/A | N/A | UPDRS-III       | Utilisation<br>Side effects             | Motor outcomes and reduction in LEDD at 6 months was comparable between directional and   |

|                                |                         |             |          |     |     |     |     |                     |                |   |
|--------------------------------|-------------------------|-------------|----------|-----|-----|-----|-----|---------------------|----------------|---|
|                                |                         |             |          |     |     |     |     |                     |                | conventional leads. The therapeutic window was significantly greater in the directional system whether or not directionality was used.  |
| Shub, A et al. 2020[19]        | 29/18                   | N/A         | STN, GPi | N/A | N/A | N/A | N/A | LEDD                | N/A            | Directional stimulation led to a significant reduction in the LEDD (P=0.008) amongst patients implanted with directional leads.   |
| Steigerwald, F et al. 2016[20] | 14/7                    | 7 d, 4m     | STN      | +   | N/A | +   | N/A | N/A                 | Utilisation    | A higher TW was seen in dDBS. At follow-up, all patients remained on directional mode with none reporting stimulation-induced side effects.   |
| Steffen, J et al. 2020[21]     | 7/7                     | 3-11m       | VIM      | N/A | N/A | +   | N/A | Tremor Rating Scale | N/A            | In patients with tremor dominant PD and VIM DBS, a significantly higher SE threshold was seen on directional or bipolar settings compared to monopolar omnidirectional (p=0.0063) settings. Additional benefit was seen with directional bipolar stimulation. |
| Wu, C et al. 2021[22]          | n/a / 386 (n/a / 2,127) | 3, 12, 24 m | N/A      | N/A | N/A | N/A | N/A | N/A                 | Adverse events | Lead complications attributable to mispositioned electrodes or lack of therapeutic effect were less likely to occur in directional leads. Rates of infection or hardware malfunction were comparable between directional and omnidirectional systems.         |
| Zitman, F et al. 2021[23]      | 59 / 30                 | 6-23m       | STN      | N/A | N/A | N/A | N/A | N/A                 | Utilisation    | At median 15 months follow up, 20% of electrodes in PD patients were on a directional mode.   |

Legend:

+, improvement with directional stimulation reported; -, no improvement with directional stimulation reported.

Abbreviations:

TW - therapeutic window, TEED - total electrical energy delivered, S/E - side-effect, SET - side-effect threshold, TC - therapeutic current, F/U - follow-up, STN - subthalamic nucleus, LEDD - Levodopa equivalent dose, UPDRS - Unified Parkinson's Disease Rating Scale, I/O - intra-operative, GPi - Globus Pallidus internus, ViM - ventral intermediate nucleus, NA - not available

**Table 2:** Summary of studies reporting on Side effects, other aspects and battery life

| Study                          | dLeads / pts<br>(cLeads/ pts) | Target | Length of f/u<br>(proportion on<br>directional settings)                | Effect of dDBS<br>on side effects<br>compared to<br>ring mode | Adverse events (%leads) | Battery life<br>(length of f/u) |
|--------------------------------|-------------------------------|--------|---|---|-------------------------|---------------------------------|
| Asahi, T et al.<br>2019[1]     | 12/6                          | STN    | n/a   | n/a   | n/a                     | n/a                             |
| Bouthour, W et al.<br>2019 [2] | 20/10                         | STN    | 3m (90% patients)<br>12m (90% patients)                                 | Dyskinesia +  | n/a                     | n/a                             |
| Dayal, V et al.<br>2020[3]     | 64 / 32                       | STN    | Initial (97% leads)<br>6m (90% leads)                                   | Dyskinesia +<br>Dysarthria +<br>Pyramidal +                   | n/a                     | n/a                             |
| Karl, J et al.<br>2022[8]      | 91 / n/a                      | STN    | 3m (22% leads)<br>12m (25% leads)<br>24m (27% leads)<br>36m (60% leads) | n/a*  | n/a                     | n/a*                            |
| Koivu, M et al.<br>2022[9]     | 106 / 53                      | STN    | Initial (93% leads)<br>6m (75% leads)                                   | n/a   | Lead replacement (n= 1) | - (6, 12, 18m)                  |

|                                |                    |     |  |   |   |        |
|--------------------------------|--------------------|-----|--|---|---|--------|
|                                |                    |     | 18m (70.5% leads)                            |   | Superficial wound infection requiring antibiotics (n= 4)<br>Severe dDBS system-related infections (0%)<br>Intracranial hemorrhage (0%)  |        |
| Maciel, R et al 2021[10]       | 25 / 14            | STN | 3m (76% leads)                               | Dyskinesia +/-<br>Dysarthria +<br>Pyramidal + | n/a   | - (3m) |
| Mishra et al. 2022[11]         | 45 / 28            | STN | Initial (60% leads)<br>14m (64% leads)       | n/a*  | Revision due to malpositioned leads (22% of leads at 6 m)   | n/a    |
| Pinter, D et al. 2023[13]      | 104/52<br>(114/57) | STN | n/a  | n/a   | Intracranial infections (0%)<br>Intracranial hemorrhage (0%)  | n/a    |
| Rammo, R et al. 2022 [14]      | 105 / 57           | STN | Initial (65% patients)<br>12m (75% patients) | n/a   | n/a   | n/a    |
| Schnitzler, A et al. 2022[17]  | 468 / 234          | STN | 6m (52.8% leads)                             | n/a*  | Intracranial infection (0%)<br>Intracranial hemorrhage (0%)<br>5.5% device or procedure related adverse events:<br>- Battery depletion (n =1)<br>- Extension breakage (n=1)<br>- Lead fracture (n=1)<br>- Lead migration (n=1)<br>- Lead malpositioning (n=1)<br>- Cognitive impairment (n=1)<br>- Edema at site of lead (n=1)<br>-Erosion (n=2)<br>- Undesirable changes in stimulation (n=1)<br>- High impedance (n=1)<br>- Impaired wound healing (n=1)<br>- Skull discoloration (n=1) | n/a*** |
| Shao, M et al. 2020[18]        | 14 / 7             | STN | 6m (36% leads)                               | Dyskinesia +                                  | n/a   | n/a    |
| Steigerwald, F et al. 2016[20] | 14 / 7             | STN | Initial (100% leads)<br>4m (100% leads)      | Dysarthria +<br>Pyramidal +                   | n/a   | n/a    |

|                              |                           |       |                 | Dysesthesia + |  |     |
|------------------------------|---------------------------|-------|-----------------|---------------|--|-----|
| Wu, C et al.<br>2021[22]     | n/a / 2127<br>(n/a / 386) | N/A** | n/a             | n/a           | No difference in infection rate or hardware malfunction; higher revision rate in conventional group. | n/a |
| Zitman, F et al.<br>2021[23] | 59 / 30                   | STN   | 15m (27% leads) | n/a*          | n/a ***  | n/a |

Legend:

+, improvement with directional stimulation reported; -, no improvement with directional stimulation reported.

\* Subjective comments provided without quantitative data

\*\* do not specify the target

\*\*\*mentioned in relation to patients who were withdrawn from the study

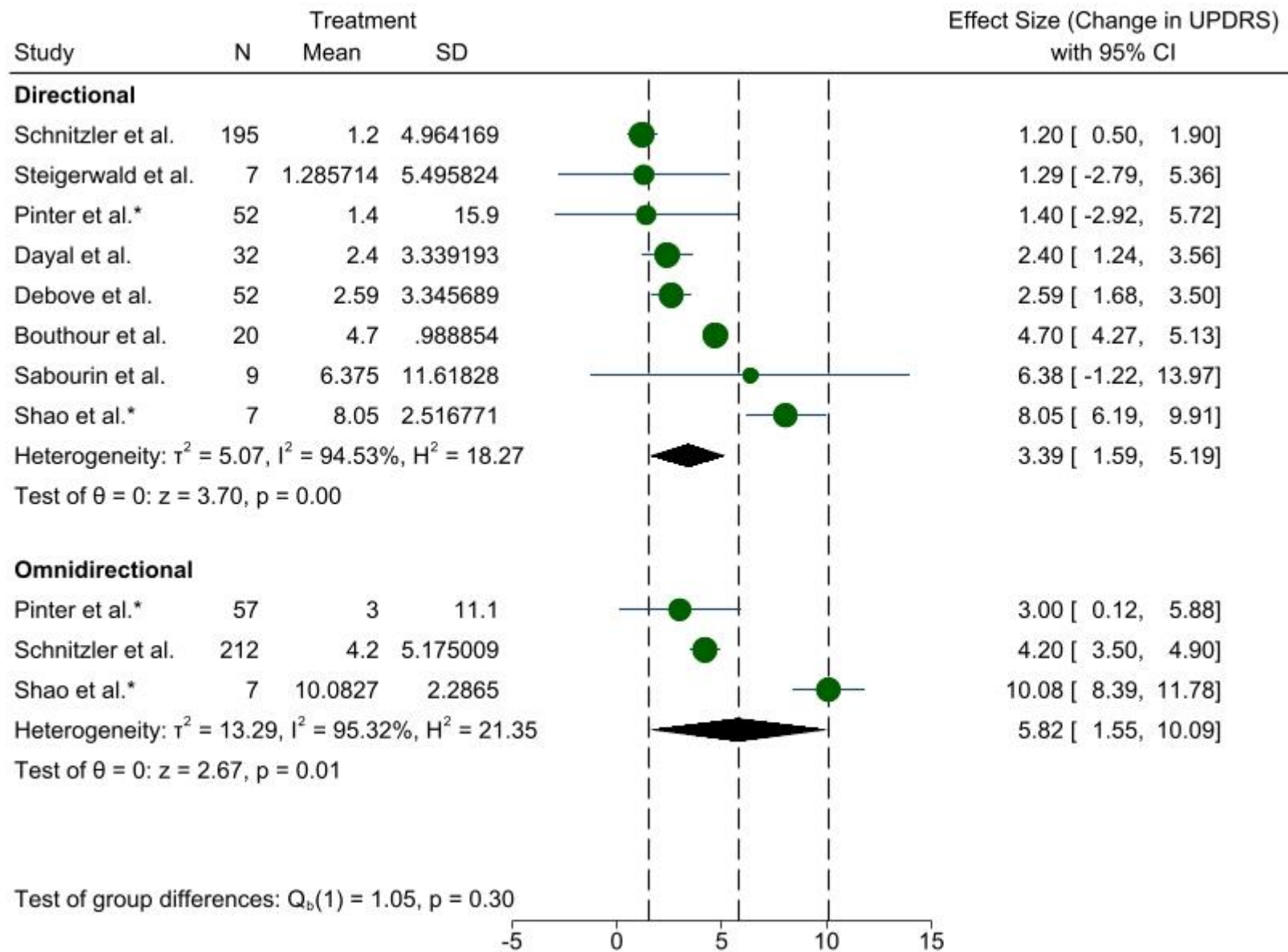
# required changes in additional stimulation parameters (e.g. pulse with)

Abbreviations:

dLeads – directional leads, cLeads – conventional leads, oDBS – omnidirectional DBS, F/U – follow up, S/E - side-effects, A/E - adverse events, n/a - not applicable, TC – therapeutic current.







Random-effects REML model

**Supplementary Figure 1.** Difference in total UPDRS III in dDBS compared to oDBS in the medication ON condition. Dashed lines indicate mean and 95 % confidence interval for conventional DBS. \*Studies on conventional omnidirectional electrodes.

| Demographic Variables |                  |                            |            |          |             |      | BASELINE                 |      |                                | OFF MEDICATION           |                        |   |                    |      |
|-----------------------|------------------|----------------------------|------------|----------|-------------|------|--------------------------|------|--------------------------------|--------------------------|------------------------|---|--------------------|------|
| First author          | FU-Time (months) | Number of participants (n) | Female (n) | Male (n) | Age (years) | (SD) | Disease duration (years) | (SD) | UPDRS III ON Medication Pre OP | UPDRS III OFF medication | UPDRS L-Dopa Challenge | Improvement during L-Dopa Challenge (% Change Off/On) | OFF STIM UPDRS-III | (SD) |
| Aman[24]              | 1-1.5            | 3                          | 2          | 1        | 58.3        | 4.6  | 7.7                      | 1.7  | *                              | 47.7                     | *                      |   | 47.7               | 3.9  |
| Asahi[1]              |                  | 6                          | 5          | 1        | 66.2        | 8.2  | 9.3                      | 3    | *                              | 30.2                     | *                      |   | 30.2               | 11.7 |
| Bouthour[2]           | 12               | 20                         | 7          | 13       | 60.4        | 2    | 9.2                      | 2.2  | 14.5                           | 46.8                     | 13.7                   | 70.72   | 46.8               | 3.6  |
| Contarino[25]         | IR               | 8                          | 3          | 5        | 56.2        | 7.8  | 10.8                     | 4.4  | *                              | 35.3                     | *                      |   | 35.3               | 7.5  |
| Dayal[3]              | 6                | 32                         | 12         | 20       | 60.1        | 8.3  | -                        | -    | 16.5                           | 47                       | ***                    |   | 47                 | 13.5 |
| De Marco[4]           | 6                | 32                         | 9          | 23       | 57          |      | -                        | -    | **                             | -                        | **                     |   | -                  | -    |
| Debove[5]             | 5-9              | 52                         | 17         | 35       | 62.1        | 9.4  | 11.4                     | 4.6  | 13.9                           | 40.5                     | ***                    |   | 40.5               | 13.3 |
| Dembek[6]             | 3-6              | 10                         | 4          | 6        | 61.5        | 9.16 | 9.7                      | 3    | ****                           | 44.2                     | 22.7                   | 48.64   | 44.2               | 17.5 |
| Hidding#[26]          | 4-10             | 6                          | 0          | 6        | 70.8        | 10.4 | 6.3                      | 2.7  | 8.6                            | 10.4                     | ***                    |   | 10.14              | 1.35 |
| Hurt[7]               | 1                | 32                         | 10         | 22       |             |      | 8.3                      | 3.3  | 25.4                           | 49.2                     | ***                    |   | 49.2               | 13.1 |
| Karl[8]               |                  | 56                         | 20         | 45       | 65          | 9    | 10                       | 6    | 28                             | 49                       | ***                    |   | 49                 | 14   |
| Koivu[9]              | 6                | 63                         | 28         | 35       | 61.6        | 1.1  | 11.1                     | 3.9  | 15                             | 34.6                     | ***                    |   | 34.6               | -    |
| Maciel[10]            | 3                | 7                          | 1          | 6        | 60          | 9.1  | -                        | -    | ****                           | 37.9                     | 11.1                   | 70.71   | 37.9               | 6.9  |
| Nguyen[12]            | 6                | 28                         | 9          | 19       | 63          | 9    | -                        | -    | *                              | 38.6                     | *                      |   | 38.6               | 14.6 |

|                        |        |            |            |            |             |            |             |            |             |           |      |       |           |             |
|------------------------|--------|------------|------------|------------|-------------|------------|-------------|------------|-------------|-----------|------|-------|-----------|-------------|
| <b>Pinter[13]</b>      | 12     | 52         | 19         | 33         | 60.3        | 7.5        | 9.7         | 4.4        | 25.6α       | α         | α    |       | -         | -           |
| <b>Rammo[14]</b>       | 1      | 57         | 28         | 36         | 64          | 8          | -           | -          | *           | 37        | *    |       | 37        | 17          |
| <b>Sabourin[15]</b>    | 2-19   | 9          | 0          | 9          | 66.4        | 1.69       | 13.3        | 1.98       | ****        | 46        | 22.9 | 50.22 | 46        | 5.3         |
| <b>Sasagawa[16]</b>    | 1      | 2          | 1          | 1          | 59          | 0          | 4           | 2          | *           | 11        | *    |       | 11        | 0           |
| <b>Schnitzler[17]</b>  | 3      | 234        | 77         | 157        | 61.7        | 8.4        | 11.7        | 7.6        | 18.6        | 35.3      | ***  |       | 35.3      | -           |
| <b>Shao[18]</b>        | 6      | 7          | 3          | 4          | 64.3        | 8.2        | -           | -          | 16.9        | 37.4      | ***  |       | 32        | 10.8        |
| <b>Steigerwald[20]</b> | 7 days | 7          | 2          | 5          | -           | -          | -           | -          | 19          | 42        | ***  |       | 42        | -           |
| <b>Mean/Total</b>      |        | <b>725</b> | <b>257</b> | <b>484</b> | <b>61.9</b> | <b>7.9</b> | <b>10.8</b> | <b>6.2</b> | <b>19.1</b> | <b>39</b> |      |       | <b>39</b> | <b>14.7</b> |
| <b># Tremor</b>        |        |            |            |            |             |            |             |            |             |           |      |       |           |             |

\* No data on baseline ON medication /L-Dopa Challenge reported

\*\* Compares OFF medication with ON stimulation. so baseline is OFF med OFF Stim and follow-up is OFF med ON Stim

\*\*\* Does NOT contain data on L-Dopa challenge

\*\*\*\* Only contains baseline L-dopa challenge

α Refers to “best” ON medication. but doesn’t define this further or specify L-Dopa challenge

Supplementary table 1

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