**Supplementary Digital Content Table 2. Summary of Adverse Events by group**

|  | **Statistic** | **PTNS (N=111)** | **Sham (N=55)** | **Total (N=166)** | **P-value** |
| --- | --- | --- | --- | --- | --- |
| Participants with any event | n (%) | 73 (66) | 31 (56) | 104 (63) | 0.31 |
| Total number of events (#AEs/person) | Mean (SE) | 1.8 (0.2) | 1.0 (0.2) | 1.5 (0.2) | 0.02 |
|  | Median | 1 | 1 | 1 |  |
|  | Range | 0, 11 | 0, 4 | 0, 11 |  |
| Incidence of events (#AEs/month) | Mean (SE) | 0.61 (0.08) | 0.33 (0.05) | 0.52 (0.06) | 0.02 |
|  | Median | 0.3 | 0.3 | 0.3 |  |
|  | Range | 0.0, 3.8 | 0.0, 1.4 | 0.0, 3.8 |  |
| Participants with event by severity | n (%) |  |  |  | 0.77 |
| Mild |  | 23 (21) | 8 (15) | 31 (19) |  |
| Moderate |  | 46 (41) | 23 (42) | 69 (42) |  |
| Severe |  | 3 (3) | 0 | 3 (2) |  |
| Participants with event by relationship | n (%) |  |  |  | 0.01 |
| Unrelated |  | 43 (39) | 26 (47) | 69 (42) |  |
| Related |  | 30 (27) | 5 (9) | 35 (21) |  |
|  |  |  |  |  |  |
| Participants with any SAE | n (%) | 4 (4) | 2 (4) | 6 (4) | >0.99 |
| Total number of events (#SAEs/person) | Mean (SE) | 0.0 (0.0) | 0.0 (0.0) | 0.0 (0.0) | 0.82 |
|  | Median | 0 | 0 | 0 |  |
|  | Range | 0, 2 | 0, 1 | 0, 2 |  |

Abbreviations:

PTNS, Percutaneous tibial nerve stimulation; AE, Adverse Event; SAE, Serious Adverse Event; SE, Standard Error.